

**SUNY Upstate Medical University**  
Research Administration  
Quality Assessment & Improvement Program (QAIP)

## **Study Initiation Visit**

### **Human Subject Research Compliance: Key Points**

- **Informed Consent**
- **Continuing Review Submission to the IRB**
- **Confidentiality and HIPAA Issues**
- **Amendments to Approved Protocols**
- **Unanticipated Problems/Adverse Event Reporting (to the IRB)**
- **Protocol Deviation Reporting to the IRB**
- **Organizational Strategies and Documentation Suggestions (sample forms)**
- **Research Compliance References Available in the Upstate Medical University Health Sciences Library**
- **IRBNet Questions & Answers**

(Please see the current IRB Guidelines & Policies for complete information)

## **Informed Consent**

### **Key Points to Remember:**

1. The consent process must assure that the potential subject understands the study and its risks and benefits and can certify his or her willingness to participate. This obligation is the responsibility of the Principal Investigator.
2. Every potential subject must read (or the form must be read to the subject), understand and sign the informed consent document before any study procedures are done (this includes any screening tests). Consent is an ongoing process that starts before the consent form is signed and continues until participation is complete.
3. A subject may require time to decide whether or not to participate, to ask questions and to confer with family or other personal advisors. It is generally not appropriate to seek consent in a rush or at the time of a procedure, diagnosis or other stressful time.
4. Having a witness signature on a consent document is not always a regulatory requirement. A witness signature is typically included if the sponsor requires it, if illiterate subjects will be enrolled, if the "short form" method is approved by the IRB and/or the IRB requires it. If there is a witness line it must be signed.
5. Information must be presented in language that is understandable to the subject.
6. The informed consent documentation requirements (OHRP & FDA) permit the use of either a written consent document or a "short form". Whichever document is used, prior IRB approval is required and a copy must be given to the person signing the document.
7. Each enrolled subject must be given a full copy of their signed consent document.
8. If the HIPAA language is included in a consent document (authorization to use/share protected health information for research), the Upstate Notices of Privacy Practices (NOPP) must be offered to the subject.
9. The investigator's files should include all pages of the original properly executed consent document(s) for every subject enrolled (including screen-fails). If it is necessary for subjects to sign a new consent document version, these should be on file as well.
10. A properly executed informed consent document:
  - is on the current IRB-stamped document
  - contains no blank lines or unchecked option boxes
  - has signatures that are personally dated
  - contains all pages as approved
  - has no handwritten changes or additions
  - is obtained by the investigator or other designated study team member
11. Document the consent process in the subject's study file and/or medical record (as appropriate), including that subjects received a copy of their signed consent document.

## Continuing Review Submission to the IRB

### Key Points to Remember:

1. Continuing Review is a federally mandated requirement. All research studies approved by the IRB must be reviewed at least annually. The expiration date is noted on the IRB approval letter and on each page of the consent document.
2. IRBNet generates an e-mail reminder 60 and 45 days prior to the expiration of the approval period (in most cases). Those with full project access will receive the reminder. You should respond to the first notice as soon as possible, to ensure that there is no lapse in study approval. It is the investigator's responsibility to complete and submit the continuing review package at least 4 weeks prior to the expiration date.
3. No grace period or extensions are allowed. If approval lapses before being re-approved (even if the continuing review materials have been submitted), the study will be closed & all research activity (including data analysis) must be halted immediately. If there are concerns for the well being of enrolled subjects, the IRB Chair should be contacted to discuss.
4. If the study expires because the materials required for continuing review have not been submitted to the IRB, the study will be closed. The study can be re-opened if the required materials are submitted within two months of the expiration date. If not, the study is permanently closed and the PI will be required to submit a new application for IRB review in order to continue the study.
5. When completing enrollment information on the Continuing Review Report, keep in mind that enrolled subjects (by Upstate IRB definition) are those who have signed a consent form (this would include any screen-fails). For studies where consent/documentation of consent has been waived, enrolled subjects are those who have been studied per the protocol.
6. Consent and assent forms should be submitted in Microsoft Word, and should **not** be submitted on letterhead. The header should be left blank for the IRB stamp.
7. If the study has a Data and Safety Monitoring Board (DSMB) or similar oversight committee, any reports received during the year should be submitted. If no reports have been received, request them from the sponsor or request a letter which states "there are no reports".
8. Do not include requests for changes as part of the continuing review submission. Proposed changes must be submitted in a separate package with an amendment request form.
9. The Upstate IRB has set a limit of 4 regular continuing reviews. After the fourth continuing review, if the study is to continue, it is necessary to re-submit the complete study for IRB review. Under no circumstances may the study proceed without the completion of the review process and approval granted. It is the investigator's responsibility to track when the 5 year continuing review is due. In IRBNet, the **Local Board Reference #**, will tell you the year the study was originally approved and how many regular continuing reviews the study has undergone.

