**INFORMED CONSENT ASSESSMENT FORM**

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| --- | --- |
| **URERB Protocol Code:**  (to be filled out by URERB Secretariat) |  |
| **Study Protocol Title:**  (to be filled out by the Researcher/PI) |  |
| **Researcher/Principal Investigator:**  (to be filled out by the Researcher/PI) |  |
| **Study Protocol Submission Date:**  (to be filled out by URERB Secretariat) |  |
| **Review Classification**  (to be filled out by the Chair) | **Full Review Expedited Review** |

**INSTRUCTIONS**

|  |  |  |  |  |  |  |  |
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| To the Researcher/Principal Investigator: |  | Please indicate in the space provided below whether or not the specified assessment point is addressed by your informed consent document. 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 **informed consent document**, as applicable, by confirming the submitted information and writing your comments on the space provided under “REVIEWER COMMENTS.”Finalize your review by indicating your conclusions under “RECOMMENDED ACTION”and affix your signature on the space provided for the primary reviewer. | | | | | |
| **Essential Elements** | | | **To be filled out by the PI** | | | | **REVIEWER COMMENTS** |
| Indicate if the study protocol contains the specified assessment point | | | Page and paragraph where it is found |
|  | | | **YES** | **NO** | **N/A** |  |  |
| 1. Is it necessary to seek the informed consent of the participants? | | |  |  |  |  | If NO, please explain: |
| 1. If YES, are the participants provided with sufficient information regarding: | | |  |  |  |  |  |
| * 1. Purpose of the study | | |  |  |  |  |  |
| * 1. Expected duration of participation | | |  |  |  |  |  |
| * 1. Procedures to be carried out | | |  |  |  |  |  |
| * 1. Discomforts and inconveniences | | |  |  |  |  |  |
| * 1. Risks (including possible discrimination) | | |  |  |  |  |  |
| * 1. Benefits to the participants | | |  |  |  |  |  |
| * 1. Random assignment to treatments | | |  |  |  |  |  |
| * 1. Compensation and/or medical treatments in case of injury | | |  |  |  |  |  |
| * 1. Responsibilities of the participant | | |  |  |  |  |  |
| * 1. Expected benefits to the community or to society, or contributions to scientific knowledge | | |  |  |  |  |  |
| * 1. Voluntary participation, and withdrawal anytime without penalty or loss of benefit | | |  |  |  |  |  |
| * 1. Confidentiality of records and the assurance that the identity of the participant will remain confidential in the event the study results are published | | |  |  |  |  |  |
| * 1. Access of participant to the findings of the study | | |  |  |  |  |  |
| * 1. Information about the institutional affiliation of the researchers/investigators, sponsor/funding agency, and nature and sources of funds | | |  |  |  |  |  |
| * 1. Nature of the researcher/investigators’ participation | | |  |  |  |  |  |
| * 1. Contact details of the lead researcher/principal investigator for further information regarding the study and in the event of study related injury or unwanted events | | |  |  |  |  |  |
| * 1. Statement that the **University Research Ethics Review Board (URERB)** has approved the study, and may be contacted regarding rights of study participants, including grievances and complaints | | |  |  |  |  |  |
| **RECOMMENDED ACTION** | | | | | | | |
| * APPROVAL | | | | | | | |
| * MINOR MODIFICATIONS | | | | | | | |
| * MAJOR MODIFICATIONS | | | | | | | |
| * DISAPPROVAL | | | | | | | |
| **JUSTIFICATION FOR RECOMMENDATION**  **Mandatory Issues to be Addressed** (you may indicate the item that needs to be addressed)  **Suggestions for Improvement** (you may indicate the item that needs to be improved) | | | | | | | |
| **REVIEWER**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  Signature over Printed Name  Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | |