



Republic of the Philippines  
Department of Health  
**SINGLE JOINT RESEARCH ETHICS BOARD**

**SJREB FORM 3**  
**INFORMED CONSENT ASSESSMENT FORM**

*To be filled up by primary reviewer*

|                    |  |               |  |
|--------------------|--|---------------|--|
| SJREB Protocol No. |  | Date (D/M/Y): |  |
|--------------------|--|---------------|--|

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

|                            |  |
|----------------------------|--|
| Coordinating Investigator: |  |
|----------------------------|--|

**A. INFORMED CONSENT DOCUMENT REVIEW** *(please put an X before your choice and N/A on the comments if there are no further comments)*

| Questions   | Comment/s: |     |  |    |
|---|------------|-----|--|----|
| 1. Does the Informed Consent document state that the procedures are primarily intended for research?  |            |     |  |    |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; text-align: center;">Yes</td> <td style="width: 25%;"></td> <td style="width: 25%; text-align: center;">No</td> <td style="width: 25%;"></td> </tr> </table> |            | Yes |  | No |
| Yes   |            | No  |  |    |
| 2. Are procedures for obtaining Informed Consent appropriate?   |            |     |  |    |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; text-align: center;">Yes</td> <td style="width: 25%;"></td> <td style="width: 25%; text-align: center;">No</td> <td style="width: 25%;"></td> </tr> </table> |            | Yes |  | No |
| Yes   |            | No  |  |    |
| 3. Does the Informed Consent document contain comprehensive and relevant information?   |            |     |  |    |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; text-align: center;">Yes</td> <td style="width: 25%;"></td> <td style="width: 25%; text-align: center;">No</td> <td style="width: 25%;"></td> </tr> </table> |            | Yes |  | No |
| Yes   |            | No  |  |    |
| 4. Is the information provided in the protocol consistent with those in the consent form?   |            |     |  |    |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; text-align: center;">Yes</td> <td style="width: 25%;"></td> <td style="width: 25%; text-align: center;">No</td> <td style="width: 25%;"></td> </tr> </table> |            | Yes |  | No |
| Yes   |            | No  |  |    |
| 5. Are study related risks mentioned in the consent form?   |            |     |  |    |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; text-align: center;">Yes</td> <td style="width: 25%;"></td> <td style="width: 25%; text-align: center;">No</td> <td style="width: 25%;"></td> </tr> </table> |            | Yes |  | No |
| Yes   |            | No  |  |    |
| 6. Is the language in the Informed Consent document understandable?   |            |     |  |    |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; text-align: center;">Yes</td> <td style="width: 25%;"></td> <td style="width: 25%; text-align: center;">No</td> <td style="width: 25%;"></td> </tr> </table> |            | Yes |  | No |
| Yes   |            | No  |  |    |
| 7. Is the Informed Consent translated into the local language/dialect?  |            |     |  |    |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; text-align: center;">Yes</td> <td style="width: 25%;"></td> <td style="width: 25%; text-align: center;">No</td> <td style="width: 25%;"></td> </tr> </table> |            | Yes |  | No |
| Yes   |            | No  |  |    |
| 8. Are there vulnerable participants?   |            |     |  |    |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; text-align: center;">Yes</td> <td style="width: 25%;"></td> <td style="width: 25%; text-align: center;">No</td> <td style="width: 25%;"></td> </tr> </table> |            | Yes |  | No |
| Yes   |            | No  |  |    |
| 9. Are the different types of consent forms (assent, patient representative)  |            |     |  |    |

|   |                          |  |                              |
|---|--------------------------|--|------------------------------|
| appropriate for the types of study participants?  |                          |  |                              |
| <input type="checkbox"/> Appropriate  | <input type="checkbox"/> | <input type="checkbox"/> Not appropriate |                              |
| 10. Are names and contact numbers from the research team and the REC in the informed consent? |                          |  |                              |
| <input type="checkbox"/> Yes  | <input type="checkbox"/> | <input type="checkbox"/> No              |                              |
| 11. Does the ICF provide privacy & confidentiality protection?                                |                          |  |                              |
| <input type="checkbox"/> Yes  | <input type="checkbox"/> | <input type="checkbox"/> No              |                              |
| 12. Is there any undue inducement for participation?  |                          |  |                              |
| <input type="checkbox"/> Yes  | <input type="checkbox"/> | <input type="checkbox"/> No              |                              |
| 13. Is there provision for medical/psychosocial support?                                      |                          |  |                              |
| <input type="checkbox"/> Yes  | <input type="checkbox"/> | <input type="checkbox"/> No              | <input type="checkbox"/> N/A |
| 14. Is there provision for treatment of study-related injuries                                |                          |  |                              |
| <input type="checkbox"/> Yes  | <input type="checkbox"/> | <input type="checkbox"/> No              | <input type="checkbox"/> N/A |
| 15. Is the amount paid to participants stated?  |                          |  |                              |
| <input type="checkbox"/> Yes  | <input type="checkbox"/> | <input type="checkbox"/> No              | <input type="checkbox"/> N/A |

## B. RECOMMENDATION

|           |                          |                              |                          |                |
|-----------|--------------------------|------------------------------|--------------------------|----------------|
| Decision: | <input type="checkbox"/> | Approval                     | <input type="checkbox"/> | Minor Revision |
|           | <input type="checkbox"/> | Major Revision/ Resubmission | <input type="checkbox"/> | Disapproval    |

|                      |  |
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| Summary of comments: |  |
|----------------------|--|

|                  |  |       |  |
|------------------|--|-------|--|
| Reviewer's Name: |  | Date: |  |
|------------------|--|-------|--|

|            |  |
|------------|--|
| Signature: |  |
|------------|--|