## Confidentiality and HIPAA Issues

### Key Points to Remember:

1. The Health Insurance Portability and Accountability Act (HIPAA) regulations (also known as The Privacy Rule) define conditions where certain health information may be used or disclosed in research activities and define conditions where 'authorization' must be obtained from the subject.
2. The HIPAA Privacy Rule pertains to all clinical research studies that utilize individually identifiable health information.
3. The HIPAA Privacy Rule requires an individual to provide signed permission, known as an '**authorization**', before a covered entity (such as Upstate) can use or disclose the individual's protected health information (PHI) for research purposes.
4. If a study is subject to the Privacy Rule, 'authorization' language is included as part of the informed consent document. (See consent form templates in the Forms and Templates section of IRBNet).
5. If a study is subject to the Privacy Rule, subjects must be provided with a copy of the **Upstate Notice of Privacy Practices (NOPP)** at the time the consent/ authorization form is signed. The Upstate NOPP can be found on the IRB website. (Note: The authorization language in the consent form is not synonymous with the NOPP. The Upstate NOPP must still be provided).
6. Coded information is not the same as de-identified information. **Coded** means that information can be linked to an individual using a key. **De-identified** means that all 18 identifiers have been removed and the information cannot be traced back to an individual.
7. Ensure that you are following all procedures regarding the safeguarding of research data (as submitted in the approved IRB Application Form section VIII).
8. For further information on privacy and confidentiality issues, contact the Institutional Privacy Office (Cindy Nappa or Robin Towles)

