

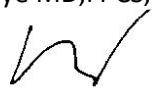


|   |   |  |
|---|---|--|
|  | <b>BATANGAS MEDICAL CENTER<br/>RESEARCH ETHICS REVIEW COMMITTEE</b> |  |
|   | <b>STANDARD FORMS<br/>WORKBOOK</b>                                  | <b>Version No: 5</b>                         |
|   |   | <b>Date of Approval:</b><br>June 04, 2021    |
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| Approved by:    | Dr. Ramoncito C. Magnaye MD,FPCS,FPSGS,MHA<br>      |
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**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**LETTER OF APPOINTMENT OF RERC MEMBER (FORM 1.1.1)**

Date

Dear \_\_\_\_\_:

I have the honor to appoint you as a Member of the Batangas Medical Center RERC for a period of two years, effective \_\_\_\_\_ until \_\_\_\_\_. As a member, you will have the following roles and responsibilities:

- Participate in the RERC meetings
- Review, discuss and consider research proposals submitted for evaluation
- Possibility of being assigned as Primary Reviewer
- Assess serious adverse event reports and recommend appropriate action(s)
- Review the progress reports and monitor ongoing studies as appropriate
- Check progress and final reports
- Maintain confidentiality of the documents and deliberations of RERC meetings
- Declare any conflict of interest;
- Participate in continuing education activities in research methodology and research ethics

If you agree with the terms of this appointment, please sign on the space provided below, date your signature, and return one copy of this letter to the Batangas Medical Center RERC Secretariat. Sign, date and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.

Very truly yours,

\_\_\_\_\_

Medical Center Chief

Conforme:

\_\_\_\_\_

(Print name and sign)

\_\_\_\_\_

Date



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**CONFIDENTIALITY AND CONFLICT OF INTEREST DISCLOSURE AGREEMENT**  
**(Form 1.1.2 / members)**

**Know all Men by these Presents:**

In view of the appointment of \_\_\_\_\_, as a member of the Batangas Medical Center Research Ethics Review Committee (BatMC RERC), and hereinafter referred to as the ***Undersigned***, and whereas:

The **Undersigned** has been asked to assess research studies and protocols involving human subjects in order to ensure that the same are conducted in a humane and ethical manner, with the highest standards of care according to the applied national and local laws and regulations, institutional policies and guidelines;

The appointment of the **Undersigned** as a member of the Batangas Medical Center RERC is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest;

The fundamental duty of an RERC member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits thereof under review; and

The Batangas Medical Center RERC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;

The following terms and conditions covering **Confidentiality and Conflict of Interest** arising in the discharge of said appointed RERC members' functions are hereby stipulated in this Agreement for purposes of ensuring the same high standards of ethical behavior necessary for the RERC to carry out its mandate.

**Confidentiality**

This Agreement thus encompasses any information deemed Confidential, Privileged, or Proprietary provided to and/or otherwise received by the ***Undersigned*** in conjunction with and/or in the course of the performance of his/her duties as a member of the Batangas Medical Center RERC.

Any written information provided to the ***Undersigned*** that is of a Confidential, Privileged, or Proprietary in nature shall be identified accordingly. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the RERC.

As such, the **Undersigned** agrees to hold in trust and in confidence all Confidential, Privileged or Proprietary information, including trade secrets and other intellectual property rights (hereinafter collectively referred to as the “information”). Moreover, the **Undersigned** agrees that the information shall be used only for contemplated purposes and none other. Neither shall the said information be disclosed to any third party.

The **Undersigned** further agrees not to disclose or utilize, directly or indirectly, any information belonging to a third party, in fulfilling this agreement. Furthermore, the **Undersigned** confirms that her performance of this agreement is consistent with Batangas Medical Center policies and any contractual obligations owed to third parties.

### **Conflict of Interest**

It is recognized that the potential for conflict of interest will always exist; however, there is concomitant faith in the ability of the BatMC RERC to manage these conflict issues, if any, in such a way that the ultimate outcome of the protection of human subjects remains.

It is the policy of the BatMC RERC that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the BatMC RERC.

The **Undersigned** will immediately disclose to the Chair of the Batangas Medical Center RERC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the BatMC RERC, and to abstain from any participation in discussions or recommendations in respect of such proposals. If an applicant submitting a protocol believes that an RERC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

If an applicant submitting a protocol believes that a BatMC RERC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chair. The request must contain evidence that substantiates the claim that a conflict exists with the BatMC RERC member(s) in question. The RERC may elect to investigate the applicant’s claim of the potential conflict.

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the RERC review or approval except to provide information requested by the Board.

Examples of conflict of interest cases may include but is not limited to any of the following:

- ☐ A member is involved in a potentially competing research program.
- ☐ Access to funding or intellectual information may provide an unfair competitive advantage
- ☐ A member’s personal biases may interfere with his or her impartial judgment.

### **Agreement on Confidentiality and Conflict of Interest**



To the **Undersigned**: Please sign and date this Agreement, if you agree with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the Batangas Medical Center RERC. A copy will be given to you for your records.]

In the course of my activities as a member of the Batangas Medical Center RERC, I will be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information, subject to applicable legislation, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my RERC duties) to the Chair upon termination of my functions as an RERC member.

Whenever I have a conflict of interest, I shall immediately inform the Chair not to count me toward a quorum for voting.

I have read and accept the aforementioned terms and conditions as explained in this Agreement.

\_\_\_\_\_  
Name of Member

\_\_\_\_\_  
Date

Noted By :

\_\_\_\_\_  
Batangas Medical Center  
RERC Chairperson

\_\_\_\_\_  
Date



## BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE

### CURRICULUM VITAE (FORM 1.1.3)

| Name (Surname)   | (First) | (Middle)   |
|--|---------|--|
| Position in RERC:<br>Date of 1 <sup>st</sup> Appointment:<br>Date of Latest Appointment:<br>Term of Office:  |         | Address:<br><br>Contact No.:<br>E-mail:  |
| 1. Educational Background<br><br>1.1 Post Graduate Degree<br>1.2 Graduate Degree<br>1.3 Bachelor's Degree<br>1.4 Specialization<br><br>1.5 Other Qualifications and specialization |         | <br><br><br><br>Board Certified <input type="checkbox"/> Yes <input type="checkbox"/> No<br>Details of Board Certification<br><br><br><br><br><br><br> |
| 2. Work Experience<br><br>2.1 Present Work Experience<br><br><br>2.2 Previous work experience  |         |  |

BATMC-RERC Member Signature \_\_\_\_\_

Date \_\_\_\_\_





## **BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE**

### **APPOINTMENT NOTICE OF RERC OFFICER TEMPLATE**

#### **(Form 1.2.1)**

Name and logo of Institution

Date

#### **NAME**

Department and Position

Institutional Affiliation

Subject: Appointment as Chair/Vice Chair/Member Secretary

Dear **Name**:

You are hereby appointed as Chair/Vice Chair/Member Secretary/Assistant Member Secretary of the Batangas Medical Center Research Ethics Review Committee (BatMC RERC) effective (from) to (to). As Chair/Vice Chair/Member Secretary/Assistant Member Secretary, your responsibilities are as follows:

(As Chair)

Over and above duties as a Member, the Chair shall have the following responsibility:

1. Represent the REC in internal and external meetings and conferences.
2. Preside over REC Meeting.
3. Oversee review of protocols.
4. Assign Primary Reviewers of protocols based on expertise and experience.
5. Supervise development and revisions of SOPs.
6. Prepare and submit annual budget of the REC.
7. Prepare and submit annual report of the REC to the office of the Institutional Authority and to PHREB.
8. Ensure initial and continuing research ethics trainings of members and staff.

(As Vice Chair)

Over and above duties as a Member, the Vice Chair shall have the following responsibilities:

1. Perform duties of the Chair in his/her absence.
2. Perform tasks assigned by Chair
3. Participate in the review of research proposals and other related reports when requested.

(As Secretary)

Over and above duties as a Member, the Member Secretary shall have the following responsibilities:

1. Supervise the administrative Staff in the daily operations of the REC.



- a. Receipt of protocol documents
  - b. Preparation of protocol files and folders
  - c. Preparation of draft of communications
  - d. Preparation of draft Agenda and Minutes
  - e. Updating of records
2. Assist the Chair in assigning Primary Reviewers.
  3. Assist the Chair in the preparation of the Agenda, Annual Report, and budget.

(As Assistant Member Secretary)

Over and above duties as a Member, the Assistant Member Secretary shall have the following responsibilities:

1. Perform duties of Member Secretary in his/her absence.
2. Perform tasks assigned by Member Secretary
3. Participate in the review of research proposals and other related reports when requested.

We look forward to partnering with you in ensuring that all health researches conform to local, national, and international ethical principles and standards towards respect for the rights, well-being and dignity of persons.

Thank you for accepting the invitation to be the Chair/Vice Chair/Member Secretary/Assistant Member Secretary of the Research Ethics Committee. Kindly signify your acceptance by signing the conforme below.

Very truly yours,

**RERC Chair**

Conforme:

---

Name and signature of Appointee



## **BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE**

### **Letter of Invitation to Independent Consultant (Form 1.3.1)**

Date:

Dear

The **BATMC-RERC** would like to invite you to be an **Independent Consultant** for a research protocol that has been submitted to our committee for approval.

**RESEARCH PROTOCOL TITLE:**  
**BATMC-RERC PROTOCOL CODE:**  
**PRIMARY INVESTIGATOR:**

As **Independent consultant**, we recognize your expertise in the field of research that is being proposed and appreciate your insights/expert opinions as well as any recommendations.

As **Independent Consultant**, you can be assigned as a primary reviewer and will accomplish the assessment forms attached to the research protocols that will be sent to you two weeks before the regular meeting of the BATMC-RERC which will be scheduled. You will be required to attend the BATMC- RERC meeting and participate in the discussion.

As **Independent Consultant**, you will not have the right to vote, you will not be counted in the quorum and your attendance will be required only during the time the protocol assigned to you is to be discussed. Your report becomes part of the study file.

Please sign Conforme below if you accept our invitation. Likewise, please go over and sign the Confidentiality/Conflict of Interest Agreements (refer to attached agreement) and return to the BATMC-RERC Secretariat along with the Confidentiality and Conflict of Interest Agreement and latest curriculum vitae. (form attached).

An honorarium will be given for your attendance and participation in the ethics review. For any questions, please feel free to contact the **BATMC-RERC** Chair at 09189456879. Thank you for your attention and hoping for your favorable response.

Respectfully,

\_\_\_\_\_  
<Name of Chairperson>

Chairperson

BatMC Research Ethics Review Committee

Conforme :

\_\_\_\_\_  
<Name of Independent Consultant>

Date : \_\_\_\_\_



## **BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE**

### **APPOINTMENT LETTER OF INDEPENDENT CONSULTANT**

#### **Form 1.3.2**

Date

**NAME**

Department and Position

Institutional Affiliation

Subject: Appointment as Independent Consultant

Dear **Name**:

You are hereby appointed as Independent Consultant of the Batangas Medical Center Research Ethics Review Committee (BatMC RERC) effective (from) to (to). As Independent Consultant, your responsibilities are as follows:

1. *Attend BatMC RERC meeting when requested to present your assessment, participate in the discussion but without right to vote.*
2. *Participate in the review of research proposals and other related reports when requested.*  
*Review must focus on:*
  - *Scientific merits of the protocol (methodology and procedures)*
  - *Benefits and risks of the intervention and how to mitigate the risks*
  - *Any new information about the disease/research topic and the proposed intervention*
3. *Completion and submission of the BatMC RERC assessment forms.*
4. *Declare any conflict of interest (COI) in the review of research proposals.*
5. *Maintain confidentiality of the documents and deliberations of the BatMC RERC meetings.*

We look forward to partnering with you in ensuring that all health researches conform to local, national, and international ethical principles and standards towards respect for the rights, well-being and dignity of persons.

Thank you for accepting the invitation to be the member / Independent Consultant of the Research Ethics Committee. Kindly signify your acceptance by signing the conforme below.

Very truly yours,

Conforme :

**RERC Chair**

**Name and Signature of Appointee**



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**CONFIDENTIALITY AND CONFLICT OF INTEREST DISCLOSURE AGREEMENT**  
**(Form 1.3.3 / Independent Consultant)**

**Know all Men by these Presents:**

In view of the appointment of \_\_\_\_\_, as independent consultant of the Batangas Medical Center Research Ethics Review Committee (BatMC RERC), and hereinafter referred to as the ***Undersigned***, and whereas:

The **Undersigned** has been asked to assess research studies and protocols involving human subjects in order to ensure that the same are conducted in a humane and ethical manner, with the highest standards of care according to the applied national and local laws and regulations, institutional policies and guidelines;

The appointment of the **Undersigned** as independent consultant of the Batangas Medical Center RERC is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest;

The fundamental duty of an RERC independent consultant is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits thereof under review; and

The Batangas Medical Center RERC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;

The following terms and conditions covering **Confidentiality and Conflict of Interest** arising in the discharge of said appointed RERC independent consultants' functions are hereby stipulated in this Agreement for purposes of ensuring the same high standards of ethical behavior necessary for the RERC to carry out its mandate.

**Confidentiality**

This Agreement thus encompasses any information deemed Confidential, Privileged, or Proprietary provided to and/or otherwise received by the **Undersigned** in conjunction with and/or in the course of the performance of his/her duties as Independent Consultant of the Batangas Medical Center RERC.

Any written information provided to the **Undersigned** that is of a Confidential, Privileged, or Proprietary in nature shall be identified accordingly. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the RERC.

As such, the ***Undersigned*** agrees to hold in trust and in confidence all Confidential, Privileged or Proprietary information, including trade secrets and other intellectual property rights (hereinafter collectively referred to as the “information”). Moreover, the ***Undersigned*** agrees that the information shall be used only for contemplated purposes and none other. Neither shall the said information be disclosed to any third party.

The ***Undersigned*** further agrees not to disclose or utilize, directly or indirectly, any information belonging to a third party, in fulfilling this agreement. Furthermore, the ***Undersigned*** confirms that his/her performance of this agreement is consistent with Batangas Medical Center policies and any contractual obligations owed to third parties.

### **Conflict of Interest**

It is recognized that the potential for conflict of interest will always exist; however, there is concomitant faith in the ability of the BatMC RERC to manage these conflict issues, if any, in such a way that the ultimate outcome of the protection of human subjects remains.

It is the policy of the BatMC RERC that no consultant may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the BatMC RERC.

The ***Undersigned*** will immediately disclose to the Chair of the Batangas Medical Center RERC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the ERC, and to abstain from any participation in discussions or recommendations in respect of such proposals. If an applicant submitting a protocol believes that an RERC member has a potential conflict, the investigator may request that the independent consultant be excluded from the review of the protocol.

If an applicant submitting a protocol believes that a BatMC RERC independent consultant has a potential conflict, the investigator may request that the independent consultant be excluded from the review of the protocol.

The request must be in writing and addressed to the Chair. The request must contain evidence that substantiates the claim that a conflict exists with the BatMC RERC independent consultant in question. The RERC may elect to investigate the applicant’s claim of the potential conflict.

When a consultant has a conflict of interest, the consultant should notify the Chairperson and may not participate in the RERC review except to provide information requested by the Board.

Examples of conflict of interest cases may include but is not limited to any of the following:

- ☐ A consultant is involved in a potentially competing research program.
- ☐ Access to funding or intellectual information may provide an unfair competitive advantage

- ☐ A consultant's personal biases may interfere with his or her impartial judgment.

**Agreement on Confidentiality and Conflict of Interest**

*To the **Undersigned:*** Please sign and date this Agreement, if you agree with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the Batangas Medical Center RERC. A copy will be given to you for your records.]

In the course of my activities as an independent consultant of the Batangas Medical Center RERC, I will be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information, subject to applicable legislation, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my RERC duties) to the Chair upon termination of my functions as an RERC member.

Whenever I have a conflict of interest, I shall immediately inform the Chair.

I have read and accept the aforementioned terms and conditions as explained in this Agreement.

|                                |       |
|--------------------------------|-------|
| _____                          | _____ |
| Name of Independent Consultant | Date  |

Noted By :

|   |       |
|---|-------|
| _____                                       | _____ |
| Batangas Medical Center<br>RERC Chairperson | Date  |



## BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE

### TRAINING RECORD OF AN RERC MEMBER (FORM 1.4.1)

|                  |                   |                    |
|------------------|-------------------|--------------------|
| <i>Last Name</i> | <i>First Name</i> | <i>Middle Name</i> |
|------------------|-------------------|--------------------|

| BASIC COURSES                                    | ORGANIZER | VENUE | DATE | FUNDING<br>SOURCE |
|--|-----------|-------|------|-------------------|
| 1. GCP Training                                  |           |       |      |                   |
| 2. Research Ethics                               |           |       |      |                   |
| 3. ERC Standard<br>Operating<br>Procedures (SOP) |           |       |      |                   |

| CONTINUING ETHICS<br>EDUCATION : Research Ethics<br>Workshops, Conferences,<br>Meetings, Lectures | ORGANIZER | VENUE | DATE | FUNDING<br>SOURCE<br>(YES/NO) |
|---|-----------|-------|------|-------------------------------|
| 1.  |           |       |      |                               |
| 2.  |           |       |      |                               |
| 3.  |           |       |      |                               |
| 4.  |           |       |      |                               |
| 5.  |           |       |      |                               |

| AS A RESOURCE<br>PERSON | TRAINING PROVIDER | VENUE | DATE | FUNDING<br>SOURCE<br>(YES/NO) |
|-------------------------|-------------------|-------|------|-------------------------------|
|                         |                   |       |      |                               |
|                         |                   |       |      |                               |
|                         |                   |       |      |                               |

*Certified Correct:*

|                          |   |
|--------------------------|---|
| <i>Secretariat Staff</i> | <i>Name: &lt;TITLE, NAME, SURNAME&gt;</i> |
| <i>Date: (dd/mm/yy)</i>  | <i>Signature</i>                          |
| <i>RERC Chair</i>        | <i>Name:</i>                              |
| <i>Date: (dd/mm/yy)</i>  | <i>Signature:</i>                         |





**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**TRAINING REFERRAL REQUEST FORM (Form 1.4.2)**

|   |  |
|---|--|
| Type of Request                                   | <input type="checkbox"/> Member requesting to participate in training activity<br><input type="checkbox"/> BATMC-RERC recommending training for member   |
| Reason for Request                                | <input type="checkbox"/> Initial Training<br><input type="checkbox"/> Update Training  |
| Name of Member                                    | <Title, Name, Surname>   |
| Date of 1 <sup>st</sup> Appointment               | <dd/mm/yy>   |
| College/Institute (and department), as applicable |  |
| Type of training requested                        | <input type="checkbox"/> Good Clinical Practice<br><input type="checkbox"/> Research Ethics<br><input type="checkbox"/> Standard Operating Procedures<br><input type="checkbox"/> Continuing Ethics Education<br><input type="checkbox"/> Other Educational Activities <specify>   |
| Training Details                                  | Date: <dd/mm/yy><br>Title:<br>Provider:  |
| Details of Participation                          | <input type="checkbox"/> Participant only<br><input type="checkbox"/> Resource person<br><input type="checkbox"/> Others: <specify>  |
| Training Cost                                     |  |
| Other sources of funding, if any                  | Amount:<br>Source:   |
| RECOMMENDED BY:                                   | <Title, name, Surname> and Signature<br>BATMC-RERC<br>Date:<dd/mm/yy>  |
| COMMITMENT TO ATTEND                              | I commit to attend the <Title Training> on <dd/mm/yy>, for which attendance I will provide a certificate of completion with the training program or agenda attached.<br><br><Title, Name, Surname> and Signature<br>Member, BATMC-RERC <number><br>Date: <dd/mm/yy>  |
| ENDORSED BY                                       | I endorse the application of <Member> for the <training requested>. I certify that the supporting documents pertaining to the application are authentic and that <Member> has been an active member of the BATMC-RERC since <date of appointment><br><br><Title, Name, Surname> and Signature<br>Chair, BATMC-Research Ethics Review Committee<br>Date: <dd/mm/yy> |



## **BATANGAS MEDICAL CENTER**

### **RESEARCH ETHICS REVIEW COMMITTEE**

*Adapted from the WHO Informed Consent Template  
([http://www.who.int/rpc/research\\_ethics/informed\\_consent/en/](http://www.who.int/rpc/research_ethics/informed_consent/en/))*

#### ***Informed Consent Form Template for***

#### ***Clinical Studies***

**(This template is for either clinical trials or clinical research : Form WHO ICF-1)**  
*(language used throughout form should be at the level of a local student of class 6<sup>th</sup>/8<sup>th</sup>)*

#### Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study.  
**The logo of the Institution must be used on the ICF and not the WHO logo.**
2. The informed consent form consists of two parts: the information sheet and the consent certificate.
3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.
4. This template includes examples of key questions that may be asked at the end of each section, that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.
5. In this template:
  - square brackets indicate where specific information is to be inserted
  - bold lettering indicates sections or wording which should be included
  - standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.

TEMPLATE ON FOLLOWING PAGE

**[Informed Consent form for \_\_\_\_\_]**

Name the group of individuals for whom this informed consent form is written. Because research for a single project is often carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for.

*(Example: This Informed Consent Form is for men and women who attend clinic Z, and who we are inviting to participate in research on X. The title of our research project is "....." )*

You may provide the following information either as a running paragraph or under headings as shown below.

**[Name of Principal Investigator]**

**[Name of Organization]**

**[Name of Sponsor]**

**[Name of Proposal and version]**

**This Informed Consent Form has two parts:**

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

**You will be given a copy of the full Informed Consent Form**

**PART I: Information Sheet**

**Introduction**

Briefly state who you are and explain that you are inviting them to participate in the research you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions now or later.

*(Example: I am X, working for the Y Research Institute. We are doing research on Z disease, which is very common in this country. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.*

*There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.*

**Purpose of the research**

Explain in lay terms why you are doing the research. The language used should clarify rather than confuse. Use local and simplified terms for a disease, e.g. local name of disease instead of malaria, mosquito instead of anopheles, "mosquitoes help in spreading the disease" rather than "mosquitoes are the vectors". Avoid using terms like pathogenesis, indicators, determinants, equitable etc. There are guides on the internet to help you find substitutes for words which are overly scientific or are professional jargon.



*(Example: Malaria is one of the most common and dangerous diseases in this region. The drugs that are currently used to help people with malaria are not as good as we would like them to be. In fact, only 40 out of every 100 people given the malaria drug XYZ are completely cured. There is a new drug which may work better. The reason we are doing this research is to find out if the new drug ABX is better than drug XYZ which is currently being used.)*

### **Type of Research Intervention**

Briefly state the type of intervention that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves a vaccine, an interview, a biopsy or a series of finger pricks.

*(Example: This research will involve a single injection in your arm as well as four follow-up visits to the clinic. )*

### **Participant selection**

State why this participant has been chosen for this research. People often wonder why they have been chosen to participate and may be fearful, confused or concerned. Indicate the number of participants to be included

*(Example: We are inviting all adults with malaria who attend clinic Z to participate in the research on the new malaria drug.)*

- **Example of question to elucidate understanding:** Do you know why we are asking you to take part in this study? Do you know what the study is about?

### **Voluntary Participation**

Indicate clearly that they can choose to participate or not. State, what the alternative - in terms of the treatment offered by the clinic - will be, if they decide not to participate. State, only if it is applicable, that they will still receive all the services they usually do whether they choose to participate or not. This can be repeated and expanded upon later in the form as well, but it is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context.

*(Example: Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will offered the treatment that is routinely offered in this clinic/hospital for disease Z, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.)*

- **Examples of question to elucidate understanding:** If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?

Include the following section only if the protocol is for a clinical trial:



### Information on the Trial Drug [Name of Drug]

- 1) give the phase of the trial and explain what that means. Explain to the participant why you are comparing or testing the drugs.
- 2) provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.
- 3) explain the known experience with this drug
- 4) explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial

*(Example: The drug we are testing in this research is called ABX. It has been tested before with people who do not have malaria but who live in areas where malaria is common. We now want to test the drug on people who have malaria. This second research is called a "phase 2" trial.*

*The drug ABX is made by Company C. You should know that it has a few side effects. One of the side effects, or problems, is that you may feel tired for the first day after being given the drug. Also, 20% of the people who tried the drug in previous research experienced temporary swelling where the injection entered the skin. We know of no other problem or risks.*

*Some participants in the research will not be given the drug which we are testing. Instead, they will be given the drug XYZ, the drug which is most commonly used in this region to treat malaria. There is no risk associated with that drug and no known problems. It does not, however, cure malaria as often as we would like.)*

### Procedures and Protocol

Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and any drugs that will be given. Explain from the outset what some of the more unfamiliar procedures involve (placebo, randomization, biopsy, etc.) Indicate which procedure is routine and which is experimental or research. Participants should know what to expect and what is expected of them. Use active, rather than conditional, language. Write "we will ask you to...." instead of "we would like to ask you to....".

In this template, this section has been divided into two: firstly, an explanation of unfamiliar procedures and, secondly, a description of process.

#### A. Unfamiliar Procedures

This section should be included if there may be procedures which are not familiar to the participant.

If the protocol is for a clinical trial:

- 1) involving randomization or blinding, the participants should be told what that means and what chance they have of getting which drug (i.e. one in four chances of getting the test drug).

*(Example: Because we do not know if the new malaria drug is better than the currently available drug for treating malaria, we need to compare the two. To do this, we will put people taking part in this research into two groups. The groups are selected by chance, as if by tossing a coin.*

*Participants in one group will be given the test drug while participants in the other group will be given the drug that is currently being used for malaria. It is important that neither you nor we know which*

*of the two drugs you are given. This information will be in our files, but we will not look at these files until after the research is finished. This is the best way we have for testing without being influenced by what we think or hope might happen. We will then compare which of the two has the best results.*

*The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned about what the drug is doing, we will find out which drug you are getting and make changes. If there is anything you are concerned about or that is bothering you about the research please talk to me or one of the other researchers)*

2) involving an inactive drug or placebo, it is important to ensure that the participants understand what is meant by a placebo or inactive drug.

*(Example: A placebo or inactive medicine looks like real medicine but it is not. It is a dummy or pretend medicine. It has no effect on a person because it has no real medicine in it. Sometimes when we want to know whether a new medicine is good, we give some people the new medicine and some people the pretend or dummy medicine. For the research to be good, it is important that you do not know whether you have been given the real medicine or the pretend or dummy medicine. This is one of the best ways we have for knowing what the medicine we are testing really does.)*

3) which may necessitate a rescue medicine, then provide information about the rescue medicine or treatment such as what it is and the criterion for its use. For example, in pain trials, if the test drug does not control pain, then intravenous morphine may be used as a rescue medicine.

*(Example: If we find that the medicine that is being used does not have the desired effect, or not to the extent that we wish it to have, we will use what is called a “rescue medicine.” The medicine that we will use is called QRS and it has been proven to control pain. If you find that the drug we are testing does not stop your pain and it is very uncomfortable for you, we can use the rescue medicine to make you more comfortable.)*

If the protocol is for clinical research:

Firstly, explain that there are standards/guidelines that will be followed for the treatment of their condition. Secondly, if as part of the research a biopsy will be taken, then explain whether it will be under local anesthesia, sedation or general anesthesia, and what sort of symptoms and side effects the participant should expect under each category.

*(Example: You will receive the treatment of your condition according to national guidelines. This means that you will be (explain the treatment). To confirm the cause of your swelling, a small sample of your skin will be taken. The guidelines say that the sample must be taken using a local anesthesia which means that we will give you an injection close to the area where we will take the sample from. This will make the area numb so that you will not feel any pain when we take the sample.)*

For any clinical study (if relevant):

If blood samples are to be taken explain how many times and how much in a language that the person understands. It may, for example, be inappropriate to tell a tribal villager that blood equal to a wine-glass full will be taken but it may be very appropriate to use pictures or other props to illustrate the procedure if it is unfamiliar.





If the samples are to be used only for this research, then explicitly mention here that the biological samples obtained during this research procedure will be used only for this research, and will be destroyed after \_\_\_\_ years, when the research is completed. If the tissues/blood samples or any other human biological material will be stored for a duration longer than the research purpose, or is likely to be used for a purpose other than mentioned in the research proposal, then provide information about this and obtain consent specifically for such storage and use in addition to consent for participation in the study - (see last section)

*(Example: We will take blood from your arm using a syringe and needle. Each time we will take about this much blood (show a spoon, vial or other small container with a small amount of water in it. In total, we will take about .....this much blood in x number of weeks/months. At the end of the research, in 1 year, any left over blood sample will be destroyed.)*

### **B. Description of the Process**

Describe to the participant what will happen on a step-by-step basis. It may be helpful to the participant if you use drawings or props to better illustrate the procedures. A small vial or container with a little water in it is one way of showing how much blood will be withdrawn.

*(Example: During the research you make five visits to the clinic.*

- In the first visit, a small amount of blood, equal to about a teaspoon, will be taken from your arm with a syringe. This blood will be tested for the presence of substances that help your body to fight infections. We will also ask you a few questions about your general health and measure how tall you are and how much you weigh.*
- At the next visit, which will be two weeks later, you will again be asked some questions about your health and then you will be given either the test drug or the drug that is currently used for malaria. As explained before, neither you nor we will know whether you have received the test or the dummy/pretend drug.*
- After one week, you will come back to the clinic for a blood test. This will involve....)*

### **Duration**

Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

*(Example: The research takes place over \_\_\_\_ (number of) days/ or \_\_\_\_ (number of) months in total. During that time, it will be necessary for you to come to the clinic/hospital/health facility \_\_\_\_\_(number of) days , for \_\_\_\_ (number of) hours each day. We would like to meet with you three months after your last clinic visit for a final check-up.*

*In total, you will be asked to come 5 times to the clinic in 6 months. At the end of six months, the research will be finished.)*

- **Examples of question to elucidate understanding:** Can you tell me if you remember the number of times that we are asking you to come to the hospital to complete the treatment? The research project? How many injections will you be given? How many tablets? How much blood will be taken from your veins, using a syringe and needle? Over how many weeks? Etc. Do you have any other questions? Do you want me to go through the procedures again?



### Side Effects

Potential participants should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

*(Example: As already mentioned, this drug can have some unwanted effects. It can make you tired and it can cause some temporary swelling around the place where the injection goes into your arm. It is possible that it may also cause some problems that we are not aware of. However, we will follow you closely and keep track of any unwanted effects or any problems. We may use some other medicines to decrease the symptoms of the side effects or reactions. Or we may stop the use of one or more drugs. If this is necessary we will discuss it together with you and you will always be consulted before we move to the next step.)*

### Risks

Explain and describe any possible or anticipated risks. Describe the level of care that will be available in the event that harm does occur, who will provide it, and who will pay for it. A risk can be thought of as being the possibility that harm may occur. Provide enough information about the risks that the participant can make an informed decision.

