Department of Veterans Affairs
Clinical Sciences Research and Development

Starting Your VA Sponsored Clinical Trial

This describes the next steps for starting your newly approved VA clinical trial. The time from the initial notice of award until the Principal Investigator (PI) is actually starting the work requires some additional administrative steps. The local VA research office will be most helpful to answer most questions, but the following information may also be useful:

Just In Time (JIT) Compliance Requirements

➢ Requirements for the (JIT) compliance process will be identified to the local VA research office on the JIT website. Your local VA research office has access to the JIT website (you do not), and they will be able to provide the JIT requirements when they are identified.

➢ For clinical trials, JIT documentation may include approval by the local R&D Committee, signed VA Research Support Agreement, IRB (or HSC) for human subjects, Bio-safety, and Clinicaltrials.gov registration. Additionally the local research office will have additional requirements before the PI can start the study.

➢ Some documents only require the PI signature, while others require local subcommittee approvals and may take a while to obtain. Once the documents are uploaded, Central Office (VA staff from CSRD) will review and respond back – again this means the PI should be in close contact with the local research office to determine whether approval has been received. The timeline will vary for each component from days to longer.

Clinical Trial Registration

➢ *Clinical Trial Registration*

Registration of Clinical Trials with clinicaltrials.gov

➢ The Food and Drug Administration Amendments Act of 2007 (FDAAA or US Public Law 110-85) requires mandatory registration and results for certain clinical trials. We highly recommend waiting until all other JIT requirements are met before registering.

➢ As of May 17, 2010 the requirements for www.clinicaltrials.gov have changed in the ART system. The Principal Investigator will be sent an e-mail with the instructions on how to access the HSRD Annual Reports (ART) System. The PI then has to enter the information on the ART Website related to this trial. ART will automatically notify the JIT system when a registration is complete and JIT

will post a link to the ClinicalTrials.gov registration. ORD staff are available to work with Principal Investigators and assist them with registering their clinical trials using the ART System. Please note that once entered in www.clinicaltrials.gov, there is a requirement for 6 month updates.

- If you have any questions about these instructions please email David Adjasoo at David.Adjasoo@va.gov.

Data Monitoring

- CSR&D has established a panel of Data Monitoring Committees (DMCs) to monitor the clinical trials funded through Merit Review, Career Development or any other non CSP mechanism. The CSR&D DMC is provided as a resource to PIs who in the past convened and managed their individual DMC for each clinical trial. The DMC is provided by Central Office at no cost to the PI. You will be notified directly if your study is assigned to the CSR&D DMC.

For questions regarding the DMC, please email Yvonne.Lucero@va.gov or Robbin.Denwood@va.gov.

Reporting Requirements

- Progress Reports are required for all CSR&D funded clinical trials, the due date will be determined by an annual schedule or in conjunction with DMC review schedule. Notifications are sent to the local research office via JIT. Progress Report forms and DMC reporting requirements are available for download from JIT.

  - Serious Adverse Events must also be reported timely (see attachment 2).

  - Changes to the protocol from the approved application will also require CSR&D concurrence. For questions related to this, please email David.Adjasoo@va.gov.

CO Contact

- Central Office communicates through the local research office and encourages the PI to ask questions of personnel there first. Central Office is also willing to answer questions when the local research office doesn't have the answers or when the PI might need up-to-the minute status. Here is the list of contacts in Central Office:

Terri Gleason	Program Manager Administrative Notes Budget Duration Salary Eligibility	Phone: 202-443-5697 E-mail: Theresa.Gleason@va.gov
David Adjasoo	Clinicaltrials.gov registration Progress Reports Administrative Support Forms	Phone: 202-443-5699 E-mail: David.Adjasoo@va.gov
Faith Brown	Just-In-Time Status	Phone: 202-443-5714 E-mail: Faith.Brown2@va.gov
Sara Clark	Financial/confirm start dates	Phone: 202-443-5673 E-mail: Sara.Clark@va.gov

Appendix A:

Just-In-Time Compliance Requirements Example for Human Subjects

Final R&D Committee Letter of Approval for the Proposal

VA Research Support Agreement

Documentation of Current Human Subjects Training

Human Studies Subcommittee Form, VAF 10-1 223 or Affiliated IRB Approval Letter

Human Consent Form, VAF 10-1 086

Research Protocol Safety Survey, VAF 10-0398

Proof of Clinical Trial Registration with the National Library of Medicine provided by the ART Team (PDF file)

Appendix B:

Serious Adverse Event Reporting Form