## ESSENTIALS THINGS TO DO BEFORE, DURING & AFTER HUMAN RESEARCH STUDIES

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| **Study Title:** |
| **Principal Investigator:** |

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| | **BEFORE STARTING ANY RESEARCH STUDY ACTIVITIES** | | | |
| 1. | All research staff members must be Atlanta VA Health Care System (AVAHCS) research credentialed. Instructions are located on the website: https://www.va.gov/atlanta-health-care/research/research-credentialing-and-training/ | Yes ☐ | No ☐ | N/A ☐ |
| 2. | Submit protocol and other required documents to the designated IRB (Emory IRB,VA Central IRB , NCI, etc.). | Yes ☐ | No ☐ | N/A ☐ |
| 3. | Obtain IRB approval. | Yes ☐ | No ☐ | N/A ☐ |
| 4. | Complete submission to AVAHCS R&DC via IRBNet. | Yes ☐ | No ☐ | N/A ☐ |
| 5. | Begin study activities ONLY AFTER receiving the notification of approval letter from the ACOS for Research that confirms all approvals have been obtained. | Yes ☐ | No ☐ | N/A ☐ |
| 6. | Obtain all final approvals in writing **prior to performing any study activities.** | Yes ☐ | No ☐ | N/A ☐ |
| 7. | Create regulatory study binder. Make paper copies of all eIRB and IRBNet documents and file them in the study binder, along with other required docs, and/or keep electronic files on a AVAHCS research drive. | Yes ☐ | No ☐ | N/A ☐ |
| | **STARTING STUDY ACTIVITIES** | | | |
| 8. | Use the most recently IRB approved version of the Informed Consent and HIPAA Form(s) when obtaining consent. | Yes ☐ | No ☐ | N/A ☐ |
| 9. | Give potential subjects sufficient time to read the informed consent and HIPAA form(s). Discuss all aspects of the study and answer their questions prior to obtaining signature. Consent must be obtained **prior to initiating any study activities. DO NOT ALTER THE CONSENT DOCUMENT.** | Yes ☐ | No ☐ | N/A ☐ |
| 10. | Ensure that each subject sign and date the signature page for themselves. Some consent forms also require the person obtaining consent to sign the consent. | Yes ☐ | No ☐ | N/A ☐ |
| 11. | If using a standalone HIPAA, ensure that the subject reads & signs the HIPAA Authorization form at the time when obtaining consent. | Yes ☐ | No ☐ | N/A ☐ |
| 12. | Have non-veteran participants sign the Notice of Privacy Practices acknowledgement form and send to medical records for scanning. See NOPP guidance on AVAHCS research website. | Yes ☐ | No ☐ | N/A ☐ |
| 13. | Give a copy of the consent and HIPAA Authorization form to the subject. | Yes ☐ | No ☐ | N/A ☐ |
| 14. | **Keep original signed consent and HIPAA forms** with the investigator's study files. | Yes ☐ | No ☐ | N/A ☐ |
| 15. | Enter a progress note titled: "Research Consent Progress Note" in the Computerized Patient Record System (CPRS) or in paper records (as appropriate) to document the consenting process and also when subjects are reconsented. Progress note entry should occur within 72 hours. | Yes ☐ | No ☐ | N/A ☐ |
| 16. | Post a "Research Flag" in CPRS if required by the AVAMC R&D Committee. | Yes ☐ | No ☐ | N/A ☐ |

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| 17. | For Investigational Drug studies, provide a copy of the "Investigational Drug Information Record VA Form 10-9012" for scanning in CPRS. Take copies for scanning to the CSC, room 11C119. | Yes ☐ | No ☐ | N/A ☐ |
| 18. | For Investigational Drug studies, provide a copy of the signed & dated consent form for each subject to the Research Pharmacist. | Yes ☐ | No ☐ | N/A ☐ |
| | **ON GOING STUDY ACTIVITIES** | | | |
| 19. | Keep all original AVAHCS research records at the AVAHCS. Copies may be stored off site if permission is obtained from the PO/ISSO. | Yes ☐ | No ☐ | N/A☐ |
| 20. | Keep a study subject log. | Yes ☐ | No ☐ | N/A ☐ |
| 21. | Promptly document research encounters in CPRS or a paper research record as appropriate. Use the ATL Research-Study clinic location when documenting in CPRS. | Yes ☐ | No ☐ | N/A ☐ |
| 22. | Use research note templates in CPRS to document research encounters. If using a paper chart, use research note templates located on the AVAHCS research website | Yes ☐ | No ☐ | N/A ☐ |
| 23. | Obtain **IRB approval for ANY changes** made to the original protocol. | Yes ☐ | No ☐ | N/A ☐ |
| 24. | Submit Continuing Review to IRB at least 30 working days prior to the expiration date.(Tip: put a reminder in your Outlook calendar 60 days ahead.) | Yes ☐ | No ☐ | N/A ☐ |
| 25. | Report Reportable Events such as Serious Adverse Events, Unanticipated Problems, Protocol Deviations, and Research Information Incidents, etc. per AVAHCS reporting requirements. Events that are both unanticipated and related need to be reported to the IRB of record within 5 days of discovery. Forms and guidance are located on AVAHCS research website. | Yes ☐ | No ☐ | N/A ☐ |
| 26. | Notify the Clinical Studies Center of external audits and monitoring visits by providing the entrance and exit "Monitoring Visit Reports" forms. | Yes ☐ | No ☐ | N/A ☐ |
| 27. | Keep VA training up-to-date. TMS training is required annually and CITI training is required every three years. | Yes ☐ | No ☐ | N/A ☐ |
| | **END OF STUDY ACTIVITIES** | | | |
| 28. | Never destroy **any** research records. Submit all research records to the CSC for storage. This includes electronic files. | Yes ☐ | No ☐ | N/A ☐ |
| 29. | Review "Procedures for Closing Out Human Research Studies" protocol located on the AVAMC research website. | Yes ☐ | No ☐ | N/A ☐ |
| 30. | Document the end of study participation of VA patients in CPRS or a paper research record. | Yes ☐ | No ☐ | N/A ☐ |
| 31. | Inactivate "Research Flags" in CPRS when each subject completes study participation (if applicable). | Yes ☐ | No ☐ | N/A ☐ |
| 32. | Close the study with the IRB through their portal and also the R&D Committee through IRBNet. | Yes ☐ | No ☐ | N/A ☐ |
| 33. | Contact the Clinical Studies Center (CSC) to obtain storage supplies and coordinate delivery with the CSC Administrative Assistant. | Yes ☐ | No ☐ | N/A ☐ |