*(Example: By participating in this research it is possible that you will be at greater risk than you would otherwise be. There is, for example, a risk that your disease will not get better and that the new medicine doesn't work even as well as the old one. If, however, the medicine is not working and your fever does not go down in 48 hours we will give you quinine injections which will bring your fever down and make you more comfortable.*

*While the possibility of this happening is very low, you should still be aware of the possibility. We will try to decrease the chances of this event occurring, but if something unexpected happens, we will provide you with\_\_\_\_\_.)*

- **Examples of question to elucidate understanding:** Do you understand that, while the research study is on-going, no-one may know which medicine you are receiving? Do you know that the medicine that we are testing is a new medicine, and we do not know everything about it? Do you understand that you may have some unwanted side-effects from the medicines? Do you understand that these side-effects can happen whether or not you are in the research study? Etc. Do you have any other questions?

### Benefits

Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation. Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question.

*(Example: If you participate in this research, you will have the following benefits: any interim illnesses will be treated at no charge to you. If your child falls sick during this period he/she will be treated free of charge. There may not be any benefit for you but your participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.)*





### Reimbursements

State clearly what you will provide the participants with as a result of their participation. WHO does not encourage incentives. However, it recommends that reimbursements for expenses incurred as a result of participation in the research be provided. These may include, for example, travel costs and money for wages lost due to visits to health facilities. The amount should be determined within the host country context.

*(Example:. We will give you [amount of money] to pay for your travel to the clinic/parking and we will give you [amount] for lost work time. You will not be given any other money or gifts to take part in this research.)*

- **Examples of question to elucidate understanding:** *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be reimbursed? Do you have any other questions?*

### Confidentiality

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant which would otherwise be known only to the physician but would now be available to the entire research team. Note that because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and is therefore more likely to be stigmatized.

*(Example: With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.*

*The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc].)*

- **Example of question to elucidate understanding:** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you have any questions about them?*

### Sharing the Results

Where it is relevant, your plan for sharing the information with the participants should be provided. If you have a plan and a timeline for the sharing of information, include the details. You should also inform the participant that the research findings will be shared more broadly, for example, through publications and conferences.

*(Example: The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not*

*be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.)*

### **Right to Refuse or Withdraw**

This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section to ensure that it fits for the group for whom you are seeking consent. The example used here is for a patient at a clinic.

*(Example: You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way.)*

**OR**

*(Example: You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.)*

### **Alternatives to Participating**

Include this section only if the study involves administration of investigational drugs or use of new therapeutic procedures. It is important to explain and describe the established standard treatment.

*(Example: If you do not wish to take part in the research, you will be provided with the established standard treatment available at the centre/institute/hospital. People who have malaria are given....)*

### **Who to Contact**

Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted. State also that the proposal has been approved and how.

*(Example: If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail])*

**This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone number.]]. It has also been reviewed by the Ethics Review Committee of the World Health Organization (WHO), which is funding/sponsoring/supporting the study.**

- **Example of question to elucidate understanding:** *Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.*

You can ask me any more questions about any part of the research study, if you wish to. Do



you have any questions?

## **PART II: Certificate of Consent**

This section should be written in the first person and have a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. The certificate of consent should avoid statements that have "I understand...." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

**I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.**

Print Name of Participant \_\_\_\_\_

Signature of Participant \_\_\_\_\_

Date \_\_\_\_\_  
Day/month/year

### **If illiterate**

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

**I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.**

Print name of witness \_\_\_\_\_

**AND Thumb print of participant**

Signature of witness \_\_\_\_\_

Date \_\_\_\_\_  
Day/month/year

### **Statement by the researcher/person taking consent**

**I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:**

- 1.
- 2.
- 3.



**I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.**

**A copy of this ICF has been provided to the participant.**

**Print Name of Researcher/person taking the consent** \_\_\_\_\_

**Signature of Researcher /person taking the consent** \_\_\_\_\_

**Date** \_\_\_\_\_  
Day/Month/Year



## **BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE**

*Adapted from the WHO Informed Consent Template  
([http://www.who.int/rpc/research\\_ethics/informed\\_consent/en/](http://www.who.int/rpc/research_ethics/informed_consent/en/))*

### ***Informed Assent Form Template for Children/Minors***

(language should be at a level appropriate to the child's age and development)

**(This template is written for a pre-adolescent or young adolescent: *Form WHO ICF-2*).**

#### Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study. **The logo of the Institution must be used on the ICF and not the WHO logo.**
2. The informed assent form consists of two parts: the information sheet and the consent certificate.
3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed assent forms that you develop and provide to participants in your research.
4. This template includes examples of key questions that may be asked at the end of each section, that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.
5. In this template:
  - square brackets indicate where specific information is to be inserted
  - bold lettering indicates sections or wording which should be included
  - standard lettering is used for explanations to researchers only and must not be included in your assent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.

TEMPLATE ON FOLLOWING PAGE

An Informed Assent Form does not replace a consent form signed by parents or guardians. The assent is in addition to the consent and signals the child's willing cooperation in the study.

**[Informed Assent Form for \_\_\_\_\_]**

Name the group of individuals for whom this assent is written. Because research for a single project is often carried out on a number of different groups of individuals - for example children with malaria, children without malaria, students - it is important that you identify which group particular assent is for.

*( This informed assent form is for children between the ages of 12 - 16 who attend clinic X and who we are inviting to participate in research Y.)*

**[Name of Principle Investigator]**

**[Name of Organization]**

**[Name of Sponsor]**

**[Name of Project and Version]**

**This Informed Assent Form has two parts:**

- **Information Sheet (gives you information about the study)**
- **Certificate of Assent (this is where you sign if you agree to participate)**

**You will be given a copy of the full Informed Assent Form**

**Part I: Information Sheet**

**Introduction**

This is a brief introduction to ensure the child knows who you are and that this is a research study. Give your name, say what you do and clearly state that you are doing research. Inform the child that you have spoken to their parents and that parental consent is also necessary. Let them know that they can speak to anyone they choose about the research before they make up their mind.

*(Example: My name is \_\_\_\_ and my job is to research and test vaccines to see which work best to stop malaria before it makes someone sick .We want to know if this new vaccine will stop children from getting sick and we think this research could help tell us that.*

*I am going to give you information and invite you to be part of a research study. You can choose whether or not you want to participate. We have discussed this research with your parent(s)/guardian and they know that we are also asking you for your agreement. If you are going to participate in the research, your parent(s)/guardian also have to agree. But if you do not wish to take part in the research, you do not have to, even if your parents have agreed.*

*You may discuss anything in this form with your parents or friends or anyone else you feel comfortable talking to. You can decide whether to participate or not after you have talked it over. You do not have to decide immediately.*

*There may be some words you don't understand or things that you want me to explain more about because you are interested or concerned. Please ask me to stop at anytime and I will take time to explain).*

**Purpose: Why are you doing this research?**

Explain the purpose of the research in clear simple terms.

*(Example: We want to find better ways to prevent malaria before it makes children sick. We have a new vaccine to prevent malaria which we are hoping might be better than the one that is currently being used. In order to find out if it is better we have to test it.)*

**Choice of participants: Why are you asking me?**

Children, like adults, like to know why they are being invited to be in the research. It is important to address any fears they may have about why they were chosen.

*(Example: We are testing this vaccine on children who are your age - between 12 and 16 years old - who live in a place where there is malaria. We are only testing the vaccine on children who do not have malaria.)*

**Participation is voluntary: Do I have to do this?**

State clearly and in child-friendly language that the choice to participate is theirs. If there is a possibility that their decision not to participate might be over-ridden by parental consent, this should be stated clearly and simply.

*(Example: You don't have to be in this research if you don't want to be. Its up to you. If you decide not to be in the research, its okay and nothing changes. This is still your clinic, everything stays the same as before. Even if you say "yes" now, you can change your mind later and its still okay.*

*If applicable: If anything changes and we want you to stay in the research study even if you want to stop, we will talk to you first.)*

- **Examples of question to elucidate understanding:** *If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

**I have checked with the child and they understand that participation is voluntary \_\_ (initial)**

**Information on the Trial Drug [Name of Drug]: What is this drug and what do you know about it?**

Include the following section only if the protocol is for a clinical trial:

- 1) give the phase of the trial and explain what that means. Explain to the participant why you are comparing or testing the drugs.
- 2) provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.
- 3) explain the known experience with this drug
- 4) explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial





*(Example: The vaccine we are testing in this research is called ABX. It has been tested twice before with adults who do not have malaria but who live in areas where malaria is common. We now want to test the vaccine on teenagers who do not have malaria. This second research is called a "phase 2" trial.*

*The vaccine ABX is made by Company C. It has very few side effects. It can make you feel tired for the first 24 hours after being given the drug. Also, 20% of the people who tried the drug in previous research experienced temporary swelling where the injection entered the skin. We know of no greater risk or other side effects. Some participants in the research will not be given the drug which we are testing. Instead, they will be given the drug XYZ, the drug which is most commonly used in this region to treat malaria. There is no risk associated with that drug and no known side effects.)*

### **Procedures: What is going to happen to me?**

Explain the procedures and any medical terminology in simple language. Focus on what is expected of the child. Describe which part of the research is experimental.

*(Example: We are going to test the vaccine by giving some of the children in the research study the new vaccine and the others are going to get the vaccine that is already being used to prevent malaria. Neither you nor the researchers will know which vaccine you were given until after the study is over. By doing the research like this, we can compare which of the vaccines is better without being influenced by what we think or hope the research will show.*

*If you decide that you want to do this, there will be three things that happen.*

*1. In about ten days, you will come to the clinic with your parents and you will get an injection/shot in your arm. This is either the vaccine that we are testing or the vaccine that is usually used to prevent malaria.*

*2.. At the clinic we will also give you a mosquito net to take home and sleep under. Maybe you have seen these before. They stop mosquitoes from biting you during the night when you sleep.*

*3. Once a month for six months after that, you will come to the clinic and the nurse will take your temperature. She will also take a little bit of your blood, about three or four drops, from your finger with a finger prick. This might hurt a little but the hurt will go away before very long.*

*Altogether you will come to the clinic 7 times over 7 months. At the end of seven months, the research will be finished.*

*I have a picture here to show you what will happen. You can ask me to stop and explain again at any time and I will explain more about the process).*

- **Examples of question to elucidate understanding:** Can you tell me if you remember the number of times that we are asking you to come to the hospital to complete the treatment? How many times extra will you have to come if you decide to take part in the research study? How many injections will you be given? How many tablets? How much blood will be taken from your veins, using a syringe and needle? Over how many weeks? Etc. Do you have any other questions? Do you want me to go through the procedures again?





I have checked with the child and they understand the procedures \_\_\_\_\_(initial))

**Risks: Is this bad or dangerous for me?**

Explain any risks using simple, clear language.

*(Example: The vaccine is considered safe. It has already been tested on adults and on other children. There has been nothing that has worried us at all. If anything unusual happens to you, however, we need to know and you should feel free to call us anytime with your concerns or questions. Another way of us knowing how you are is by having you come to the clinic every month for a check-up. If you get sick or have concerns or questions in-between the scheduled visits to clinic, you should let me or the staff nurse know. You don't have to wait for a scheduled visit.)*

**Discomforts: Will it hurt?**

If there will be any discomforts state these clearly and simply. State that they should tell you and/or their parents if they are sick, experience discomfort or pain. Address what may be some of the child's worries, for example, missing school or extra expense to parents.

*(Example: There are a few other things that I want you to know.*

*The injection might hurt for just a second when it goes into your arm. It might get a little bit red and hard around the place where the injection/needle goes in. That should go away in a day. If it hurts longer than that, or if it stays hard for longer or swells up, tell your parents or me. If you feel bad or strange, tell us.*

*Sleeping under a mosquito net can be uncomfortable because it can be hot and stuffy.*

*Sometimes you may not want to come to the clinic to get your blood checked or have your temperature taken. Its important that you try to come. It won't take very long. You will miss a little bit of school - about an hour every month - and we will tell your teacher about that so that she knows its okay.)*

- **Examples of question to elucidate understanding:** Do you understand that, while the research study is on-going, no-one may know which medicine you re receiving? Do you know that the medicine that we are testing is a new medicine, and we do not know everything about it? Do you understand that you may have some unwanted side-effects from the medicines? Do you understand that these side-effects can happen whether or not you are in the research study? Etc. Do you have any other questions?

I have checked with the child and they understand the risks and discomforts \_\_\_\_ (initial)

**Benefits: Is there anything good that happens to me?**

Describe any benefits to the child.

*(Example: Nothing really good might happen to you. The vaccine may not stop you from getting malaria. But this research might help us to find a vaccine now or later that could help other children. There are a couple of good things if you do decide that you want to do this. You do get regular check-*



*ups with the nurse so that if you are sick, we will know very soon and this can be important. And you will keep the mosquito net which will help keep mosquitoes away from you. Because mosquitoes cause malaria, this is important.)*

**I have checked with the child and they understand the benefits\_\_\_\_\_ (initial)**

**Reimbursements: Do I get anything for being in the research?**

Mention any reimbursements or forms of appreciation that will be provided. Any gifts given to children should be small enough to not be an inducement or reason for participating. WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in the research. These expenses may include, for example, travel expenses and reimbursement for time lost. The amount should be determined within the host country context.

*(Example:Because you live quite far from the clinic, we will give your parents enough money to pay for the trip here and (whatever other expense is reasonable).*

- **Examples of question to elucidate understanding:** *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be reimbursed? Do you have any other questions?*

**Confidentiality: Is everybody going to know about this?**

Explain what confidentiality means in simple terms. State any limits to confidentiality. Indicate what their parents will or will not be told.

*(Example:We will not tell other people that you are in this research and we won't share information about you to anyone who does not work in the research study. After the research is over, you and your parents will be told which of the two injections you received and the results.*

*Information about you that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc].)*

- **Example of question to elucidate understanding:** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you have any questions about them?*

**Compensation: What happens if I get hurt?**

Describe to the ability of the child to understand and explain that parents have been given more information.

*(Example:If you become sick during the research, we will look after you. We have given your parents information about what to do if you are hurt or get sick during the research.)*

**Sharing the Findings: Will you tell me the results?**



Describe to the ability of the child to understand that the research findings will be shared in a timely fashion but that confidential information will remain confidential. If you have a plan and a timeline for the sharing of information, include the details. Also tell the child that the research will be shared more broadly, i.e. in a book, journal, conferences, etc.

*(Example: When we are finished the research, I will sit down with you and your parent and I will tell you about what we learnt. I will also give you a paper with the results written down. Afterwards, we will be telling more people, scientists and others, about the research and what we found. We will do this by writing and sharing reports and by going to meetings with people who are interested in the work we do.)*

**Right to Refuse or Withdraw: Can I choose not to be in the research? Can I change my mind?**

You may want to re-emphasize that participation is voluntary and any limits to this.

*(Example: You do not have to be in this research. No one will be mad or disappointed with you if you say no. It's your choice. You can think about it and tell us later if you want. You can say "yes" now and change your mind later and it will still be okay.)*

**Who to Contact: Who can I talk to or ask questions to?**

List and give contact information for those people who the child can contact easily (a local person who can actually be contacted). Tell the child that they can also talk to anyone they want to about this (their own doctor, a family friend, a teacher).

*(Example: You can ask me questions now or later. You can ask the nurse questions. I have written a number and address where you can reach us or, if you are nearby, you can come and see us. If you want to talk to someone else that you know like your teacher or doctor or auntie, that's okay too.)*

**If you choose to be part of this research I will also give you a copy of this paper to keep for yourself. You can ask your parents to look after it if you want.**

- **Example of question to elucidate understanding:** *Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.*

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

**PART 2: Certificate of Assent**

This section can be written in the first person. It should include a few brief statements about the research and be followed by a statement similar to the one identified as 'suggested wording' below. If the child is illiterate but gives oral assent, a witness must sign instead. A researcher or the person going over the informed assent with the child must sign all assents.

*(Example: I understand the research is about testing a new vaccine for malaria and that I might get either the new vaccine which is being tested or the vaccine which is currently being used. I understand*



*that I will get an injection and that I will come for regular monthly check-ups at the clinic where I will give a blood sample with a finger prick.)*

**I have read this information ( or had the information read to me) I have had my questions answered and know that I can ask questions later if I have them.**

**I agree to take part in the research.**

**OR**

**I do not wish to take part in the research and I have not signed the assent below. \_\_\_\_\_(initialled by child/minor)**

**Only if child assents:**

**Print name of child \_\_\_\_\_**

**Signature of child: \_\_\_\_\_**

**Date: \_\_\_\_\_  
day/month/year**

***If illiterate:***

A literate witness must sign (if possible, this person should be selected by the participant, not be a parent, and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

**I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.**

**Print name of witness (not a parent) \_\_\_\_\_ AND Thumb print of participant**

**Signature of witness \_\_\_\_\_**

**Date \_\_\_\_\_  
Day/month/year**

**I have accurately read or witnessed the accurate reading of the assent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.**

**Print name of researcher \_\_\_\_\_**



Signature of researcher \_\_\_\_\_

Date \_\_\_\_\_  
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the child understands that the following will be done:

- 1.
- 2.
- 3.

I confirm that the child was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this assent form has been provided to the participant.

Print Name of Researcher/person taking the assent \_\_\_\_\_

Signature of Researcher /person taking the assent \_\_\_\_\_

Date \_\_\_\_\_  
Day/month/year

Copy provided to the participant \_\_\_\_\_(initialed by researcher/assistant)

Parent/Guardian has signed an informed consent \_\_\_Yes \_\_\_No \_\_\_(initialed by researcher/assistant)



## **BATANGAS MEDICAL CENTER**

### **RESEARCH ETHICS REVIEW COMMITTEE**

*Adapted from the WHO Informed Consent Template*  
([http://www.who.int/rpc/research\\_ethics/informed\\_consent/en/](http://www.who.int/rpc/research_ethics/informed_consent/en/))

#### ***Informed Consent Form Template for Qualitative Studies***

**(This template is for research interventions that use questionnaires, in-depth interviews or focus group discussions: *Form WHO ICF-3* )**

*(language used throughout form should be at the level of a local student of class 6<sup>th</sup>/8<sup>th</sup>)*

#### Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study. **The logo of the Institution must be used on the ICF and not the WHO logo.**
2. The informed consent form consists of two parts: the information sheet and the consent certificate.
3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.
4. This template includes examples of key questions that may be asked at the end of each section, that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.
5. In this template:
  - square brackets indicate where specific information is to be inserted
  - bold lettering indicates sections or wording which should be included
  - standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.

TEMPLATE ON THE FOLLOWING PAGE

**[Informed Consent Form for \_\_\_\_\_]**

Name the group of individuals for whom this consent is written. Because research for a single project is often carried out with a number of different groups of individuals - for example counselors, community members, clients of services - it is important that you identify which group this particular consent is for.

*(Example: This informed consent form is for social service providers in the community X and who we are inviting to participate in research Y, titled "The Community Response to Malaria Project".)*

You may provide the following information either as a running paragraph or under headings as shown below.

**[Name of Principle Investigator]**

**[Name of Organization]**

**[Name of Sponsor]**

**[Name of Project and Version]**

**This Informed Consent Form has two parts:**

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you choose to participate)**

**You will be given a copy of the full Informed Consent Form**

**Part I: Information Sheet**

**Introduction**

Briefly state who you are and that you are inviting them to participate in research which you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions at anytime.

*(Example: I am X, working for the Y organization. I am doing research on the disease malaria which is very common in this country and in this region. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.*

*This consent form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.)*

**Purpose of the research**

Explain the research question in lay terms which will clarify rather than confuse. Use local and simplified words rather than scientific terms and professional jargon. In your explanation, consider local beliefs and knowledge when deciding how best to provide the information. Investigators however need to be careful not to mislead participants, by suggesting research interests that they do not have. For example, if the study wants to find out about treatments provided by local practitioners, wording should not suggest that they want to find out about how the practitioners are advertising themselves. Misleading participants may



be essential and justified in certain circumstances, but that needs to be carefully argued, and approved by an ethics committee.

*(Example: Malaria is making many people sick in your community. We want to find ways to stop this from happening. We believe that you can help us by telling us what you know both about malaria and about local health practices in general . We want to learn what people who live or work here know about the causes of malaria and why some people get it. We want to learn about the different ways that people try to stop malaria before someone gets it or before it comes to the community, and how people know when someone has it. We also want to know more about local health practices because this knowledge might help us to learn how to better control malaria in this community.)*

### **Type of Research Intervention**

Briefly state the type of intervention that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves a vaccine, an interview, a questionnaire, or a series of finger pricks.

*(Example: This research will involve your participation in a group discussion that will take about one and a half hour, and a one hour interview).*

### **Participant Selection**

Indicate why you have chosen this person to participate in this research. People wonder why they have been chosen and may be fearful, confused or concerned.

*(Example: You are being invited to take part in this research because we feel that your experience as a social worker (or as a mother, or as a responsible citizen) can contribute much to our understanding and knowledge of local health practices.)*

- **Example of question to elucidate understanding:** Do you know why we are asking you to take part in this study? Do you know what the study is about?

### **Voluntary Participation**

Indicate clearly that they can choose to participate or not. State, only if it is applicable, that they will still receive all the services they usually do if they choose not to participate. Explanation: It may be more applicable to assure them that their choosing to participate or not will not have any bearing on their job or job-related evaluations. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context. Although, if the interview or group discussion has already taken place, the person cannot 'stop participation' but request that the information provided by them not be used in the research study.

*(Example: Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate all the services you receive at this Centre will continue and nothing will change.*

*OR*

*The choice that you make will have no bearing on your job or on any work-related evaluations or reports. You may change your mind later and stop participating even if you agreed earlier.)*





- **Examples of question to elucidate understanding:** *If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

## Procedures

A. Provide a brief introduction to the format of the research study.

*(Example: We are asking you to help us learn more about malaria in your community. We are inviting you to take part in this research project. If you accept, you will be asked to.....:)*

B. Explain the type of questions that the participants are likely to be asked in the focus group, the interviews, or the survey. If the research involves questions or discussion which may be sensitive or potentially cause embarrassment, inform the participant of this.

*(Example 1 (for focus group discussions)*

*take part in a discussion with 7-8 other persons with similar experiences. This discussion will be guided by [name of moderator/guider] or myself.*

*The group discussion will start with me, or the focus group guide or moderator (use the local word for group discussion leader), making sure that you are comfortable. We can also answer questions about the research that you might have. Then we will ask you questions about the malaria and give you time to share your knowledge. The questions will be about malaria in your community, how is it recognized, what people do to stop it from spreading to other people, who people go to for help and what happens when people become sick with it.*

*We will also talk about community practices more generally because this will give us a chance to understand more about malaria but in a different way. These are the types of questions we will ask..... **We will not ask you to share personal beliefs, practices or stories and you do not have to share any knowledge that you are not comfortable sharing.***

*The discussion will take place in [location of the FGD], and no one else but the people who take part in the discussion and guide or myself will be present during this discussion. The entire discussion will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s)] will have access to the tapes. The tapes will be destroyed after \_\_\_\_\_ number of days/weeks.*

*Example 2 (for interviews)*

*participate in an interview with [name of interviewer] or myself.*

*During the interview, I or another interviewer will sit down with you in a comfortable place at the Centre. If it is better for you, the interview can take place in your home or a friend's home. If you do not wish to answer any of the questions during the interview, you may say so and the interviewer will move on to the next question. No one else but the interviewer will be present unless you would like someone else to be there. The information recorded is confidential, and no one else except [name of person(s)] will access to the information documented during your interview. The entire interview will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s)] will have access to the tapes. The tapes will be destroyed after \_\_\_\_\_ number of days/weeks.*



**Example 3 (for questionnaire surveys)**

*fill out a survey which will be provided by [name of distributor of blank surveys] and collected by [name of collector of completed surveys]. OR You may answer the questionnaire yourself, or it can be read to you and you can say out loud the answer you want me to write down.*

*If you do not wish to answer any of the questions included in the survey, you may skip them and move on to the next question. [Describe how the survey will be distributed and collected]. The information recorded is confidential, your name is not being included on the forms, only a number will identify you, and no one else except [name of person(s) with access to the information] will have access to your survey.)*

**Duration**

Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

*(Example: The research takes place over \_\_\_\_ (number of) days/ or \_\_\_\_ (number of) months in total. During that time, we will visit you three times for interviewing you at one month interval and each interview will last for about one hour each. The group discussion will be held once and will take about one and a half hour.)*

- **Examples of question to elucidate understanding:** *If you decide to take part in the study, do you know how much time will the interview take? Where will it take place? Do you know that we will be sending you transport to pick you up from your home? Do you know how much time will the discussion with other people take? If you agree to take part, do you know if you can stop participating? Do you know that you may not respond to the questions that you do not wish to respond to? Etc. Do you have any more questions?*

**Risks**

Explain and describe any risks that you anticipate or that are possible. The risks depend upon the nature and type of qualitative intervention, and should be, as usual, tailored to the specific issue and situation.

*(If the discussion is on sensitive and personal issues e.g. reproductive and sexual health, personal habits etc. then an example of text could be something like "We are asking you to share with us some very personal and confidential information, and you may feel uncomfortable talking about some of the topics. You do not have to answer any question or take part in the discussion/interview/survey if you don't wish to do so, and that is also fine. You do not have to give us any reason for not responding to any question, or for refusing to take part in the interview"*

*OR If for example, the discussion is on opinions on government policies and community beliefs, and in general no personal information is sought, then the text under risks could read something like "There is a risk that you may share some personal or confidential information by chance, or that you may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. You do not have to answer any question or take part in the discussion/interview/survey if you feel the question(s) are too personal or if talking about them makes you uncomfortable.)*

**Benefits**

Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question.

Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation.

*(Example: There will be no direct benefit to you, but your participation is likely to help us find out more about how to prevent and treat malaria in your community).*

### Reimbursements

State clearly what you will provide the participants with as a result of their participation. WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in the research. These may include, for example, travel costs and reimbursement for time lost. The amount should be determined within the host country context.

*Example: You will not be provided any incentive to take part in the research. However, we will give you [provide a figure, if money is involved] for your time, and travel expense (if applicable).*

- **Examples of question to elucidate understanding:** Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be reimbursed? Do you have any other questions?

### Confidentiality

Explain how the research team will maintain the confidentiality of data with respect to both information about the participant and information that the participant shares. Outline any limits to confidentiality. Inform the participant that because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and therefore more likely to be stigmatized. If the research is sensitive and/or involves participants who are highly vulnerable - research concerning violence against women for example - explain to the participant any extra precautions you will take to ensure safety and anonymity.

*(Example: The research being done in the community may draw attention and if you participate you may be asked questions by other people in the community. We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc])*

The following applies to focus groups:

Focus groups provide a particular challenge to confidentiality because once something is said in the group it becomes common knowledge. Explain to the participant that you will encourage group participants to respect confidentiality, but that you cannot guarantee it.

*(Example: We will ask you and others in the group not to talk to people outside the group about what was said in the group. We will, in other words, ask each of you to keep what was said in the group confidential. You should know, however, that we cannot stop or prevent participants who were in the group from sharing things that should be confidential.)*

- **Example of question to elucidate understanding:** Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you understand that we cannot guarantee complete confidentiality of information that you share with us in a group discussion? Do you have any more questions?

### Sharing the Results

Your plan for sharing the findings with the participants should be provided. If you have a plan and a timeline for the sharing of information, include the details. You may also inform the participant that the research findings will be shared more broadly, for example, through publications and conferences.

*(Example: Nothing that you tell us today will be shared with anybody outside the research team, and nothing will be attributed to you by name. The knowledge that we get from this research will be shared with you and your community before it is made widely available to the public. Each participant will receive a summary of the results. There will also be small meetings in the community and these will be announced. Following the meetings, we will publish the results so that other interested people may learn from the research.)*

### Right to Refuse or Withdraw

This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section to ensure that it fits for the group for whom you are seeking consent. The example used here is for a community social worker. Participants should have an opportunity to review their remarks in individual interviews and erase part or all of the recording or note.

*(Example: You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your job or job-related evaluations in any way. You may stop participating in the [discussion/interview] at any time that you wish without your job being affected. I will give you an opportunity at the end of the interview/discussion to review your remarks, and you can ask to modify or remove portions of those, if you do not agree with my notes or if I did not understand you correctly.)*

### Who to Contact

Provide the name and contact information of someone who is involved, informed and accessible - a local person who can actually be contacted. State also the name (and contact details) of the local IRB that has approved the proposal. State also that the proposal has also been approved by the WHO ERC.

*(Example: If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail])*



*This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact \_\_\_\_ .)*

This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone number.]). It has also been reviewed by the Ethics Review Committee of the World Health Organization (WHO), which is funding/sponsoring/supporting the study.

- **Example of question to elucidate understanding:** *Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.*

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

## Part II: Certificate of Consent

This section must be written in the first person. It should include a few brief statements about the research and be followed by a statement similar the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. Because the certificate is an integral part of the informed consent and not a stand-alone document, the layout or design of the form should reflect this. The certificate of consent should avoid statements that have "I understand...." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

*Example: I have been invited to participate in research about malaria and local health practices.*

**(This section is mandatory)**

**I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study**

Print Name of Participant \_\_\_\_\_

Signature of Participant \_\_\_\_\_

Date \_\_\_\_\_

Day/month/year



*If illiterate*<sup>1</sup>

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness \_\_\_\_\_

Thumb print of participant

Signature of witness \_\_\_\_\_

Date \_\_\_\_\_  
Day/month/year

**Statement by the researcher/person taking consent**

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

- 1.
- 2.
- 3.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent \_\_\_\_\_

Signature of Researcher /person taking the consent \_\_\_\_\_

Date \_\_\_\_\_  
Day/month/year

<sup>1</sup> A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.





## **BATANGAS MEDICAL CENTER**

### **RESEARCH ETHICS REVIEW COMMITTEE**

*Adapted from the WHO Informed Consent Template*  
([http://www.who.int/rpc/research\\_ethics/informed\\_consent/en/](http://www.who.int/rpc/research_ethics/informed_consent/en/))

#### ***Informed Parental Consent Template for Research Involving Children (Qualitative Studies)***

**(For use with Participant Observation, Focus Group Discussions, Interviews, and Surveys: Form WHO ICF-4)**  
*(language used throughout form should be at the level of a local student of class 6<sup>th</sup>/8<sup>th</sup>)*

#### Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study. **The logo of the Institution must be used on the ICF and not the WHO logo.**
2. The informed consent form consists of two parts: the information sheet and the consent certificate.
3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.
4. This template includes examples of key questions that may be asked at the end of each section, that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.
5. In this template:
  - square brackets indicate where specific information is to be inserted
  - bold lettering indicates sections or wording which should be included
  - standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.

