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| **PAM IRB 02\_103 PAM Principal Investigator Sefl-Assessment – Social, Behavior, and Educational Research** | | | | |
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| Principal Investigator: |  | | | |
| Protocol Number: |  | | | |
| Protocol Title: |  | | | |
| Name of the Person Completing Checklist: |  | | | |
| Date Completed: |  | | | |
| This checklist is designed to help investigators conduct a self-assessment for quality improvement purposes. It is intended for research studies related to social, behavioral, or educational fields and is not considered clinical trials. It's important to note that not all sections of this self-assessment may apply to each study. Therefore, the reviewer should identify and complete only the relevant sections for each unique study.   |  |  | | --- | --- | | **Apply** | **Section** | |  | [A. REGULATORY DOCUMENTATION](#_A._REGULATORY_DOCUMENTATION) | |  | [B. RESEARCH PERSONNEL](#_B._RESEARCH_PERSONNEL) | |  | [C. PARTICIPANT RECRUITMENT AND SCREENING](#_C._PARTICIPANT_RECRUITMENT) | |  | [D. INFORMED CONSENT DOCUMENTATION](#_D._INFORMED_CONSENT) | |  | [E. INFORMED CONSENT PROCESS](#_E._INFORMED_CONSENT) | |  | [F. RESEARCH PROTOCOL](#_F._RESEARCH_PROTOCOL) | |  | [G. PRIVACY, DATA STORAGE, AND CONFIDENTIALITY](#_G._PRIVACY,_DATA) | |  | [H. DATA AND SAFETY MONITORING](#_H._DATA_AND) | |  | [I. CONTINUING REVIEW](#_I._CONTINUING_REVIEW) | |  | [J. PROJECT COMPLETION](#_J._PROJECT_COMPLETION) | |  | [K. DOCUMENT RETENTION](#_K._DOCUMENT_RETENTION) | | | | | |
| A. REGULATORY DOCUMENTATION | | **Yes** | **No** | **N/A** |
| Does the project have current IRB approval? | |  |  |  |
| Is the project supported by a grant, starting funds, or sponsor? | |  |  |  |
| Does the project have a sponsor agreement or contract? | |  |  |  |
| Have all revisions to the project been reviewed and approved by the IRB prior to implementation? | |  |  |  |
| Is the most recent version of the IRB approved protocol on file on file and available to the research team? | |  |  |  |
| Is the most recent version of the IRB approved advertisement or recruitment materials and available to the research team? | |  |  |  |
| Is the most recent version of the IRB approved consent document on file and available to the research team? | |  |  |  |
| Are the most recent versions of the IRB approved parental permission/assent document(s) on file and available to the research team? | |  |  |  |
| If using an oral script, was the script approved by the IRB? | |  |  |  |
| Are the most recent versions of the IRB approved study tools, e.g., survey/questionnaire on file and available to the research team? | |  |  |  |
| Does the researcher have available the most recently approved protocol, consent form, and study documents for review? | |  |  |  |
| Are all IRB related records being retained in an accessible location? All records must be kept for at least 3 years after closure of the project. Examples: approval letters, signed applications, approved consent forms, correspondence, protocol, etc. | |  |  |  |

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| B. RESEARCH PERSONNEL | **Yes** | **No** | **N/A** |
| Are all project team members current (completed in last 3 years) in their human participants’ protections training (CITI/NIH)? |  |  |  |
| Are all project team members’ training certificates on file? |  |  |  |
| Are each personnel trained to conduct the role they are assigned appropriately and according to the protocol? |  |  |  |
| Are all personnel (i.e., PIs, Co-PIs, research staff) aware of all IRB-approved modifications? |  |  |  |
| Are all research team members that have contact with participants or the participants’ identified data listed as personnel on the study? |  |  |  |
| If not, is a personnel modification needed? |  |  |  |

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| C. PARTICIPANT RECRUITMENT AND SCREENING | **Yes** | **No** | **N/A** |
| Are the IRB-approved recruitment methods being followed? |  |  |  |
| Have all recruitment materials (e.g., advertisement and telephone scripts) been approved by the IRB? Note: All recruitment material must be approved prior to use and must be reapproved at the time of continuing review |  |  |  |
| 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? |  |  |  |
| How many have been approved by the IRB? |  |  |  |
| Is the number of participants enrolled up to date no greater than the IRB approved participant enrollment? |  |  |  |
| Have any participants withdrawn from study? |  |  |  |
| If yes, is reason documented? |  |  |  |

