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| **FORM 2.4 INFORMED CONSENT / ASSENT EVALUATION** |

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| WVSU-URERC Protocol Number |  |
| Sponsor Protocol Number\* |  |
| Study Protocol Title\* |  |
| Date of Submission |  |
| Principal Investigator/ Researcher\* | *(Title, Name, Middle Initial, Surname)* |
| Institution/Department\* |  |
| Contact Number\* |  |
| Sponsor\* |  |

*\*To be filled out by Principal Investigator/Researcher*

*The following are for WVSU-URERC use only.*

|  | *To be filled out by the Primary Reviewers* | | | |
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| **ESSENTIAL ELEMENTS** | *Indicate if the ICF has the specified element* | | | **REVIEWER COMMENTS & RECOMMENDATIONS** |
|  | **YES** | **NO** | **N/A** |  |
| 1. Statement that the study is primarily intended for research |  |  |  |  |
| 1. Statement describing the objectives of the study |  |  |  |  |
| 1. Study-related treatments and probability for random assignment |  |  |  |  |
| 1. Study procedures including consent process, data gathering, and all invasive procedures |  |  |  |  |
| 1. Responsibilities of the participant |  |  |  |  |
| 1. Expected duration of participation in the study |  |  |  |  |
| 1. Approximate number of participants in the study |  |  |  |  |
| 1. Study aspects that are experimental |  |  |  |  |
| 1. 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   Risks from allowable use of placebo (as applicable) |  |  |  |  |
| 1. Reasonably expected benefits; or absence of direct benefit to participants, as applicable |  |  |  |  |
| 1. Expected benefits to the community or to society, or contributions to scientific knowledge |  |  |  |  |
| 1. Adequate protection of vulnerable participants |  |  |  |  |
| 1. Different forms (consent, assent, LAR) appropriate for the type of study participants |  |  |  |  |
| 1. Description of post-study access to the study product or intervention that have been proven safe and effective, as applicable |  |  |  |  |
| 1. Alternative procedures or treatment available to participant |  |  |  |  |
| 1. 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 |  |  |  |  |
| 1. Statement on psycho-social support |  |  |  |  |
| 1. 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 |  |  |  |  |
| 1. Anticipated expenses, if any, to the participant in the course of the study |  |  |  |  |
| 1. Statement that participation is voluntary and may be withdrawn anytime without penalty or loss of benefit to which the participant is entitled |  |  |  |  |
| 1. For research involving children and adolescents, statement that consent will be obtained if the participant reaches legal age in the duration of the study, as applicable |  |  |  |  |
| 1. Statement that the study monitor(s), auditor(s), the Ethics Review Panel, and regulatory authorities will be granted direct access to participant’s medical records for purposes **ONLY** of verification of clinical trial procedures and data |  |  |  |  |
| 1. 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 |  |  |  |  |
| 1. Description of data protection plan and details about storage (including who has access to the study-related documents, how long identifying data will be stored, and manner of storage) |  |  |  |  |
| 1. Description of policy regarding the use of genetic tests and familial genetic information, as applicable, and the precautions in place to prevent disclosure of results to immediate family relative or to others without consent of the participant |  |  |  |  |
| 1. 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, as applicable |  |  |  |  |
| 1. Plans to destroy collected biological specimen at the end of the specified storage period, as applicable; 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 |  |  |  |  |
| 1. Plans to develop commercial products from biological specimens and whether the participant will receive monetary or other benefit from such development |  |  |  |  |
| 1. 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 |  |  |  |  |
| 1. Foreseeable circumstances and reasons under which participation in the study may be terminated |  |  |  |  |
| 1. Sponsor, institutional affiliation of the investigators, and nature and sources of funds |  |  |  |  |
| 1. Statement whether the investigator is serving only as an investigator or as both investigator and the participant’s healthcare provider |  |  |  |  |
| 1. 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 |  |  |  |  |
| 1. Statement that the Ethics Review Panel (specify) has approved the study, and may be reached through the following contact for information regarding rights of study participants, including grievances and complaints:   **Name of WVSU-URERC Chair:**  **Address:**  **Email:**  **Tel:** |  |  |  |  |
| 1. Comprehensibility of language used, including local language/dialect (if applicable) |  |  |  |  |
| 1. Are the provisions for the mitigation of risks in the protocol consistent with what is in the ICF? |  |  |  |  |
| 1. Other comments not addressed by items 1-34 |  |  |  |  |

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| **RECOMMENDATION** |  | Approval |  | Minor Revision/ Resubmission |
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|  | Major Revision/ Resubmission |  | Disapproval |

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| **SUMMARY OF RECOMMENDATIONS** |  |

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| Reviewer’s Name and Signature |  | Date |  |