**Checklist: PI Protocol Self-Assessment**

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| **Overview & Instructions** |

* This checklist may be requested by the Department of Human Research (DHR) as part of the post approval monitoring program or as part of the first step of an audit.
* Checklists completed by a PI as best practices must be submitted to DHR so any identified corrective action steps are resolved.
* Note: Not all sections of the checklist may apply to your study.

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| **Protocol Information** |
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| Principal Investigator | Click or tap here to enter text. |
| Protocol Title & (IRB Number) | Click or tap here to enter text. |
| Initial IRB Approval Date | Click or tap here to enter text. |
| IRB expiration date, if applicable | Click or tap here to enter text. |
| Enrollment goal | Click or tap here to enter text. |
| Number of subjects enrolled to date | Click or tap here to enter text. |

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| **Assessment information** |
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| Individual completing the self-assessment checklist | Click or tap here to enter text. |
| Date of assessment | Click or tap here to enter text. |

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| **Research team: Roles & responsibilities** |

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| --- | --- | --- | --- | --- |
|  | Yes | No | N/A | Notes/Comments |
| Are all personnel working on the research project included on the current Research Team form? |  |  |  |  |
| Is current human subject research training on file for each research team member? |  |  |  |  |
| Have study procedures and tasks been delegated to trained and qualified personnel and are these individuals only doing the responsibilities delegated to them? |  |  |  |  |

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| **Subject recruiting: Process, records & documentation** |

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|  | Yes | No | N/A | Notes/Comments |
| Are all recruitment methods being used as described in the IRB application? |  |  |  |  |
| Are inclusion/exclusion criteria documented and eligibility confirmed, per participant, prior to enroll? |  |  |  |  |
| Are subject withdrawals and dropouts documented? |  |  |  |  |

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| **Informed consent: Process, records & documentation** |

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|  | Yes | No | N/A | Notes/Comments |
| is the consent process being implemented per the approved protocol? |  |  |  |  |
| Are appropriate personnel conducting the consent process? |  |  |  |  |
| Is a signed and dated copy of the consent form on file for each participant? |  |  |  |  |
| Is the correct informed consent version being used for each participant? |  |  |  |  |

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| **Protocol adherence**  |

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|  |  |  |  | Notes/Comments |
| Are all study procedures being conducted according to the current approved protocol? |  |  |  |  |
| Is there a record of all modifications submitted to and approved by the IRB? |  |  |  |  |

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| **Privacy, data storage & confidentiality** |

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|  | Yes | No | N/A | Notes/Comments |
| If the protocol proposed to collect the data anonymously, has anonymity been maintained in the physical and electronic records? Are identifiers tied to subject data? |  |  |  |  |
| if the study uses a coding system with a master list; i/e. key, is this master list being kept separately and in accordance with the IRB approved protocol? |  |  |  |  |
| Is the subject's privacy protected and or safeguards in place as approved by the IRB? |  |  |  |  |
| Are hard copies of consent forms and data collection instruments stored in a secure locked location? |  |  |  |  |
| Are electronic data files password protected or encrypted? |  |  |  |  |
| Is access to computer, electronic files, and physical files limited to the appropriate research team members? |  |  |  |  |
| Was the research data stored and disposed of as approved by the approved IRB protocol? |  |  |  |  |

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| **IRB Post Approval Communication** |

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|  | Yes | No | N/A | Notes/Comments |
| Did any research specific activities occur prior to IRB approval or during a lapse in IRB approval? |  |  |  |  |
| Were all modifications approved by the IRB prior to implementation? |  |  |  |  |
| Were there any lapses in IRB approval? |  |  |  |  |
| Are renewals accurate and complete? |  |  |  |  |
| Is there a process in place to capture and document all adverse events as defined in the protocol? |  |  |  |  |
| Were all incidences, adverse events and reportable information communicated with the IRB/sponsor/funding agency/FDA, etc.? |  |  |  |  |
| If the study uses a DSMB or other independent monitor, have the monitoring reports been submitted to the IRB in a timely manner? |  |  |  |  |

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| **Regulatory files** |

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|  | Yes | No | N/A | Notes/Comments |
| Did the study files include copies of all versions of the IRB approved protocols? |  |  |  |  |
| The study files include copies of all IRB correspondence; e.g., IRB determinations. |  |  |  |  |
| The study files include all sponsored and FDA correspondence, as applicable? |  |  |  |  |

Findings:

Corrective action measures:

Self-Assessment summary:

☐ Satisfactory

☐ Findings – may require reporting to IRB, changes to protocol, CAPA, etc.