TEMPLATE ON FOLLOWING PAGE





**[Informed Consent Form for \_\_\_\_\_]**

Name the group of individuals for whom this consent is written. Because research for a single project is often carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for.

*(e.g. This informed consent form is for parents of adolescent girls and boys participating in the research titled. "What do we want: Adolescents and health systems ")*

**[Name of Principle Investigator]**

**[Name of Organization]**

**[Name of Sponsor]**

**[Name of Project and Version]**

**This Informed Consent Form has two parts:**

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you agree that your child may participate)**

**You will be given a copy of the full Informed Consent Form**

**Part I: Information Sheet**

**Introduction**

Briefly state who you are and explain that you are inviting them to have their child participate in research which you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want their child to participate or not. Assure the parent that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they may ask questions now or later.

*(Example: I am X, and I work at Y organization in \_\_\_\_\_. I am doing some research which might help your clinic/hospital do more to help teenagers become and stay healthier. In our research we will talk to many teenagers, both girls and boys, and ask them a number of questions. Whenever researchers study children, we talk to the parents and ask them for their permission. After you have heard more about the study, and if you agree, then the next thing I will do is ask your daughter/son for their agreement as well. Both of you have to agree independently before I can begin.*

*You do not have to decide today whether or not you agree to have your child participate in this research. Before you decide, you can talk to anyone you feel comfortable with.*

*There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.)*

**Purpose**

Explain in lay terms why the research is being done and what is expected from the results. Explain why you need to conduct the research with children.

*(Example: It is possible that the clinics and the hospital in this region are not providing some of the services that are important for teenagers. In this study we will talk to teenage girls and boys about what they know about caring for their bodies in a healthy way including sexual and reproductive health. We will invite them to share their knowledge and understanding with us so that we can find ways of meeting their needs at the local clinics and hospital.)*

### **Type of Research Intervention**

Briefly state the intervention. This will be expanded upon in the procedures section.

*(Example: A questionnaire OR a focus group OR an interview)*

### **Selection of Participants**

State clearly why you have chosen their child to participate in this study. Parents may wonder why their children have been chosen for a study and may be fearful, confused or concerned.

*(Example: We want to talk to many teenagers about their health and what information or services they want for themselves. One part of health that we want to talk to them about is sexuality. We would like to ask your daughter/son to participate because she/he is a teenager and lives in this region.)*

- **Example of question to elucidate understanding:** Do you know why we are asking your child to take part in this study? Do you know what the study is about?

### **Voluntary Participation**

Indicate clearly that they can choose for their child to participate or not and reassure they will still receive all the services they usually do if they choose not to participate. Also inform them that their child will also have input into the decision. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context. Participants may also be more alert at the beginning.

*(Example: You do not have to agree that your daughter/son can talk to us. You can choose to say no and any services that you and your family receive at this centre will not change. We know that the decision can be difficult when it involves your children. And it can be especially hard when the research includes sensitive topics like sexuality. You can ask as many questions as you like and we take the time to answer them. You don't have to decide today. You can think about it and tell me what you decide later.)*

- **Examples of question to elucidate understanding:** If you decide not to allow your child to take part in this research study, do you know what the options for him are? Do you know that your child does not have to take part in this research study, if you do not wish so? Do you have any questions?

### **Procedure**

Explain what each of the steps or procedures involve. Indicate when the research will take place and where. If there are surveys, indicate where and how the surveys will be collected and distributed.

*(Examples:*

1) the following applies only to focus group discussions:

*Your daughter/son will take part in a discussion with 7-8 other teenagers, or a mix of teenagers and social service workers from the community. The girls and boys will be in separate groups. This discussion will be guided by [give name of moderator] or me.*

2) the following applies only to interviews:

*Your daughter/son will participate in an interview with [name of interviewer] or myself.*

3) the following applies only to questionnaire surveys:

*Your daughter/son will fill out a questionnaire which will be provided by [name of distributor of blank questionnaires] and collected by [name of collector of completed questionnaires]. **OR** The questionnaire can be read aloud and she/he can give me the answer which she/he wants me to write.)*

Explain the type of questions that the participants are likely to be asked in the focus group discussion, interview or in the questionnaire. If the questions are sensitive, acknowledge this, try to anticipate parents' concerns and protective responses, and address these. Parents may be concerned that if researchers talk to their children about sexuality it may encourage them to explore sexual activities with their peers. Other concerns may include disbelief that their child is ready to talk about sexuality, or parents may be personally embarrassed.

*(Examples:*

1) The following applies only to focus group discussions:

*The group discussion will start with me, or the focus group guide (use the local word for group discussion leader), making sure that the participants are comfortable. We will also answer questions about the research that they might have. Then we will ask questions about the health system in this community. We will talk about where they go for information about health, and whether they get the information and services they need and want. We will encourage them to talk about sexual and reproductive health as well as other important health topics such as food and nutrition. These are the types of questions we will ask. We will not ask them to share personal stories or anything that they are not comfortable sharing.*

*The discussion will take place in [location of the FGD], and no one else but the people who take part in the discussion and the guide or I will be present during this discussion. The entire discussion will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s) with access to the tapes] will be allowed to listen to the tapes. [The tapes will be destroyed after \_\_\_\_ period of time.]*

2) The following applies only to interviews:

*If your daughter does not wish to answer any of the questions during the interview, she may say so and the interviewer will move on to the next question. The interview will take place in [location of the interview], and no one else but the interviewer will be present unless your child asks for someone else to be there. The information recorded is confidential, and no one else except [name of person(s) with*

access to the information] will have access to the information documented during your interview.) [The tapes will be destroyed after \_\_\_\_\_period of time.]

### 3) The following applies only to questionnaires and surveys:

*If your daughter/son does not wish to answer some of the questions included in the questionnaire, she/he may skip them and move on to the next question. The information recorded is confidential, and no one else except [name of person(s) with access to the information] will have access to her questionnaire. [The questionnaires will be destroyed after \_\_\_\_\_period of time.])*

### **Duration**

Include a statement about the time commitments of the study for the child and any time commitments on the part of the parent(s). Include both the duration of the study and follow-up, if relevant.

*(Example: We are asking your child to participate in an interview which will take about 1 hour of her/his time. We can do this outside of school/work hours. There is also a questionnaire that we will either provide to your child or which we will do together with her/him. This also takes about an hour. Altogether, we are asking for about 2 hours of your child's time.)*

- **Examples of question to elucidate understanding:** *If you decide that your child can take part in the study, do you know how much time will the interview take? Where will it take place? Do you know that we will be sending a transport to pick up your child from your home? Do you know how much time will the discussion with other people take? If you agree that your child can take part, do you know if he/she can stop participating? Do you know that your child may not respond to the questions that he/she does not wish to respond to? Etc. Do you have any more questions?*

### **Risks and Discomforts**

Explain any risks or discomforts including any limits to confidentiality.

*(If the discussion is on sensitive and personal issues e.g. reproductive and sexual health, personal habits etc. then an example of text could be something like "We are asking your son/daughter to share with us some very personal and confidential information, and he/she may feel uncomfortable talking about some of the topics. You must know that he/she does not have to answer any question or take part in the discussion/interview/survey if he/she doesn't wish to do so, and that is also fine. He/she does not have to give us any reason for not responding to any question, or for refusing to take part in the interview"*

*OR If for example, the discussion is on opinions on government policies and community beliefs, and in general no personal information is sought, then the text under risks could read something like "There is a risk that your son/daughter may share some personal or confidential information by chance, or that he/she may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. You must know that he/she does not have to answer any question or take part in the discussion/interview/survey if he/she feels the question(s) are too personal or if talking about them makes him/her uncomfortable.)*



*Your daughter/son may choose to tell you about the interview and the questionnaire but she/he does not have to do this. We will not be sharing with you either the questions we ask nor the responses given to us by your child.)*

### Benefits

Describe any benefits to their child, to the community, or any benefits which are expected in the future as a result of the research.

*(Example: There will be no immediate and direct benefit to your child or to you, but your child's participation is likely to help us find out more about the health needs of teenage girls and boys and we hope that these will help the local clinics and hospitals to meet those needs better in the future.)*

### Reimbursements

State clearly what you will provide the participants with as a result of their participation. WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in research. The expenses may include, for example, travel expenses and reimbursement for time lost. The amount should be determined within the host country context.

*(Example: Your daughter/son will not be provided with any payment to take part in the research. However, she/he will be given with [provide a figure, if money is involved] for her/his time, and travel expense (if applicable).)*

- **Examples of question to elucidate understanding:** *Can you tell me if you have understood correctly the benefits that your child will have if you allow him/her to take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be re-imbursed? Do you have any other questions?*

### Confidentiality:

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant. Outline any limits there are to confidentiality. Note that with focus groups confidentiality cannot be guaranteed because what is said within the group becomes common knowledge. Participants can be asked not to share outside of the group but this does not guarantee confidentiality.

*(Examples:*

*Because something out of the ordinary is being done through research in your community, it will draw attention. If your daughter/son participates, she and you may be asked questions by other people in the community.*

*We will not be sharing information about your son or daughter outside of the research team. The information that we collect from this research project will be kept confidential. Information about your child that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about your child will have a number on it instead of his/her name. Only the researchers will know what his/her number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc].*



The following applies to focus groups:

*We will ask your child and others in the group not to talk to people outside the group about what was said in the group. We will, in other words, ask each participant to keep what was said in the group confidential. You should know, however, that we cannot stop or prevent participants who were in the group from sharing things that should be confidential.)*

- **Example of question to elucidate understanding:** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about your child will remain confidential? Do you understand that we cannot guarantee complete confidentiality of information that your child shares with us in a group discussion? Do you have any more questions?*

### **Sharing of Research Findings**

Include a statement indicating that the research findings will be shared in a timely fashion but that confidential information will remain confidential. If you have a plan and timeline for the sharing of information, include the details. Also inform the parent that the research findings will be shared more broadly, for examples, through publications and conferences.

*(Example: At the end of the study, we will be sharing what we have learnt with the participants and with the community. We will do this by meeting first with the participants and then with the larger community. Nothing that your child will tell us today will be shared with anybody outside the research team, and nothing will be attributed to him/her by name. A written report will also be given to the participants which they can share with their families. We will also publish the results in order that other interested people may learn from our research.)*

### **Right to refuse or withdraw**

Explain again the voluntary nature of consent. Also explain that their child will be asked to agree - or assent - and that the child's concerns and wishes will be taken very seriously.

*(Example: You may choose not to have your child participate in this study and your child does not have to take part in this research if she/he does not wish to do so. Choosing to participate or not will not affect either your own or your child's future treatment at the Centre here in any way. You and your child will still have all the benefits that would otherwise be available at this Centre. Your child may stop participating in the discussion/interview at any time that you or she/he wish without either of you losing any of your rights here.)*

### **Who to Contact**

Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted. State also that the proposal has been approved and how.

*(Example: If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail]*

*This proposal has been reviewed and approved by [name of the IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find out more about the IRB, contact [name, address, telephone number.]*





- ***Example of question to elucidate understanding: Do you know that you do not have to allow your child take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.***

## **PART II: Certificate of Consent**

### **Certificate of Consent**

This section can be written in the first person. It should include a few brief statements about the research and be followed by a statement similar to the one in bold below. If the participant is illiterate but gives oral consent a witness must sign. A researcher or the person going over the informed consent must sign each consent. Because the certificate is an integral part of the information sheet and not a stand-alone document, the layout or design of the form should reflect this.

*I have been asked to give consent for my daughter/son to participate in this research study which will involve her completing one interview and one questionnaire* **I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for my child to participate as a participant in this study.**

Print Name of Parent or Guardian \_\_\_\_\_

Signature of Parent of Guardian \_\_\_\_\_

Date \_\_\_\_\_  
Day/month/year

### ***If illiterate***

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

**I have witnessed the accurate reading of the consent form to the parent of the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.**

Print name of witness \_\_\_\_\_

**AND**

**Thumb print of participant**

Signature of witness \_\_\_\_\_

Date \_\_\_\_\_  
Day/month/year





**Statement by the researcher/person taking consent**

**I have accurately read out the information sheet to the parent of the potential participant, and to the best of my ability made sure that the person understands that the following will be done:**

- 1.**
- 2.**
- 3.**

**I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.**

**A copy of this Informed Consent Form has been provided to the parent or guardian of the participant**

\_\_\_\_\_

**Print Name of Researcher/person taking the consent**\_\_\_\_\_

**An Informed Assent Form will \_\_\_\_ OR will not \_\_\_\_ be completed.**



## **BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE**

*Adapted from the WHO Informed Consent Template  
([http://www.who.int/rpc/research\\_ethics/informed\\_consent/en/](http://www.who.int/rpc/research_ethics/informed_consent/en/))*

***Informed Consent Form Template for  
Consent for Storage and Future Use of  
Unused Samples (Form WHO ICF-5)***

### Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study. **The logo of the Institution must be used on the ICF and not the WHO logo.**
2. The informed consent form consists of two parts: the information sheet and the consent certificate.
3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.
4. In this template:
  - square brackets indicate where specific information is to be inserted
  - bold lettering indicates sections or wording which should be included
  - standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.

TEMPLATE ON FOLLOWING PAGE

### Additional Consent to [Name of Project]

Include the following section if the research protocol calls for storage and future use of samples

**This Statement of Consent consists of two parts:**

- **Information Sheet (to share information about unused samples with you)**
- **Certificate of Consent (to record your agreement)**

**You will be given a copy of the full Statement of Consent**

#### **Part 1. Information Sheet**

Explain that you are seeking permission to store their unused samples for possible future use in either your own research or someone else's research. State that they need to make some decisions about their blood/tissue/sperm/sputum sample because they gave you permission only to use it for the current research.

Explain that sometimes people don't want their samples used for research into areas they might not agree with, for example, research into birth control or reproductive technology. Use lay terms to explain research possibilities. If genetic research is a possibility, explain what this is and any implications for them. State that they can tell you if there is something they don't want their sample used for, or if they don't want their sample used at all.

Inform the participant that at present, the researchers can trace which blood/tissue/sperm/sputum sample belongs to the participant. In most cases, the participant must decide whether they want to let the researchers keep the sample but get rid of all identifying information, or whether they are comfortable with the researchers knowing whose sample it is. Explain the risks and benefits of each of these options. Inform the participant of researcher obligations in cases where the sample remains linked. These obligations include informing the participant of results which have immediate clinical relevance.

Inform participants that their sample will not be sold for profit and that any research which uses their sample will have been approved.

#### **Right to Refuse and Withdraw**

Explain that the participant may refuse to allow samples to be kept or put restrictions on those samples with no loss of benefits and that the current research study will not be affected in any way. Inform the participant that they may withdraw permission at anytime and provide them with the name, address, and number of the person and sponsoring institution to contact.

#### **Confidentiality**

Briefly explain how confidentiality will be maintained including any limitations.

You can ask me any more questions about any part of the information provided above, if you wish to. Do you have any questions?



## Part II. Certificate of Consent

If any of the (TYPE OF SAMPLE i.e. blood, tissue) I have provided for this research project is unused or leftover when the project is completed (Tick **one** choice from each of the following boxes)

- ☐ I wish my [TYPE OF SAMPLE] sample to be destroyed immediately.
- ☐ I want my [TYPE OF SAMPLE] sample to be destroyed after \_\_\_\_ years.
- ☐ I give permission for my [TYPE OF SAMPLE] sample to be stored indefinitely

AND (if the sample is to be stored)

- ☐ I give permission for my (TYPE OF SAMPLE) sample to be stored and used in future research but only on the same subject as the current research project : [give name of current research]
- ☐ I give my permission for my [TYPE OF SAMPLE] sample to be stored and used in future research of any type which has been properly approved
- ☐ I give permission for my [TYPE OF SAMPLE] sample to be stored and used in future research except for research about [NAME TYPE OF RESEARCH]

AND

- ☐ I want my identity to be removed from my (TYPE OF SAMPLE) sample.
- ☐ I want my identity to be kept with my (TYPE OF SAMPLE) sample.

**I have read the information, or it has been read to me. I have had the opportunity to ask questions about it and my questions have been answered to my satisfaction. I consent voluntarily to have my samples stored in the manner and for the purpose indicated above.**

**Print Name of Participant** \_\_\_\_\_

**Signature of Participant** \_\_\_\_\_

**Date** \_\_\_\_\_

**Day/month/year**

### If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

**I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.**



Print name of witness \_\_\_\_\_

AND Thumb print of participant

Signature of witness \_\_\_\_\_

Date \_\_\_\_\_

Day/month/year

**Statement by the researcher/person taking consent**

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

- 1.
- 2.
- 3.

I confirm that the participant was given an opportunity to ask questions about the nature and manner of storage of the samples, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent \_\_\_\_\_

Signature of Researcher /person taking the consent \_\_\_\_\_

Date \_\_\_\_\_

Day/month/year



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**PROTOCOL PACKAGE CHECKLIST (Form 2.6.1)**

**Protocol Title:** \_\_\_\_\_

**PROTOCOL CODE:** \_\_\_\_\_

**PRIMARY INVESTIGATOR:** \_\_\_\_\_

**Date of Submission:** \_\_\_\_\_

**Basic Documents** (*ALL must be submitted*)

- ☐ Protocol package checklist ([Form 2.6.1](#))
- ☐ Application form for Protocol Review ([Form 2.6.2](#))
- ☐ Protocol Evaluation Review ([Form 2.6.3](#))
- ☐ Protocol Summary Sheet ([Form 2.6.4](#))
- ☐ Study Protocol
- ☐ Diagrammatic work flow
- ☐ Gantt Chart for Schedule of activities
- ☐ Supplementary Documents (if applicable)
  - ☐ Questionnaire
  - ☐ Data Collection Forms
  - ☐ Product Brochure
  - ☐ Investigator's Brochure (for clinical trials phase I, II, III) or Basic Product Information Document (for Phase IV clinical trials)
  - ☐ Philippine FDA Marketing Authorization or Import License
  - ☐ Permit/s for Special Population (please specify)  
\_\_\_\_\_
- ☐ Informed Consent Form
  - ☐ English      ☐ Tagalog      ☐ Others
- ☐ Assent Form (if applicable)
  - ☐ English      ☐ Tagalog      ☐ Others
- ☐ Technical Review Certificate
- ☐ Statistical and Turnitin Similarity Clearance (valid for 6 months from date of initial issuance)
- ☐ Good Clinical Practice (GCP) Training Certificate of PI, Co-I and the rest of the study team: updated at least within THREE (3) years (for clinical trials)
- ☐ Curriculum Vitae for all members of the Study Team
- ☐ Non-Disclosure Agreement <Principal Investigator> ([Form 2.6.5](#))
- ☐ Proof of Payment of Initial Review Fee, if applicable
- ☐ Study Protocol Assessment Form ([Form 2.14.1](#))
- ☐ Informed Consent Assessment Form ([Form 2.14.2](#))

**Study Specific Documents** (*submit as needed particularly for externally originated studies and sponsored studies*)

- ☐ Recruitment advertisements (as needed by the study protocol)
- ☐ Other information or documents for participants (such as diaries, etc.)
- ☐ Material Transfer Agreement (for any research involving transfer of biological specimens)



- ☐ Memorandum of Agreement (for collaborative studies)
- ☐ Site Resources Checklist for Clinical Trial Outside BATMC By BATMC Personnel
- ☐ Site Resources Checklist for Clinical Trial Outside BATMC By non-BATMC Personnel
- ☐ Previous ethical review approvals/clearances (for students/personnel of foreign universities researching in the Philippines or those with prior ethical review)
- ☐ National Commission for Indigenous People (NCIP) Clearance (for studies with indigenous populations; can be processed while BATMC-RERC review is ongoing)
- ☐ Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, as applicable)
- ☐ Contracts and/or Approval of relevant offices / regulatory authorities (Written review agreement / Authorization and Acknowledgement of review)

WHO Templates for Informed Consent and Assent Forms *(use as Guide only)*

- ☐ WHO TEMPLATE: Informed Consent form in English and Local language (for studies involving adult human participants) *(Use as Guide : WHO Form ICF-1)*
- ☐ WHO TEMPLATE: Informed Consent form for Co-signature in English and Local language (for studies involving minors ages more than or equal to 15 years up to less than 18 years of age and relevant populations deemed incompetent to execute decision and signing of informed consent form) *(Use as Guide : WHO Form ICF-1)*
- ☐ WHO TEMPLATE: Assent form in English and Local language (for studies involving minors less than or equal to 12-15 years of age and relevant populations deemed incompetent to sign an informed consent form) *(Use as Guide : WHO Form ICF-2 )*
- ☐ WHO TEMPLATE: Informed Consent for Qualitative Studies -research interventions that use questionnaires, in-depth interviews or focus group discussions *(Use as Guide : WHO Form ICF-3)*
- ☐ WHO TEMPLATE: Informed Parental Consent for Research Involving Children (Qualitative Studies) *(Use as Guide : WHO Form ICF-4)*
- ☐ WHO TEMPLATE: informed Consent for Storage and Future Use of Unused Sample *(Use as Guide : WHO Form ICF-5)*





**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**APPLICATION FORM FOR PROTOCOL REVIEW (Form 2.6.2)**

|   |  |   |                                |                              |                                |
|---|--|---|--------------------------------|------------------------------|--------------------------------|
|   |  | RERC Protocol Number:   |                                |                              |                                |
| Sponsor Protocol Number   |  |   |                                | Submission Date:             |                                |
| Type of Submission:   |  | <input type="checkbox"/> Initial Review <input type="checkbox"/> Continuing Review<br><input type="checkbox"/> Resubmission for re-review <input type="checkbox"/> Protocol Termination<br><input type="checkbox"/> Protocol Amendments <input type="checkbox"/> Final Report   |                                |                              |                                |
| Protocol Title:   |  |   |                                |                              |                                |
| Principal Investigator  |  |   |                                |                              |                                |
| Telephone Number  |  |   |                                | Fax:                         |                                |
| E-mail  |  | Preferred Contact:  | <input type="checkbox"/> Phone | <input type="checkbox"/> Fax | <input type="checkbox"/> Email |
| Institute:  |  |   |                                |                              |                                |
| Sponsor:  |  |   |                                |                              |                                |
| Conflict of Interest Declaration<br>(Relationship with sponsor)       |  | Are you a regular employee of the sponsor? <input type="checkbox"/> Yes <input type="checkbox"/> No<br>Did you do consultancy or part time work for the sponsor? <input type="checkbox"/> Yes <input type="checkbox"/> No<br>In the past year, did you receive any monetary remuneration from the sponsor? <input type="checkbox"/> Yes <input type="checkbox"/> No<br>Other ties with the sponsor <input type="checkbox"/> Yes <input type="checkbox"/> No |                                |                              |                                |
| PI Signature:   |  |   |                                |                              |                                |
| Verified Complete by:<br>(to be accomplished by BATMC-RERC staff)     |  |   |                                |                              |                                |
| Classification of Review:<br>(to be accomplished by BATMC-RERC staff) |  | <input type="checkbox"/> EXPEDITED<br><input type="checkbox"/> FULL-BOARD   |                                |                              |                                |
| Assigned Primary Reviewers :  |  |   |                                |                              |                                |
| Independent Consultant to be Invited                                  |  |   |                                |                              |                                |
| Classified by the:  |  | <input type="checkbox"/> BATMC-RERC CHAIR<br><input type="checkbox"/> BATMC-RERC SECRETARY  |                                |                              |                                |



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**PROTOCOL EVALUATION FORM (FORM 2.6.3)**

|                                     |   |              |
|-------------------------------------|---|--------------|
| <b>BATMC-RERC CODE:</b>             |   | <b>DATE:</b> |
| <b>NAME OF PRIMARY INVESTIGATOR</b> |   |              |
| <b>PROTOCOL TITLE</b>               |   |              |
| 1. Type of Submission               | <input type="checkbox"/> 2.1 Initial Review<br><input type="checkbox"/> 2.2 Resubmission (responses to initial review recommendations or submission of studies with investigator-initiated changes prior to ethics approval.) NOTE: version and date of version must be inserted as a document footer for all submissions.<br><input type="checkbox"/> Continuing Review/Progress Report<br><input type="checkbox"/> Protocol Termination<br><input type="checkbox"/> Protocol Amendments <input type="checkbox"/> Final Report   |              |
| 2. Date of Submission               |   |              |
| 3. Study Category                   | <input type="checkbox"/> 4.1 Research involving human participants  |              |
| 4. Type of Study                    | <input type="checkbox"/> 5.1 Pre – clinical Research<br><input type="checkbox"/> 5.2 Non-clinical trial, specifically (choose one):<br><input type="checkbox"/> 5.2.1 Diagnosis<br><input type="checkbox"/> 5.2.2 In vitro study<br><input type="checkbox"/> 5.2.3 Stem Cell Research<br><input type="checkbox"/> 5.2.4 Herbal Research<br><input type="checkbox"/> 5.2.5 Complementary and Alternative Medicine Research<br><input type="checkbox"/> 5.2.6 Review of medical records<br><input type="checkbox"/> 5.2.7 Epidemiological study<br><input type="checkbox"/> 5.2.8 Socio-behavioral research<br><input type="checkbox"/> 5.2.9 Health Informatics<br><input type="checkbox"/> 5.2.10 Operations/process research<br><br><input type="checkbox"/> 5.3 Clinical Trial Type 1 ( <i>drug or pharmaceutical trials, diagnostic trials, trials on devices, and other therapy trials</i> ) intended for marketing registration<br><br><input type="checkbox"/> 5.4 Clinical Trial Type 2 ( <i>drug or pharmaceutical trials, diagnostic trials, trials on devices, and other therapy trials</i> ) NOT intended for marketing registration<br><br><input type="checkbox"/> 5.5 Post Marketing Surveillance<br><br><input type="checkbox"/> 5.6 Others, please indicate |              |
| 6. Category of Investigator         | <input type="checkbox"/> 6.1 BATMC Research Center initiated study  |              |



|   |  |
|---|--|
|   | <input type="checkbox"/> 6.2 BATMC<br><input type="checkbox"/> 6.2.1 Active and; Associate-Active, Visiting Consultants<br><input type="checkbox"/> 6.2.2 Residents-in-training<br><input type="checkbox"/> 6.2.3 Fellows-in-training<br><input type="checkbox"/> 6.2.4 Residents/Fellows graduated completing research requirements<br><input type="checkbox"/> 6.2.5 Nursing<br><input type="checkbox"/> 6.2.6 Other Researches (administrative etc, ) please specify:<br><br><input type="checkbox"/> 6.3 Non-BATMC<br><input type="checkbox"/> 6.3.1 Active and; Associate-Active, Visiting Consultants<br><input type="checkbox"/> 6.3.2 Residents-In-Training<br><input type="checkbox"/> 6.3.3 Fellows-In-training<br><input type="checkbox"/> 6.3.4 Residents/Fellows graduated completing research requirements<br><input type="checkbox"/> 6.3.5 Nursing<br><input type="checkbox"/> 6.3.6 Other Researches (administrative etc) please specify; |
| 7. Proposed Study                             | <input type="checkbox"/> 7.1 Academic requirements (Thesis, Dissertation, Training Requirement)<br><input type="checkbox"/> 7.2 Independent research work<br><input type="checkbox"/> 7.3 Multi-institutional or multi-country collaboration<br><input type="checkbox"/> 7.4 Others (indicate):  |
| 8. PI Fascimile/CONTACT NUMBER/ EMAIL ADDRESS |  |
| 9. Classification of REVIEW                   | <input type="checkbox"/> EXPEDITED REVIEW  |
| ( FOR RERC ONLY)                              | <input type="checkbox"/> FULL BOARD REVIEW   |
|   | <input type="checkbox"/> EXEMPTED from REVIEW  |
| 10. Assigned Primary Reviewers                |  |
| 11. Independent Consultant                    |  |



**BATANGAS MEDICAL CENTER  
RESEARCH ETHICS REVIEW COMMITTEE  
PROTOCOL SUMMARY SHEET (FORM 2.6.4)**

Date: \_\_\_\_\_

|                                  |                |
|----------------------------------|----------------|
| <b>RERC Protocol NO:</b>         | <b>Title</b>   |
|                                  |                |
| <b>Principal Investigator</b>    | <b>Sponsor</b> |
|                                  |                |
| <b>Rationale</b>                 |                |
|                                  |                |
| <b>Objectives</b>                |                |
|                                  |                |
| <b>Study Design/ Methodology</b> |                |
|                                  |                |
| <b>Inclusion Criteria</b>        |                |
|                                  |                |
| <b>Exclusion Criteria</b>        |                |
|                                  |                |
| <b>Data Analysis Plan</b>        |                |
|                                  |                |
| <b>Study Outcomes</b>            |                |
|                                  |                |



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**NON-DISCLOSURE AGREEMENT (FORM 2.6.5)**

I, \_\_\_\_\_, all of legal age, Filipino, and resident of \_\_\_\_\_, hereby depose and say that:

WITNESSETH THAT

1. I am an (employee/student) of \_\_\_\_\_, having office at \_\_\_\_\_;
2. I am espousing a research proposal entitled: “\_\_\_\_\_” that includes the need to gather personal and medical information of certain population.
3. I hereby undertake to protect and make confidential such information;
4. I understand that Confidential Information means any information disclosed by or in possession of the data subject identified as confidential when first disclosed and provided in tangible form, or if disclosed orally summarized in writing, other than information that:
  - a. is or becomes generally available to the public other than as a result of disclosure by the data subject
  - b. is already known by or in our possession at the time of disclosure;
  - c. is obtained by us from a third party that has not breached any obligations of confidentiality.
5. Subject to exceptions stated below, I shall not disclose or use any information that I may have acquired other than for the purpose disclosed in the study and in compliance with the Data Privacy Act of 2021
6. I shall use reasonable care not to disclose to any third party information I may have known or acquired by reason of our research except those identified people who need to know the Confidential Information to carry out the research. Further, I shall not offer for sale, or otherwise disclose to any third party devices containing information gathered in the conduct of our research, unless otherwise permitted in writing by the data subject and subject to applicable laws.
7. The information subject of this agreement shall pertain to all data or information collated, transmitted to and transcribed reason of my research.
8. I undertake not to disclose any information obtained by reason of my research and the same shall continue to take effect notwithstanding the non-continuity of the research or the completion of the same. I shall destroy all copies, reproductions, summaries and notes of the contents of the personal information in accordance with our Data Privacy Policy after the lapse of the retention period;



9. I acknowledge and agree that disclosure, divulgence or unauthorized use of the Confidential Information could damage the data subject, therefore, has a strong interest in protecting the Confidential Information by all legal means.
10. In the event that I violate my obligations under this Agreement, I shall fully indemnify the data subject for all damages caused by such breach. Moreover, because money damages may not be a sufficient remedy for any breach of the foregoing covenants and agreements, the data subject shall be entitled to specific performance and injunctive and other equitable relief as a remedy for any such breach of this Undertaking in addition to all monetary or other remedies available at law or in equity

I fully understand the concepts regarding confidentiality and privacy of personal information. In addition, I also know and agree that my failure to fulfil any of the agreements set forth in this Undertaking and/or our violation of any terms of this Undertaking shall result in our being subject to appropriate legal actions.

