

Guidelines for New Protocol Submissions

The **Investigator (PI)** is responsible for:

1. Submitting all required forms with proposal. All proposal documents must be completed and signed prior to submission or it will be considered incomplete. ***Do not staple documents, paper clips only.***
2. Getting written approval from all care lines whose resources will be affected. (***Submit Personnel Support Letter***)
3. **Research Proposal must include the following:**
 - a) Abstract- A concise statement of the problem to be investigated including objectives, research design and methodology
 - b) A description of the approach to be taken
 - c) Survey of the literature in the area with references
 - d) A description of the procedures involved (include sample size, sex, age, inclusion/exclusion criteria)
 - e) Description of the technical methods to be used in data collection and analysis
 - f) A statement of the applicant's expertise in the area

4. **Deadline:**

Completed proposals are due to the Research Office no later than 4:30pm on the 1st of the month to be considered by the IRB committee at the next months meeting. If the 1st falls on a weekend, proposals must be submitted prior to then. **This deadline is strictly enforced without exception.** Please schedule an appointment with **Jessica Miller** to review the proposal and study documents prior to submission.

5. One copy of the research proposal must be submitted with the original. VA Form 10-9012 is required when drugs are used as part of the study and must be given directly to Heshia Desai, Pharmacy Service (119).
6. E-mail your Initial Submission Application form and any forms completed electronically to the IRB coordinator, jessica.miller1@va.gov, prior to bringing copies to office.
7. **Forms Required:** Please note that not all forms may be needed for your study, however forms marked with an * must be submitted. (***Do Not Staple Forms***)

Please submit forms in the following order:

- a) *New Submission Cover Sheet
- b) *Initial Submission Application Packet
- c) VA-Form 10-1086 Informed Consent Form
- d) VAWNY Waiver of Informed Consent
- e) VA-Form 10-3203 Consent for Use of Picture and/or Voice
- f) HIPAA Authorization
- g) HIPPA Waiver
- h) VA Form 10-9012 Investigational Drug Information Record
- i) *Conflict of Interest Statement for all study personnel
- j) * Functional Statement Form for all new study personnel **OR** if existing personnel, submit Functional Statement Memo/Addendum
- k) *CV/Resume (signed and dated) for all staff members
- l) VA-Form 10-5368 Investigative Data Sheet (for first time VA Investigators)
- m) *Personnel Support Letter (for all VA staff – not for personnel with WOC appointment)
- n) Data Collection Tools, Surveys, Questionnaire
- o) Advertisement/Recruitment Materials
- p) *Protocol or Research Plan
- q) *VA-Form 10-0398 Research Protocol Safety Survey
- r) *Checklist for Reviewing Privacy, Confidentiality and Information Security in Research
- s) VA-Form 2105 Request to Transport VA Sensitive Data to Unprotected Site

If you have any questions please contact Jessica Miller in the Research Office at (716) 862-5574