


THE IRB PROCESS




 Joan Rankin Shapiro
 V.P. Clinical and Translational Research
 St. Joseph's Hospital and Medical Center




What is the IRB?

- The Institutional Review Board (IRB) is a committee established to review and approve research involving human subjects.
- The primary purpose of the IRB is to protect the rights and welfare of the human subjects.



What are the Responsibilities of the IRB?

- Conducting initial and continuing reviews of research
- Reporting findings and actions to both the investigator and the institution
- Determining which projects need review more often than annually
- Determining projects that need verification from sources other than the investigator that no material changes have occurred since the previous IRB review



What are the Responsibilities of the IRB? (cont.)

- Enduring proposed changes in a research activity are promptly submitted to the IRB and are approved by the IRB before such changes are made, except when such changes are for the immediate safety of the subjects
- Maintain appropriate records of all activities
- Ensuring prompt reporting to institutional official
 - Unanticipated problems involving risks to subjects
 - Serious or continuing non-compliance with requirements or determinations of the IRB
 - Suspension or termination of an IRB approved investigation



What is Research?

- Research contributes to generalizable knowledge.
- Research is designed in advance.
- Research utilizes a systematic approach.



What is a Human Subject?

- A human subject is defined by Federal Regulations as “a living individual about whom an investigator conducting research obtains:
 - (1) data through intervention or interaction with the individual, or;
 - (2) identifiable private information.” (45 CFR 46.102(f))
Research contributes to generalizable knowledge.



What kinds of IRB Review are there?

- There are three levels of IRB
 - Review by full board
 - Expedited
 - Determining if exempt from continuing review
- The level of review is determined by the nature of the protocol, level of potential risk to human subjects, and the subject population.
- The determination of level of review applicable to a particular study is made by the IRB in consultation with the Clinical Trials Office.
- Each level of review has a specific application submission form.



Convened IRB Review Full Board

- Any study involving greater than minimal risk requires a review by the convened IRB. This includes studies with vulnerable populations and sensitive questions as well as studies with the possibility of physical risk.
- A full board review requires the following documents:
 - - Full Board Application
 - - Informed Consent Template
 - - HIPAA Authorization Template
 - - Conflicts of Interest and Disclosure Statement
- Studies assigned to full board review have been reviewed by the Scientific Committee and/or the Chair of the submitting Department. If recombinant DNA technology is involved it will also be reviewed by the Institutional Biosafety Committee. When the proposal is scheduled for discussion the Investigator (Principal Investigator) is asked to attend the meeting to present the research project and address any questions that the committee may have. Following the presentation the IRB committee will continue discussion and vote on whether or not to approve the study.



Expedited IRB Review

- Only research involving no more than minimal risk to subjects may be considered for expedited review.
- An expedited review is conducted by a sub-committee of the IRB which will review the IRB application then provide a recommendation to the IRB Chairperson who will accept or reject the recommendation. Expedited reviews do not go to the full board.
- Federal guidelines provide categories for expedited review. Examples of categories include:
 - review of records collected for non-research purposes (such as chart reviews)
 - survey research
 - blood sampling in minimal amounts
- An Expedited review requires the following documents:
 - - Expedited Application
 - - Informed Consent Template (if applicable)
 - - HIPAA Authorization Template (if applicable)
 - - Request for Waiver of Consent/HIPAA Authorization (if applicable)
 - - Conflicts of Interest and Disclosure Statement



Exempt from Continuing IRB Review

- Research with very minimal risk to human subjects as determined by regulatory guidelines may be exempted from continuing review at the discretion of the IRB.
- An exemption is granted by the IRB upon review of the application.
- Since this constitutes a review, protocols that are deemed exempt are effectively "exempt from continuing review."



Do I Have to get Consent from Study Participants?

- The standard expectation is that all research subjects will sign a document containing all the elements of informed consent.
- The informed consent process gives potential subjects a description of the study that is clear and complete with enough information for that individual to judge whether she or he wants to participate.
- The consent form should provide readily understandable information in an amount appropriate to the level of risk in participating.
- Some or all of the elements of consent, including signatures, may be waived under certain circumstances.



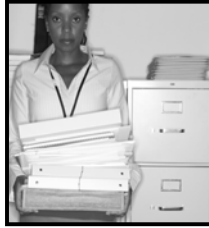
What information must be included in a consent form?

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others that may be reasonably expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;



What information must be included in a consent form?

- A statement describing the extent, if any, to which confidentiality of the records identifying the subject will be maintained;
- For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research related injury to the subject, if relevant. Typically, questions concerning a research project should be referred to the PI for that project, whereas questions concerning the rights of human subjects should be referred to the IRB.



What information must be included in a consent form?

- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- Other requirements may apply that are specific to the study.



How do I obtain consent from Non-English speaking participants?

- Researchers should take great care when obtaining informed consent from individuals who do not speak English or whose understanding of the language is limited.
- Researchers should be fluent in the subject's language or an interpreter should be available during the consent process and throughout the subject's participation as needed.
- Consent forms prepared in the language understandable to potential subjects are provided by certified translational services. This is an absolute requirement for high risk studies or for working with vulnerable populations.



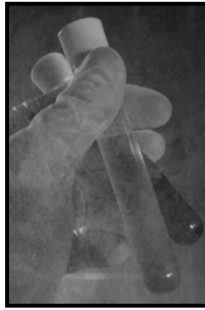
What are the exceptions to informed consent requirements?

- The IRB may waive the requirement for written consent if the consent document is the only link between the subject and the research and the principal risk of harm would come from a breach of confidentiality.
- The IRB may waive consent if:
 - The research involves no more than minimal risk to the subjects;
 - The waiver will not adversely affect the rights and welfare of the subjects;
 - The research could not practically be carried out without the waiver;
 - If appropriate, the subjects will be provided with additional information after participation.
- Consent may also be waived for some types of research regarding public service programs.



Are there special requirements for use of biological specimens?

- Yes. There are detailed instructions for applications that use biological specimens.
- In additions, there are special consent forms for the use of *stored* specimens, one for identified tissue and one for unidentified tissue specimens.



Questions?

What does it mean for data to be "de-identified"?

● A de-identified data set may not include any direct identifiers of the individual or of the individual's relatives, employers, or household members, examples are:

- Dates
- Addresses, including email address
- Social security number
- Medical record number
- IP address numbers, Web URLs
- Device identifiers and serial numbers