Study #:

Reviewer:

**REVIEWER CHECKLIST: CONTINUING REVIEW OF A HUMAN RESEARCH STUDY**

**45 CFR 46.111 and 21 CFR 56.111**

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|  | When conducting continuing review, the IRB reviewer should start with the assumption that that the research, as previously approved, satisfied all of the criteria under 45 CFR 46.111 or 21 CFR 56.111. The IRB reviewer should focus on any new information provided by the investigator, or otherwise available to the IRB, that may alter the IRB’s prior determinations, particularly with respect to the IRB’s prior evaluation of the potential benefits or risks to the subjects. The IRB reviewer should also assess whether there is any new information that would necessitate revision to the protocol and/or the informed consent document. | Yes | No | N/A |
| 1 | **Is an adequate status report on the study’s progress provided?*** Are the information and documents provided in the continuing review consistent with the IRB’s prior approval of the study?
* If enrollment is notably slow, is adequate justification/explanation provided to continue with the study?
* Is the number of, and reasons for, subject withdrawals reasonable?
 |[ ] [ ] [ ]
| 2 | **Is there any significant new information that may change a subject’s willingness to participate?*** If yes, has the protocol and informed consent been updated?
* Are the plans for conveying the information to and/or reconsent of existing subjects reasonable?
 |[ ] [ ] [ ]
| 3 | **Has the protocol changed since the last IRB Review?** * Are requested changes updated in protocol and all appropriate study materials?
* Do the requested changes alter the risk/benefit ratio of the subjects?
 |[ ] [ ] [ ]
| 4 | **Has the PI submitted any new deviations or exceptions since the last IRB review?*** Do the reported deviations or exceptions alter the risk/benefit ratio?
* Are any protocol changes required or recommended to prevent similar events in the future ?
 |[ ] [ ] [ ]
| 5 | **Have there been any incidents/reportable events reported since the last IRB review?** * Do any of these events alter the risk/benefit ratio?
* Should other subjects be informed of the events and/or changes to risk/benefit ratio?
* Should the consent or protocol be amended to include new information resulting from these events?
* Were any subject complaints documented for this study to raise concern about whether it should be issued continuing approval?
 |[ ] [ ] [ ]
| 6 | **Are there any changes to procedures to maintain confidentiality of data?*** Are the revised procedures adequate to protect the privacy and assure confidentiality of subjects?
 |[ ] [ ] [ ]
| 7 | **Are there revisions needed to the informed consent documents?*** Does the consent document, script, or information sheet contain accurate, up-to-date information about the study?
* Are they written in understandable language?
* Are all relevant elements of consent/authorization included in consent form?
 |[ ] [ ] [ ]
| 8 | **Is there continued appropriate monitoring of subjects during and after study?*** If appropriate, are counseling referrals or support services provided?
* If appropriate, is a Data Safety and Monitoring Plan needed?
 |[ ] [ ] [ ]
| 9 | **Do risks continue to be minimized and reasonable in relation to the benefits and knowledge to be gained?*** Procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.
 |[ ] [ ] [ ]
| 10 | **Are there any new local or institutional issues that need to be addressed?*** Are new potential conflicts of interests disclosed and described?
* Are there changes in investigator situation or qualifications (e.g. expired credentials, suspensions, etc.)?
* Changes in the acceptability of the proposed research in terms of institutional commitments (e.g., personnel and financial resources)?
 |[ ] [ ] [ ]
| 11 | **Is independent verification of no material changes since previous IRB review recommended?*** Complex protocols involving unusual levels or types of risks to subjects.
* Protocols conducted by Principal Investigators who previously have failed to comply with Federal regulations or the requirements or determinations of the IRB.
* Protocols where concern about possible material changes occurring without IRB approval have been raised based on information provided in continuing review reports or from other sources.
 |[ ] [ ] [ ]
|  | **Outcome – Full Board** | [ ] Approve | [ ] Require Changes | [ ] Return to Full Board Committee/Table |
|  | Continuing review Period | [ ] 12 Months | [ ]  \_\_\_ Months | [ ] Minimal Risk (CR by Expedited Review) |

