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| **IRB Post-Approval Monitoring Self-Assessment Report**  |



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IRB Post Approval Monitoring Report v. 1/23/ 2024

**Institutional**

**Review Board**

**Office**

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| **PAM Check List** |
| 1. **Approval and Record Keeping**
 | **Yes** | **No** | **N/A** | **Notes** |
| Does the project have current IRB approval? | [ ]  | [ ]  | [ ]  |       |
| Are all IRB related records being retained in an accessible location? (Examples: approval letters, signed applications, approved consent forms, correspondence, protocol, etc.) | [ ]  | [ ]  | [ ]  |       |
| Are all research team members current in their Human Participants’ Protections Training (CITI)?  | [ ]  | [ ]  | [ ]  |       |
| Are all research team member training certificates on file?  | [ ]  | [ ]  | [ ]  |       |
| Have all revisions to the project been reviewed and approved by the IRB prior to implementation?  | [ ]  | [ ]  | [ ]  |       |
| 1. **Participant Recruitment and Screening**
 | **Yes** | **No** | **N/A** | **Notes** |
| Were participants identified and recruited according to the procedures approved by the IRB? | [ ]  | [ ]  | [ ]  |       |
| Were the advertising and/or recruitment materials used approved by the IRB prior to use? | [ ]  | [ ]  | [ ]  |       |
| Were all inclusion and exclusion requirements followed as listed and approved by the IRB?  | [ ]  | [ ]  | [ ]  |       |
|  If **no**, were the deviations reported to the IRB? | [ ]  | [ ]  | [ ]  |       |
| For participants that did not meet eligibility requirements (failed screening), were IRB approved procedures followed? | [ ]  | [ ]  | [ ]  |       |
| How many participants have been enrolled to date?       |  |  |  |       |
| Is the number of participants enrolled greater than the IRB approved maximum participant enrollment? | [ ]  | [ ]  | [ ]  |       |
| 1. **Informed Consent Process and Documentation**
 | **Yes** | **No** | **N/A** | **Notes** |
| Was the IRB approved version of the consent(s)/assent(s) used to enroll participants? | [ ]  | [ ]  | [ ]  |       |
| If using an oral or online consent, was the IRB approved script/text used to enroll participants? | [ ]  | [ ]  | [ ]  |       |
| Were all consent forms used to enroll participants approved by the IRB? | [ ]  | [ ]  | [ ]  |       |
| Did an appropriately trained research team member obtain consent from all participants? | [ ]  | [ ]  | [ ]  |       |
| Is there a signed and dated consent form on file for every participant enrolled in the project? | [ ]  | [ ]  | [ ]  |       |
| Did the research team member sign and date each consent form? | [ ]  | [ ]  | [ ]  |       |
| Do the participant and researcher consent dates match? | [ ]  | [ ]  | [ ]  |       |
| If changes were made to the consent form, were the changes submitted and approved by the IRB prior to use? | [ ]  | [ ]  | [ ]  |       |
| Did every participant receive a copy of the consent form? | [ ]  | [ ]  | [ ]  |       |
| 1. **Research Protocol**
 | **Yes** | **No** | **N/A** | **Notes** |
| Was the research conducted consistent with the description and procedures as approved by the IRB? | [ ]  | [ ]  | [ ]  |       |
| Were the data collection tools (e.g. surveys, interview questions, etc.) used approved by the IRB, prior to use? | [ ]  | [ ]  | [ ]  |       |
| For each participant, was consent obtained prior to any project procedures? | [ ]  | [ ]  | [ ]  |       |
| Are all participant compensation records being documented and stored appropriately? | [ ]  | [ ]  | [ ]  |       |
| If changes were made to the protocol, were the changes submitted and approved by the IRB prior to implementation? | [ ]  | [ ]  | [ ]  |       |
| Have all reportable events been addressed as required by the IRB? | [ ]  | [ ]  | [ ]  |       |
| 1. **Privacy, Data Storage, and Confidentiality**
 | **Yes** | **No** | **N/A** | **Notes** |
| Were privacy standards and procedures implemented as approved by the IRB? | [ ]  | [ ]  | [ ]  |       |
| If you collected data anonymously, has anonymity been maintained in the physical/electronic records? | [ ]  | [ ]  | [ ]  |       |
| Are signed consent forms and coded research data stored separately?  | [ ]  | [ ]  | [ ]  |       |
| Are signed consent forms secured as approved by the IRB? Provide location:       | [ ]  | [ ]  | [ ]  |       |
| Are research data secured as approved by the IRB? Provide location(s):       | [ ]  | [ ]  | [ ]  |       |
| If electronic data are being stored on a desktop, is it secured as approved by the IRB? Provide computer location:       | [ ]  | [ ]  | [ ]  |       |
| Are electronic data secured (e.g. password protected, encrypted, etc.) as approved by the IRB? | [ ]  | [ ]  | [ ]  |       |
| Are you aware of the security on your computer and server? | [ ]  | [ ]  | [ ]  |       |
| Is access to computer, electronic files, and physical files limited to appropriate research personnel? | [ ]  | [ ]  | [ ]  |       |
| Was/are identifiers stored/disposed of as approved by the IRB? | [ ]  | [ ]  | [ ]  |       |
| Was/is the research data (raw) stored/disposed of as approved by the IRB? | [ ]  | [ ]  | [ ]  |       |

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| **6. Biospecimen Collection & Storage** | **Yes** | **No** | **N/A** | **Notes** |
| Are biospecimens being collected in accordance with IRB approved procedures?  | [ ]  | [ ]  | [ ]  |       |
| Are the biospecimens being properly stored/disposed of as approved by the IRB?  | [ ]  | [ ]  | [ ]  |       |
| Are there appropriate biohazard disposal containers placed where the biospecimens are being collected? | [ ]  | [ ]  | [ ]  |       |
| Are the biospecimen collection areas being properly sanitized in accordance with IRB approved procedures? | [ ]  | [ ]  | [ ]  |       |
| Do all members of the research team have the BBP training on file and up to date? | [ ]  | [ ]  | [ ]  |       |

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| **7. Continuing Review** | **Yes** | **No** | **N/A** | **Notes** |
| Are you aware of when the IRB approval for this project expires? Expiration date:       | [ ]  | [ ]  | [ ]  |       |
| Have you placed a reminder on your schedule to submit continuing review documents 30 days prior to expiration? | [ ]  | [ ]  | [ ]  |       |
| Has IRB approval for this project ever expired?  | [ ]  | [ ]  |  |       |
|  If **yes**, did you report any research activity that was done while IRB approval was expired? | [ ]  | [ ]  |  |       |
| Have there been any adverse events, unanticipated problems, or complaints while conducting this research?  | [ ]  | [ ]  |  |       |
|  If **yes**, have all details been reported to the IRB? | [ ]  | [ ]  | [ ]  |       |
| Has the researcher become aware of new information that changes the risk benefit ratio of this project? | [ ]  | [ ]  |  |       |
| Does the enrollment number reported in the continuing review application include all individuals who signed an informed consent document? | [ ]  | [ ]  | [ ]  |       |

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| **8.** **Project Completion** | **Yes** | **No** | **N/A** | **Notes** |
| Is data collection complete for this project? | [ ]  | [ ]  | [ ]  |       |
|  If data collection is ongoing**, what is your anticipated end date for data collection?** Anticipated end date.        |
| Have all identifiers been destroyed in accordance with IRB approved procedures? | [ ]  | [ ]  | [ ]  |       |
| If **yes to both questions above**, submit a Closure Application (and supporting documentation) to the IRB Office. |