## Amendments to Approved Protocols

### Key Points to Remember:

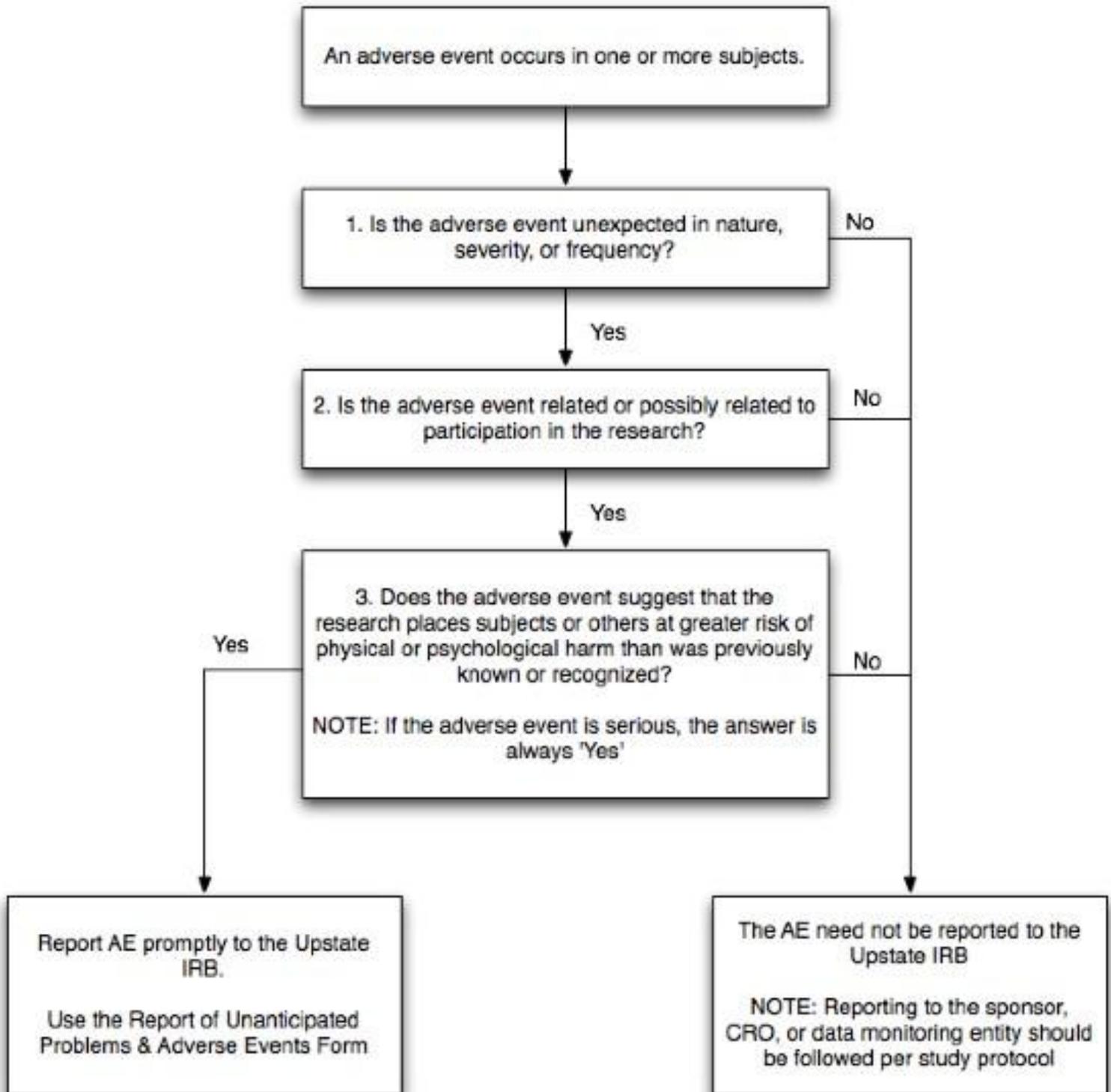
1. Once the IRB has approved a project, it must be carried out exactly as planned. Implementation of any change must not occur prior to IRB approval **unless the change is required to eliminate an immediate hazard to the subjects**. In this case, the IRB should be notified as soon as possible of the change.
2. Changes requiring an amendment include, but are not limited to:
  - subject population
  - recruitment plans
  - research procedures
  - study design
  - study instruments/questionnaires
  - study performance sites
  - research personnel
3. Amendments are submitted by creating a new package for an existing project in IRBNet (see IRBNet Instructions: “How to Submit an Amendment for IRB Review”).
4. Pay particular attention to how question 3 is answered when submitting an Amendment Request Form: “Are subjects currently enrolled in this study? If yes, does this amendment require additional information be provided to subjects? Indicate how the information will be communicated to the subjects (people already enrolled in the study).”
  - For each previously enrolled subject you must follow through with the stated plan, and document that you did so.
  - If you indicated that an amended consent document will be signed by all previously enrolled subjects, the additional signed consent documents should be on file for these subjects.
5. **Important:** Make sure to update the version date in the footer of all revised consent and other documents.

## **Requirements for Notifying the IRB of Unanticipated Problems and Adverse Events:**

### **Key Points to Remember:**

1. Unanticipated problems must be promptly reported to the IRB, so that human subjects can be better protected from avoidable harms. It should be noted that only a small subset of adverse events occurring in research subjects are unanticipated problems that must be reported to the IRB. (See algorithm on pg 7).
2. **Unanticipated Problems** includes any incident, experience, or outcome that meets all of the following criteria:
  - A. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
  - B. related or possibly related to participation in the research (*possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
  - C. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
3. Upon becoming aware of an **internal** incident and/or adverse event, the investigator must first determine whether or not the adverse event meets the criteria for an unanticipated problem (as described in #2). If the adverse event is determined to be an unanticipated problem, it must be promptly reported to the Upstate IRB.  
**External** adverse events (those which occurred at other institutions) should only be reported to all the investigators and IRBs at all institutions when a determination has been made that the events meet the criteria for an unanticipated problem. (The investigator may need additional information from the monitoring entity to make this determination).
4. Time-Frame for investigators to report ALL Unanticipated Problems (including unanticipated adverse events) to the IRB:
  - Unanticipated Problems that are **serious** adverse events should be reported to the IRB within 1 week of the investigator becoming aware of the event.
  - Any **other** Unanticipated Problem should be reported to the IRB within 2 weeks of the investigator becoming aware of the problem.
5. Report Unanticipated Problems to the IRB by submitting the Report of Unanticipated Problems and Adverse Events Form via IRBNet.

## Algorithm for Determining Whether an Adverse Event is an Unanticipated Problem



## **Reporting Protocol Deviations/Violations to the Upstate IRB**

### **Key Points to Remember:**

- 1. Only protocol deviations that meet the definition of an unanticipated problem should be submitted to the IRB. See definition in previous section.**

If a protocol deviation meets the above definition then it must be reported promptly to the IRB using the Report of Unanticipated Problems & Adverse Events.