---

(Name and signature)/ (Date)



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**Checklist for Exemption from Ethical Review**  
**(Form 2.10.1)**

**STUDY PROTOCOL INFORMATION**

|  |  |
|--|--|
| <b>BATMC RERC Protocol Code:</b>       |  |
| <b>Study Protocol Title:</b>           |  |
| <b>Principal Investigator:</b>         |  |
| <b>Study Protocol Submission Date:</b> |  |

**INSTRUCTIONS**

To the Primary Reviewer: Please evaluate how the exemption criteria outlined below apply to the study protocol by confirming the submitted information and putting your comments in the space provided under "REVIEWER COMMENTS." Finalize your review by indicating your conclusions under "RECOMMENDED ACTION" and signing in space provided for the primary reviewer.

|   | <b>To be filled out by the Primary Reviewer</b>                |           |                          |
|---|--|-----------|--------------------------|
| <b>CRITERIA FOR EXEMPTION</b>   | Indicate if the assessment point applies to the study protocol |           | <b>REVIEWER COMMENTS</b> |
| <b>1. PROTOCOL ASSESSMENT</b>   | <b>YES</b>   | <b>NO</b> |                          |
| 1.1. Does this research involve human participants?   |  |           |                          |
| 1.2. Does this research involve use of non-identifiable human tissue/ biological samples?   |  |           |                          |
| 1.3. Does this research involve use of non-identifiable publicly available data?<br><i>*Protocols that neither involve human participants, nor identifiable human tissue, biological samples and data shall be exempted from review (NEGHHR 2017)</i> |  |           |                          |
| 1.4. Does this research involve interaction with human participants?  |  |           |                          |
| 1.5. Type of research<br>1.5.1. Institutional quality assurance   |  |           |                          |





|  |  |  |  |
|--|--|--|--|
| <p>1.5.2.Evaluation of public service program</p> <p>1.5.3.Public health surveillance</p> <p>1.5.4.Educational evaluation activities</p> <p>1.5.5.Consumer acceptability test</p> <p><i>*These 5 have been identified in the NEGHHR as exemptible, as long as it does not involve more than minimal risk.</i></p>  |  |  |  |
| <p>1.6. What is/are the method/s of data collection <i>(please tick appropriate box)</i></p> <p>1.6.1.Surveys and/or questionnaire, Interviews, or observations of public behavior</p> <p>1.6.2.Audio/video recordings of public behavior</p> <p>1.6.3.Research which only uses existing data</p> <p><i>*These have been identified in the NEGHHR as exemptible, as long as anonymity and/or confidentiality is maintained.</i></p>  |  |  |  |
| <p>1.7. Will the collected data be anonymized or de-identified?</p>  |  |  |  |
| <p>1.8. Is there a data protection plan?<br/><i>Measures or guarantees to protect privacy and confidentiality of participant information and in compliance with the Data Privacy Act of 2012 as indicated by data collection methods including data protection plans including the steps to be taken so that all who have access to the data and the identities of the respondents can safeguard privacy and confidentiality (ex. providing adequate instructions to research assistants, transcribers, or translators) (NEGHHR 2017); Plan on</i></p> |  |  |  |



|   |            |            |  |
|---|------------|------------|--|
| <i>processing personal data, storage of data, access, disposal, and terms of use (NEGHHR 2017; Data Privacy Act of 2012)</i>  |            |            |  |
| <p>1.9. Is this research likely to involve any foreseeable risk of harm or discomfort to participants; above the level experienced in everyday life? (NEGHRR 2017)</p> <p><i>*Please refer to section 2. Risk Assessment, prior to answering this item</i></p> <p><i>*If YES, then this protocol does not qualify for exemption</i></p> |            |            |  |
| <b>2. RISK ASSESSMENT</b>   | <b>YES</b> | <b>N/A</b> |  |
| 1.1. Does this research involve the following ( <i>please select all that apply</i> ):  |            |            |  |
| 1.1.1. Any vulnerable groups?   |            |            |  |
| 1.1.2. Sensitive topics that may make participants feel uncomfortable ( <i>i.e. sexual behaviour, illegal activities, racial biases, etc.</i> )   |            |            |  |
| 1.1.3. Use of drugs   |            |            |  |
| 1.1.4. Invasive procedure (e.g. blood sampling) and specify   |            |            |  |
| 1.1.5. Physical stress/distress, discomfort   |            |            |  |
| 1.1.6. Psychological/mental stress/distress   |            |            |  |
| 1.1.7. Deception of/or withholding information from subjects  |            |            |  |
| 1.1.8. Access to data by individuals or organizations other than the investigators  |            |            |  |
| 1.1.9. Conflict of interest issues  |            |            |  |



|  |  |  |  |
|--|--|--|--|
| 1.1.10. Or any other ethical dilemmas  |  |  |  |
| 1.1.11. Is there any blood sampling involved in the study?   |  |  |  |
| <b>RECOMMENDED ACTION:</b><br><input type="checkbox"/> QUALIFIED FOR EXEMPTION<br><input type="checkbox"/> NOT QUALIFIED FOR EXEMPTION |  |  |  |
| <b>SUMMARY OF RECOMMENDATIONS:</b><br>1.<br>2.<br>3.<br>4.<br>5.   |  |  |  |
| <b>JUSTIFICATION FOR RECOMMENDED ACTION</b>  |  |  |  |
| <b>PRIMARY REVIEWER/s</b> Signature<br>1.<br>2.<br><hr/>   |  |  |  |
| Date: <dd/mm/yyyy>                      Name                      <Title, Name, Surname>   |  |  |  |

*(Adapted from UPMREB Form)*



## BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE

### CERTIFICATE of EXEMPTION from ETHICAL REVIEW (FORM 2.10.2)

Date:

This is to certify that the following protocol and related documents have been granted **EXEMPTION** from **REVIEW** by the Batangas Medical Center RERC.

|                         |  |                      |     |
|-------------------------|--|----------------------|-----|
| BATMC RERC Protocol No. |  | Sponsor Protocol No. | N/A |
|-------------------------|--|----------------------|-----|

|                          |  |         |     |
|--------------------------|--|---------|-----|
| Principal Investigator/s |  | Sponsor | N/A |
|--------------------------|--|---------|-----|

|       |  |
|-------|--|
| Title |  |
|-------|--|

| RERC-Chairman | Name | Signature | Date |
|---------------|------|-----------|------|
|---------------|------|-----------|------|

Received by:

\_\_\_\_\_  
Signature Over Printed Name

\_\_\_\_\_  
Date



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**STUDY PROTOCOL ASSESSMENT (Form 2.14.1)**

**STUDY PROTOCOL INFORMATION**

|                                 |                        |
|---------------------------------|------------------------|
| RERC Protocol No:               |                        |
| Study Protocol Title:           |                        |
| Principal Investigator:         | <Title, Name, Surname> |
| Study Protocol Submission Date: | <dd/mm/yyyy>           |
| Primary Reviewers :             |                        |

**INSTRUCTIONS**

To the Principal Investigator: Please indicate in the space provided below whether or not the specified assessment point is addressed by your study protocol. To facilitate the evaluation of the assessment point, indicate the page and paragraph where this information can be found.

To the Primary Reviewer: Please evaluate how the assessment points outlined below have been appropriately addressed by the study protocol, as applicable, by confirming the submitted information and putting your comments in the space provided under "REVIEWER COMMENTS". Finalize your review by indicating your conclusions under "RECOMMENDED ACTION" and signing in space provided for the primary reviewer.

|  | To be filled out by the PI   |    |                                      |                   |
|--|--|----|--------------------------------------|-------------------|
| ASSESSMENT POINTS  | Indicate if the study protocol contains the specified assessment point |    | Page and paragraph where it is found | REVIEWER COMMENTS |
| 1.SCIENTIFIC DESIGN  | YES  | NO |                                      |                   |
| 1.1 Objectives<br>Review of viability of expected output   |  |    |                                      |                   |
| 1.2 Literature review<br>Review of results of previous animal/human studies showing known risks and benefits of intervention, including known adverse drug effects, in case of drug trials |  |    |                                      |                   |
| 1.3 Research design<br>Review of appropriateness of design in view of objectives   |  |    |                                      |                   |
| 1.4 Sampling design<br>Review of appropriateness of sampling methods and techniques  |  |    |                                      |                   |
| 1.5 Sample size  |  |    |                                      |                   |



|   |  |  |  |  |
|---|--|--|--|--|
| Review of justification of sample size  |  |  |  |  |
| <b>1.6 Statistical analysis plan (SAP)</b><br>Review of appropriateness of statistical methods to be used and how participant data will be summarized                     |  |  |  |  |
| <b>1.7 Data analysis plan</b><br>Review of appropriateness of statistical and non-statistical methods of data analysis  |  |  |  |  |
| <b>1.8 Inclusion criteria</b><br>Review of precision of criteria both for scientific merit and safety concerns; and of equitable selection                                |  |  |  |  |
| <b>1.9 Exclusion criteria</b><br>Review of criteria precision both for scientific merit and safety concerns; and of justified exclusion                                   |  |  |  |  |
| <b>1.10 Withdrawal criteria</b><br>Review of criteria precision both for scientific merit and safety concerns   |  |  |  |  |
| <b>2.CONDUCT OF STUDY</b>   |  |  |  |  |
| <b>2.1.Specimen handling</b><br>Review of specimen storage, access, disposal, and terms of use  |  |  |  |  |
| <b>2.2.PI qualifications</b><br>Review of CV and relevant certifications to ascertain capability to manage study related risks  |  |  |  |  |
| <b>2.3.Suitability of site</b><br>Review of adequacy of qualified staff and infrastructures   |  |  |  |  |
| <b>2.4.Duration</b><br>Review of length/extent of human participant involvement in the study  |  |  |  |  |
| <b>3. ETHICAL CONSIDERATIONS</b>  |  |  |  |  |
| <b>3.1.Conflict of interest</b><br>Review of management of conflict arising from financial, familial, or proprietary considerations of the PI, sponsor, or the study site |  |  |  |  |



|   |  |  |  |  |
|---|--|--|--|--|
| <b>3.2.Privacy and confidentiality</b><br>Review of measures or guarantees to protect privacy and confidentiality of participant information as indicated by data collection methods including data protection plans  |  |  |  |  |
| <b>3.3.Informed consent process</b><br>Review of application of the principle of respect for persons, who may solicit consent, how and when it will be done; who may give consent especially in case of special populations like minors and those who are not legally competent to give consent, or indigenous people which require additional clearances   |  |  |  |  |
| <b>3.4.Vulnerability</b><br>Review of involvement of vulnerable study populations and impact on informed consent (see 3.3). Vulnerable groups include children, the elderly, ethnic and racial minority groups, the homeless, prisoners, people with incurable disease, people who are politically powerless, or junior members of a hierarchical group. Vulnerability must always be assessed in the context of the protocol and the participants. |  |  |  |  |
| <b>3.5.Recruitment</b><br>Review of manner of recruitment including appropriateness of identified recruiting parties  |  |  |  |  |
| <b>3.6.Assent</b><br>Review of feasibility of obtaining assent vis à vis incompetence to consent; Review of applicability of the assent age brackets in children:<br>0-under 7: No assent<br>7-under 12: Verbal Assent<br>12-under15: Simplified Assent Form<br>15-under18: Co-sign informed consent form with parents  |  |  |  |  |
| <b>3.7.Risks</b><br>Review of level of risk and measures to mitigate these risks (including   |  |  |  |  |





|  |  |  |  |  |
|--|--|--|--|--|
| physical ,psychological, social, economic), including plans for adverse event management; Review of justification for allowable use of placebo as detailed in the Declaration of Helsinki (as applicable)  |  |  |  |  |
| <b>3.8.Benefits</b><br>Review of potential direct benefit to participants; the potential to yield generalizable knowledge about the participants' condition/problem; non-material compensation to participant (health education or other creative benefits), where no clear, direct benefit from the project will be received by the participant |  |  |  |  |
| <b>3.9.Incentives or compensation</b><br>Review of amount and method of compensations, financial incentives, or reimbursement of study-related expenses  |  |  |  |  |
| <b>3.10.Community considerations</b><br>Review of impact of the research on the community where the research occurs and/or to whom findings can be linked; including issues like stigma or draining of local capacity; sensitivity to cultural traditions, and involvement of the community in decisions about the conduct of study.             |  |  |  |  |
| <b>3.11. Collaborative study terms of reference</b><br>Review of terms of collaborative study especially in case of multi-country/multi-institutional studies, including intellectual property rights, publication rights, information and responsibility sharing, transparency, and capacity building   |  |  |  |  |
| <b>Other issues</b><br>Review of issues not subsumed in the issues covered by items 3.1 to 3.11  |  |  |  |  |



**TYPE OF REVIEW:** \_\_\_\_ Full Board Review \_\_\_\_ Expedited Review

**RECOMMENDED ACTION:**

- ☐ **APPROVE**
- ☐ **MINOR MODIFICATIONS**
- ☐ **MAJOR MODIFICATIONS**
- ☐ **REQUEST FOR MORE INFORMATION / CLARIFICATORY INTERVIEW**
- ☐ **DISAPPROVE**

***SUMMARY OF REVIEWER'S COMMENTS :***

**PRIMARY REVIEWERS**

**Signature**

**DATE: mm/dd/yyyy**

1.

2.

**Names: Other reviewer members  
if full board review.**

**Signature**

**Date: mm/dd/yyyy**

1.

2.

3.

4.

*(Adapted from UPMREB Form 2(C) 2012)*



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**INFORMED CONSENT ASSESSMENT (FORM 2.14.2)**

**STUDY PROTOCOL INFORMATION**

|                                 |                        |
|---------------------------------|------------------------|
| RERC Protocol No:               |                        |
| Study Protocol Title:           |                        |
| Principal Investigator:         | <Title, Name, Surname> |
| Study Protocol Submission Date: | <dd/mm/yyyy>           |
| Primary Reviewers :             |                        |

**INSTRUCTIONS**

To the Principal Investigator: Please indicate in the space provided below whether or not the specified element is addressed by the informed consent form (ICF). To facilitate the evaluation of the assessment point, indicate the page and paragraph where this information can be found.

To the Primary Reviewer: Please evaluate how the elements outlined below have been appropriately addressed by the informed consent form (ICF), as applicable, and by confirming the submitted information and putting your comments in the space provided under "REVIEWER COMMENTS." In your comments, ensure that vulnerability, recruitment process, and process of obtaining informed consent are always assessed in the context of the study protocol and the participant. Finalize your review by indicating your conclusions under "RECOMMENDED ACTION" and signing in space provided for the primary reviewer.

| Essential Elements<br>(as applicable to the study)               | To be filled out by the PI                    |   |  | REVIEWER COMMENTS |
|--|---|---|--|-------------------|
|  | Indicate if the ICF has the specified element | Page and paragraph where element is found |  |                   |
|  | YES   | NO  |  |                   |
| 1.Statement that the study involves research                     |   |   |  |                   |
| 2.Statement describing the purpose of the study                  |   |   |  |                   |
| 3.Study-related treatments and probability for random assignment |   |   |  |                   |
| 4.Study procedures including all invasive procedures             |   |   |  |                   |
| 5.Responsibilities of the participant                            |   |   |  |                   |
| 6.Expected duration of participation in the study                |   |   |  |                   |



|  |  |  |  |  |
|--|--|--|--|--|
| 7. Approximate number of participants in the study   |  |  |  |  |
| 8. Study aspects that are experimental   |  |  |  |  |
| 9. Foreseeable risks to participant/embryo/fetus/nursing infant; including pain, discomfort, or inconvenience associated with participation including risks to spouse or partner; and integrating risks as detailed in the investigator's brochure |  |  |  |  |
| 10. Risks from allowable use of placebo (as applicable)  |  |  |  |  |
| 11. Reasonably expected benefits; or absence of direct benefit to participants, as applicable  |  |  |  |  |
| 12. Expected benefits to the community or to society, or contributions to scientific knowledge   |  |  |  |  |
| 13. Description of post-study access to the study product or intervention that have been proven safe and effective   |  |  |  |  |
| 14. Alternative procedures or treatment available to participant   |  |  |  |  |
| 15. Compensation or insurance or treatment entitlements of the participant in case of study-related injury   |  |  |  |  |
| 16. Anticipated payment, if any, to the participant  |  |  |  |  |



|   |  |  |  |  |
|---|--|--|--|--|
| in the course of the study; whether money or other forms of material goods, and if so, the kind and amount  |  |  |  |  |
| 17.Compensation (or no plans of compensation) for the participant or the participant's family or dependents in case of disability or death resulting from study-related injuries  |  |  |  |  |
| 18.Anticipated expenses, if any, to the participant in the course of the study  |  |  |  |  |
| 19.Statement that participation is voluntary, and that participant may withdraw anytime without penalty or loss of benefit to which the participant is entitled   |  |  |  |  |
| 20.Statement that the study monitor(s), auditor(s), the BATMC-RERC, and regulatory authorities will be granted direct access to participant's medical records for purposes ONLY of verification of clinical trial procedures and data |  |  |  |  |
| 21.Statement that the records identifying the participant will be kept confidential and will not be made publicly available, to the extent permitted by law; and that the identity of the participant will remain                     |  |  |  |  |



|  |  |  |  |  |
|--|--|--|--|--|
| confidential in the event the study results are published; including limitations to the investigator's ability to guarantee confidentiality  |  |  |  |  |
| 22.Description of policy regarding the use of genetic tests and familial genetic information, and the precautions in place to prevent disclosure of results to immediate family relative or to others without consent of the participant   |  |  |  |  |
| 23.Possible direct or secondary use of participant's medical records and biological specimens taken in the course of clinical care or in the course of this study  |  |  |  |  |
| 24.Plans to destroy collected biological specimen at the end of the study; if not, details about storage (duration, type of storage facility, location, access information) and possible future use; affirming participant's right to refuse future use, refuse storage, or have the materials destroyed |  |  |  |  |
| 25.Plans to develop commercial products from biological specimens and whether the participant will receive monetary or other benefit from such development.  |  |  |  |  |



|  |  |  |  |  |
|--|--|--|--|--|
| 26. Statement that the participant or participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to willingness of the participant to continue to participation |  |  |  |  |
| 27. Statement describing access of participant to the result of the study  |  |  |  |  |
| 28. Statement describing extent of participant's right to access his/her records (or lack thereof <i>vis à vis</i> pending request for approval of non or partial disclosure)  |  |  |  |  |
| 29. Foreseeable circumstances and reasons under which participation in the study may be terminated   |  |  |  |  |
| 30. Sponsor, institutional affiliation of the investigators, and nature and sources of funds   |  |  |  |  |
| 31. Statement whether the investigator is serving only as an investigator or as both investigator and the participant's healthcare provider  |  |  |  |  |
| 32. Person(s) to contact in the study team for further information regarding the study and whom to contact in the event of study-related injury  |  |  |  |  |
| 33. Statement that the BATMC-RERC (specify) has  |  |  |  |  |





|  |                    |                                 |  |  |                         |                    |                                 |    |  |  |    |  |  |  |                  |                         |    |  |  |    |  |  |    |  |  |    |  |  |
|--|--------------------|---------------------------------|--|--|-------------------------|--------------------|---------------------------------|----|--|--|----|--|--|--|------------------|-------------------------|----|--|--|----|--|--|----|--|--|----|--|--|
| approved the study, and may be reached through the following contact for information regarding rights of study participants, including grievances and complaints:<br><u>RERC Chairperson</u><br><u>BATMC-RERC 0437061229</u>   |                    |                                 |  |  |                         |                    |                                 |    |  |  |    |  |  |  |                  |                         |    |  |  |    |  |  |    |  |  |    |  |  |
| 34. Comprehensibility of language used   |                    |                                 |  |  |                         |                    |                                 |    |  |  |    |  |  |  |                  |                         |    |  |  |    |  |  |    |  |  |    |  |  |
| 35. Other comments not addressed by items 1-34   |                    |                                 |  |  |                         |                    |                                 |    |  |  |    |  |  |  |                  |                         |    |  |  |    |  |  |    |  |  |    |  |  |
| <b>TYPE OF REVIEW:</b> <u>    </u> FULL BOARD REVIEW <u>    </u> EXPEDITED REVIEW  |                    |                                 |  |  |                         |                    |                                 |    |  |  |    |  |  |  |                  |                         |    |  |  |    |  |  |    |  |  |    |  |  |
| <b>RECOMMENDED ACTION:</b><br><input type="checkbox"/> APPROVE<br><input type="checkbox"/> MINOR MODIFICATIONS<br><input type="checkbox"/> MAJOR MODIFICATIONS<br><input type="checkbox"/> REQUEST FOR MORE INFORMATION / CLARIFICATORY INTERVIEW<br><input type="checkbox"/> DISAPPROVE   |                    |                                 |  |  |                         |                    |                                 |    |  |  |    |  |  |  |                  |                         |    |  |  |    |  |  |    |  |  |    |  |  |
| <b>SUMMARY OF REVIEWER'S COMMENTS</b>  |                    |                                 |  |  |                         |                    |                                 |    |  |  |    |  |  |  |                  |                         |    |  |  |    |  |  |    |  |  |    |  |  |
| <table style="width: 100%; border: none;"> <tr> <td style="width: 40%;"><b>PRIMARY REVIEWER</b></td> <td style="width: 30%;"><b>Signature :</b></td> <td style="width: 30%;"><b>Date: &lt;dd/mm/yyyy&gt;</b></td> </tr> <tr> <td style="height: 40px; vertical-align: top;">1.</td> <td></td> <td></td> </tr> <tr> <td style="height: 40px; vertical-align: top;">2.</td> <td></td> <td></td> </tr> </table> <table style="width: 100%; border: none; margin-top: 10px;"> <tr> <td style="width: 35%;"><b>Names: Other reviewer members:<br/>if Full board review</b></td> <td style="width: 30%;"><b>Signature</b></td> <td style="width: 35%;"><b>Date: mm/dd/yyyy</b></td> </tr> <tr> <td style="height: 40px; vertical-align: top;">1.</td> <td></td> <td></td> </tr> <tr> <td style="height: 40px; vertical-align: top;">2.</td> <td></td> <td></td> </tr> <tr> <td style="height: 40px; vertical-align: top;">3.</td> <td></td> <td></td> </tr> <tr> <td style="height: 40px; vertical-align: top;">4.</td> <td></td> <td></td> </tr> </table> |                    |                                 |  |  | <b>PRIMARY REVIEWER</b> | <b>Signature :</b> | <b>Date: &lt;dd/mm/yyyy&gt;</b> | 1. |  |  | 2. |  |  | <b>Names: Other reviewer members:<br/>if Full board review</b> | <b>Signature</b> | <b>Date: mm/dd/yyyy</b> | 1. |  |  | 2. |  |  | 3. |  |  | 4. |  |  |
| <b>PRIMARY REVIEWER</b>  | <b>Signature :</b> | <b>Date: &lt;dd/mm/yyyy&gt;</b> |  |  |                         |                    |                                 |    |  |  |    |  |  |  |                  |                         |    |  |  |    |  |  |    |  |  |    |  |  |
| 1.   |                    |                                 |  |  |                         |                    |                                 |    |  |  |    |  |  |  |                  |                         |    |  |  |    |  |  |    |  |  |    |  |  |
| 2.   |                    |                                 |  |  |                         |                    |                                 |    |  |  |    |  |  |  |                  |                         |    |  |  |    |  |  |    |  |  |    |  |  |
| <b>Names: Other reviewer members:<br/>if Full board review</b>   | <b>Signature</b>   | <b>Date: mm/dd/yyyy</b>         |  |  |                         |                    |                                 |    |  |  |    |  |  |  |                  |                         |    |  |  |    |  |  |    |  |  |    |  |  |
| 1.   |                    |                                 |  |  |                         |                    |                                 |    |  |  |    |  |  |  |                  |                         |    |  |  |    |  |  |    |  |  |    |  |  |
| 2.   |                    |                                 |  |  |                         |                    |                                 |    |  |  |    |  |  |  |                  |                         |    |  |  |    |  |  |    |  |  |    |  |  |
| 3.   |                    |                                 |  |  |                         |                    |                                 |    |  |  |    |  |  |  |                  |                         |    |  |  |    |  |  |    |  |  |    |  |  |
| 4.   |                    |                                 |  |  |                         |                    |                                 |    |  |  |    |  |  |  |                  |                         |    |  |  |    |  |  |    |  |  |    |  |  |

*(Adapted from UPMREB Form 2(D) 2012)*



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**REVIEW OF RESUBMITTED STUDY PROTOCOL (FORM 2.15.1)**

| BATMC-RERC Code:   |                          | Date of Submission:   |           | Date of Initial Submission:   |  |  |  |      |           |             |                          |    |  |    |  |  |                        |    |  |    |  |    |  |    |  |    |  |
|--|--------------------------|---|-----------|---|--|--|--|------|-----------|-------------|--------------------------|----|--|----|--|--|------------------------|----|--|----|--|----|--|----|--|----|--|
| Study Protocol Title   |                          |   |           |   |  |  |  |      |           |             |                          |    |  |    |  |  |                        |    |  |    |  |    |  |    |  |    |  |
| Total Participants:  |                          | Initial Review Date:  |           | <input type="checkbox"/> 2 <sup>nd</sup> Review <input type="checkbox"/> 3 <sup>rd</sup> Review |  |  |  |      |           |             |                          |    |  |    |  |  |                        |    |  |    |  |    |  |    |  |    |  |
| Principal Investigator:  |                          | Date of Second Review:<br>Date of Third Review:   |           | Date of Last Review:  |  |  |  |      |           |             |                          |    |  |    |  |  |                        |    |  |    |  |    |  |    |  |    |  |
| <b>ITEMS FOR REVISION / RECOMMENDATIONS</b>  |                          | <b>PRIMARY INVESTIGATOR COMPLIANCE (INDICATE PAGE &amp; HIGHLIGHT REVISION in PROTOCOL)</b>   |           | <b>REVIEWER'S COMMENTS</b>  |  |  |  |      |           |             |                          |    |  |    |  |  |                        |    |  |    |  |    |  |    |  |    |  |
|  |                          |   |           |   |  |  |  |      |           |             |                          |    |  |    |  |  |                        |    |  |    |  |    |  |    |  |    |  |
| <b>DECISION</b><br><input type="checkbox"/> APPROVE<br><input type="checkbox"/> MINOR MODIFICATION<br><input type="checkbox"/> MAJOR MODIFICATION<br><input type="checkbox"/> DISAPPROVE |                          | JUSTIFICATION FOR RECOMMENDED ACTION:   |           |   |  |  |  |      |           |             |                          |    |  |    |  |  |                        |    |  |    |  |    |  |    |  |    |  |
|  |                          | <table border="1"> <thead> <tr> <th colspan="2"></th> <th>NAME</th> <th>Signature</th> </tr> </thead> <tbody> <tr> <td rowspan="2"><b>DATE</b></td> <td rowspan="2"><b>PRIMARY REVIEWERS</b></td> <td>1.</td> <td></td> </tr> <tr> <td>2.</td> <td></td> </tr> <tr> <td rowspan="5"></td> <td rowspan="5"><b>OTHER REVIEWERS</b></td> <td>1.</td> <td></td> </tr> <tr> <td>2.</td> <td></td> </tr> <tr> <td>3.</td> <td></td> </tr> <tr> <td>4.</td> <td></td> </tr> <tr> <td>5.</td> <td></td> </tr> </tbody> </table> |           |   |  |  |  | NAME | Signature | <b>DATE</b> | <b>PRIMARY REVIEWERS</b> | 1. |  | 2. |  |  | <b>OTHER REVIEWERS</b> | 1. |  | 2. |  | 3. |  | 4. |  | 5. |  |
|  |                          | NAME  | Signature |   |  |  |  |      |           |             |                          |    |  |    |  |  |                        |    |  |    |  |    |  |    |  |    |  |
| <b>DATE</b>  | <b>PRIMARY REVIEWERS</b> | 1.  |           |   |  |  |  |      |           |             |                          |    |  |    |  |  |                        |    |  |    |  |    |  |    |  |    |  |
|  |                          | 2.  |           |   |  |  |  |      |           |             |                          |    |  |    |  |  |                        |    |  |    |  |    |  |    |  |    |  |
|  | <b>OTHER REVIEWERS</b>   | 1.  |           |   |  |  |  |      |           |             |                          |    |  |    |  |  |                        |    |  |    |  |    |  |    |  |    |  |
|  |                          | 2.  |           |   |  |  |  |      |           |             |                          |    |  |    |  |  |                        |    |  |    |  |    |  |    |  |    |  |
|  |                          | 3.  |           |   |  |  |  |      |           |             |                          |    |  |    |  |  |                        |    |  |    |  |    |  |    |  |    |  |
|  |                          | 4.  |           |   |  |  |  |      |           |             |                          |    |  |    |  |  |                        |    |  |    |  |    |  |    |  |    |  |
|  |                          | 5.  |           |   |  |  |  |      |           |             |                          |    |  |    |  |  |                        |    |  |    |  |    |  |    |  |    |  |



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**PROTOCOL AMENDMENT REVIEW (FORM 3.16.1)**

|                   |                     |                    |                  |
|-------------------|---------------------|--------------------|------------------|
| RERC Protocol No. | Sponsor Protocol No | Date of submission | Date of Approval |
|                   |                     |                    |                  |

|       |  |
|-------|--|
| Title |  |
|-------|--|

|                        |         |                |
|------------------------|---------|----------------|
| Principal Investigator | Sponsor | Contact Number |
|                        |         |                |

| <u>List of Amendments</u> | <u>Reason for Amendments</u> | <u>Reviewer's Comments</u> |
|---------------------------|------------------------------|----------------------------|
| 1. _____<br>_____         | 1. _____<br>_____            | 1. _____<br>_____          |
| 2. _____<br>_____         | 2. _____<br>_____            | 2. _____<br>_____          |
| 3. _____<br>_____         | 3. _____<br>_____            | 3. _____<br>_____          |

**TYPE OF REVIEW:** \_\_\_\_ Full Board Review \_\_\_\_ Expedited Review

**RECOMMENDED ACTION:**

- ☐ **APPROVE**  
☐ **MINOR MODIFICATIONS**  
☐ **MAJOR MODIFICATIONS**  
☐ **OTHER RECOMMENDATIONS (pls specify) :** \_\_\_\_\_  
☐ **REQUEST FOR FUTHER INFORMATION / CLARIFICATORY INTERVIEW**  
☐ **DISAPPROVE**

**COMMENTS (identify items for revision) Write comments of all members if full board review.**

**PRIMARY REVIEWERS**

**Signature**

**DATE: mm/dd/yyyy**

**1.**



2.

