VA Pathway for Human Subjects Research

PLANNING

Issues to consider may include hiring staff; obtaining space; purchasing unique IT equipment; requesting data access; creating a data repository; identifying subject payment processes; and determining recruitment strategies. Human subjects protection, privacy, data security, and data access requirements will influence the project implementation timeline and GANTT chart.

SEEK FUNDING

Funding processes, application documents, and deadlines differ depending on the funding source, type of grant ,and whether it is a first submission or a resubmission. Plan out the application timeline and note that funding agencies may require preliminary notification prior to the full submission. Grant applications are submitted electronically and require a high level of detail. Be prepared to submit prior to the sponsor's deadline to allow time for revisions if needed. Incorrect submissions can be rejected without review. *Unfunded research is subject to the same regulatory requirements as funded research.*

APPROVALS

The Research & Development Committee (RDC) assesses the impact of a protocol on the facility. The Institutional Review Board (IRB), an RDC subcommittee, reviews the protocol to ensure the protection of human subjects and the security of identifiable data and biospecimens. Data security and HIPAA Privacy reviews are conducted in conjunction with IRB review. Additional RDC subcommittee approvals may be required. The Associate Chief of Staff for Research (ACOS/R) must provide final written approval of all VA research before any study activities can begin. Data access requests, Data Use Agreements (DUAs), contracts, and other research-related approvals may be necessary for your study.

PI RESPONSIBILITIES

The Principal Investigator (PI) must hold a current VA appointment to conduct VA research. The PI is responsible for all aspects of research conducted under their protocol. The PI must review and sign the document "Attestation of the Principal Investigator" for each study at least annually. (This form is available on the IRB's SharePoint and in the Research section of the Minneapolis VA's internet website.)

GOT SUBJECTS?

Communication with subjects via email is prohibited. Prior to initiating any telephone contact, initial contact with potential subjects must be in person or by letter unless there is written documentation that the individual has agreed to be contacted by phone. The most recent IRB-approved consent form and HIPAA Authorization must be used. The documents must be signed and dated by the individual or a qualified surrogate before any study procedures are conducted.

ADVERSE EVENTS

Serious Adverse Events (SAEs) that are both *unanticipated* and *local (*i.e., occurring with a Minneapolis VA research subject) must be reported to the IRB within five business days of <u>any</u> study staff becoming aware of the event. (For more information, see "Serious Adverse Event Reporting" on the IRB's SharePoint and in the Research section of the Minneapolis VA internet site.)

RENEWAL

Research projects require annual "Continuing Review" by the bodies that granted initial approval, including the IRB and RDC. Research staff must complete mandatory training within required timeframes. Additional renewal requirements may apply for CPRS access, DUAs, and other processes. It is the responsibility of the PI to ensure that all renewals are completed on time.

CH-CH-CH-CH-CHANGES

Submit an Amendment Request for IRB review when changes or additions to an approved protocol are proposed and when new members are added to the study team. Except when necessary to eliminate apparent immediate hazards to the subjects, all modifications to the research protocol or consent form must be approved by the IRB prior to implementing the changes.

COMPLIANCE AUDITS

Mandatory audits of study activities are performed to assess compliance with regulatory requirements related to the consenting process, documentation practices, data management, and research staff safety. These audits are conducted by the local Research Compliance Officers. Additional audits can be carried out by RDC, IRB, VA, or sponsor.

PUBLICATIONS

VA acknowledgement should be noted in all presentations and publications of VA research. Requirements include listing the author's VA affiliation and including disclaimer language and grant identification. Publications must be reported to the Research Office for upload to the Office of Research & Development (ORD) database.

STUDY CLOSURE

Submit a Request for Closure form to the IRB and all other applicable subcommittees when study activities have been completed. Annual IRB reviews are still required if identifiable data can still be accessed by the PI. RDC oversight will continue until all analyses and writing are finished.

RECORDS RETENTION

Original VA research records belong to VA and must be retained in accordance with local facility and national VA requirements. The original format of the research record (i.e., paper or electronic) is the official recordkeeping copy. (For more information, see "Record Retention" on the IRB'sSharePoint and in the Research section of the Minneapolis VA internet site.)