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| D. INFORMED CONSENT DOCUMENTATION | **Yes** | **No** | **N/A** |
| If using an oral or online consent, was the IRB approved script/text used to enroll participants? |  |  |  |
| Are there any handwritten modifications to the informed consent document? |  |  |  |
| If changes were made to the consent form, were the changes submitted and approved by the IRB prior to use? |  |  |  |
| Did an appropriately trained project 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 project team member sign and date each consent form? |  |  |  |
| Do the participant and researcher consent dates match? |  |  |  |
| Did every participant receive a copy of the consent form? |  |  |  |
| Were all consent documents signed by subjects prior to enrollment (research procedures)? |  |  |  |
| Were any not approved consent forms used to consent participants? |  |  |  |
| Are consent documents properly stored per the IRB approved application (i.e., separate from coded research data)? |  |  |  |

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| E. INFORMED CONSENT PROCESS | **Yes** | **No** | **N/A** |
| The consent process minimizes the possibility of undue influence or coercion. |  |  |  |
| The consent discussion and document are in a language that is understandable to participants and is culturally appropriate |  |  |  |
| The consent process does not include any exculpatory language and the information is provided to subjects in a way that does not waive (or appear to waive) any of the subject’s legal rights, or releases or appears to release the investigator, sponsor, institution or its agents from liability for negligence. |  |  |  |
| The consent process (whether documented or oral) includes the basic and appropriate elements of consent. |  |  |  |
| The consent process provides subjects sufficient time to consider whether or not they want to participate. |  |  |  |
| Were any subjects consented using a process that differed from the IRB approved process? |  |  |  |

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| F. RESEARCH PROTOCOL | **Yes** | **No** | **N/A** |
| Was the research conducted consistent with the description and procedures as approved by the IRB? |  |  |  |
| If changes were made to the protocol, were the changes submitted and approved by the IRB prior to implementation? |  |  |  |
| For each participant, was consent obtained prior to any project procedures? |  |  |  |
| Are all participant compensation records being documented and stored appropriately? |  |  |  |
| Have all reportable events been addressed as required by the IRB? |  |  |  |
| Have any adverse events occurred? |  |  |  |
| Were all reported to the IRB? |  |  |  |
| Have there been any protocol deviations? |  |  |  |
| If so, have they been reported to the IRB? |  |  |  |
| Have there been any unanticipated problems with protocol implementation? |  |  |  |
| Have there been any participant complaints? |  |  |  |

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| G. PRIVACY, DATA STORAGE, AND CONFIDENTIALITY | **Yes** | **No** | **N/A** |
| 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? |  |  |  |
| If you collected identifiable data, has confidentiality been maintained in the physical/electronic records? |  |  |  |
| Are you coding data per the protocol? |  |  |  |
| Was/are identifiers stored/disposed of as approved by the IRB? |  |  |  |
| Are signed consent forms and coded project data stored separately? |  |  |  |
| Are signed consent forms secured as approved by the IRB? |  |  |  |
| Is project data secured as approved by the IRB? |  |  |  |
| If electronic data is being stored on a desktop, is it secured as approved by the IRB? |  |  |  |
| 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 computers, electronic files, and physical files limited to appropriate project personnel? |  |  |  |
| Was/is the research data (raw) stored/disposed of as approved by the IRB? |  |  |  |

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| H. DATA AND SAFETY MONITORING | **Yes** | **No** | **N/A** |
| Is there a Data Safety Monitoring Plan (DSMP) for this study? |  |  |  |
| Has the DSMP been followed per the IRB approved protocol? |  |  |  |
| Is there a Data Safety Monitoring Board (DSMB) for this study? |  |  |  |
| Have all DSMB reports been submitted to the IRB? |  |  |  |

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| I. CONTINUING REVIEW | **Yes** | **No** | **N/A** |
| Are you aware of when the IRB approval for this project expires? |  |  |  |
| 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? |  |  |  |
| Has the number enrolled on the continuing reviews included individuals who consented but did not complete the project? |  |  |  |

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| J. PROJECT COMPLETION | **Yes** | **No** | **N/A** |
| Is data collection complete for this project? |  |  |  |
| 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 OIRB. |  |  |  |

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| K. DOCUMENT RETENTION | **Yes** | **No** | **N/A** |
| Regulatory documentation (e.g., contents of the regulatory binder) are retained for at least 3 years after closing out the Human Research |  |  |  |
| Records for sponsored research are retained until the sponsor authorizes the destruction of the records. Instructions or date of authorized destruction? |  |  |  |