**Names: Other reviewer  
members if full board review.**

**Signature**

**Date: mm/dd/yyyy**

1.

2.

RERC Decision

Name of Chair

Date

Signature



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**LETTER OF APPROVAL OF AMENDMENTS (FORM 3.16.2)**

<dd/mm/yy>

<NAME OF PI>

Principal Investigator

<Institution/Affiliation>

<Address>

Re: <BATMC-RERC Code><Study Protocol Title><>

Dear<TITLE OF PI><SURNAME>

We wish to inform you that the Batangas Medical Center Research Ethics Review Committee approved the proposed amendment/s in your study entitled, "Study Protocol Title" (BATMC-RERC CODE) during its meeting on <Date of Full Board meeting>. Upon review of BATMC-RERC Form 3.16.1: Study Protocol/Informed Consent Amendment Submission Form and <proposed amendment/s>, the following documents have been approved for use:

| BATMC RERC CODE: | PROTOCOL TITLE and Version: | PRIMARY INVESTIGATOR/SPONSOR | DATE OF INITIAL APPROVAL OF STUDY PROTOCOL & ICF |
|------------------|-----------------------------|------------------------------|--|
|                  |                             |                              |  |

| BATMC RERC CODE:<br>PROTOCOL TITLE: | Version # | DATE of Amendment Approval | APPROVED AMENDMENT: |
|-------------------------------------|-----------|----------------------------|---------------------|
| STUDY PROTOCOL FILE 1               |           |                            |                     |
| STUDY PROTOCOL FILE 2               |           |                            |                     |

Thank you.

Very truly yours

<NAME OF REVIEW CHAIR>

Chair, BATMC-RERC



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**PROGRESS REPORT (FORM 3.17.1)**

|                  |  |               |  |
|------------------|--|---------------|--|
| ERC Protocol No. |  | Approval Date |  |
|------------------|--|---------------|--|

|                |  |
|----------------|--|
| Protocol Title |  |
|----------------|--|

|              |  |         |  |
|--------------|--|---------|--|
| Investigator |  | Sponsor |  |
|--------------|--|---------|--|

**ACTION REQUESTED:**

- ☐ Renew - New participant accrual to continue  
☐ Renew - Enrolled participant follow up only  
☐ Renew – Completion of protocol requirements  
☐ Terminate – Protocol discontinued

Any amendment since the last review? (Describe briefly) ☐ No ☐ Yes

Any change in participant population, recruitment or selection  
Criteria since the last review? (Explain the changes) ☐ No ☐ Yes

Any change in the Informed Consent process or documentation since  
The last review? (Please explain) ☐ No ☐ Yes

Is there any new information in recent literature or similar research  
That may change the risk/benefit ratio for participants in the study?  
(Discuss and attach a narrative) ☐ No ☐ Yes

Any unexpected complication or side effect noted since the last  
Review? (Discuss and attach a narrative) ☐ No ☐ Yes

Did any participant withdraw from this study since the last approval?  
(Reasons for withdrawal) ☐ No ☐ Yes

Any new investigator that has been added to or removed from the  
Yes ☐ No ☐



Research team since the last review? (Please identify them and submit  
The CVs of new investigators.)

Summary of protocol participants

- ☐ Accrual ceiling set by RERC \_\_\_\_\_  
☐ New participants accrued since last review \_\_\_\_\_  
☐ Total participants accrued since protocol began \_\_\_\_\_

Accrual Exclusions

- ☐ None  
☐ Male  
☐ Female  
☐ Others (Specify) \_\_\_\_\_

Are there any new collaborating sites that have been added or

☐ No ☐

Yes

Deleted since the last review? Please identify the sites and note the  
Addition or deletion.

Impaired Participants

- ☐ None  
☐ Physically \_\_\_\_\_  
☐ Cognitively \_\_\_\_\_  
☐ Both \_\_\_\_\_

*To be filled up RERC*

Date received:

Received by:

Printed Name

Signature

**PRIMARY REVIEWERS**

**Signature**

**DATE: mm/dd/yyyy**

1.

2.

**Names: Other reviewer  
members if full board  
review.**

**Signature**

**Date: mm/dd/yyyy**

1.

2.





**Recommendations**

- ☐ Approve  
☐ Request an amendment to the protocol or the consent form  
☐ Request further information  
☐ Suspend or terminate the study  
☐ Others  
\_\_\_\_\_

**Type of review:**

- ☐ Expedited review  
☐ Full Board review

**Date of meeting**  
\_\_\_\_\_

**Change to the protocol recommended?**

☐ No ☐ Yes

**Comments:**

**Changes to the informed consent form recommended?**

☐ No ☐ Yes

**Comments:**

**ERC Final Decision:**

**Certified by:**

**RERC Chair**

|  |
|--|
|  |
|--|

**Signature**

|  |
|--|
|  |
|--|

**Date**

|  |
|--|
|  |
|--|



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**

**DEVIATION / NON-COMPLIANCE / VIOLATION REPORT/ SUMMARY REPORT**  
**Form 3.18.1**

|  |  |   |            |
|--|--|---|------------|
| Title of Study   |  |   |            |
| REC Code (To be provided by REC)   |  | Study Site  |            |
| Name of Researcher)  |  | Contact Information                                 | Tel No:    |
|  |  |   | Mobile No: |
| Co-researcher (if any)   |  |   | Fax No:    |
|  |  |   | Email:     |
| Institution  |  |   |            |
| Address of Institution   |  |   |            |
| Ethical clearance effectivity period   |  |   |            |
| Progress Report  |  |   |            |
| Start of study   |  | Expected end of study                               |            |
| Number of enrolled participants  |  | Number of required participants                     |            |
| Number of participants who withdrew  |  |   |            |
| Indicate each protocol deviation/violation:                                      |  | Actions taken to prevent future deviation/violation |            |
| 1.   |  | 1   |            |
| 2.   |  | 2   |            |
| 3.   |  | 3   |            |
| Impact of deviation/violation on participants' risks/harms and integrity of data |  | How would you address these factors?                |            |
|  |  |   |            |



## BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE

BATMC RERC Protocol Noncompliance  
(Deviation or Violation) SUMMARY Report (Form 3.18.1)

(FOR BATMC RERC USE ONLY)

|   |                                |
|---|--------------------------------|
| <b>BATMC-RERC Code:</b>   |                                |
| <b>Project Title:</b>   |                                |
| <b>Principal Investigator:</b>  | <b>Email:</b>                  |
|   | <b>Telephone:</b>              |
|   | <b>Mobile:</b>                 |
| <b>Approval Date:</b>   | <b>Report Submission Date:</b> |
| <b>Study Site Name:</b>   | <b>Study Site Address:</b>     |
| <b>NATURE OF REPORT</b><br><input type="checkbox"/> MINOR PROTOCOL DEVIATION - (non-systematic protocol noncompliance with minor consequences, in terms of its effect on the participant's/subject's rights, safety or welfare, or the integrity of study data; includes deviations that are administrative in nature)<br><input type="checkbox"/> MAJOR PROTOCOL DEVIATION - Persistent protocol noncompliance with potentially serious consequences that could critically affect data analysis or put patients' safety at risk) |                                |
| <b>DESCRIPTION OF REPORTED DEVIATION/VIOLATION:</b>   |                                |
| <b>DESCRIPTION OF INVESTIGATOR CORRECTIVE ACTION:</b>   |                                |
| <b>Found by:</b><br><input type="checkbox"/> Principal Investigator/Study Team<br><input type="checkbox"/> Sponsor/Monitor<br><input type="checkbox"/> BATMC-RERC<br>Date: _____  |                                |
| <b>Reported by:</b> _____<br>Date: _____  |                                |
| <b>Recommended Action:</b><br><input type="checkbox"/> UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION<br><input type="checkbox"/> REQUEST INFORMATION: (specify)<br><input type="checkbox"/> RECOMMEND FURTHER ACTION  |                                |



- ☐ SITE VISIT NEEDED
- ☐ Suspend the study (until additional information is made available)
- ☐ Suspend the study (until recommendations are implemented by the P.I. and found to be satisfactory)
- ☐ Revoke approval of the current study
- ☐ Reprimand the Principal Investigator

| PRIMARY REVIEWERS                        | Signature | Date signed |
|--|-----------|-------------|
| 1.                                       |           |             |
| 2.                                       |           |             |
| <b>Other Reviewers</b><br>1.<br>2.<br>3. |           |             |

**BATMC-RERC SECRETARY**

Date: < mm/dd/yy >

**BATMC-RERC CHAIR**

Date: < mm/dd/yy >

Signature Name: Signature Name: Signature Name:

\_\_\_\_\_  
<Title, Name, Surname>

\_\_\_\_\_  
<Title, Name, Surname>

\_\_\_\_\_  
<Title, Name, Surname>



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**SAE / SUSARs / RNE SUBMISSION CHECKLIST (Form 3.19.0)**

|  |  |
|--|--|
| <b>Protocol Code</b>                   |  |
| <b>Study Protocol Title</b>            |  |
| <b>Principal Investigator</b>          |  |
| <b>PI Email and Contact Number</b>     |  |
| <b>Study Protocol Approval Date</b>    |  |
| <b>Study Site Name</b>                 |  |
| <b>Study Site Address</b>              |  |
| <b>Sponsor</b>                         |  |
| <b>Sponsor Contact Representative</b>  |  |
| <b>Sponsor Email &amp; Contact No.</b> |  |
| <b>Report Submission Date</b>          |  |

***On-Site :***

- ☐ BATMC-RERC FORM 3.19.1A SAE & SUSAR REPORT
  - ☐ BATMC-RERC FORM 3.19.1B RNE REPORT
  - ☐ BATMC-RERC FORM 3.19.2A SAE & SUSAR Reports Summary (On-Site)
  - ☐ CIOMS Suspect Adverse Reaction Form
  - ☐ Latest Investigator's Brochure
  - ☐ Protocol Summary
  - ☐ Other Supporting Documents, if any
- 

***Off-Site :***

- ☐ BATMC-RERC FORM 3.19.1A SAE & SUSAR REPORT
  - ☐ BATMC-RERC FORM 3.19.1B RNE REPORT
  - ☐ BATMC-RERC FORM 3.19.3A SAE & SUSAR Reports Summary (Off-Site)
  - ☐ CIOMS Suspect Adverse Reaction Form
  - ☐ Latest Investigator's Brochure
  - ☐ Protocol Summary
  - ☐ Other Supporting Documents, if any
-



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**SAE/SUSAR REPORT (FORM 3.19.1A)**

|   |  |   |  |
|---|--|---|--|
| Principal Investigator:                             |  | BATMC RERC Code:  |  |
| Study Protocol Title:                               |  |   |  |
| Name of the study medicine/device                   |  | Report Date: dd/mm/yyyy<br><input type="checkbox"/> Initial<br><input type="checkbox"/> Follow-up<br>Onset date: dd/mm/yyyy |  |
| Sponsor:  |  | Date of first use:  |  |
| Patient's Initial/Number:                           |  | Age:  | <input type="checkbox"/> Male<br><input type="checkbox"/> Female |
| Patient's Date of Birth: dd/mm/yyyy                 |  | Weight: kg  | Height: cm   |
| Relevant medical history and concurrent conditions: |  |   |  |

**I. REACTION INFORMATION:**

|  |  |
|--|--|
| <p>_____ (use CIOMS definition- see Appendix )</p> <p>List all relevant tests/ lab data:</p> | <p>Check all appropriate to adverse reaction:</p> <p><input type="checkbox"/> Patient died</p> <p><input type="checkbox"/> Involved or prolonged inpatient hospitalization</p> <p><input type="checkbox"/> Involved persistence or significant disability or incapacity</p> <p><input type="checkbox"/> Life threatening</p> |
|--|--|

**II. SUSPECT DRUG/S INFORMATION:**

|                                       |                            |   |
|---------------------------------------|----------------------------|---|
| Suspect drug/s (include generic name) |                            | Did reaction abate after stopping drug?<br><input type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> NA |
| Daily dose/s:                         | Route's of administration: | Did reaction appear after reintroduction?<br><input type="checkbox"/> Yes   |
|                                       |                            |   |



|  |  |  |
|--|--|--|
| Indication/s for use:  |  | <input type="checkbox"/> No<br><input type="checkbox"/> NA         |
| Therapy date/s: (from/to)  | Therapy duration:  |  |
| Is this reaction <input type="checkbox"/> Unexpected <input type="checkbox"/> Expected   |  |  |
| Treatment given for Adverse Event:   |  |  |
| Causality Assessment By Investigator (Using WHO-UMC Causality Assessment System)<br><input type="checkbox"/> Certain<br><input type="checkbox"/> Probable<br><input type="checkbox"/> Possible<br><input type="checkbox"/> Unlikely<br><input type="checkbox"/> Unclassifiable |  |  |
| Outcome of reaction/event at the time of last observation:   |  |  |
| <input type="checkbox"/> Recovered<br><input type="checkbox"/> Recovering  | <input type="checkbox"/> Recovering with sequelae<br><input type="checkbox"/> Not recovering | <input type="checkbox"/> Death<br><input type="checkbox"/> Unknown |

### III. CONCOMITANT DRUG/S AND HISTORY:

|   |
|---|
| Concomitant drug/s and dates of administration (exclude drug used to treat reaction)            |
| Other relevant history (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) |

### IV. MANUFACTURER'S INFORMATION:

|   |  |  |
|---|--|--|
| Name and address of manufacturer:   |  |  |
| Manufacturer control no.  |  |  |
| Date received by manufacturer:<br>dd/mm/yyyy  | Report source<br><input type="checkbox"/> Study<br><input type="checkbox"/> Literature<br><input type="checkbox"/> Health professional |  |
| Date of this report: dd/mm/yyyy   | Report type<br><input type="checkbox"/> Initial<br><input type="checkbox"/> Follow-up  |  |
| <b>PRINCIPAL INVESTIGATOR SIGNATURE:</b>  |  |  |
| <b>RECOMMENDED ACTION:</b> (for BATMC RERC- use only)<br><input type="checkbox"/> No further action |  |  |





- ☐ Modification of participant inclusion or exclusion criteria to mitigate the newly identified risks or informed consent documents to include a description of newly recognized risks
- ☐ Recommend implementation of additional procedures for protecting/ safeguarding participants;
- ☐ Suspension of enrolment of new participants or research procedures among participants who are currently enrolled (check consistency)
- ☐ Request information
- ☐ Recommend suspension of the entire study

**PRIMARY REVIEWER**

Signature \_\_\_\_\_

Date: <dd/mm/yyyy>

Name

<Title, Given Name, Surname>

**CHAIR**

Signature \_\_\_\_\_

Date: <dd/mm/yyyy>

Name

<Title, Given Name, Surname>



## RESEARCH ETHICS REVIEW COMMITTEE

### REPORT of NEGATIVE EVENTS (RNE) FORM 3.19.1B

*Instructions to the Researcher: Please accomplish this form.*

| General Information                              |  |   |            |
|--|--|---|------------|
| Title of Study                                   |  |   |            |
| REC Code<br>(To be provided by REC)              |  | Study Site  |            |
| Name of Researcher)                              |  | Contact Information   | Tel No:    |
| Co-researcher (if any)                           |  |   | Mobile No: |
|  |  |   | Fax No:    |
|  |  |   | Email:     |
| Institution                                      |  |   |            |
| Address of Institution                           |  |   |            |
| Ethical clearance effectivity period             |  |   |            |
| RNE Report                                       |  | Date submitted:   |            |
| 1. Start of study                                |  | 2. Expected end of study  |            |
| 3. Number of enrolled participants               |  | 4. Number of required participants                                  |            |
| 5. Description of Negative (harms, risks) Events |  | 6. Actions taken to prevent future RNEs, interventions and Outcomes |            |
| a. Involving Participants                        |  |   |            |
| b. Involving members of the Study Team           |  |   |            |
| c. Involving Data safety and integrity           |  |   |            |
| 7. Recommendations                               |  |   |            |

|              |                    |           |               |
|--------------|--------------------|-----------|---------------|
| Received by: | Name & designation | Signature | Date:         |
| Chairman:    | Printed Name:      | Signature | Date Received |



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**SAE & SUSAR REPORTS SUMMARY (ON SITE)**  
**FORM 3.19.2A**

|                         |  |
|-------------------------|--|
| PROTOCOL TITLE          |  |
| Drug/Intervention:      |  |
| BATMC RERCCODE:         |  |
| Title:                  |  |
| Principal Investigator: |  |
| Date of Report/s:       |  |
| Date of Meeting:        |  |

| Report No. | Reaction<br>(Initial/Follow-up)       | Report Date/<br>Date Received by<br>BATMC RERC | Off site /<br>On site | Onset/<br>Stop of<br>SUSAR/<br>Outcome | Date Drug<br>Started/<br>Stopped | Age | Sex | Country | Comorbidities | Causality Assessment of<br>Investigator | Causality Assessment of<br>Sponsor | Action | Reviewer's<br>Causality<br>Assessment/<br>Comments/<br>Reasons |
|------------|---------------------------------------|--|-----------------------|--|----------------------------------|-----|-----|---------|---------------|---|------------------------------------|--------|--|
| 1          | <Reaction><br><br>(Initial/Follow-up) |  |                       |  |                                  |     |     |         |               |   |                                    |        |  |
| 2          | <Reaction><br><br>(Initial/Follow-up) |  |                       |  |                                  |     |     |         |               |   |                                    |        |  |

|                             |   |  |                                |   |  |
|-----------------------------|---|--|--------------------------------|---|--|
| Total Number of New Events  | = |  | Total Number of Unclassifiable | = |  |
| Total Number of Certain     | = |  | Total Number of Deaths         | = |  |
| Total Number of Probable    | = |  | Items Which Need Follow-up     | = |  |
| Total Number of Possible    | = |  |                                |   |  |
| Total Number of Unlikely    | = |  |                                |   |  |
| Total Number of Conditional | = |  |                                |   |  |

**RECOMMENDED ACTION:**

- ☐ No further action  
☐ Request information: (indicate action)  
☐ Recommend further action: (indicate action)  
☐ Pending, if major clarifications are required before a decision can be made



Republic of the Philippines  
Department of Health, Center for Health Development (CHD) IV-CALABARZON  
**BATANGAS MEDICAL CENTER**  
Batangas City  
**ISO 9001:2015 CERTIFIED**



**COMMENTS/ ASSESSMENT OF SAE/SUSAR REPORT:**

| SAE COMMITTEE PRIMARY REVIEWER | NAME | SIGNATURE | DATE |  |
|--------------------------------|------|-----------|------|--|
|                                |      |           |      |  |
| CHAIRMAN:                      |      |           |      |  |



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**SAE AND SUSAR REPORTS SUMMARY (OFFSITE)**  
**FORM 3.19.2B**

|                         |  |
|-------------------------|--|
| PROTOCOL TITLE          |  |
| Drug/Intervention:      |  |
| BATMC RERCCODE:         |  |
| Title:                  |  |
| Principal Investigator: |  |
| Date of Report/s:       |  |
| Date of Meeting:        |  |

| Report No. | Reaction<br>(Initial/Follow-up)       | Report Date/<br>Date Received<br>by BATMC<br>RERC | Off site<br>/ Onsite | Onset /<br>Stop of<br>SUSAR/<br>Outcome | Date Drug<br>Started/<br>Stopped | Age | Sex | Country | Comorbidities | Causality Assessment of<br>Investigator | Causality Assessment of<br>Sponsor | Action | Reviewer's<br>Causality Assessment/<br>Comments/<br>Reasons |
|------------|---------------------------------------|---|----------------------|---|----------------------------------|-----|-----|---------|---------------|---|------------------------------------|--------|---|
| 1          | <Reaction><br><br>(Initial/Follow-up) |   |                      |   |                                  |     |     |         |               |   |                                    |        |   |
| 2          | <Reaction><br><br>(Initial/Follow-up) |   |                      |   |                                  |     |     |         |               |   |                                    |        |   |

|                             |   |  |                                |   |  |
|-----------------------------|---|--|--------------------------------|---|--|
| Total Number of New Events  | = |  | Total Number of Unclassifiable | = |  |
| Total Number of Certain     | = |  | Total Number of Deaths         | = |  |
| Total Number of Probable    | = |  | Items Which Need Follow-up     | = |  |
| Total Number of Possible    | = |  |                                |   |  |
| Total Number of Unlikely    | = |  |                                |   |  |
| Total Number of Conditional | = |  |                                |   |  |

**RECOMMENDED ACTION:**

- ☐ No further action
- ☐ Request information: (indicate action)
- ☐ Recommend further action: (indicate action)
- ☐ Pending, if major clarifications are required before a decision can be made



**COMMENTS/ ASSESSMENT OF SAE/SUSAR REPORT:**

| SAE COMMITTEE PRIMARY REVIEWER | NAME | SIGNATURE | DATE |
|--------------------------------|------|-----------|------|
|                                |      |           |      |
| CHAIRMAN:                      |      |           |      |



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**

**EARLY STUDY TERMINATION (FORM 3.20.1)**

|   |  |                       |  |
|---|--|-----------------------|--|
| RERC Protocol No:   |  | Sponsor Protocol No.: |  |
| Protocol Title:   |  |                       |  |
| Principal Investigator:   |  |                       |  |
| Phone:  |  | E-mail:               |  |
| Department:   |  |                       |  |
| Sponsor:  |  |                       |  |
| RERC Approval Date:   |  | Date of Last Report:  |  |
| Starting Date:  |  | Termination Date:     |  |
| No. of Participants:  |  | No. enrolled:         |  |
| Summary of Results:   |  |                       |  |
| Accrual Data:   |  |                       |  |
| Reason/s for early termination:<br>Indicate justification   |  |                       |  |
| Is this a temporary halt to the study?<br>What is the justification for temporarily halting the study?<br>When do you expect the study to re-start? |  |                       |  |



Are there any potential implications for research participants as a result of terminating/halting the study prematurely? Please describe the steps taken to address them.

P.I. Signature

Date:

*To be filled up by RERC*

Date received:

Received by:

Printed name:

Signature :

Primary Reviewers

Signature

Date

1.

2.

Other member reviewers

1.

2.

3.

Recommendations

- ☐ Accept decision for termination  
☐ Request for additional information  
☐ Require further action in termination plan

Type of review:

- ☐ Expedited review  
☐ Full Board review

Date of meeting

ERC Final Decision:

Certified by:

Name of Member-Secretary

Signature

Date





**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**

**Continuing Review Application Form (Form 3.21.1)**

|  |  |   |
|--|--|---|
| <b>STUDY PROTOCOL TITLE:</b>   |  |   |
| <b>APPROVAL DATE:</b> <dd/mm/yyyy>   |  | <b>EXPIRY OF ETHICAL CLEARANCE:</b><br><dd/mm/yyyy> |
| <b>PRINCIPAL INVESTIGATOR:</b>   |  |   |
| <b>Email:</b>  | <b>Telephone:</b>  | <b>Mobile:</b>                                      |
| <b>STUDY SITE:</b>   |  |   |
| <b>STUDY SITE ADDRESS:</b>   |  |   |
| <b>SPONSOR:</b>  |  |   |
| <b>SPONSOR CONTACT PERSON:</b>   |  |   |
| <b>Email:</b>  | <b>Telephone:</b>  | <b>Mobile:</b>                                      |
| <b>1. START DATE:</b><br>1.1. Date of research site initialization: <dd/mm/yyyy><br>1.2. Explanation, if not yet initialized as of date of this application: <reason/s>  |  |   |
| <b>2. ACTION REQUESTED:</b><br>2.1. <input type="checkbox"/> Renewal: New participant accrual to continue<br>2.2. <input type="checkbox"/> Renewal: Enrolled participant follow up only<br>2.3. <input type="checkbox"/> Renewal: Data analysis only<br>2.4. <input type="checkbox"/> Other (specify): |  |   |
| <b>3. HAVE THERE BEEN ANY AMENDMENTS SINCE THE LAST REVIEW/APPROVAL?</b><br>3.1. <input type="checkbox"/> No<br>3.2. <input type="checkbox"/> Yes (Describe briefly and indicate date/s of Study Protocol Amendment Submission/s)  |  |   |
| <b>4. HAVE THERE BEEN ANY DEVIATION/NONCOMPLIANCE REPORTS SINCE THE LAST REVIEW/APPROVAL?</b><br>4.1. <input type="checkbox"/> No<br>4.2. <input type="checkbox"/> Yes (Describe briefly and indicate date/s of Study Protocol Deviation Submission/s)   |  |   |
| <b>5. SUMMARY OF STUDY PROTOCOL PARTICIPANTS:</b>  |  |   |
| <number>   | 4.1 <input type="checkbox"/> Accrual ceiling set by the Panel                      |   |
| <number>   | 4.2 <input type="checkbox"/> New participants accrued since last review/approval   |   |
| <number>   | 4.3 <input type="checkbox"/> Total participants accrued since study protocol began |   |
| <b>6. ACCRUAL EXCLUSIONS</b><br>6.1. <input type="checkbox"/> None<br>6.2. <input type="checkbox"/> Male<br>6.3. <input type="checkbox"/> Female<br>6.4. <input type="checkbox"/> Other (specify):   |  |   |
| <b>7. IMPAIRED PARTICIPANTS</b><br>7.1. <input type="checkbox"/> None<br>7.2. <input type="checkbox"/> Physically<br>7.3. <input type="checkbox"/> Cognitively<br>7.4. <input type="checkbox"/> Both   |  |   |
| <b>8. HAVE THERE BEEN ANY CHANGES IN THE PARTICIPANT POPULATION, RECRUITMENT OR SELECTION CRITERIA SINCE THE LAST REVIEW/APPROVAL?</b><br>8.1. <input type="checkbox"/> No<br>8.2. <input type="checkbox"/> Yes (Explain changes and indicate date/s of Study Protocol Amendment Submission/s )        |  |   |



|  |                                    |                      |                                   |               |                                   |          |  |         |
|--|------------------------------------|----------------------|-----------------------------------|---------------|-----------------------------------|----------|--|---------|
| <p><b>9. HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW/ APPROVAL? Attach latest version of participant information sheet and informed consent form/document</b></p> <p>9.1. <input type="checkbox"/> No</p> <p>9.2. <input type="checkbox"/> Yes (Explain changes and indicate date/s of Study Protocol Amendment Submission/s)</p>   |                                    |                      |                                   |               |                                   |          |  |         |
| <p><b>10. HAS ANY INFORMATION APPEARED IN THE LITERATURE, OR EVOLVED FROM THIS OR SIMILAR RESEARCH THAT MIGHT AFFECT THE PANEL'S EVALUATION OF THE RISK/BENEFIT ASSESSMENT OF HUMAN PARTICIPANTS INVOLVED IN THIS STUDY PROTOCOL?</b></p> <p>10.1. <input type="checkbox"/> No</p> <p>10.2. <input type="checkbox"/> Yes (Describe briefly and provide copy of literature cited, including the Investigator's Brochure if applicable)</p>  |                                    |                      |                                   |               |                                   |          |  |         |
| <p><b>11. HAVE THERE BEEN ANY UPDATES OR MEASURES IN THE PROTOCOL TO GUARANTEE PROTECTION OF PRIVACY AND CONFIDENTIALITY OF PARTICIPANT INFORMATION IN COMPLIANCE WITH LOCAL REGULATIONS (e.g. DATA PRIVACY ACT OF 2012)?</b></p> <p>11.1. <input type="checkbox"/> No</p> <p>11.2. <input type="checkbox"/> Yes (Describe briefly these provisions)</p>   |                                    |                      |                                   |               |                                   |          |  |         |
| <p><b>12. IS A BIOBANK BEING MAINTAINED FOR THIS STUDY?</b></p> <p>12.1. <input type="checkbox"/> No</p> <p>12.2. <input type="checkbox"/> Yes (Describe governance and custodianship, access to data and transfer of materials, and measures protecting privacy and confidentiality)</p>  |                                    |                      |                                   |               |                                   |          |  |         |
| <p><b>13. HAVE ANY UNEXPECTED DISCOMFORTS, COMPLICATIONS, OR SIDE EFFECTS BEEN NOTED SINCE LAST REVIEW/ APPROVAL?</b></p> <p>13.1. <input type="checkbox"/> No</p> <p>13.2. <input type="checkbox"/> Yes (Summarize and indicate date/s of SUSAR report submission/s )</p>   |                                    |                      |                                   |               |                                   |          |  |         |
| <p><b>14. HAVE ANY PARTICIPANTS WITHDRAWN FROM THIS STUDY SINCE THE LAST REVIEW/APPROVAL?</b></p> <p>14.1. <input type="checkbox"/> No</p> <p>14.2. <input type="checkbox"/> Yes (Explain context surrounding withdrawal and documenting due diligence exerted by the study team in managing these withdrawals)</p>  |                                    |                      |                                   |               |                                   |          |  |         |
| <p><b>15. HAVE THERE BEEN NEW/ADDITIONAL INVESTIGATIONAL NEW DRUG/DEVICE REGISTRATIONS ASSOCIATED WITH THIS STUDY SINCE THE LAST REVIEW/APPROVAL? (Indicate registration information)</b></p> <table border="0"><tr><td>12.1 <input type="checkbox"/> None</td><td>FDA Registration No.</td></tr><tr><td>12.2 <input type="checkbox"/> IND</td><td>Product Name:</td></tr><tr><td>12.3 <input type="checkbox"/> IDE</td><td>Sponsor:</td></tr><tr><td></td><td>Holder:</td></tr></table> | 12.1 <input type="checkbox"/> None | FDA Registration No. | 12.2 <input type="checkbox"/> IND | Product Name: | 12.3 <input type="checkbox"/> IDE | Sponsor: |  | Holder: |
| 12.1 <input type="checkbox"/> None   | FDA Registration No.               |                      |                                   |               |                                   |          |  |         |
| 12.2 <input type="checkbox"/> IND  | Product Name:                      |                      |                                   |               |                                   |          |  |         |
| 12.3 <input type="checkbox"/> IDE  | Sponsor:                           |                      |                                   |               |                                   |          |  |         |
|  | Holder:                            |                      |                                   |               |                                   |          |  |         |
| <p><b>16. HAVE THERE BEEN ANY NEW INTERVENTION(S) OR METHODS IN THE CONDUCT OF STUDY THAT IS/ARE NOT IN THE APPROVED PROTOCOL</b></p> <p>16.1. <input type="checkbox"/> No</p> <p>16.2. <input type="checkbox"/> Yes (Describe use and indicate date/s of Study Protocol Deviation/Non-Compliance/Violation Report Submission/s)</p>   |                                    |                      |                                   |               |                                   |          |  |         |
| <p><b>17. HAVE ANY INVESTIGATORS BEEN ADDED OR DELETED SINCE LAST REVIEW/ APPROVAL?</b></p> <p>17.1. <input type="checkbox"/> No</p> <p>17.2. <input type="checkbox"/> Yes (Enumerate personnel and indicate date/s of Study Protocol Amendment Submission/s. Append CV if not yet submitted to the UPMREB Review Panel)</p>   |                                    |                      |                                   |               |                                   |          |  |         |
| <p><b>18. HAVE ANY NEW COLLABORATING SITES (INSTITUTIONS) BEEN ADDED OR DELETED SINCE THE LAST REVIEW/ APPROVAL?</b></p> <p>18.1. <input type="checkbox"/> No</p> <p>18.2. <input type="checkbox"/> Yes (Enumerate sites and indicate date/s of Study Protocol Amendment Submission/s)</p>   |                                    |                      |                                   |               |                                   |          |  |         |
| <p><b>19. HAVE ANY INVESTIGATORS DEVELOPED EQUITY OR CONSULTATIVE RELATIONSHIP WITH A PARTY RELATED TO THIS STUDY PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST SINCE THE LAST REVIEW/ APPROVAL?</b></p> <p>19.1. <input type="checkbox"/> No</p> <p>19.2. <input type="checkbox"/> Yes (Append a statement of disclosure)</p>   |                                    |                      |                                   |               |                                   |          |  |         |
| <p><b>20. HAVE THERE BEEN CHANGES IN STUDY PERSONNEL SINCE THE LAST REVIEW/ APPROVAL?</b></p> <p>20.1. <input type="checkbox"/> NONE:</p>  |                                    |                      |                                   |               |                                   |          |  |         |