**ELEMENTS OF CONSENT**

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|  | Following are the REQUIRED elements of consent. | Additional Elements, if applicable |
|  | Language Is Understandable to Subject (8th Grade Reading Level) | Disclosure of Appropriate Alternative Procedures or Courses of Treatment |
|  | No Exculpatory Language (Does Not Waive Rights) | Statement that Treatment May Involve Risks that are Currently Unforeseeable |
|  | Key Information (Reasons Why One Might or Might Not Want to Participate) | Anticipated Circumstances by Which Participant May Be Terminated |
|  | Statement Study Involves Research | Additional Costs to Subjects |
|  | Statement That Participation Is Voluntary | Consequences of Subject’s Decision to Withdraw |
|  | Statement That Refusal to Participate Will Not Result in Penalty or Loss of Benefits | Financial Interest Disclosure |
|  | Statement That Subjects May Withdraw at Any Time with No Penalty | Approximate Number of Subjects |
|  | Explanation of Purpose of Research | Statement if Subject’s Biospecimens Will/Will Not be Used for Commercial Profit |
|  | Accurate & Complete Description of Procedures (Identify Experimental Procedures) | GINA Language Included (If Study Involves Genetic Analysis) |
|  | Expected Duration of Participation | If Research Involves Biospecimens, whether whole Genome Sequencing will occur |
|  | Description of Compensation to Participant | Clinical Trials.gov Statement (All Clinical Trials) |
|  | Description of Reasonably Foreseeable Risks or Discomforts to Participant | Certificate of Confidentiality Language (All NIH Funded Studies Plus Those Applying for CoC.) |
|  | Description of Benefits to Participant | Radiation Risk Language |
|  | Statement Describing the Extent to Which Privacy and Confidentiality Will Be Maintained | Statement that Significant New Findings that May Impact Subject’s Willingness to Participate will be Provided |
|  | Explanation of Medical Treatment Which Are Available If Injury Occurs (More Than Minimal Risk Only) | Statement Regarding Whether Clinically Relevant Research Results will be Disclosed to Subjects |
|  | Explanation of Who to Contact for Questions About the Research or In the Event of a Research Related Injury |  |
|  | Explanation of Who to Contact for Information About Subjects Rights (IRB) |  |
|  | Statement That Data Will/Will Not Be Used in Future Research Studies |  |

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|  | HIPAA Authorization, if applicable |
|  | Contains WSU-Approved Template Language |
|  | If yes, PI and proper Covered Entity referenced, purpose customized, PHI listed, signature line includes authorization language |
|  | If no, check all the following in non-template authorization language: |
|  | Proper Covered Entity is Named (e.g., Miami Valley, Premier Health, Wright State Physicians) |
|  | Name(s) of persons authorized to request authorization (e.g., PI Name and his/her study team) |
|  | Description of PHI to be created, used or disclosed in a specific and meaningful manner |
|  | Description of purpose of requested use or disclosure (e.g., study title and overall study purpose) |
|  | Statement of authorization expiration date or event |
|  | Names of individuals, organizations, to whom PI can share subject’s PHI with including covered entity officials, IRB, Sponsor |
|  | Place for subject or LAR signature and date. If one signature for both consent and authorization, certification language includes subject giving “authorization” as well as consent. |
|  | Statement of the subject’s right to revoke authorization and how to do so (e.g., mailing address or email) and if there are any consequences for revoking authorization. |
|  | Statement explaining whether non-research treatment, payment, enrollment, or eligibility of benefits can be conditioned on authorization. In addition, whether a subject can still participate in research study if they don’t provide authorization. |
|  | A statement of the potential risk that PHI will be re-disclosed by the recipient and no longer protected by the Privacy Rule. This may be a general statement that the Privacy Rule may no longer protect health information disclosed to the recipient. |
|  | Non-template authorization is written in plain language. |