- 2. Audits or reports by the sponsor, CRO, or other entity which document serious non-compliance with a study protocol (including, but not limited to, enrolling subjects who do not meet eligibility criteria) must also be promptly forwarded to the IRB.**

# **Organizational Strategies And Documentation Suggestions**

- **Subject Enrollment Log**
- **Consent Checklist**
- **Eligibility Checklist**
- **Consent And Eligibility Checklist (Combined)**
- **Study Team Signature and Delegation of Responsibility Log**

## Subject Enrollment Log

**Study Title:**

**IRBNet#**

Subject name or number	Date enrolled (signed consent)	Person Obtaining Consent	Subject Given Signed Consent Copy & NOPP	Subject Met Eligibility Criteria
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				7/30/2014

## Consent Checklist

**Study Title:** \_\_\_\_\_ **IRBNet #** \_\_\_\_\_

**Principal Investigator:** \_\_\_\_\_

**Subject Name:** \_\_\_\_\_ **Subject Number:** \_\_\_\_\_

**Date Enrolled (signed consent):** \_\_\_\_\_

- Study explained by a designated study team member
- Subject determined to have capacity to provide informed consent
- Subject's questions were answered to their satisfaction
- All signatures and dates on the consent document were completed
- Option or choice boxes were properly completed (if present)
- Consent was obtained prior to any study procedure
- Subject was provided with a copy of their signed consent
- Subject given a copy of the Upstate Notice of Privacy Practices (if subject to HIPAA)
- Original signed consent was placed in subject/study file
- Copy of signed consent placed in subject's medical record (if appropriate)
- Eligibility Checklist completed

Subject was:             eligible             ineligible

**Study team member signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

## Eligibility Checklist

(All subjects enrolled must meet eligibility criteria based on the inclusion/exclusion criteria detailed in the protocol approved by the IRB)

**Study Title:** \_\_\_\_\_

**IRBNet #:** \_\_\_\_\_

**Date form completed:** \_\_\_\_\_ **Person completing form:** \_\_\_\_\_

**Subject Name/ID#:** \_\_\_\_\_

Inclusion Criteria (list each criteria)	Yes	No	Supporting Documentation* (all must be “yes” for eligibility)
1.			
2.			
3.			
4.			
5.			
6.			
Exclusion Criteria (list each criteria)	Yes	No	Supporting Documentation* (all must be “no” for eligibility)
1.			
2.			
3.			
4.			
5.			
6.			

**\*Supporting documentation to confirm subject eligibility includes but is not limited to, laboratory test results, radiology test results, subject self-report, and medical records.**

## Consent and Eligibility Checklist (combined)

IRBNet #: \_\_\_\_\_

Subject name and/or #: \_\_\_\_\_

Study Title:

Principal Investigator:

Date Enrolled (signed consent): \_\_\_\_\_

### Consent:

- The study was explained to the subject, including procedures, potential risks/ benefits & alternatives
- Subject determined to have capacity to provide informed consent
- The subject was given time to read the consent/assent document and questions were answered
- Study consent/assent was obtained (signed) prior to research-related procedures
- The subject was provided with a copy of their signed consent/assent form(s)

