Human Rights and Protection Program for VA Long Beach

Newsletter

Issue 6, July 2014

Initial Review Process

Ever wonder why initial submissions take so long to review?

Once you have submitted your new project to the IRB, we will do a quick review. The main thing we look is if all the forms are signed, all the forms are present and if you have used the current versions. Once we have done a quick review, we then make 3 copies of your submission. 3 different people then review your project. These people are: 1) An **IRB Pre-Reviewer** 2) **The Information Security Officer** and 3) **The Privacy Officer**.

The IRB Pre-Reviewer is looking for things that the IRB will have an issue with. They closely look at your submission to ensure that everything is consistent and filled out completely. The purpose of this review is to help your study not get tabled at the IRB meeting. Their comments will be suggestions, and you can choose to not complete them. However, this might delay your approval even further.

The Information Security Officer will review forms regarding to Veterans information security. How you store your data and where you are sending your results are very important to the ISO. There are questions throughout the application that ask about data security, he needs these to be explained fully and completely.

The Privacy Officer will be mainly looking at the Consent form and the HIPAA Authorization. He will make sure you are clear on where the patient data is being sent and how it will be stored. Please be consistent with your answers.

When all 3 of the "pre-reviewers" have reviewed your submission, they will email the IRB office. Once we have received all reviews, we will then combine all of their comments and send you one large email.

While the pre-review is being completed, your safety survey is being reviewed by the Safety Committee and your impact estimation worksheets are being reviewed by the Pharmacy and Labs. Your study staff is being reviewed to confirm they have completed the Human Subject Training and Credentialing. They might also have concerns regarding your study, and will also contact the Research Office for additional information.

When you have re-submitted all of the changes to the Research Office, we will then contact the pre-reviewers, and ask them to re-review your submission. Once we have received the final approval by all the pre-reviewers, it will then be on the next IRB agenda.

Once it is reviewed by the IRB, they might have additional stipulations. The IRB coordinator will contact you (via your VA email) with the required changes. If you choose to not complete these stipulations you will need to submit a memo with your explanation. This memo might need to be reviewed by the IRB and will delay your approval.

When the IRB stipulations have been submitted and approved by the IRB chair (depending on your study being conditionally approved or tabled), your study will be on the next R&D agenda.

In order to have your study approved and ready to start, you will need the following approvals:

- The Information Security
- The Privacy Officer
- HRPP Officer (HST&C)
- Research Pharmacist
- Diagnostic & Molecular Medicine
- IRB
- R&D
- Safety Committee