IRB Tools and Tips

Issue 10: IRB Internal Auditing/Quality Improvement Program

IRB Policies and forms in Clinic Policy Library

This issue of the IRB Tools and Tips newsletter was developed to provide you with some basic information about the IRB’s internal auditing/quality improvement program. This issue will also address the IRB Policies and Procedures and IRB forms that are now located on-line in the Clinic’s Policy Library.

Of course, all of the above studies do require IRB approval and oversight; however, C would most likely be monitored most closely by the IRB...at least through a quality assurance initiative recently implemented by the Research Compliance office. The reason for this is not that the IRB necessarily believes the study involves more risk than the other studies, but since there is no external entity monitoring this study, it falls to the IRB to monitor or audit the study more closely. The following paragraphs will discuss how the IRB will be implementing several QA auditing processes.

As this institution moves toward accreditation of its human subject protection program, it is imperative that the IRB begin a process of internal monitoring of research to ensure that all studies are in compliance with federal regulations governing human subject research.

Initial Informed Consent Auditing

Any study that is internally funded (and therefore not subject to review by any external oversight body) and whose approval contains a requirement for written informed consent will undergo a review of the first subjects enrolled at each site. At the time the study is approved, the researcher will be asked to submit to the Research Compliance Office a copy of the first consent form signed by an adult subject and a copy of the first consent form signed by a minor at each enrolling site. If the study has a separate consent for case and control subjects, the researcher will be asked to submit a copy of the first case consent and the first control consent. These consents are to be received in the Research Compliance Office within five working days of the subject’s enrollment. Upon receipt, Research Compliance staff will review the consent form to ensure that the signature line is completed appropriately, and will review study records to ensure that informed consent was obtained prior to initiation of any study procedures. Research Compliance staff will also determine whether the consent process is in line with the process described in the IRB application and approved by the IRB.

The researcher will receive written notification of the outcome of the QA review. A personal meeting with the researcher and study staff will occur as deemed necessary by the Director of Research Compliance. Any issues of non-compliance will be handled in accordance with the IRB’s Non-Compliance policy.

The IRB application forms will ask the question “Are there plans for external monitoring/auditing of this study? If so, note the group that will be conducting the monitoring/audit visit(s) and the number of times you anticipate this occurring over the next year.”

Researchers whose extramurally funded studies do not have monitoring/audit visits planned will be asked, at the time the study is approved, to submit to the Research Compliance Office a copy...
of the first consent form signed by an adult subject and a copy of the first consent form signed by a minor. The Research Compliance Office will review these studies in the manner described above for auditing of internally funded studies.

**Continuing Review Auditing**

By now you should have noticed that the continuing review report form asks the question “How many times was your study monitored/audited by an external party over the past year?” The form will also direct the researcher to attach a copy of any report from that monitoring/audit visit. If no written report is available, the researcher is asked to summarize the findings presented to the researcher or research staff after the visit.

When those reports or summaries of findings from monitoring/audit visit(s) are received in the IRB office, they are forwarded for review to the IRB along with the continuing review report. At the IRB’s discretion, additional auditing may be conducted on these studies. Those studies likely to require additional auditing would be those where little detail is provided in regard to the external monitoring/audit visit or no findings are reported over several years.

Beginning early in 2004, studies that were approved with a requirement for written informed consent that did not have an external monitoring/audit visit within the last year will require an internal quality assurance audit. For these studies, upon receipt of the continuing review form noting no external monitoring/audit, the researcher will be asked to submit a list of subjects enrolled in the last year. A random sample of 2% of the subjects enrolled over the year or 5 subjects, whichever is greater, will be selected for internal QA monitoring. The monitoring will include a review of the consent forms to ensure that the signature lines are completed appropriately, and a review of study records to ensure that informed consent was obtained prior to initiation of any study procedures. Research Compliance staff will also determine whether the consent process is in line with the process described in the IRB application and approved by the IRB.

As with other audits, the researcher will receive notification of the outcome of the review, and any issues of non-compliance will be handled in accordance with the IRB’s Non-Compliance policy.

**Reconsent Auditing**

On a quarterly basis (which began October 1, 2003) Research Compliance staff will run a report from the Research Studies Database that will show all studies for which the IRB required reconsent of subjects for a defined three-month period.

From the quarterly report, a random sample (10% or 5 studies, whichever is greater) of the studies will be selected for audit. The Research Compliance Office will determine the number of subjects that were to be reconsented. If the number is five or less, the investigator will be asked to produce the original signed documents showing that reconsent had been obtained. If the number of subjects to be reconsented is greater than five, the investigator will be asked for a list of names of subjects and a random sample of 2% of the subjects will be selected for audit.

The audit will focus on whether the investigator obtained reconsent of subjects in the manner and timeframe dictated by the IRB. As with other audits, the researcher will receive notification of the outcome of the review, and any issues of non-compliance will be handled in accordance with the IRB’s Non-Compliance policy.

**Submission of Incorrect Consent Form**

As you are aware, investigators are asked to submit a copy of the currently approved consent form with continuing review reports, amendments and other changes to the study or consent form. When received in the IRB office, staff checks the version submitted against the most recently approved version in the Word consent form directory. If the consent forms do not match, IRB staff sends a copy of the correct version to the investigator or coordinator.

Effective November 1, 2003, the following studies will be audited to ensure that the appropriate consent form was utilized:

- Studies where an incorrect version of the consent form is submitted
- Studies where the investigator or staff can not produce a copy of the consent

A random sample of 2% of the subjects enrolled in the study, or 5 subjects, whichever is greater, will be selected for internal QA monitoring.