20.2. ☐ DELETED (Enumerate and indicate date/s of Study Protocol Amendment Submission/s )

20.3. ☐ ADDED (Enumerate and indicate date/s of Study Protocol Amendment Submission/s)

**21. HAVE THERE BEEN OTHER CHANGES NOT MENTIONED ABOVE SINCE THE LAST REVIEW/APPROVAL? Attach protocol synopsis.**

21.1. ☐ No

21.2. ☐ Yes (Describe changes and indicate date/s of Study Protocol Amendment Submission/s)

**22. HAS THE STUDY SITE BEEN VISITED BY BATMC RERC OR ANOTHER ETHICS COMMITTEE, AUDITED BY SPONSOR, OR INSPECTED BY ANY REGULATORY AGENCY?**

22.1. ☐ No

22.2. ☐ Yes (Provide details regarding the visit/audit/inspection (when, where, etc), findings and recommendations, and corrective action of the site, if any)

**23. PROGRESS STATUS (List the different components or activities in approved study protocol, provide a short description and indicate completion status, e.g., 50% complete, 75% complete)**

23.1. <Component 1><Provide description as needed>

23.2. <Add components as necessary>

**SIGNATURE OF PRINCIPAL INVESTIGATOR:**

**DATE SIGNED:** <dd/mm/yyyy>

RECOMMENDATIONS (for BATMCRERC use only)

**Comments of Primary Reviewer**

**RECOMMENDED ACTION:**

\_\_\_ APPROVE

\_\_\_ REQUEST INFORMATION: (INDICATE INFORMATION)

\_\_\_ RECOMMEND FURTHER ACTION: (INDICATE ACTION)

\_\_\_ PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE

| PRIMARY REVIEWER | Signature | DATE |
|------------------|-----------|------|
| 1.               |           |      |
| 2.               |           |      |
| RERC MEMBER      |           |      |
| 1.               | 1.        |      |
| 2.               | 2.        |      |
| 3.               | 3.        |      |
|                  | 4.        |      |
| CHAIRMAN         |           |      |
| Member Secretary |           |      |



**BATANGAS MEDICAL CENTER  
RESEARCH ETHICS REVIEW COMMITTEE**

**FINAL REPORT (FORM 3.22.1)**

|   |  |                   |  |
|---|--|-------------------|--|
| RERC Protocol No.   |  | Approval Date     |  |
| Protocol Title  |  |                   |  |
| Principal Investigator                                      |  |                   |  |
| Phone Number:   |  | E-mail address:   |  |
| Sponsor's Name  |  |                   |  |
| Address   |  |                   |  |
| Phone Number:   |  | E-mail address:   |  |
| Study site(s):  |  |                   |  |
| Total Number of study participants:                         |  | No. of Study Arms |  |
| Number of participants who received the test articles:      |  |                   |  |
| Study materials:  |  |                   |  |
| Treatment form:   |  |                   |  |
| Study dose(s):  |  |                   |  |
| Duration of the study                                       |  |                   |  |
| Objectives:   |  |                   |  |
| Results: (Use extra blank paper, if more space is required) |  |                   |  |
| Conclusion: (add more space as needed)                      |  |                   |  |



Republic of the Philippines  
Department of Health, Center for Health Development (CHD) IV-CALABARZON  
**BATANGAS MEDICAL CENTER**  
Batangas City  
**ISO 9001:2015 CERTIFIED**



|   |  |
|---|--|
| <b>DATE SUBMITTED:</b>  |  |
| <b>Signature of P.I.</b>  |  |
| <b>PRIMARY REVIEWERS:</b> (signature over printed name)   |  |
| <b>DECISION:</b><br><input type="checkbox"/> <b>APPROVED:</b><br><input type="checkbox"/> <b>MINOR REVISIONS:</b><br><input type="checkbox"/> <b>MAJOR REVISIONS:</b><br><input type="checkbox"/> <b>DISAPPROVED:</b> | <b>Justification for recommended action:</b> |
| <b>DATE:</b>  |  |
| <b>Noted by: Chairman<br/>BATMC RERC</b>  |  |



## **BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE**

### **LETTER OF APPEAL**

**Re: BATMC RERC DECISION ON REVIEW OF RESEARCH PROTOCOL (FORM 3.23.1)**

**DATE:** mm/day/ year

*To PI : Please bring all documents relevant to the activity.*

|                                    |  |
|------------------------------------|--|
| <b>Title of study</b>              |  |
| <b>BATMCE RERC CODE:</b>           |  |
| <b>Principal Investigator:</b>     |  |
| <b>Date of Initial Submission:</b> |  |
| <b>Date of Last Review:</b>        |  |
| <b>Sponsor</b>                     |  |

Dear ( Chairman):

(entity: PI, or Sponsor, or Institution) wish to appeal the following BATMC RERC decisions:

|  |  |
|--|--|
| <b>Specify RERC decision for appeal:</b> | <b>Indicate the points in question and provide justification for the request for reconsideration or repeal of the decision by providing evidences or corrective measures for a RERC CONSIDERATION.</b> |
|  |  |

---

### **PRINCIPAL INVESTIGATOR/SPONSOR/HEAD OF INSTITUTION**

|               |                    |
|---------------|--------------------|
| Received by:  | NAME and SIGNATURE |
| DATE RECEIVED |                    |



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**

**LETTER OF INVITATION TO MEMBER OF SITE VISIT TEAM (FORM 3.24.1)**

< dd/mm/yyyy>

**Dear (Member):**

**Re:**

|                                     |  |
|-------------------------------------|--|
| <b>BATMC RERC CODE:</b>             |  |
| <b>PROTOCOL TITLE:</b>              |  |
| <b>SPONSOR:</b>                     |  |
| <b>DATE of APPROVAL of PROTOCOL</b> |  |

We wish to inform you that the BATMC RERC has requested you to be a member of the Site Visit Team responsible for verifying compliance of the study site with BATMC RERC approved protocol and related documents, such as, contents of the informed consent form, etc. This site visit is being organized because of: \_\_\_\_\_. As part of the team, your responsibilities include the following:

1. Review the study protocol and the ICF (note: make sure that the site is using the most recent version)
2. Review the post-approval documents (note: make sure that the site is using the most recent version)
3. Ask the PI or staff to explain the informed consent process
4. Ensure security, privacy, and confidentiality of the documents at the study site
5. Discuss the findings with the research team
6. Solicit feedback from the study site

The details of the Site Visit are as follows:

|                   |              |
|-------------------|--------------|
| <b>Study Site</b> |              |
| <b>Address</b>    |              |
| <b>Date</b>       | <dd/mm/yyyy> |
| <b>Time</b>       | <hh:mm>      |

To facilitate the intended site visit, please signify your confirmation by signing in the space provided below, date your signature, and return one copy of this letter to the BATMC RERC Secretariat. Also, if you have any questions regarding the information outlined in this notification, you may visit the BATMC Secretariat at the RERC Office, email [lerc\\_batmc.doh.gov.ph](mailto:lerc_batmc.doh.gov.ph), or call telephone number (043) 740-8306 loc 1021 for assistance.

Thank you and best regards.

Very truly yours,

**Name and Signature**

Chair

CONFORME MEMBER

DATE SIGNED: \_\_\_\_\_



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**NOTICE OF SITE VISIT to PRINCIPAL INVESTIGATOR (FORM 3.24.2)**

<mm/dd/yyyy>

<NAME OF PI>  
Principal Investigator

Re: <Study Protocol Title><BATMC-RERC CODE>

**Sir/Ma'am:**

We wish to inform you that the **BATMC-RERC** has scheduled a Site Visit for your site beginning on \_\_\_\_\_ at \_\_\_\_\_ and lasting for \_\_\_\_ hours. In addition to yourself, I would appreciate the opportunity to meet the other members of your team during this visit.

During the visit, the team would like to verify the compliance of the study site and to perform the following:

1. Review the study protocol and the ICF (note: make sure that the site is using the most recent version)
2. Review the post-approval documents (note: make sure that the site is using the most recent version)
3. Ask you or your staff to explain the informed consent process
4. Verify security, privacy, and confidentiality of the documents at the study site
5. Discuss the findings with the research team
6. Solicit feedback from the study site

We appreciate the time you and your staff have planned for this visit and look forward to meeting with you.

To facilitate the intended site visit, please signify your confirmation by signing in the space provided below, date your signature, and return one copy of this letter to the BATMC- RERC Secretariat. If you have any questions or concerns about anything outlined in this notification or any study related issues, you may visit the Secretariat at the BATMC-RERC Office, email us at [lerc@batmc.doh.gov.ph](mailto:lerc@batmc.doh.gov.ph), or call telephone number (043) 7408306 local 1021 for assistance.



Thank you.

Sincerely,

<NAME OF BATMC-REC CHAIR>

Chair, BATMC-RERC

---

CONFORME of Principal Investigator



## BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE

| SITE VISIT REPORT FORM 3.24.3   |                     |  |  |
|---|---------------------|--|--|
| <b>General Information: <i>Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the documents that you submitted in the Protocol package checklist (Form 2.6.1)</i></b> |                     |  |  |
| *Title of Study   |                     |  |  |
| *REC Code<br>(To be provided by REC)  |                     | *Study Site  |  |
| Principal Investigator  | Contact Information | *Tel No:   |  |
| Sub-Investigator  |                     | *Mobile No:  |  |
|   |                     | Fax No:  |  |
|   |                     | *Email:  |  |
| Study Coordinator/s:  |                     |  |  |
| *Institution  |                     |  |  |
| *Address of Institution   |                     |  |  |
| Ethical clearance effectivity period  |                     |  |  |
| Start of study  |                     | Expected end of study  |  |
| Number of enrolled participants   |                     | Number of required participants  |  |
| PI COMMENTS on the Status of the Research Study:  |                     | <ul style="list-style-type: none"> <li>○ On-going</li> <li>○ Completed</li> <li>○ Accrual Completed</li> <li>○ Follow-up</li> <li>○ Suspended</li> <li>○ Terminated</li> <li>○ Closed</li> <li>○ Closed Prematurely</li> </ul> |  |
| Reasons for Site Visit  |                     | Person/s present during visit  |  |
| <b>Are site facilities appropriate:</b><br><input type="checkbox"/> Yes<br><input type="checkbox"/> No  |                     | <b>COMMENTS:</b>   |  |



|  |                  |
|--|------------------|
| <b>Are informed consent documents updated to the version approved by the BATMC-RERC Panel?</b><br><br><input type="checkbox"/> Yes<br><input type="checkbox"/> No                                      | <b>COMMENTS:</b> |
| <b>Are there any SAE reports not previously reported to the BATMC-RERC?</b><br><br><input type="checkbox"/> Yes<br><input type="checkbox"/> No   | <b>COMMENTS:</b> |
| <b>Are there any events of protocol noncompliance not previously reported to the BATMC-RERC?</b><br><br><input type="checkbox"/> Yes<br><input type="checkbox"/> No                                    | <b>COMMENTS:</b> |
| <b>Are investigation products and study documents secured adequately?</b><br><br><input type="checkbox"/> Yes<br><input type="checkbox"/> No   | <b>COMMENTS:</b> |
| <b>Are all other BATMC-RERC-Panel-approved documents (e.g. advertisements) used in accordance with the approved study protocol?</b><br><br><input type="checkbox"/> Yes<br><input type="checkbox"/> No | <b>COMMENTS:</b> |
| <b>Are there any significant findings in this visit that could affect participant's/subject's rights, safety or welfare?</b><br><br><input type="checkbox"/> Yes<br><input type="checkbox"/> No        | <b>COMMENTS:</b> |
| <b>Overall, does the study site provide adequate protection for the rights, safety or welfare of study participants/subjects?</b>  | <b>COMMENTS:</b> |



|   |  |
|---|--|
| <input type="checkbox"/> Yes<br><input type="checkbox"/> No   |  |
| How well are participants protected?  | COMMENTS:  |
| Are there further actions or queries resulting from this site visit?<br><br><input type="checkbox"/> Yes<br><input type="checkbox"/> No | COMMENTS:  |
| Findings:   | Recommended Action:<br><input type="checkbox"/> Uphold Original<br><input type="checkbox"/> Approval With No Further Action<br><input type="checkbox"/> Request information:<br><input type="checkbox"/> Recommend Further Action: |

| Site Visit Team (NAMES) | SIGNATURE | DATE: |
|-------------------------|-----------|-------|
| 1.                      |           |       |
| 2.                      |           |       |
| 3.                      |           |       |
| Report submitted by:    |           |       |
| CHAIRMAN:               |           |       |



**BATANGAS MEDICAL CENTER  
RESEARCH ETHICS REVIEW COMMITTEE**

**Notice of Meeting (Form 4.26.1)**

**Batangas Medical Center Research Ethics Review Committee**

Address

Telephone

(Date)

For: Name of RERC Members

Position

Date of Meeting:

Venue:

Time:

Items for Discussion: *Expedited Review*

- ☐ **PROTOCOL REVIEW – All Expedited**
  - New Protocols
  - Review of Protocol Resubmission
  - Protocol Amendments
  - Progress Report
  - Protocol Deviations/Violations
  - Continuing Review
  - Final Report
- ☐ **Other Matters**

Items for Discussion: *Full Board*

- ☐ **PROTOCOL REVIEW**
  - New Protocols under Full Review
  - Review of Protocol Resubmission
  - Protocol Amendments
  - Progress Report
  - Protocol Deviations
  - RNE Reports
  - SAE and SUSAR Report
  - Early Study Termination
  - Continuing Review
  - Final Report
  - Management of Appeals
- Site Visits Report



- Queries or Complaints
- Report of Protocols under Expedited Review
  - Approved Protocols
  - Approved Resubmitted Protocols
  - Approved Amendments (Minor)
  - Approved Progress Reports
  - Decisions on Protocol Deviations / Violations (Minor)
  - Decision on Off-site SAE/SUSARs
  - Decision on Continuing Review Applications
- Report of Final Reports
- Report on Exempt from Review Protocols
- ☐ Other Matters

Prepared By :

Approved By :

<RERC Secretariat>

<RERC Chair>



**BATANGAS MEDICAL CENTER  
RESEARCH ETHICS REVIEW COMMITTEE**

**AGENDA OF THE EXPEDITED PR REVIEW MEETING (FORM 4.26.2a)**

Batangas Medical Center Research Ethics Review Committee

Address

Telephone

(Date)

**NOTICE OF MEETING**

To: (Name of Hospital) Ethics Review Committee Members:

(NAME OF RERC MEMBER 1)

(NAME OF RERC MEMBER 2)

(NAME OF RERC MEMBER 3)

(NAME OF RERC MEMBER 4)

(NAME OF RERC MEMBER 5)

(NAME OF RERC MEMBER 6)

(NAME OF RERC MEMBER 7)

(NAME OF RERC MEMBER 8)

DATE OF MEETING:

VENUE OF MEETING:

TIME OF MEETING:

AGENDA:

**1. PROTOCOL REVIEW**

1.1. New Protocols for Expedited Review

1.2. Review of Protocol Resubmissions

1.3. Protocol Amendments

1.4. Progress Report

1.5 Protocol Deviations / Violations

1.6 Continuing Review

1.7 Final Report

**2. OTHER MATTERS**

Prepared by

(Name of RERC Member-Secretary)

Approved by

(Name of RERC Chair)



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**

**AGENDA OF THE FULL BOARD REVIEW MEETING (FORM 4.26.2b)**

Batangas Medical Center Research Ethics Review Committee

Address

Telephone

(Date)

**NOTICE OF MEETING**

To: (Name of Hospital) Ethics Review Committee Members:

(NAME OF RERC MEMBER 1)

(NAME OF RERC MEMBER 2)

(NAME OF RERC MEMBER 3)

(NAME OF RERC MEMBER 4)

(NAME OF RERC MEMBER 5)

(NAME OF RERC MEMBER 6)

(NAME OF RERC MEMBER 7)

(NAME OF RERC MEMBER 8)

DATE OF MEETING:

VENUE OF MEETING:

TIME OF MEETING:

AGENDA:

**1. PROTOCOL REVIEW**

1.1. New Protocols for Full Review

1.2. Review of Protocol Resubmissions

1.3. Protocol Amendments

1.4. Progress Report

1.5 Protocol Deviations / Violations

1.6 RNE Reports

1.7 SAE and SUSAR Report

1.8 Early Study Termination

1.9 Continuing Review

1.10 Final Reports

1.11 Management of Appeals

1.12 Site Visits Report

1.13 Queries or Complaints

1.14 Report of Protocols under Expedited Review

1.14.1 Approved Protocols

1.14.2 Approved Resubmitted Protocols

1.14.3 Approved Amendments (Minor)

1.14.4 Approved Progress Reports

1.14.5 Decisions on Protocol Deviations / Violations (Minor)

1.14.6 Decision on Off-site SAE/SUSARs

1.14.7 Decision on Continuing Review Applications

1.14.8 Report of Final Reports





1.15 Report on Exempt from Review Protocols

1.16 Report on SJREB Protocols

## 2. OTHER MATTERS

Prepared by  
(Name of RERC Member-Secretary)

Approved by  
(Name of RERC Chair)



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**

**CONFLICT OF INTEREST DECLARATION FORM – PROTOCOL REVIEW**  
For Members and Consultants of the BatMC RERC (Form 4.27.1)

**Conflict of Interest (COI):** Real, potential or perceived COI arise when an individual in a position of trust has competing professional or personal interests. Such competing interests may influence his or her professional judgment, objectivity and independence and can potentially influence the outcome of a decision, for personal benefit. A COI may exist even if no unethical or improper act results from the conflict.

The Members (including the Chair) of the Batangas Medical Center Research Ethics Review Committee and its consultants shall sign this agreement to disclose any *Conflict of Interest* that they may have in the review of research protocols and other related documents.

**This Declaration is in reference to the research protocol/s :**

|                        |  |
|------------------------|--|
| RERC Protocol Number   |  |
| Study Protocol Title   |  |
| Principal Investigator |  |
| Sponsor Organization   |  |
| Date of Review         |  |

**INSTRUCTIONS TO RERC MEMBERS OR CONSULTANTS :**

*Before affixing your signature below, please consider each of the following statements in relation to: 1) all your past and current official positions; and 2) all your immediate family members, especially spouse and children. Then, check (v) your answer in the 'yes' or the 'no' column.*

I have interests or commitments to disclose, as described below /AS CHECKED

- ☐ Financial Conflict of Interest (*please describe and elaborate*)  
\_\_\_\_\_  
☐ Non-financial Conflict of Interest (*please describe and elaborate*)  
\_\_\_\_\_

| STATEMENTS   | YES | NO | NA |
|--|-----|----|----|
| • I/My family have owned stocks and shares in the proponent organization(s).   |     |    |    |
| • I/My family have received a salary, an honorarium, a compensation, concessions and gifts from the proponent organization(s).                               |     |    |    |
| • I/My family have served as an officer, director, advisor, trustee, consultant or an active participant in the activities of the proponent organization(s). |     |    |    |
| • I/My family/my other organizations have had research work experience with the principal investigator(s) / sponsor(s).                                      |     |    |    |



|  |   |  |  |                                    |   |   |  |  |  |
|--|---|--|--|------------------------------------|---|---|--|--|--|
| <ul style="list-style-type: none"> <li>I/My family/my other organizations have a long-standing issue against the principal investigator(s), the proponent organization(s), or the funding agency.</li> </ul>   |   |  |  |                                    |   |   |  |  |  |
| <ul style="list-style-type: none"> <li>I/My family have regular social activities, such as parties, home visits and sports events, with the principal investigator(s).</li> </ul>  |   |  |  |                                    |   |   |  |  |  |
| <ul style="list-style-type: none"> <li>I/My family/my other organizations have an interest in or an ownership issue against the proposed topic.</li> </ul>   |   |  |  |                                    |   |   |  |  |  |
| <ul style="list-style-type: none"> <li>I/My family have a role in the conduct and possible publication of the referenced protocol as :               <table border="0"> <tr> <td><input type="checkbox"/> Principal Investigator</td> <td><input type="checkbox"/> Study Coordinator</td> </tr> <tr> <td><input type="checkbox"/> Co-Investigator</td> <td><input type="checkbox"/> Co-Author</td> </tr> <tr> <td><input type="checkbox"/> Sub-Investigator</td> <td><input type="checkbox"/> Research Adviser</td> </tr> </table> </li> </ul> | <input type="checkbox"/> Principal Investigator | <input type="checkbox"/> Study Coordinator | <input type="checkbox"/> Co-Investigator | <input type="checkbox"/> Co-Author | <input type="checkbox"/> Sub-Investigator | <input type="checkbox"/> Research Adviser |  |  |  |
| <input type="checkbox"/> Principal Investigator  | <input type="checkbox"/> Study Coordinator      |  |  |                                    |   |   |  |  |  |
| <input type="checkbox"/> Co-Investigator   | <input type="checkbox"/> Co-Author              |  |  |                                    |   |   |  |  |  |
| <input type="checkbox"/> Sub-Investigator  | <input type="checkbox"/> Research Adviser       |  |  |                                    |   |   |  |  |  |
| <ul style="list-style-type: none"> <li>I/My family have a proprietary interest(s) or potential proprietary interest, in the product under study or the outcome of the research including, but not limited to, patents, trademarks, copyrights and licensing agreements</li> </ul>  |   |  |  |                                    |   |   |  |  |  |
| <ul style="list-style-type: none"> <li>Other possible sources of conflict : <i>Please describe and elaborate</i></li> </ul>  |   |  |  |                                    |   |   |  |  |  |

As a member/consultant of the Batangas Medical Center Research Ethics Review Committee I am disclosing any conflict of interest, **real, perceived or potential**, that I may have in connection with the review of specific research protocols and related documents.

I am doing this before or during any deliberations so that I may not participate in the decision regarding the said protocol.

|                                      |  |
|--------------------------------------|--|
| SIGNATURE                            |  |
| PRINTED NAME                         |  |
| POSITION < RERC Member / Consultant> |  |
| DATE Signed                          |  |



## **BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE**

### **LETTER FOR CLARIFICATORY INTERVIEW FORM 4.27.2**

< dd/mm/yyyy>

|                                   |  |
|-----------------------------------|--|
| <b>PRINCIPAL INVESTIGATOR</b>     |  |
| <b>ADDRESS:</b>                   |  |
| <b>BATMC RERC CODE</b>            |  |
| <b>PROTOCOL TITLE</b>             |  |
| <b>SPONSOR</b>                    |  |
| <b>DATE OF INITIAL SUBMISSION</b> |  |

Dear <TITLE OF PI> <SURNAME>:

We wish to inform you that the BATMC RERC reviewed your <submission> during its regular meeting on <Date of RERC Meeting>. Upon review, the BATMC RERC found issues requiring clarifications such as:

1.

In this regard, the BATMC RERC requests for a clarificatory interview with you during the next meeting on <Date of Next Full Board meeting> from <requested time> at the <venue>. Alternatively, we could arrange a teleconference meeting within the Meeting time if you will not be able to appear in person. Kindly provide a number where you can be reached by telephone.

Should you have any questions or clarifications regarding the abovementioned recommendations, please contact the undersigned through the BATMC RERC OFFICE 043 7408306 loc 1021 or through [erc\\_batmc.doh.gov.ph](mailto:erc_batmc.doh.gov.ph)

The BATMC RERC looks forward to your immediate response and action

Very truly yours,

**CHAIR**  
BATMC RERC



**BATANGAS MEDICAL CENTER  
RESEARCH ETHICS REVIEW COMMITTEE**

**MINUTES OF THE EXPEDITED PR REVIEW MEETING (FORM 4.29.1a)**

**Batangas Medical Center Research Ethics Review Committee**

Minutes of the Meeting

(Date), (Venue), (Time)

**ATTENDANCE**

**PRESENT:**

**ABSENT:**

1. CALL TO ORDER
2. DISCLOSURE OF CONFLICT OF INTEREST (COI)
3. READING AND APPROVAL OF THE PROVISIONAL AGENDA
4. PROTOCOL REVIEW

**4.1. New Protocols for Expedited Review**

|   |                      |
|---|----------------------|
| Protocol Code   |                      |
| Protocol Submission Date  |                      |
| Protocol Title  |                      |
| Principal investigator  |                      |
| Primary reviewers   |                      |
| Technical Review  |                      |
| <b>Sponsor/CRO</b>  |                      |
| Quorum status   |                      |
| Conflict of interest  |                      |
| Type of Review: <input type="checkbox"/> Expedited <input type="checkbox"/> Full Board<br><input type="checkbox"/> Exempted   | <b>VOTE RESULT :</b> |
| <b>Discussion/Comments:</b><br><br><b>Scientific Soundness:</b><br><br><b>Ethical Considerations</b><br>-Social Value<br>-Vulnerability issue<br>-Measures to protect vulnerability population<br>-Risk/benefit ratio<br>-Measures to mitigate risks<br>-Confidentiality and privacy<br>-Informed Consent process, form and content<br><br><b>PR Summary of Issues of all member:</b> |                      |



### RERC Chair Summary of Recommendations and Call for Vote :

|  |                      |
|--|----------------------|
| Decision: <input type="checkbox"/> Approved <input type="checkbox"/> Disapproved<br><input type="checkbox"/> Minor modification<br><input type="checkbox"/> Major modification | <b>VOTE RESULT :</b> |
| Decision Letter date   |                      |
| Approval Expiration Date   |                      |
| Frequency of Continuing Review   |                      |

### 4.2 REVIEW OF PROTOCOL RESUBMISSIONS

|   |                      |
|---|----------------------|
| Protocol Code   |                      |
| Protocol Resubmission Date  |                      |
| Protocol Title  |                      |
| Principal Investigator  |                      |
| Primary Reviewers   |                      |
| Technical Review  |                      |
| <b>Sponsor/CRO</b>  |                      |
| Quorum status   |                      |
| Conflict of Interest  |                      |
| Assessment of PI response to initial review   |                      |
| Recommendations   |                      |
| Approval expiration date  |                      |
| Frequency of continuing review (in case of approval)  |                      |
| Type of Review <input type="checkbox"/> expedited <input type="checkbox"/> Full Board <input type="checkbox"/> Exempted           |                      |
| Decision: Decision: Approved: <input type="checkbox"/> Disapproved: <input type="checkbox"/><br>Abstain: <input type="checkbox"/> | <b>VOTE RESULT :</b> |

### 4.3 PROTOCOL AMENDMENTS

|  |                    |
|--|--------------------|
| Protocol Code  |                    |
| Protocol Approval Date   |                    |
| Amendment Submission Date  |                    |
| Protocol Title   |                    |
| Principal Investigator   |                    |
| Primary Reviewers  |                    |
| Technical Review   |                    |
| Sponsor/CRO  |                    |
| Quorum status  |                    |
| Conflict of Interest:  |                    |
| Assessment of amendment Requested  |                    |
| Recommendations  |                    |
| Decision <input type="checkbox"/> APPROVE; <input type="checkbox"/> MAJOR MOD<br><input type="checkbox"/> MINOR MOD <input type="checkbox"/> DISAPPROVED | <b>VOTE RESULT</b> |



Type of Review: ☐ expedited ☐ Full board ☐ Exempted

#### 4.4 PROGRESS REPORT

|  |                    |
|--|--------------------|
| Protocol Code  |                    |
| Protocol Approval Date   |                    |
| Progress Report Submission Date  |                    |
| Protocol Title   |                    |
| Principal Investigator   |                    |
| Primary Reviewers  |                    |
| Technical Review   |                    |
| Sponsor/CRO  |                    |
| Quorum status  |                    |
| Conflict of Interest:  |                    |
| Assessment of Study Progress   |                    |
| Recommendations  |                    |
| Decision <input type="checkbox"/> APPROVE; <input type="checkbox"/> MAJOR MOD<br><input type="checkbox"/> MINOR MOD <input type="checkbox"/> DISAPPROVED | <b>VOTE RESULT</b> |
| Type of Review: <input type="checkbox"/> expedited <input type="checkbox"/> Full board <input type="checkbox"/> Exempted                                 |                    |

#### 4.5 PROTOCOL DEVIATIONS / VIOLATIONS

|                                    |  |
|------------------------------------|--|
| Protocol Code                      |  |
| Protocol Approval Date             |  |
| Protocol Deviation Submission Date |  |
| Protocol Title                     |  |
| Principal Investigator             |  |
| Primary Reviewers                  |  |
| Technical Review                   |  |
| Sponsor/CRO                        |  |
| Quorum status                      |  |
| Conflict of Interest:              |  |
| Assessment of Deviation Report     |  |
| Recommendations                    |  |
| Decision                           |  |
| Type of Review                     |  |

#### 4.6 CONTINUING REVIEW

|                               |  |
|-------------------------------|--|
| Protocol Code                 |  |
| Protocol Approval Date        |  |
| Continuing Review Report Date |  |
| Protocol Title                |  |
| Principal Investigator        |  |



|                                    |            |
|------------------------------------|------------|
| Primary Reviewers                  |            |
| Technical Review                   |            |
| Sponsor/CRO                        |            |
| Quorum status                      |            |
| Conflict of Interest:              |            |
| Assessment of progress<br>Reported |            |
| Recommendations                    |            |
| Decision                           | (Approval) |
| Type of Review                     |            |