### Eligibility Criteria (per protocol):

#### Inclusion Criteria:

- |    |   |   |
|----|---|---|
| 1. | Y | N |
| 2. | Y | N |
| 3. | Y | N |

#### Exclusion Criteria:

- |    |   |   |
|----|---|---|
| 1. | Y | N |
| 2. | Y | N |
| 3. | Y | N |

Designated study team member signature: \_\_\_\_\_

Date: \_\_\_\_\_



## **Research Compliance References Available in the SUNY Upstate Medical University Health Sciences Library**

1. Introduction to Clinical Research (For Medical Students, Residents, and Fellows)  
Tetyana L. Vasylyeva, editor. Amarillo, TX: Hale Publishing, 2012.  
Book Collection (3<sup>rd</sup> Floor) W 20.5 I61 2012 **\*(recommended reading)**
2. Good Clinical Practice: A Question & Answer Reference Guide  
Mark P. Mathieu, editor. Needham MA: Barnett International, 2009  
Book Collection (3<sup>rd</sup> Floor) QV 771 G646 2009
3. Ethics and Research with Children: A Case-Based Approach  
Eric Kodish, editor. Oxford; New York: Oxford University Press, 2005.  
Book Collection (3rd Floor) WS 21 E845 2005
4. Scientific Integrity: Text and Cases in Responsible Conduct of Research  
Francis L. Macrina. Washington, D.C. : ASM Press, c2005.  
Reserve Collection - Closed (1st Floor) W 20.5 M174s 2005
5. The CRC's Guide to Coordinating Clinical Research  
Karen E. Woodin. Boston, MA: Thomson CenterWatch c2004  
Book Collection (3<sup>rd</sup> Floor) QV 771 W891c 2004 **\*(recommended reading)**
6. Protecting Study Volunteers in Research: A Manual for Investigative Sites  
Cynthia McGuire Dunn & Gary L. Chadwick. Boston, MA : CenterWatch, 2004.  
Book Collection (3rd Floor) W 32.5 AA1 D923p 2004 **\*(recommended reading)**
7. Ethical Conduct of Clinical Research Involving Children  
Marilyn J. Field and Richard E. Behrman, editors.  
Washington, D.C. : National Academies Press, 2004.  
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8. Responsible Research : A Systems Approach to Protecting Research Participants  
Daniel D. Federman, Kathi E. Hanna, and Laura Lyman Rodriguez, editors.  
Washington, D.C.: National Academies Press, 2003.  
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9. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance  
Fay A. Rozovsky, Rodney K. Adams. San Francisco : Jossey-Bass, 2003.  
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10. Responsible Conduct of Research  
Adil E. Shamoo and David B. Resnik.  
Oxford, New York: Oxford University Press, 2003.  
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11. Ethics of the Use of Human Subjects In Research  
Adil E. Shamoo and Felix A. Khin-Maung-Gyi  
New York: Garland Science Publishing, 2002  
Book Collection (3<sup>rd</sup> Floor) W 20.55 H9 S528e 2002
12. Lessons from a Horse Named Jim: A Clinical Trials Manual  
Liu, Margaret B. Duke Clinical Research Institute, 2001  
Book Collection (3<sup>rd</sup> Floor) QV 771 L783 2001 **\*(recommended reading)**
13. Ethics in Research with Human Participants  
Bruce D. Sales and Susan Folkman, editors.  
Washington, D.C. : American Psychological Association, 2000.  
Book Collection (3rd Floor) W 20.55 H9 E84 2000
14. Human experimentation : Methodologic Issues Fundamental to Clinical Trials  
Ton J. Cleophas. Dordrecht ; Boston : Kluwer Academic Publishers, 1999.  
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15. Ethics in Psychiatric Research: A Resource Manual for Human Subjects Protection  
Harold Alan Pincus and Jeffrey A. Lieberman, editors.  
Washington, DC : American Psychiatric Association, 1999.  
Book Collection (3rd Floor) WM 20 E835 1999
16. Beyond Consent: Seeking Justice in Research  
Jeffrey P. Kahn, Anna C. Mastroianni, and Jeremy Sugarman, editors.  
New York : Oxford University Press, 1998.  
Book Collection (3rd Floor) W 20.55 H9 B573 1998
17. Ethics of Research with Human Subjects : Selected Policies and Resources  
Jeremy Sugarman, Anna C. Mastroianni, and Jeffrey P. Kahn, editors.  
Frederick, Md. : University Pub. Group, 1998.  
Book Collection (3rd Floor) W 20.55 H9 E84 1998
18. Volunteers in Research and Testing  
Bryony Close ... [et al.] editors. London: Bristol, PA : Taylor & Francis, 1997.  
Book Collection (3rd Floor) W 20.55 H9 V949 1997
19. The Ethics of Research Involving Human Subjects: Facing the 21<sup>st</sup> Century  
Harold Y. Vanderpool, editor. Frederick, Md.: University Pub.Group, 1996.  
Book Collection (3rd Floor) W 50 E8452 1996
20. Children as Research Subjects : Science, Ethics, and Law  
Michael A. Grodin, Leonard H. Glantz, editors.  
New York: Oxford University Press, 1994.  
Book Collection (3rd Floor) W 20.5 C536 1994