All IRB policies can be found on our website at: [http://research.marshfieldclinic.org/dept/irb/irb_policies.asp](http://research.marshfieldclinic.org/dept/irb/irb_policies.asp)
MARSHFIELD CLINIC POLICY LIBRARY

Most of you are probably already familiar with the Clinic’s electronic policy library located at http://marshmedi1/clinic/policies. You are probably also familiar with the Clinic’s reason for moving to this electronic environment. To recap, the Clinic chose to move institutional policies into a common electronic environment location in order to:

- eliminate outdated policy binders
- eliminate multiple requests from departments to list their policies, handbooks and forms on-line
- allow for easier access to policies, forms, and handbooks.
- provide for a consistent policy format.
- provide for a revision process where documents must be reviewed at least every three years
- provide the ability to archive and retire documents
- provide one central location for system-wide documents.

One of the great features of the policy library is that it allows a user to quickly search for documents via entity (i.e., System-wide, Clinic and Research Foundation.) The advanced search option allows users to search for documents by entity, division, center and even department. In both the Policy and Forms library, a user can search the document title, body, key words or a combination. Additionally, forms can be attached directly to a policy for even easier access. For example, if a user wants to look up the IRB’s adverse event reporting policy, he/she can open the adverse event reporting form directly from the policy without having to do any further searching. The adverse event reporting decision flow chart is also attached to the policy and can be accessed by a single click.

In the future the IRB will be moving away from having its standard templates in Microsoft Word (File/New/MCRF, etc.) and instead all forms will be located in the Clinic forms library. (In fact, all the forms are currently available in the forms library.) The forms still open as Word templates, however, so there’s no need to worry about learning a new system. One big advantage to having the forms in the library is that they will be accessible system-wide. Currently there are some research staff located in outreach sites or at St. Joseph’s hospital who do not have access to the MCRF Word templates.

So, let’s take a quick walk through how to access the policies and forms. From the Marshfield Clinic Intranet home page, click on the icon named “Handbook & Policy Library.” From there choose “Policies, Protocols, Procedures, and Guidelines”. You will be directed to a search screen. To search for IRB policies, you will want to choose “System Wide” as the entity. You may either enter “IRB” to see all IRB policies, or you may enter a term such as “adverse” to view the specific policy that you’re searching for. If you don’t find the policy you’re looking for, you may want to choose “Title and Body” as your search criteria, in case the term you’ve chosen is not in the title of the policy.

Let’s suppose you’re searching for the IRB’s adverse event reporting policy. You use “adverse” as your word to search, leave “All Entities” (the default) in the entity search box, and search “Title” only. You will notice that your search reveals 2 documents. Because the Department of Clinical Research has its SOPs located in the Policy Library, and many of those SOPs deal with IRB issues, your search has resulted in both the IRB policy and the Clinical Research SOP. You can tell the difference at a glance by noticing that under each title the entity and department are listed. All IRB policies are System Wide while the Clinical Research entity is Research Foundation and the department (Clinical Research Center) is also listed.

The search for forms is similar. From the Marshfield Clinic Intranet home page, click on the icon named “Handbook & Policy Library.” From there choose “Forms.” You will be directed to a search screen. To search for all IRB policies, you can choose the letter “I” (which will give you all policies beginning with I) or you can enter “IRB” as your search criteria. You may also search for a specific form by entering a term such as “adverse” to view the specific form you’re looking for.

All IRB policies can be found on our website at: http://research.marshfieldclinic.org/dept/irb/irb_policies.asp
If you have any problems with either the Policy or Forms library, contact the Policy Coordinator.

### What’s New?

**Revocation of Authorization for Research form**
The language in the sample informed consent dealing with a patient’s withdrawal from the study was recently revised to make it more clear that written notification of withdrawal is only necessary if a patient wishes to withdraw his/her permission to allow for use of his/her identifiable health information. The previous wording caused some confusion about when it was necessary to obtain written documentation of withdrawal from a study.

**Description of Financial Interest**
The IRB application forms have recently been revised. The revision is to the question asking about Financial Disclosures (formerly question (b) on the application.) The revision form has been revised to include this same wording. Rather than ask this as a question, the following check box is now located at the end of the form:

- A Description of Financial Interest form must be submitted for any investigator who now has a significant financial interest in this project. This is different from the standard Disclosure form. (see Conflict of Interest Policy for more information.)

---

For an interesting look at some issues involved with informed consent, check out the two links below. When reading these articles, remember that they were written 2 years ago in 2001, so you’ve likely already heard about these issues. The articles are still interesting, however, and remind us of our responsibility for protecting human research subjects.

**WASHINGTONPOST.COM**
**Informed Consent**
Alan Milstein says he wants to rescue us from unscrupulous doctors, undisclosed risks and greedy institutions. But is he a shining knight, or an enemy of medical progress?
**By Jennifer Washburn**  Sunday, December 30, 2001; Page W16

*For a fictional account of the subject of research-related lawsuits (with the main character possibly based on Alan Milstein?), check out John Grisham’s book “The King of Torts.”*

**seattletimes.com**
**Uninformed Consent**
What patients at “The Hutch” weren’t told about the experiments in which they died.

*A five part Seattle Times investigative series by Duff Wilson and David Heath Copyright © 2001; Seattle Times*

---

All IRB policies can be found on our website at: [http://research.marshfieldclinic.org/dept/irb/irb_policies.asp](http://research.marshfieldclinic.org/dept/irb/irb_policies.asp)