#### 4.7 FINAL REPORTS

|                              |  |
|------------------------------|--|
| Protocol Code                |  |
| Protocol Approval Date       |  |
| Final Report Submission Date |  |
| Protocol Title               |  |
| Principal Investigator       |  |
| Primary Reviewers            |  |
| Technical Review             |  |
| Sponsor/CRO                  |  |
| Quorum status                |  |
| Conflict of Interest:        |  |
| Assessment of final report   |  |
| Recommendations              |  |
| Decision                     |  |
| Type of Review               |  |

#### 5. OTHER MATTERS

#### 6. ADJOURNMENT

Prepared by:

Signature over Name  
(Name of Hospital) RERC SECRETARIAT  
Date:

Approved by:

Signature over Name  
(Name of Hospital) RERC Chair  
Date:





**BATANGAS MEDICAL CENTER  
RESEARCH ETHICS REVIEW COMMITTEE**

**MINUTES OF THE FULL BOARD REVIEW MEETING (FORM 4.29.1b)**

**Batangas Medical Center Research Ethics Review Committee**

Minutes of the Meeting

(Date), (Venue), (Time)

**ATTENDANCE**

**PRESENT:**

**ABSENT:**

1. CALL TO ORDER
2. DETERMINATION OF QUORUM
3. DISCLOSURE OF CONFLICT OF INTEREST (COI)
4. READING AND APPROVAL OF THE PROVISIONAL AGENDA
5. REVIEW AND APPROVAL OF MINUTES OF PREVIOUS MEETING
6. BUSINESS ARISING FROM THE MINUTES
7. PROTOCOL REVIEW

**7.1. New Protocols for Full Review**

|   |  |
|---|--|
| Protocol Code   |  |
| Protocol Submission Date  |  |
| Protocol Title  |  |
| Principal investigator  |  |
| Primary reviewers   |  |
| Technical Review  |  |
| <b>Sponsor/CRO</b>  |  |
| Quorum status   |  |
| Conflict of interest  |  |
| Type of Review: <input type="checkbox"/> Expedited <input type="checkbox"/> Full Board<br><input type="checkbox"/> Exempted |  |
| <b>Discussion/Comments:</b>   |  |
| <b>Scientific Soundness:</b>  |  |
| <b>Ethical Considerations</b>   |  |
| -Social Value   |  |
| -Vulnerability issue  |  |
| -Measures to protect vulnerability population   |  |
| -Risk/benefit ratio   |  |
| -Measures to mitigate risks   |  |
| -Confidentiality and privacy  |  |



**-Informed Consent process, form and content**

**PR Summary of Issues of all member:**

**RERC Chair Summary of Recommendations and Call for Vote :**

Decision: ☐ Approved ☐ Disapproved  
☐ Minor modification  
☐ Major modification

**VOTE RESULT :**

Decision Letter date

Approval Expiration Date

Frequency of Continuing Review

**7.2 REVIEW OF PROTOCOL RESUBMISSIONS**

|   |                      |
|---|----------------------|
| Protocol Code   |                      |
| Protocol Resubmission Date  |                      |
| Protocol Title  |                      |
| Principal Investigator  |                      |
| Primary Reviewers   |                      |
| Technical Review  |                      |
| <b>Sponsor/CRO</b>  |                      |
| Quorum status   |                      |
| Conflict of Interest  |                      |
| Assessment of PI response to initial review   |                      |
| Recommendations   |                      |
| Approval expiration date  |                      |
| Frequency of continuing review (in case of approval)  |                      |
| Type of Review <input type="checkbox"/> expedited <input type="checkbox"/> Full Board <input type="checkbox"/> Exempted           |                      |
| Decision: Decision: Approved: <input type="checkbox"/> Disapproved: <input type="checkbox"/><br>Abstain: <input type="checkbox"/> | <b>VOTE RESULT :</b> |

**7.3 PROTOCOL AMENDMENTS**

|                                      |  |
|--------------------------------------|--|
| Protocol Code                        |  |
| Protocol Approval Date               |  |
| Amendment Submission Date            |  |
| Protocol Title                       |  |
| Principal Investigator               |  |
| Primary Reviewers                    |  |
| Technical Review                     |  |
| Sponsor/CRO                          |  |
| Quorum status                        |  |
| Conflict of Interest:                |  |
| Assessment of amendment<br>Requested |  |
| Recommendations                      |  |



|  |                    |
|--|--------------------|
| Decision <input type="checkbox"/> APPROVE; <input type="checkbox"/> MAJOR MOD<br><input type="checkbox"/> MINOR MOD <input type="checkbox"/> DISAPPROVED | <b>VOTE RESULT</b> |
| Type of Review: <input type="checkbox"/> expedited <input type="checkbox"/> Full board <input type="checkbox"/> Exempted                                 |                    |

#### 7.4 PROGRESS REPORT

|  |                    |
|--|--------------------|
| Protocol Code  |                    |
| Protocol Approval Date   |                    |
| Progress Report Submission Date  |                    |
| Protocol Title   |                    |
| Principal Investigator   |                    |
| Primary Reviewers  |                    |
| Technical Review   |                    |
| Sponsor/CRO  |                    |
| Quorum status  |                    |
| Conflict of Interest:  |                    |
| Assessment of Study Progress   |                    |
| Recommendations  |                    |
| Decision <input type="checkbox"/> APPROVE; <input type="checkbox"/> MAJOR MOD<br><input type="checkbox"/> MINOR MOD <input type="checkbox"/> DISAPPROVED | <b>VOTE RESULT</b> |
| Type of Review: <input type="checkbox"/> expedited <input type="checkbox"/> Full board <input type="checkbox"/> Exempted                                 |                    |

#### 7.5 PROTOCOL DEVIATIONS / VIOLATIONS

|                                    |  |
|------------------------------------|--|
| Protocol Code                      |  |
| Protocol Approval Date             |  |
| Protocol Deviation Submission Date |  |
| Protocol Title                     |  |
| Principal Investigator             |  |
| Primary Reviewers                  |  |
| Technical Review                   |  |
| Sponsor/CRO                        |  |
| Quorum status                      |  |
| Conflict of Interest:              |  |
| Assessment of Deviation Report     |  |
| Recommendations                    |  |
| Decision                           |  |
| Type of Review                     |  |

#### 7.6 RNE REPORTS / 7.7 SAE and SUSAR REPORTS

|                        |  |
|------------------------|--|
| Protocol Code          |  |
| Protocol Approval Date |  |
| RNE Date               |  |
| Protocol Title         |  |



|                             |  |
|-----------------------------|--|
| Principal Investigator      |  |
| Primary Reviewers           |  |
| Technical Review            |  |
| Sponsor/CRO                 |  |
| Quorum status               |  |
| Conflict of Interest:       |  |
| Assessment of SAE's Reports |  |
| SAE I                       |  |
| Submission Date             |  |
| Date of SAE                 |  |
| Date of randomization       |  |
| Age                         |  |
| Sex                         |  |
| Country                     |  |
| Nature of AE                |  |

#### 7.8 EARLY STUDY TERMINATION

|  |                      |
|--|----------------------|
| Protocol Code  |                      |
| Protocol Approval Date   |                      |
| Early Study Termination Submission Date  |                      |
| Protocol Title   |                      |
| Principal Investigator   |                      |
| Primary Reviewers  |                      |
| Technical Review   |                      |
| Sponsor/CRO  |                      |
| Quorum status  |                      |
| Conflict of Interest:  |                      |
| Assessment of risk from early termination  |                      |
| Recommendations  |                      |
| Type of Review <input type="checkbox"/> expedited <input type="checkbox"/> full board<br><input type="checkbox"/> Exempted |                      |
| Decision: Approved: <input type="checkbox"/> Disapproved: <input type="checkbox"/> Abstain: <input type="checkbox"/>       | <b>VOTE RESULT :</b> |

#### 7.9 CONTINUING REVIEW

|                               |  |
|-------------------------------|--|
| Protocol Code                 |  |
| Protocol Approval Date        |  |
| Continuing Review Report Date |  |
| Protocol Title                |  |
| Principal Investigator        |  |
| Primary Reviewers             |  |
| Technical Review              |  |
| Sponsor/CRO                   |  |
| Quorum status                 |  |
| Conflict of Interest:         |  |



|                                 |            |
|---------------------------------|------------|
| Assessment of progress Reported |            |
| Recommendations                 |            |
| Decision                        | (Approval) |
| Type of Review                  |            |

#### 7.10 FINAL REPORTS

|                              |  |
|------------------------------|--|
| Protocol Code                |  |
| Protocol Approval Date       |  |
| Final Report Submission Date |  |
| Protocol Title               |  |
| Principal Investigator       |  |
| Primary Reviewers            |  |
| Technical Review             |  |
| Sponsor/CRO                  |  |
| Quorum status                |  |
| Conflict of Interest:        |  |
| Assessment of final report   |  |
| Recommendations              |  |
| Decision                     |  |
| Type of Review               |  |

#### 7.11 MANAGEMENT OF APPEALS

|  |                      |
|--|----------------------|
| Protocol Code  |                      |
| Protocol Approval Date   |                      |
| Appeal Application Date  |                      |
| Protocol Title   |                      |
| Principal Investigator   |                      |
| Primary Reviewers  |                      |
| Technical Review   |                      |
| Sponsor/CRO  |                      |
| Quorum status  |                      |
| Conflict of Interest:  |                      |
| Assessment of Appeal   |                      |
| Recommendations  |                      |
| Type of Review <input type="checkbox"/> expedited <input type="checkbox"/> full board<br><input type="checkbox"/> Exempted |                      |
| Decision: Approved: <input type="checkbox"/> Disapproved: <input type="checkbox"/> Abstain: <input type="checkbox"/>       | <b>VOTE RESULT :</b> |

#### 7.12 SITE VISIT REPORTS

|                        |  |
|------------------------|--|
| Protocol Code          |  |
| Protocol Approval Date |  |
| Site Visit Report Date |  |



|                                  |   |
|----------------------------------|---|
| Protocol Title                   |   |
| Principal Investigator           |   |
| Primary Reviewers                |   |
| Technical Review                 |   |
| Sponsor/CRO                      |   |
| Quorum status                    |   |
| Conflict of Interest:            |   |
| Assessment of Site Visit Reports |   |
| Recommendations                  |   |
| Decision                         | Uphold original approval with no further action, Request information, Recommend further action) |
| Co-morbidities                   |   |
| Status                           |   |
| Recommendations                  |   |
| Decision                         |   |

#### 7.13 QUERIES OR COMPLAINTS

|                                  |  |
|----------------------------------|--|
| Protocol Code                    |  |
| Protocol Approval Date           |  |
| Query/Complaint Filing Date      |  |
| Protocol Title                   |  |
| Principal Investigator           |  |
| Primary Reviewers                |  |
| Technical Review                 |  |
| Sponsor/CRO                      |  |
| Quorum status                    |  |
| Conflict of Interest:            |  |
| Assessment of query or complaint |  |
| Recommendations                  |  |
| Decision                         |  |

#### 7.14 Report of Approved Protocols under Expedited Review

|                          |  |
|--------------------------|--|
| Protocol Code            |  |
| Protocol Submission Date |  |
| Protocol Title           |  |
| Principal investigator   |  |
| Primary reviewers        |  |
| Technical Review         |  |
| Sponsor/CRO              |  |

#### 7.15 Report on Exempt from Review Protocols

|                          |  |
|--------------------------|--|
| Protocol Code            |  |
| Protocol Submission Date |  |

|                        |  |
|------------------------|--|
| Protocol Title         |  |
| Principal investigator |  |
| Primary reviewers      |  |
| Technical Review       |  |
| Sponsor/CRO            |  |

#### 7.16 Report of SJREB Protocols

|                          |  |
|--------------------------|--|
| Protocol Code            |  |
| Protocol Submission Date |  |
| Protocol Title           |  |
| Principal investigator   |  |
| Primary reviewers        |  |
| Technical Review         |  |
| Sponsor/CRO              |  |
| Discussion               |  |

#### 8. OTHER MATTERS

#### 9. ADJOURNMENT

Prepared by:

Approved by:

Signature over Name  
 (Name of Hospital) RERC SECRETARIAT  
 Date:

Signature over Name  
 (Name of Hospital) RERC Chair  
 Date:



**BATANGAS MEDICAL CENTER  
RESEARCH ETHICS REVIEW COMMITTEE**

**Notice of Receipt of Study Protocol & Assessment for Review Fee (Form 4.30.0)  
(Non-Institutional PI-Initiated Protocols)**

<dd/mm/yyyy>

<TITLE, NAME, SURNAME OF PI>

Principal Investigator

<Institution/Affiliation>

<Address>

Re: Study Protocol Title

Dear <TITLE OF PI> <SURNAME>:

Good Day.

We would like to inform you that your study protocol has been received by the Batangas Medical Center Research Ethics Board (BatMC RERC) and has been classified for <EXPEDITED REVIEW/FULL BOARD REVIEW> scheduled to be reviewed on <date of full board meeting>. Your study has been assigned study protocol code <BatMC code> which should be used for all communication to the BatMC RERC related to this study.

|                        |  |
|------------------------|--|
| Protocol Code          |  |
| Protocol Title         |  |
| Date of Submission     |  |
| Type of Review         |  |
| Principal Investigator |  |
| Review fee             |  |

In line with this and with the DOH Department Order No. 2017-0265 on Guidelines for the Streamlined Research Ethics Review Process in the Department of Health, we would like to inform you that as per Annex C of the mentioned Department Order, you are required to pay the Ethics Review Fees as indicated above accorded to a <classification of PI> researcher.

Kindly secure the charge slip from the Research Ethics Review Committee office and submit a copy of the official receipt once settled.

Should you have any questions or clarifications regarding the above, please contact the BatMC RERC Secretariat at (043) 740-8306 local 1021 or email us at [rec@batmc.doh.gov.ph](mailto:rec@batmc.doh.gov.ph).

Respectfully yours,

<Name of BatMC RERC Chair>

RERC Chairman





**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**APPROVAL LETTER (FORM 4.30.1)**

Date: \_\_\_\_\_

This is to certify that the following protocol and related documents have been granted approval by the Batangas Medical Center RERC for implementation

|                          |  |  |                                |
|--------------------------|--|--|--------------------------------|
| RERC Protocol No.        |  | Sponsor Protocol No.                   |                                |
| Principal Investigator/s |  | Sponsor                                |                                |
| Title                    |  |  |                                |
| Protocol Version No.     |  | Version Date                           |                                |
| ICF Version No.          |  | Version Date                           |                                |
| Other Documents          |  |  |                                |
| Type of Review           | <input type="checkbox"/> Expedited<br><input type="checkbox"/> Full Board<br>Meeting Date: | Duration of Approval<br>From (date) to | Frequency of continuing review |

**Investigator Responsibilities after Approval:**

- Submit document amendments for RERC approval before implementing them
- Submit SAE and SUSAR reports to the RERC within 7 days
- Submit progress report every \_\_\_\_ months
- Submit final report not later than 1 month after end of the study
- Apply for continuing review at least 2 months before expiry of ethical clearance
- Report protocol deviation/ violation
- Comply with all relevant international and national guidelines and regulations
- PI to accomodate possible SITE VISIT
- Abide by the principles of good clinical practice and ethical research

Very truly yours ,

<RERC Chair>

Received by: <Name and Signature>

Date : \_\_\_\_\_



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**Notification of RERC DECISION (Form 4.30.2A)**

Date:

To:

Contact No. :

This is to inform you of the ERC decision related to your application for review of the following documents:

|                   |  |                      |  |
|-------------------|--|----------------------|--|
| RERC Protocol No. |  | Sponsor Protocol No. |  |
|-------------------|--|----------------------|--|

|                    |   |                     |
|--------------------|---|---------------------|
| Type of Submission | <input type="checkbox"/> Initial review | Documents submitted |
|                    | <input type="checkbox"/> Resubmission   | 1.                  |
|                    | <input type="checkbox"/> Amendment      | 2.                  |
|                    | <input type="checkbox"/> Others         | 3.                  |

|                        |  |         |  |
|------------------------|--|---------|--|
| Principal Investigator |  | Sponsor |  |
|------------------------|--|---------|--|

|       |  |
|-------|--|
| Title |  |
|-------|--|

|                      |  |              |  |
|----------------------|--|--------------|--|
| Protocol Version No. |  | Version Date |  |
|----------------------|--|--------------|--|

|                 |  |              |  |
|-----------------|--|--------------|--|
| ICF Version No. |  | Version Date |  |
|-----------------|--|--------------|--|

|                 |  |
|-----------------|--|
| Other Documents |  |
|-----------------|--|

Type of Review

☐ Expedited

☐ Full Board

Meeting Date:

\_\_\_\_\_

RERC Decision

☐ Approved

☐ Minor revisions Required

☐ Major revisions required

☐ More information required

☐ Disapproved

\_\_\_\_\_

|                   |      |           |      |
|-------------------|------|-----------|------|
| RERC Chair Person | Name | Signature | Date |
|                   |      |           |      |



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**Letter For Modifications (Form 4.30.2B)**

DATE:

**PRINCIPAL INVESTIGATOR:**

**PROTOCOL CODE:**

**PROTOCOL TITLE:**

Dear Dr.:

We wish to inform you that the Batangas Medical Center Research Ethics Review Committee reviewed your study protocol during its regular meeting <date> and is requesting further revisions. Your study has been assigned study protocol code **<Protocol Code>** which should be used for all communication to the BATMC-RERC related to this study.

As a result of the review, the action is **MAJOR MODIFICATIONS / MINOR MODIFICATIONS**. Recommended revisions and/or clarification are summarized below:

| REVIEWERS' COMMENTS                         |                   |
|---|-------------------|
| Points of Revision – Study Protocol         | Recommendations : |
| Points for Revision – Informed Consent Form | Recommendations : |

Note that the BATMC-RERC is requesting you to submit the following:

1. REVISED STUDY PROTOCOL/INFORMED CONSENT> and related documents in <ten/four><10/4> printed copies. Submit the electronic copy of all documents to batmc\_erc@yahoo.com.ph. Fill out the BATMC-RERC FORM 2.9: REVIEW OF RESUBMITTED PROTOCOL FORM with the first column filled-out with recommendations and the second column are the responses if the recommendations are met.
2. Modified part should be underlined and bold-faced with indicated page where the revisions were made; and
3. Include footer in all pages that indicates both the DATE and VERSION NUMBER of the resubmitted study protocol, ICF and other documents forming part of the protocol.

Please note that the cut-off date for submission of revised study protocol is on \_\_\_\_\_. Also, please note that resubmission can only be accepted until \_\_\_\_\_. Failure to respond with the specified date will inactivate the application and study protocol will be archived. Subsequent submissions will be processed as initial review. Should you have any questions or clarifications regarding the abovementioned recommendations, please contact the undersigned through the BATMC-RERC Secretariat.

The BATMC – RERC looks forward to your immediate response and action.

Very truly yours

<BATMC RERC CHAIRMAN>



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**Letter of Exemption from Ethical Review (Form 4.30.2C)**

DATE:

**PRINCIPAL INVESTIGATOR:**

**PROTOCOL TITLE:**

**PROTOCOL CODE:**

Dear Dr.:

We wish to inform you that the Batangas Medical Center Research Ethics Committee (BatMC RERC) has reviewed your study protocol entitled, "*Study Protocol Title (BatMC-RERC-code)*".

Upon review of the study protocol, the BatMC RERC deemed it appropriate that the above proposal be **EXEMPTED FROM ETHICAL REVIEW**. This means that the study may be implemented without undergoing an expedited or full review. Neither will the proponents be required to submit further documents to the committee as long as there is no amendment nor alteration in the protocol that will change the nature of the study nor the level of risk involved. BatMC RERC must be provided with a copy of the Final Report not later than one (1) month after the end of the study.

Please note that any changes to the protocol must be brought to the notice of the BatMC RERC prior to implementation. The BatMC RERC will determine whether the requested protocol changes alter the risk-benefit analysis of the study, thereby requiring a change in exemption category. You may contact the BatMC RERC office if you have any questions.

The BatMC RERC recommended the commencement of archiving procedures and reclassified the protocol as **INACTIVE**. The protocol records will be made available for three (3) years from this date.

Very truly yours,

Name and Signature  
<BatMC RERC Chair>



**BATANGAS MEDICAL CENTER  
RESEARCH ETHICS REVIEW COMMITTEE**

**Reminder Letter for Continuing Review / Progress Report / Final Report (Form 4.30.2D)**

<dd/mm/yyyy>

<TITLE, NAME, SURNAME OF PI>

Principal Investigator

<Institution/Affiliation>

<Address>

|  |  |
|--|--|
| <b>BatMC RERC Code</b>                     |  |
| <b>Study Protocol Title</b>                |  |
| <b>Date of RERC Approval</b>               |  |
| <b>Date of Expiry of Ethical Clearance</b> |  |

Dear <TITLE OF PI> <SURNAME>:

We wish to remind you that the <progress/final/continuing review> report for the study protocol <Study Protocol Title> <BatMC RERC Code> is due on/had been due since < every \_\_\_\_ from date of approval for progress report > / < 1 month after end of the study for final report > / < 2 months before expiry of ethical clearance for continuing review application >. Based on the records of the **Batangas Medical Center Research Ethics Review Committee (BatMC RERC)**, there had been no communication regarding the progress of this study, which is still in our active file and has an active ethical clearance. Please be reminded that data collection can only continue with active ethical clearance.

If the study had been concluded, kindly fill out a final report form [*BatMC RERC Form 3.22.1*]; or if still ongoing, a progress report form [*BatMC RERC Form 3.17.1*], or a continuing review application form [*BatMC RERC Form 3.21.1*] in case of expiring or expired ethical clearance. Study protocol non-compliance (deviation/violation) should also be reported, whether minor or major, at the soonest possible time up to one (1) month after the event, using the applicable form [*BatMC RERC Form 3.18.1 Deviation/Non Compliance/Violation Report*]. Forms may be requested from the BatMC RERC Secretariat.

Kindly submit the relevant report/form within thirty (30) days of receiving this letter. If no submission is received within the indicated grace period, the committee will be constrained to implement standard procedures for non-compliance with reportorial requirements and considered as protocol deviation. This may result in a recommendation for revocation of ethical clearance; and the study file subsequently inactivated and archived.

Should you have any questions or clarifications regarding the abovementioned recommendations, please contact the **BatMC RERC** Secretariat at (043) 740-8306 or batmc\_erc@yahoo.com.ph.

Thank you.

Very truly yours,

<BatMC RERC Chair>

## BATANGAS MEDICAL CENTER RESEARCH ETHICS REVIEW COMMITTEE

### LETTER OF DOCUMENT RECEIPT AND RECOMMENDATION FOR FURTHER ACTION (FORM 4.30.3)

<dd/mm/yy>

Principal Investigator

<Institution/Affiliation>

<Address>

Re: <Study protocol title><Study Protocol code>

Dear <TITLE OF PI><SURNAME>

We wish to inform you that the Batangas Medical Center Research Ethics review Committee acknowledged receipt of <Progress Report/Continuing Review Application/Final report/Study Protocol Non-Compliance Record/SAE Report/Site Visit Report>dated<date of document>.

Upon review of <Progress Report/Continuing Review Application Form/Final Report Form/Study Protocol non-compliance Record/serious Adverse Event Report Form/site visit Report Form> and <submitted document/s>, BATMC RERC action <REQUEST INFORMATION/RECOMMENDATION FOR FURTHER ACTION/>. Recommended revisions and/or classifications are summarized below:

|                           |                     |                           |
|---------------------------|---------------------|---------------------------|
| PROTOCOL TITLE:           |                     | BATMC RERC CODE:          |
| PRIMARY INVESTIGATOR (PI) |                     | DATE OF APPROVAL(Initial) |
| Documents Received:       | Recommended Action: | DATE:                     |
|                           |                     |                           |
|                           |                     |                           |

Please note that the cut-off date for submission is on <cut-off-date>. Should you have any questions or clarifications regarding the abovementioned recommendations, please contact the undersigned through the BATMC-RERC Secretariat.

The BATMC-RERC looks forward to your immediate response and action.

Very truly yours,

<Name of RERC Chair>



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**ARCHIVING NOTIFICATION (FORM 4.33.1)**

<dd/mm/yyyy>

**NAME OF PRINCIPAL INVESTIGATOR:**

**INSTITUTION/AFFILIATION:**

**ADDRESS:**

**Dear < Name of Principal Investigator>**

We wish to inform you that the **Batangas Medical Center Research Ethics Review Committee** has reviewed your protocol, with details as follows:

**BatMC RERC Code:**

**Study Protocol Title :**

**Date of Notice of RERC Decision** *<for approved or initial review if Inactive Protocol>*

**Date of Final / Early Termination Report** *< if Completed or Terminated Protocol >*

**RERC Decision : APPROVED** *<for completed, terminated, approved protocols>* **MAJOR MODIFICATION** *< for initial review with resubmission>*

**Date of Archiving**

*(Instructions to secretariat: Use template 1 for approved protocols and template 2 for protocols that are not yet approved and template 3 for completed or terminated protocols.)*

Template 1:

The protocol is reclassified as **INACTIVE** and ethical clearance automatically **EXPIRED**. The protocol records will be made available for **three years** from date of inactivation. Should you have any questions or clarifications regarding the abovementioned recommendations, please contact the undersigned through the BatMC RERC Secretariat at (043) 706-1229 or batmc\_erc@yahoo.com.ph.

Template 2:

The application for ethical review is reclassified as **INACTIVE** and study protocol will be **ARCHIVED**. Any subsequent submissions will be processed as initial review. The protocol records will be made available for **three years** from date of inactivation. Should you have any questions or clarifications regarding the abovementioned recommendations, please contact the undersigned through the BatMC RERC Secretariat at (043) 706-1229 or batmc\_erc@yahoo.com.ph.

Template 3 :

The protocol is now considered **COMPLETED / TERMINATED** and ethical clearance automatically **EXPIRED**. The study protocol will be **ARCHIVED**. The protocol records will be made available for **three years** from date of inactivation (5 years for Clinical Trial or as provided in the CTA whichever is longer). Should you have any questions or clarifications regarding the abovementioned recommendations, please contact the undersigned through the BatMC RERC Secretariat at (043) 7408306 loc 1021 or batmc\_erc@yahoo.com.ph.

**<NAME OF BATMC RERC CHAIR>**



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**REGISTER OF ARCHIVED PROTOCOLS ( FORM 4.33.2)**

| Date Archived | Protocol Number | Principal Investigator | Protocol Title | Date Disposed |
|---------------|-----------------|------------------------|----------------|---------------|
|               |                 |                        |                |               |
|               |                 |                        |                |               |
|               |                 |                        |                |               |
|               |                 |                        |                |               |
|               |                 |                        |                |               |
|               |                 |                        |                |               |
|               |                 |                        |                |               |
|               |                 |                        |                |               |
|               |                 |                        |                |               |
|               |                 |                        |                |               |
|               |                 |                        |                |               |
|               |                 |                        |                |               |
|               |                 |                        |                |               |
|               |                 |                        |                |               |

*Guide for Archiving :*

*Completed Protocols – upon receipt of Final Report*

*Terminated Protocols – upon receipt of Early Termination Report*

*Inactive Protocols – Approved but no communication within 1 year from issuance of Ethical Clearance*

*Inactive Protocols – Protocols with initial review but without resubmission or communication within 6 months from notice of board action*





**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**REGISTER OF DISPOSED STUDY PROTOCOLS ( FORM 4.33.3)**

| Date of Disposal | Protocol Number | Principal Investigator | RERC Member Witness | Signature of Witness | RERC Staff | Signature of RERC Staff |
|------------------|-----------------|------------------------|---------------------|----------------------|------------|-------------------------|
|                  |                 |                        |                     |                      |            |                         |
|                  |                 |                        |                     |                      |            |                         |
|                  |                 |                        |                     |                      |            |                         |
|                  |                 |                        |                     |                      |            |                         |
|                  |                 |                        |                     |                      |            |                         |
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*Guide for Disposal :*

*Inactive Protocols – three (3) years from date of archiving*

*Completed Protocols – three (3) years from date of archiving*

*Terminated Protocols – three (3) years from date of archiving*

*Clinical Trial Protocols – five (5) years from date of archiving OR retention period as per Clinical Trial Agreement whichever is later*



**BATANGAS MEDICAL CENTER  
RESEARCH ETHICS REVIEW COMMITTEE**

| REQUEST TO ACCESS DOCUMENT ( FORM 4.34.1 ) |                                  |             |  |
|--|----------------------------------|-------------|--|
| Request Number :                           | BATMC – RERC – Req – YYYY - 0000 |             |  |
| Date received:                             |                                  | Received by |  |

|               |  |       |
|---------------|--|-------|
| Request from: | <input type="checkbox"/> Telephone call Number | _____ |
|               | <input type="checkbox"/> Fax call Number       | _____ |
|               | <input type="checkbox"/> Mailed letter/ Date   | _____ |
|               | <input type="checkbox"/> E-mail / Date         | _____ |
|               | <input type="checkbox"/> Walk-in/Date/Time     | _____ |
|               | <input type="checkbox"/> Others, specify       | _____ |

|   |  |        |  |
|---|--|--------|--|
| Requestor's Name  |  |        |  |
| Contact Address:  |  | Phone: |  |
| Title of the Participating Study  |  |        |  |
| Principal Investigator  |  |        |  |
| Nature of Request<br>Borrowed on site /<br>max 2 days off site<br>Photocopy - REC staff |  |        |  |

|                        |  |  |  |
|------------------------|--|--|--|
| Action taken           |  |  |  |
| Signature of Requestor |  |  |  |
| Approved By            |  |  |  |



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**LOGBOOK OF REQUEST TO ACCESS ( Form 4.34.2 )**

| Name of Borrower | Protocol Number | Document Borrowed | Date Document Retrieved | Signature of Borrower | Date Document Returned | Signature of RERC Staff |
|------------------|-----------------|-------------------|-------------------------|-----------------------|------------------------|-------------------------|
|                  |                 |                   |                         |                       |                        |                         |
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**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**Logbook of Request for Copies of Documents (Form 4.34.3)**

| Name of Requester | Protocol Number | Title of Document | # of Copies | Signature of Requester | Date Received | Initial of RERC Staff |
|-------------------|-----------------|-------------------|-------------|------------------------|---------------|-----------------------|
|                   |                 |                   |             |                        |               |                       |
|                   |                 |                   |             |                        |               |                       |
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**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**CONFIDENTIALITY AGREEMENT FORM FOR NON-MEMBERS**  
**REQUESTING TO ACCESS BATANGAS MEDICAL CENTER RERC DOCUMENTS**  
( FORM 4.34.4 )

I, (Name, Surname) as a non-member of the Batangas Medical Center Research Ethics Review Committee, understand that the documents I am given access to by the Batangas Medical Center Research Ethics Review Committee are confidential. I shall use the information only for the purpose indicated in this form and shall not duplicate, give or distribute these documents to any person(s) without permission from the Batangas Medical Center Research Ethics Review Committee. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential. Should I no longer have any use for the requested document or have utilized the same for the declared purpose, I will return of the copy requested to REC or cause the destruction of such in a manner as permitted by law and will thereafter inform the REC of the said destruction. In no case shall the data be in my possession beyond three (3) years unless I am permitted by law to retain the same longer than the said period.

|                            |  |
|----------------------------|--|
| Requested document         |  |
| Reason for request         |  |
| Number of copies requested |  |
| RERC Decision              |  |

Room Use: \_\_\_\_\_  
Date to be returned : \_\_\_\_\_ (max of 2 days)

RECIPIENT:  
Date: <dd/mm/yyyy>

Signature  
Name: \_\_\_\_\_  
<Title, Name, Surname>  
ID :

RERC MEMBER-SECRETARY  
Date: <dd/mm/yyyy>

Signature  
Name: \_\_\_\_\_  
<Title, Name, Surname>  
ID :



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**

| QUERY / COMPLAINT FORM ( FORM 4.35.1 ) |                                 |             |  |
|--|---------------------------------|-------------|--|
| Query/Complaint No                     | BATMC – RERC – QC – YYYY - 0000 |             |  |
| Date received:                         |                                 | Received by |  |

|               |  |       |
|---------------|--|-------|
| Request from: | <input type="checkbox"/> Telephone call Number | _____ |
|               | <input type="checkbox"/> Fax call Number       | _____ |
|               | <input type="checkbox"/> Mailed letter/ Date   | _____ |
|               | <input type="checkbox"/> E-mail / Date         | _____ |
|               | <input type="checkbox"/> Walk-in/Date/Time     | _____ |
|               | <input type="checkbox"/> Others, specify       | _____ |

|                                  |  |        |  |
|----------------------------------|--|--------|--|
| Complainant's Name               |  |        |  |
| Contact Address:                 |  | Phone: |  |
| Title of the Participating Study |  |        |  |
| Principal Investigator           |  |        |  |
| Nature of Query or Complaint     |  |        |  |
| Action taken                     |  |        |  |
| Signature of Complainant         |  |        |  |
| Primary Reviewer                 |  |        |  |
| RERC Chairperson                 |  |        |  |



**BATANGAS MEDICAL CENTER  
RESEARCH ETHICS REVIEW COMMITTEE  
QUERY / COMPLAINT RESPONSE ( FORM 4.35.2 )**

<dd/mm/yy>

<NAME OF COMPLAINANT>

<Address>

Re: <Nature of Query / Complaint >  
<BATMC-RERC-QC- Code>

Dear <Name of Complainant>

We wish to inform you that the Batangas Medical Center Research Ethics Review Committee has reviewed your filed <query / complaint > during its regular meeting <date of meeting>.