## IRBNet FAQs (Frequently Asked Questions)

- Q:** Can I log in to IRBNet with someone else's username and password?  
**A:** **No.** You may only sign in under your own username and no one else's, **without exception.**
- Q:** Where can I find my stamped consent document in IRBNet?  
**A:** Go into your project in IRBNet, click on "Project Overview", then "Review Details", and under the Board Documents section click on "Stamped Document". Make sure to use the most current stamped consent/assent document(s).
- Q:** I can't find the Registration form in IRBNet. How do I get to it?  
**A:** On the designer page, select "Add New Document". In the lower shaded "On-line Document" box, select "Registration Form for IRB Review" then click on the "Add" button. (Remember to "Save and Exit").
- Q:** I need to share my project with a person at another institution, but that other institution is not listed in the organization drop-down list on the IRBNet registration site. Can we still share with them?  
**A:** **Yes.** When the person at the other organization registers on IRBNet, if their organization is not listed under any of the organization types (Research Institutions, Boards, or Sponsors), that person may add their organization's name and complete the registration process.
- Q:** Do we have to submit a 'clean' and a 'marked' copy of amended documents (i.e., applications and consent forms)?  
**A:** **No.** Submit amended documents with 'track changes'. No clean copy is necessary. Remember that consent documents must be submitted in Microsoft Word and not on letterhead. Remember to leave the header completely empty for the IRB stamp. Sponsor required information can be moved to the footer.
- Q:** I have forgotten my password and can't get into my IRBNet account. What do I do? Should I call the IRB Office for my password?  
**A:** **No.** The IRB Office does not have access to your IRBNet password. Go to the IRBNet login page, and click on "Forgot your password?" in the upper right hand corner of the screen. Enter your IRBNet User Name or your contact email address and IRBNet will email your password to you. You also have the option of changing your user profile (also in upper right of the screen).
- Q:** I have an amendment and a Continuing Review Report to submit at the same time. Can these be submitted in one package via IRBNet?  
**A:** **No.** Submit one action (submission category) per package.
- Q:** Can I submit more than one package at a time on the same study?  
**A:** **Yes.** Different requests can be submitted for the same study simultaneously. Just make sure they are submitted in different packages (e.g., an amendment and a continuing review).
- Q:** How do I re-lock a package once the requested revisions have been completed?  
**A:** Once you have made revisions, click on "Mark revisions complete" at the top of the designer page. This will re-lock the package and send the IRB office an automated e-mail that the revisions are completed.

10. **Q:** If a package has been locked, can the package still be signed?  
**A: Yes.** You can continue to obtain signatures on a locked package. Note: Under no circumstances should you create a new package just for the purpose of obtaining signatures.
11. **Q:** Regarding the financial conflict of interest questions on the Registration Form: Do these questions pertain to the Principal Investigator only?  
**A: No.** The conflict of interest questions pertain to all study team members. It is each study team member's responsibility to review this section and ensure it is answered correctly.
12. **Q:** How do I spell-check?  
**A:** You can download the Google Toolbar to your internet browser. To find it, search for Google Toolbar in your search engine and follow the instructions.
13. **Q:** How do I change the Principal Investigator on a project?  
**A:** Go into the project. Click on "project overview". You should see "edit" (in yellow) at the top of the screen. Click on the "edit" button. Now you are able to go in and type in the name of the new PI. Clicks "save" to complete. Next, click on the edit pencil icon next to the Registration form, Jump to the PI section and the new name should be there. Click "save and exit". Remember: the new PI and PI's Department Chair are required to sign the package.
14. **Q:** Can I upload a password-protected protocol or IB into IRBNet?  
**A: No.** Documents must open without a password. There are other options the sponsor can use to protect documents, as follows: When the PDF is created; the sponsor can select the "Restrict editing and printing of the document" security option instead. That way it can be viewable only and not printed nor changed. They can also disable the ability to copy text and images.
15. **Q:** How do I edit a document previously submitted in another package?  
**A:** To revise a previously submitted document, first download the previously submitted document by clicking on its document type or the paper icon. Make the necessary changes and save the revised document to your desk top. Click on the pencil icon next to that document in the Designer. Browse your computer, select your revised document, and click the update button. The revised document will appear in the current package with a revision history (indicated by the "stack of paper" icon). When you have attached all the required documents, submit the package to the IRB, complete with required signatures.
16. **Q:** What are project tags? Can researchers and study coordinators use them to manage and track their studies?  
**A: Yes.** Each user (with the proper level of access) can create their own personalized tags for use on "My Projects". Any person with "Write" or "Full" access to a project may add or remove their own tags. These tags can be seen by every individual with access to the project. You can also search by tag.
17. **Q:** When do study team members have to sign a package in IRBNet?  
**A:** Members of the study team must sign the package when they are listed in the Registration Form on a new study, when added to the study by an amendment, or when included in an Individual Investigator Agreement.