# INITIATING AND MANAGING A CLINICAL STUDY AT THE VA

**Question: Are there enough active patients in the VA data base that would meet the Inclusion and Exclusion criteria of my trial?**

***Answer:***

1) In most cases these are patients that are under your care or that your group and your clinic roster can provide the information.

2) For a much more detailed and comprehensive survey of the eligible patient pool, the VA has a superb integrated patient management system called DSS. You can access it through the site manager, Carol Ward at VA extension 4138. She will take your special eligibility criteria plus the required demographics and provide you a list of potentially eligible patients including what clinic(s) they are being followed in, their phone numbers, and their primary care physicians, etc.

**Question: How do I start the application process to initiate a clinical study at the VA?**

***Answer:***

1) You can call Lena Molen VA Research Office, extension 4281 or go to her office C404 on the 4th floor of the Clinical Addition and get the appropriate information.

**Question: I have a university/hospital salaried research nurse. What does she/he need to do to follow VA patients in the study?**

***Answer:***

1) All non-VA salaried physicians, nurses, technicians working in the VA must have a Without Compensation (WOC) appointment to be eligible for any necessary care, compensation and/or liability through the University/University Hospital that might arise because of an incident occurring at the VA.

   To initiate this process, call Debie Hayse, extension 4927 or go to her office at C403, VA Research Service. For protocols involving humans educational training must be obtained by all personnel on the protocol Debie will also have the information for the training needed.

2) Nurses must apply for WOC status through the VA Nursing Service.

**Question: Who needs to review and approve a study before it is submitted to the R&D committee?**

1) All **relevant** service chiefs must sign off on the project. For example, a patient on the Medical Service that will receive a new drug and require some specialized nursing would require the approval of the Medical, Pharmacy and Nursing Services. Please use attachments provided on this website to obtain the signatures required.

**Question: After I have completed the forms and gotten the signatures, what happens next?**

***Answer:***

1) When all the forms, including the IRB approval letter, have been completed, bring them (complete as a packet) to Lena Molen. If you are submitting items for full approval by the R&D committee use the blue (last) column. If you are submitting the protocol for provisional approval bring the forms listed in the green (middle) column. She will put your project on the agenda for the next Research and Development Committee.

2) In rare exceptions, a study will be with patients that are very unusual or the disease is rare. In this instance, once the forms have received IRB approval, the ACOS for R&D and the Chair of R&D Committee can authorize temporary approval until the next meeting of the full Committee.

3) The study will not be initiated at the VA until the first VA patient has beenentered on the study. It will be held in a "Pending" file. It is the PI'sresponsibility to provide the Research Office with the patient's name and SS#. At that time, a project number will be assigned. It is also the PI's responsibility to see that the patient's medical record is flagged in CPRS to indicate the patient is a Research Study Participant.

**Question: Is there a requirement for Progress Reports?**

***Answer:***

1) Yes, the Research Office will send you a form annually asking for the total number of VA patients entered, adverse events reported to the IRB, activity status of the study and list of related publications. There will also be a Final report at the termination of the project. NO PROJECT DATA SHEET SHOULD BE RETURNED WITHOUT AN UPDATE. This information is reviewed by the R&D Committee and entered in a nationwide data base. Failure to provide the necessary reports can lead to termination of the project at the VA.

2) It is the responsibility of the PI to supply the Research Office with annual IRB continuation review approval letters and current consent forms if still enrolling subjects. The PI must also supply the Research Office with any modifications/amendments to their studies.

**Question: Is there a chart review for compliance?**

*Answer:*

1) At this time, the patient's charts are reviewed quarterly for the presence of Consent Forms and determination of whether the Inclusion and Exclusion criteria were met. Patient's names and SS# are to be provided by the PI.

**Question: How can I learn how to use the VA computer system to access patient's data?**

***Answer:***

1) Contact Carolyn Brown or Debie Hayse in the Research Service, Room C403 or C405, phone # VA X 5947 or 4927. They will help you get started on computers they have in the Research Office. It is possible to obtain laboratory, x-ray, pathology and even clinical information as of June 1, 1999 through the computer system. Nurses need to contact Nursing Service.

**Question: Who is responsible for entering the information that a patient is on a study in CPRS?**

***Answer:***

1) VA patients on a drug study are entered in CPRS by Tracy Hart in the Pharmacy. Surgery patients on a device study are entered by the surgical coordinator on the study. Other patient studies are entered by the coordinator of the specific project.