On the above stated <query / complaint>, please be advised of the following resolutions:

- 1.
- 2.
- 3.

Should you have any questions or clarifications regarding the abovementioned resolution, please contact the undersigned through the BATMC-RERC Secretariat.

Very truly yours,

<NAME OF REVIEW CHAIR>

Chair, BATMC-RERC



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**Request for Revision of an SOP or Guideline**  
**Form 5.36.1**

Please complete this form whenever a problem or a deficiency in an SOP is identified and submit to the BATMC RERC Coordinator for processing.

|  |                        |
|--|------------------------|
| SOP or Guideline Code  | SOP or Guideline TITLE |
| Reason for request (citing details of problems or deficiency in current document): |                        |
| Description of requested changes   |                        |
| Revision Requested by:<br>(Name and signature)                                     | Date: (dd/mm/yyyy)     |

|  |                        |
|--|------------------------|
| BATMC RERC Coordinator Comments:   |                        |
| Recommendations by BatMC RERC Coordinator                                    |                        |
| <input type="checkbox"/> Revision requirement confirmed, forward to SOP Team |                        |
| <input type="checkbox"/> Request further information (state)                 |                        |
| <input type="checkbox"/> Forward to content expert for opinion               |                        |
| Signature  |                        |
| Name of BatMC RERC Coordinator   | <Title, Name, Surname> |
| Date   | <dd/mm/yyyy>           |



**BATANGAS MEDICAL CENTER**  
**RESEARCH ETHICS REVIEW COMMITTEE**  
**SOP TEMPLATE (Form 5.36.2)**

<TITLE OF SOP>

- 1. Policy Statement** - consists of institutional or committee policies upon which the activity and procedures are based. This section may also include specific provisions from international and national guidelines pertinent to the activity.
- 2. Objective/s of the Activity** - this defines the purpose and intended outcome
- 3. Scope** - this defines the extent of coverage of the SOP and its limitations
- 4. Workflow** – provides a graphic representation of the essential steps to implement the SOP and the responsible person for each step.
- 5. Description of Procedures** – this explains in detail the steps listed in the workflow describes the performance of each step in the Workflow. The person/s responsible and the forms to be used are mentioned and cited. The active forms of verbs are used. It is important to ensure that the number of steps in the Workflow is the same number of steps described in this section.
- 6. Glossary** – acronyms and terms which need to be defined as used in the SOP
- 7. Forms** - documents or standardized forms to be accomplished by different parties as required by the SOP ; lists the specific forms (and corresponding codes) used in the activity (e.g. application form, checklist, review guide, communication templates).
- 8. History** - presents the different versions (from draft to final version) of the SOP by author, version, date and description of changes
- 9. References** – list of guidelines, other institutional SOPs, manuals used in the development of the SOP.

|                |  |
|----------------|--|
| Supersedes     | <version number>                               |
| Version:       | <version number>                               |
| Authored by:   | <TITLE, NAME, SURNAME>                         |
| Version Date:  | dd/mm/yyyy                                     |
| Approved by:   | Batangas Medical Center – Medical Center Chief |
| Approval Date: | dd/mm/yyyy                                     |





## Clinical Trial Agreement

This Clinical Study Agreement (“Agreement”) is entered into by and among

**[Research or Sponsor Entity]** located at [insert address] represented herein by its \_\_\_\_\_, hereinafter referred to as the “**Research/Sponsor Entity**”;

**BATANGAS MEDICAL CENTER**, a DOH-retained level 3 hospital with address at Bihi Road, Kumintang Ibaba, Batangas City represented herein by its Medical Center Chief II, DR. RAMONCITO C. MAGNAYE hereinafter referred to as the “**Institution**”; and

**[Insert Principal Investigator]**, Nationality, of legal age with residence at \_\_\_\_\_, hereinafter referred as “**Investigator**”

### WITNESSETH

**WHEREAS**, (statement of any national incident which necessitates the study, if applicable);

**WHEREAS**, (statement of the nature of existence of the research or sponsor entity relating to the study);

**WHEREAS**, the Institution is a Level 3 hospital that has the appropriate facilities needed in the study;

**WHEREAS**, the Research/Sponsor Entity has identified and the Institution has agreed to support conduct of the study that will be conducted by the Investigator in its facilities;

**NOW THEREFORE**, for and in consideration of the foregoing premises and the terms and conditions set forth, the parties herein agree as follows:

### 1. SCOPE OF WORK

- 1.1 Conduct of the Study. The parties agree to conduct the Study based upon terms and conditions contained in this Agreement and in accordance with the Protocol attached as Appendix A.
- 1.2 The Study Team is composed of the following:

### 2. OBJECTIVES OF THE PROJECT

### 3. RESPONSIBILITIES OF THE RESEARCH/SPONSOR ENTITY

- 3.1. To provide administrative and financial support for the duration of the implementation of the Project.
- 3.2. To provide through the Principal Investigator hiring project personnel on a contractual basis and co-terminus with this Agreement. The Research/Sponsor Entity is responsible for the processing of the honorarium of the team provided that the necessary documents are accomplished and submitted to the Secretariat a week before the end of the month.
- 3.3 To provide the Institution with the necessary background information needed for the appropriate and safe conduct of the Study.



- 3.4. To ensure necessary training and orientation of the Principal Investigator and other personnel of the Institution involved in the Study in order to conduct the Study in accordance with the protocol;
- 3.5. To inform the Institution of the completion of the Study;
- 3.6. To provide the Institution with the data and documents needed for conducting the Study and guaranteeing the safety of the participants. The data and documents provided by the Research/Sponsor Entity may be used solely for the conduct of this Study in accordance with this agreement.

#### **4. RESPONSIBILITIES OF THE INSTITUTION**

- 4.1 To conduct the Study through Principal Investigator;
- 4.2. To ensure that Principal Investigator conducts the Study in accordance with this Agreement;
- 4.3. To recommend replacement of the Principal Investigator acceptable to Research/Sponsor Entity if Principal Investigator becomes unavailable to conduct the Study.
- 4.4. TO allow monitoring and auditing at the Study Site to be conducted by the Research/Sponsor Entity, as well as domestic and foreign authorities, and, if necessary, to assist in the executing thereof.

#### **5. RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR**

- 5.1. To conduct the Study with professional skill and care under the direction of Institution in accordance with:
  - a. the Protocol
  - b. the conditions of any reviewing institutional review board and/or ethics committee;
  - c. relevant professional standards, all applicable laws, rules and regulations and the requirements of any applicable Regulatory Authority;
  - d. Good Clinical Practice;
  - e. Research/Sponsor Entity's instructions; and
  - f. the terms of this Agreement.
- 5.2 To perform the Study and will not be subject to any obligations that may interfere with the conduct of the Study;
  - a. provides the curriculum vitae and any other documents required to evidence qualifications of Principal Investigator and their Personnel to Research/Sponsor Entity and Institution;
  - b. provides their and the Personnel's applicable statements of financial disclosure and all other relevant consents to such disclosure to applicable Regulatory Authorities
- 5.3. To submit all trial documents for ethics review for approval prior to commencing the Study;
- 5.4 To be responsible for the acts and omissions of investigators and site staff in relation to the conduct of the Study
- 5.5. To understand the Protocol, Investigator's Brochure and any other information provided by Research/Sponsor Entity in relation to the conduct of the Study through
  - a. preparation and maintenance of complete and accurate Study Data, Records and reports as required by the Research/Sponsor Entity;



- b. obtains an informed consent form which has been approved by the applicable ethics committee or institutional review board from each Study Participant prior to their participation in the Study;
- c. reviews all CRFs for accuracy and completeness

5.6. To provide Study Data and any additional written reporting to Research/Sponsor Entity

5.7. To be available when personnel of Research/Sponsor Entity attend the Site to monitor the Study (subject to reasonable notice) and is contactable by telephone and email, and cooperate to allow access to facilities and records (and copies of records subject to Study Participant confidentiality) as required

5.8. To notify as soon as possible the Research/Sponsor Entity, Institution and any reviewing institutional review board and/or ethics committee of any adverse events and serious adverse events or any material deviation that may occur during the Study in accordance with the requirements set out in the Protocol and immediately execute necessary precautions for the protection of the participants;

## 6. CONFIDENTIALITY

6.1. Each party shall keep in confidence all information exchanged among them in the course of the Study. All documents and electronic records that contain confidential information must be stored in a manner that no third party may have access thereto. Retention of the records shall be made by \_\_\_\_\_ for a period of \_\_\_\_\_ after the expiry of this Agreement.

6.2. Exceptions. The confidentiality obligation shall not, however, be applied to Confidential Information which:

6.6.2.1. Was, as evidenced, in the possession of the receiving party prior to receipt of the confidential information from the other party.

6.2.2. Has been publicly available or has become publicly available through no act or omission by the party or its employee or a consultant or breach of this agreement

6.2.3. The party has received from a third party without any obligation of confidentiality and which has a right to deliver such information to the other party, or on ground of law has to be delivered.

6.2.5. Any party invoking an exception set forth above has the burden of proof with respect to the existence of such exception.

6.3. Each party shall promptly return to the other party any Confidential Information no longer needed for the purposes of this agreement or if so requested by the other party.

6.4. Should any third party, e.g. Regulatory Authority demand access to Confidentiality Information on grounds of law, the party shall without any delay and prior to making such a disclosure notify the other party of such a demand in writing. The party may then deliver only the specified Confidential Information, which the request concerns.

## 7. DATA PRIVACY

7.1. All Parties must ensure the confidentiality of all Study related personal data and sensitive information. Each party must ensure that any Personal Information of Study Participant's or Personnel it obtains or holds as a result of the conduct of the Study is collected, stored, processed, used and disclosed by it in accordance with the Philippine Data Privacy Act of 2012 and its implementing rules and regulation.



- 7.2. The Principal Investigator shall promptly notify Research/Sponsor Entity and Institution should it become aware of, and do anything reasonably required by the National Privacy Commission, at their cost, to prevent or restrain, a breach or suspected breach of the confidentiality provisions of this Agreement

## **8. STUDY RESULTS AND INTELLECTUAL PROPERTY**

- 8.1. All information, documents, reports, materials and other results accrued in connection with this Study apart from the patient records and other data collected by the Principal Investigation are the property of the \_\_\_\_\_, the use of which the \_\_\_\_\_ may decide independently.
- 8.2. All intellectual properties resulting from the Project shall be governed by the provisions of the Intellectual Property Code of the Philippines (RA No. 8293), Philippine Technology Transfer act of 2009 (RA No. 10055) and its implementing Rules and Regulations (Joint DOST-IPO A.O. No. 02-2010, the Guidelines on Intellectual Property Valuation, Commercialization and Information Sharing (Joint DOST-DTI-IPOPHL AO No. 001 s. 2012). The DOST IP Policy (DOST AO No. 004 s 2015), the Revised Guidelines for the Grant-in-Aid Funds of DOST and its Agencies, as amended, and other applicable laws, rules and policies.
- 8.3. The Research/Sponsor Entity has the exclusive right of exploitation of the aforementioned copyrights, industrial rights and other intellectual property rights. It can however allow other parties to make reasonable publication or presentation of final results of the Study provided there is prior consent thereto. Research/Sponsor Entity shall not unreasonably withhold their consent to allow Institution and/or Principal Investigator to publish or present but may require reasonable amendments so that Confidential Information and/or Study Intellectual Property are not disclosed.

If the Study is a multi-centre Study, then any publication or presentation by Institution and/or Principal Investigator may only occur together with the other sites in the Study.

## **9. ASSIGNMENT**

- 9.1. The parties may not assign this agreement, any part thereof, or any right or obligation related to any third party without the prior written consent of the other party.

## **10. INDEMNIFICATION**

- 10.1. Research/Sponsor Entity shall indemnify and hold harmless the Institution and Principal Investigator from any and all liability of Study subjects, loss, or damage it may suffer as a result of Research/Sponsor Entity's negligence or breach of contract or caused by the Study Devices and medicines, compliance with the protocol, or use of the Results.
- 10.2. Principal Investigator and Institution shall immediately notify Sponsor in writing of any claim of illness or injury that is alleged to be due to an adverse reaction to the Study or any of the clinical intervention or procedures that are provided for or required by the Protocol to which the Study Participants would have not have been exposed but for their participation in the Study. Principal Investigator and Institution shall allow Research/Sponsor Entity to handle such claim, including, if applicable, settlement negotiations, and shall cooperate fully with Research/Sponsor Entity in the handling of the claim.

## **11. PROJECT DURATION**

The project shall be completed within \_\_\_\_\_ covering the period of \_\_\_\_\_.



## **12. ANTI-BRIBERY**

- 12.1. Institution and Principal Investigator represent and warrant that neither it nor any of Representatives, or any other person used in any capacity in connection with the Study at Institution has been debarred, sanctioned by or excluded from participation in any government health care program or any local country equivalent.
- 12.2. Institution, Principal Investigator and the Personnel, hereby agree that they will not make any payment or provide any benefit, directly or indirectly, to a party for the purpose of influencing decisions or actions with respect to the Study or the Research/Sponsor Entity.

## **13. PAYMENT**

- 13.1 As consideration for Institution's performance of the Study, Research/Sponsor Entity shall pay Institution in accordance with Schedule B.

## **14. FORCE MAJEURE**

- 14.1. Any event occurring after signing the agreement, which a party could not reasonably have taken into account at the time of the conclusion of the agreement and which prevents or delays the affected party from fulfilling its obligations under the agreement or makes the fulfillment thereof unreasonably difficult and which cannot be overcome without unreasonable loss of time or cost, shall constitute an event of force majeure.
- 14.2. An event of force majeure shall include strike, war, revolt. Import or export prohibition, acts of God, interruption of public traffic or distribution of energy, legal labor dispute, fire or any other reason having as severe and unusual effects beyond the control of the party.
- 14.3. If a party would wish to invoke existence of an event of force majeure as a cause for the non-compliance with any of its obligations under the agreement or delay or exemption from liability, it shall without delay inform the other party of the delay or termination of its contractual obligation in writing.

## **15. RETENTION AND DESTRUCTION OF STUDY RECORDS**

- 15.1. The Institution shall store the original Study Results and codes at minimum \_\_\_ years after termination of the Study. The storage of Study Records is included in the compensation paid by the Research/Sponsor Entity to the Institution for the Conduct of the Study.
- 15.2. The Research/Sponsor Entity shall notify the Institution in good time in advance and in writing if it wants the Institution to keep the records or codes after the above mentioned \_\_\_ years.
- 15.3. The Research/Sponsor Entity shall notify the Institution of the time after which the records related to the study must no longer be stored and reimburse the Institution all additional cost incurred due to the storage exceeding )) years. With respect to storage of records, the instruction set forth in Sections 4.9 and 5.5 of the ICH GCP are followed.

## **16. COMPLAINTS AND LIABILITIES**



16.1. A party is obliged to notify the other party immediately in writing of all errors, omissions and deficiencies detected in the conduct of the other party based on this agreement. Thereafter the defaulting party has a duty to correct the report, error, omission or deficiency.

16.2 A party shall be liable to compensate the other party the damages caused by its branch of contract. The parties shall not, however, be liable for any indirect or consequential damages. Except for the damages caused deliberately or by gross negligence.

## **17. TERM AND TERMINATION OF THE AGREEMENT**

17.1. This agreement shall become effective upon signing by both parties. The agreement shall continue in effect until \_\_\_\_\_ or until all parties have fulfilled their obligations set forth by this agreement.

17.2. Without prejudice to the term of the agreement, a party may terminate this agreement without immediate effect, if:

17.2.1. The other party is in material default of any of its obligations under this agreement and the breach is of significant importance to the other party.

17.2.2. The other party fails to comply with its obligations under this agreement and has not corrected its default, omission, or deficiency within four (4) weeks after the non-defaulting party has given the defaulting party written notice thereof.

17.2.3. The principal investigator, the Institution or the Research/Sponsor Entity has the right to suspend the conduct of the study and serve notice of termination with immediate effect due to any cause relating to the safety of the participants or any ethical reason.

17.2.4. In the event a complaint based on the Study has not led to correction of an error or deficiency, the Research/Sponsor Entity shall in addition have the right without separate obligation of compensation or refund to suspend the Study and terminate immediately in writing this agreement in the following circumstances:

17.2.4.1. If a favourable opinion of the Ethics Committee is not obtained;

17.2.4.2. If no subjects have been recruited within one (1) month followed by the initial visit of the Research/Sponsor Entity.

17.2.4.3. If the Institution has enrolled Study participants, who do not fulfil the criteria set for the subjects as defined by the protocol,

17.2.4.4. If the Institution does not follow the protocol,

17.2.4.5. If the Institution failed to comply with the 2017 National Ethical Guidelines for Health and Health-Related Research

17.2.4.6. If the Principal Investigator gives notice or is given notice by the unit conducting the Study or otherwise ceases to work for the Study as defined by this agreement, and the parties fail to reach mutual understanding on the new principal investigator, or

17.2.4.7 If the Research/Sponsor Entity decides to terminate the Study for scientific, ethical or administrative reasons





Provided that when the Research/Sponsor Entity serves notice of termination to to any causes referred to in the preceding paragraph, the Research/Sponsor Entity shall be obliged to compensate the Institution all necessary, irrevocable, documented, and direct costs incurred by the suspension of the Study due to the conduct of the Study.

The terms and conditions and responsibilities relating to the rights of the Research/Sponsor Entity and the authorities, confidentiality of information, data privacy, study results, intellectual property, retention and destruction of study record and governing law and dispute resolution shall survive termination or cancellation of this agreement.

## **18. GOVERNING LAW**

This agreement shall be governed by the laws of the Republic of the Philippines as well as international guidelines relating to good clinical practices.

## **19. DISPUTE RESOLUTION**

- 19.1. In case of disputes, claims and controversies arising from the interpretation and application of this Agreement, the parties agree to freely and voluntarily submit themselves to consultation and negotiation to amicably settle the dispute;
- 19.2. Should the parties fail to reach an amicable settlement the dispute shall be administratively settled or adjudicated in the manner provided in the Rules on Alternative Dispute Resolution, or any amendments or revisions thereto.

## **20. NOTICES**

- 20.1. Form of Notice. All notices, requests, claims, demands, and other communications between the parties shall be in writing.
- 20.1. Method of Notice. All notices shall be given (i) by delivery in person, (ii) by a nationally recognized next day courier services, (iii) by first class, registered or certified mail, postage prepaid; or (iv) by email
- 20.3. Receipt of Notice. All notices shall be effective:
  - 20.3.1. Upon receipt by the party to which notice is given
  - 20.3.2. On the day the mail is returned to sender because the addressee no longer resides at the given address in this contract without notifying the other party of the new address,
  - 20.3.3. after two (2) failed attempts to personally deliver the notices, requests, claims, demands and other communications, the party delivering the notice may leave the notice, request, claim, demand or other communications to a person of legal age, residing or working in the address or to the supervisor of the site.;
  - 20.3.4. On the date of receipt of the email.
- 20.4. Refusal of Delivery. Rejection or other refusal to accept or the inability to deliver because of change of address where the other party was not notified thereof shall be deemed to be receipt of the notice as of the date of such rejection, refusal or inability to deliver.
- 20.5 Party to Notify. All notices, requests, claims demands, and other communications shall be valid, effective, and binding if received by the following offices in the addresses indicated below:

For the Research/Sponsor Entity  
Attention: \_\_\_\_\_



Address : \_\_\_\_\_  
Email : \_\_\_\_\_

For the Institution  
Attention: \_\_\_\_\_  
Address : \_\_\_\_\_  
Email : \_\_\_\_\_

For the Principal Investigator  
Attention: \_\_\_\_\_  
Address : \_\_\_\_\_  
Email : \_\_\_\_\_

## 21. MISCELLANEOUS

- 21.1. **Amendment.** The parties may mutually amend the terms and conditions of this agreement in writing.
- 21.2. **Divisibility.** If any provision of this Agreement becomes or is declared illegal, invalid or unenforceable, such provision will be divisible from this Agreement and will be deemed to be deleted from this Agreement. If such deletion substantially alters the basis of this Agreement the parties will negotiate in good faith to amend the provisions of this Agreement to give effect to the original intent of the parties.
- 21.3. **Independent Contractors.** Institution, Research/Sponsor Entity, Principal Investigator are independent contractors, and neither is an agent, joint venture or partner of the other.
- 21.4. **Entire Agreement.** This agreement, including its Appendices, represents the entire understanding between the parties with respect to the conduct of the Study and superseded all prior oral or written agreements between the parties related thereto.
- 21.5. **Non-Waiver.** The failure of any party to enforce any term or provision hereof shall not be construed to be a waiver of such term or provision and shall in no way affect the right of such party thereafter to enforce such provision or any other term or provision thereof.
- 21.6. **Counterparts.** This agreement may be executed in multiple counterparts, each of which will be deemed an original, but all of which will constitute one and the same Agreement, and the signature pages from any counterpart may be appended to any other counterpart to assemble full executed counterpart. Counterparts of this Agreement also may be exchanged via electronic PDF copy and an electronic PDF copy of any party's signature will be deemed to be an original signature for all purposes.

**IN WITNESS WHEREOF**, the parties hereto have hereunto caused these presents to be signed on the date and at places first above written.

Research/Sponsor Entity

Institution

Principal Investigator

## ACKNOWLEDGMENT





REPUBLIC OF THE PHILIPPINES)  
CITY OF \_\_\_\_\_) S.S.

BEFORE ME, a Notary Public for and in the City of \_\_\_\_\_, Philippines, personally appeared:

\_\_\_\_\_  
\_\_\_\_\_

All known to me and to me known to be the same persons who executed the foregoing acknowledged to me that same is their free and voluntary act and deed

This instrument, consisting of \_\_\_\_ (\_\_) pages, including this page whereon this acknowledgement is written, has been signed by the parties together with their instrumental witnesses on each and every page thereof.

WITNESS MY HAND AND SEAL this \_\_\_\_\_ day of \_\_\_\_\_, 2020 in the City of \_\_\_\_\_, Philippines.



## MEMORANDUM OF AGREEMENT

*This Memorandum of Agreement (“Agreement”) is entered into by and among*

**BATANGAS MEDICAL CENTER**, a DOH-retained level 3 hospital with address at Bihi Road, Kumintang Ibaba, Batangas City represented herein by its Medical Center Chief II, **DR. RAMONCITO C. MAGNAYE** hereinafter referred to as the **“FIRST PARTY”**;

*and*

\_\_\_\_\_, with address at \_\_\_\_\_  
\_\_\_\_\_, represented herein by its \_\_\_\_\_  
\_\_\_\_\_, hereinafter referred to as **“SECOND PARTY”**

### WITNESSETH

**WHEREAS**, (statement of rationale of the MOA);

**WHEREAS**,

**WHEREAS**;

**WHEREAS**;

**NOW THEREFORE**, for and in consideration of the foregoing premises and the terms and conditions set forth, the parties herein agree as follows:

#### 1. SCOPE OF WORK

1.1

#### 2. OBJECTIVES OF THE PROJECT

2.1.

#### 3. RESPONSIBILITIES OF THE FIRST PARTY

3.1. .

#### 4. RESPONSIBILITIES OF THE SECOND PARTY

4.1

#### 5. CONFIDENTIALITY

5.1. Both parties acknowledge that confidential information may be acquired during the existence of this Agreement. Thus, neither party shall, without the written consent of the other, disclose any nor all parts of the confidential information acquired by the parties to any person, including any third party or employee of the parties, unless such persons are required to have knowledge to such confidential information for the parties to achieve their mutual purposes in accordance with the Data Privacy Act of 2012.



It is expressly agreed and understood that in case of doubt as to the identification whether or not information is confidential in nature, a party intending to disclose an information shall refer the same in writing to the party who owns such information for clarification and guidance. The clarification or determination made shall be binding and conclusive upon the parties. This confidentiality clause shall survive even after the termination of this Agreement.

Upon termination of this agreement between the Parties or after the lapse of the retention period in accordance with the term of the Study, all records, any documents and other items which contain, disclose and/or embody any Confidential Information (including, without limitation, all copies, reproductions, summaries and notes of the contents thereof), regardless of the person causing the same to be in such form, shall be returned to the Disclosing Party or destroyed by the Receiving Party, and the Receiving Party will certify that the provisions of this paragraph have been complied with

## **17. TERM AND TERMINATION OF THE AGREEMENT**

17.1. This agreement shall become effective upon signing by both parties. The agreement shall continue in effect until \_\_\_\_\_ or until all parties have fulfilled their obligations set forth by this agreement.

## **18. GOVERNING LAW**

This agreement shall be governed by the laws of the Republic of the Philippines as well as international guidelines relating to good clinical practices.

## **19. DISPUTE RESOLUTION**

19.1. In case of disputes, claims and controversies arising from the interpretation and application of this Agreement, the parties agree to freely and voluntarily submit themselves to consultation and negotiation to amicably settle the dispute;

19.2. Should the parties fail to reach an amicable settlement the dispute shall be administratively settled or adjudicated in the manner provided in the Rules on Alternative Dispute Resolution, or any amendments or revisions thereto.

## **20. NOTICES**

20.1. Form of Notice. All notices, requests, and other communications between the parties shall be in writing.

20.2. Party to Notify. All notices, requests, claims demands, and other communications shall be valid, effective, and binding if received by the following offices in the addresses indicated below:

For the First Party

Attention: \_\_\_\_\_  
Address : \_\_\_\_\_  
Email : \_\_\_\_\_

For the Second Party

Attention: \_\_\_\_\_  
Address : \_\_\_\_\_  
Email : \_\_\_\_\_



## 21. MISCELLANEOUS

- 21.1. **Amendment.** The parties may mutually amend the terms and conditions of this agreement in writing.
- 21.2. **Divisibility.** If any provision of this Agreement becomes or is declared illegal, invalid or unenforceable, such provision will be divisible from this Agreement and will be deemed to be deleted from this Agreement. If such deletion substantially alters the basis of this Agreement the parties will negotiate in good faith to amend the provisions of this Agreement to give effect to the original intent of the parties.
- 21.3. **Independent Contractors.** Institution, Research/Sponsor Entity, Principal Investigator are independent contractors, and neither is an agent, joint venture or partner of the other.
- 21.4. **Entire Agreement.** This agreement, including its Appendices, represents the entire understanding between the parties with respect to the conduct of the Study and superseded all prior oral or written agreements between the parties related thereto.
- 21.5. **Non-Waiver.** The failure of any party to enforce any term or provision hereof shall not be construed to be a waiver of such term or provision and shall in no way affect the right of such party thereafter to enforce such provision or any other term or provision thereof.
- 21.6. **Counterparts.** This agreement may be executed in multiple counterparts, each of which will be deemed an original, but all of which will constitute one and the same Agreement, and the signature pages from any counterpart may be appended to any other counterpart to assemble full executed counterparty. Counterparts of this Agreement also may be exchanged via electronic PDF copy and an electronic PDF copy of any party's signature will be deemed to be an original signature for all purposes.

**IN WITNESS WHEREOF**, the parties hereto have hereunto caused these presents to be signed on the date and at places first above written.

FIRST PARTY

SECOND PARTY

## ACKNOWLEDGMENT

REPUBLIC OF THE PHILIPPINES)  
CITY OF \_\_\_\_\_) S.S.

BEFORE ME, a Notary Public for and in the City of \_\_\_\_\_, Philippines, personally appeared:

\_\_\_\_\_  
\_\_\_\_\_

All known to me and to me known to be the same persons who executed the foregoing acknowledged to me that same is their free and voluntary act and deed

This instrument, consisting of \_\_\_\_ (\_\_\_\_) pages, including this page whereon this acknowledgement is written, has been signed by the parties together with their instrumental witnesses on each and every page thereof.

WITNESS MY HAND AND SEAL this \_\_\_\_\_ day of \_\_\_\_\_, 2020 in the City of \_\_\_\_\_, Philippines.