

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

Study Title:
Principal Investigator:

	BEFORE STARTING ANY RESEARCH STUDY ACTIVITIES			
1.	All research staff members must be Atlanta VAMC (AVAMC) research credentialed. Contact Nakela Jackson at ext. 6177 for more information.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
2.	Submit protocol and other required documents to Emory IRB via eIRB or through the VA Central IRB (VACIRB). Submit protocol and other required documents to AVAMC R&D starting <u>only</u> with the PO/ISO section via eRRRP.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
3.	Obtain IRB approval.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
4.	Complete the R&D and SRS sections in eRRRP.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
5.	Begin study activities <u>ONLY AFTER</u> receiving the notification of approval letter from the ACOS for Research that confirms all approvals have been obtained.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
6.	Obtain all final approvals in writing prior to performing any study activities.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
	STARTING STUDY ACTIVITIES			
7.	Use the <u>most recently IRB approved</u> version of the Informed Consent Form when obtaining consent.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
8.	Give potential subjects sufficient time to read the informed consent form. Discuss all aspects of the study and answer their questions prior to signing the consent form. Consent must be obtained prior to initiating any study activities. DO NOT ALTER THE CONSENT DOCUMENT.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
9.	Ensure that the subject and the person obtaining consent (unless waived by the IRB), each sign, date, and record the time on the consent signature page for themselves.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
10.	Ensure that the subject reads & signs the HIPAA Authorization form at the time when obtaining consent.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
11.	Give a copy of signed/dated consent and HIPAA Authorization form and unsigned Revocation letter to the subject. Keep the original consent form with the investigator's study files.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
12.	Enter a progress note titled: "Research Consent Progress Note" in the Computerized Patient Record System (CPRS) to document the consenting process. Progress note entry should occur within 72 hours.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
13.	Provide a legible copy of the consent form for scanning in CPRS. Take copies for scanning to the CSC, room 11C119. (This is no longer required to be done and is optional).	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
14.	Post a "Research Flag" in CPRS if determined to be required by the AVAMC R&D Committee.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
15.	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 <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
16.	For Investigational Drug studies, provide a copy of the signed & dated consent form for each subject to the Research Pharmacist.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>

ON GOING STUDY ACTIVITIES				
17.	Keep all original AVAMC research records at the AVAMC. Copies may be stored off site if permission obtained from the PO/ISO	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
18.	Keep a study subject log.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
19.	Document research encounters in CPRS using the <u>ATL Research-Study</u> clinic location within 72 hours of study visit. This includes phone study assessments.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
20.	Use research note templates in CPRS to document research encounters.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
21.	Have <u>non-veteran</u> participants sign the Notice of Privacy Practices acknowledgement form. See NOPP guidance on AVAMC Research Website.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
22.	If subjects are re-consented, document it in CPRS.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
23.	Make paper copies of <u>all eIRB and eRRRP documents</u> and file them in the study binder.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
24.	Obtain <u>IRB approval for ANY changes</u> made to the original investigational plan.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
25.	IRB-approved modifications/amendments will be sent to the Science Information Office (SIO), by the IRB liaison for R&D review and/or acknowledgement. Certain amendments may require full R&D review.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
26.	Submit Continuing Review to Emory IRB 45 working days prior to the expiration date. (Tip: put a reminder in your Outlook 60 days before it's due).	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
27.	Report Reportable Events such as Serious Adverse Events, Unanticipated Problems, and Protocol Violations, etc. per AVAMC reporting requirements. All unanticipated events need to be reported <u>to the VA Research Admin Office within 5 days</u> of discovery. Forms and guidance are located on AVAMC research website.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
28.	Notify the Clinical Studies Center of external audits and monitoring visits by faxing or emailing the entrance "Monitoring Visit Report".	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
29.	Keep VA training up-to-date. TMS training is required annually and CITI training is required every two years.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
END OF STUDY ACTIVITIES				
30.	Keep <u>ALL</u> research records indefinitely.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
31.	Review "Procedures for Closing Out Human Research Studies" protocol located on the AVAMC research website.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
32.	Document the end of study participation of VA patients in CPRS (Non-veterans in a separate paper chart (if applicable)).	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
33.	Inactivate "Research Flags" in CPRS when each subject completes study participation (if applicable).	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
34.	Submit the "Termination of Protocol" form to the IRB and provide a copy to the AVAMC Science Information Office.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
35.	Notify the Science Information Office in writing (email or paper form) of study termination once all study data has been analyzed . Provide a final summary of the study (finding, analysis, publications, etc).	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
36.	Contact the Clinical Studies Center (CSC) to obtain storage supplies and coordinate delivery with the CSC Administrative Assistant.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>