

Human Subjects Research: The Nuts & Bolts of the Loyola IRB

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Objectives

- What is Research and a Human Subject?
- Understanding the IRB:
 - What is the IRB?
 - The IRB and Investigator's Responsibilities
- Process:
 - How does it work?



Why

- Protect Human Subjects
- Assurance with Federal Government
- Protect University and researchers



When (must you apply for IRB approval)

- Any research involving data collected from or about Human Subjects



What is Research?

A systematic investigation designed to develop or contribute to generalizable knowledge.

45 CFR 46.102 (d)



What is a Human Subject:

A living individual about whom an investigator conducting research obtains:

- data through intervention or interaction with the individual,
- and/ or
- identifiable private information

45 CFR 46.102(f)



The Belmont Report

Ethical Principles and Guidelines for the Protection of Human Subjects of Research

Three Basic Ethical Principles:

- **Respect for Persons** ▶ Informed Consent (voluntary)
 - Treat as autonomous agents
 - Protect those with reduced autonomy
- **Beneficence** ▶ Assessment of Benefits and Risks
 - Do no harm (obligation to protect)
 - Maximize benefits and minimize risks
- **Justice** ▶ Equitable Distribution of Burdens and Benefits
 - Study design includes all groups that may benefit – does not single out one group
 - Equitable selection of subjects so that the risks and benefits of research are fairly distributed in the population

Understanding the IRB

Responsibilities of the IRB and Investigators

Institutional Review Board (IRB):

- A Health Sciences campus-wide committee charged with the review of human participants research to assure that the rights and welfare of human participants are adequately protected.



IRB Membership

- An IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members.



IRB Responsibilities

- Protect human subjects
- Risks are minimized and benefits maximized
- Procedures for obtaining informed consent are adequate
- Selection of Subjects are equitable
- Safeguards for vulnerable subjects



Investigator Responsibilities

- Protect human subjects
- Ensure all research personnel comply with protocol requirements and determinations of IRB
- Submit changes in research to IRB for approval prior to implementation
- Minimize undue influence in enrolling subjects
- Ensure that informed consent is adequate and understandable to subjects
- Report unanticipated problems and adverse events

Process:



How does it work?



Types of Review:

- **Exemptions** (45 CFR 46.101(b)) – minimal risk and all study procedures fall into one of the six exemption categories
- **Expedited** (45 CFR 46.110) – minimal risk and all study procedures fall into one of the nine expedited categories
- **Full Committee** – all studies that do not qualify for exempt or expedited review



Exempt Review

- Must be minimal risk research
- Does not involve “sensitive” topics
- Generally does not include identifiers
- Fits one of six categories
- Review is typically conducted by an IRB Administrator



Exemptions Six Categories

1. Educational tests
2. Surveys and interviews
3. Observation of public behavior
4. Existing documents, data specimens if publicly available or unidentifiable
5. Studies of federal benefits
6. Taste and food quality evaluation and consumer acceptance studies



Expedited Review

- Must be minimal risk research
- Usually involves non-sensitive topics and non-vulnerable populations
- Rigor same as full committee review, but only one IRB member reviews the project
- Fits one of nine categories



Expedited Review

(Summation of the categories)

- Device Studies not requiring an IDE and the device will not come into contact with a living human body
- Noninvasive collection of tissue
- Noninvasive prospective collection of biological specimens for research purposes
- Noninvasive data collection in clinical practice
- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes
- Collection of data from voice, video, digital, or image recordings made for research purposes
- Research on individual or group characteristics or behavior



Full Committee Review

- Any study which does not meet the Exemption or Expedited Criteria
- All members participate in the discussion and vote
- Decision is rendered by a majority of the assembled quorum
- No member with a conflict of interest can participate in the decision

Informed Consent:

What it is:

- ✓ An ongoing process of communication and mutual understanding



What it isn't:

- ✓ A piece of paper
- ✓ A moment in time
- ✓ A legal contract

General Requirements

- ❖ Obtain legally effective informed consent from the participant or legally authorized representative
- ❖ In language understandable to the participant
- ❖ Allows participant to consider whether or not to participate, and minimizes coercion
- ❖ Participant does not waive any legal rights



Eight Elements of Informed Consent

1. Statement that the study involves research
2. Reasonably foreseeable risks or discomforts
3. Reasonably foreseeable benefits; participant or others
4. Appropriate alternatives procedures or treatments
5. Statement describing the extent of confidentiality
6. Compensation for research related injury
7. A contact to answer questions about participants' rights
8. Statement that participation is voluntary



Additional Elements of Informed Consent

- May involve unforeseeable risks
- Situations in which the investigator may terminate subject's participation
- Any additional cost to the subject
- Consequences and procedure for subject's early withdrawal
- Revelations of new findings
- List the number of subjects involved in the study



Keep in Mind...

- Informed consent assures that prospective human subjects will *understand* the nature of the research and can *knowledgeably* and *voluntarily* decide whether or not to participate.
- Information must be written in a language that is understandable to the subject or representative.
- Informed consent is not just a form that must be signed, it is an ongoing educational process.



Recruitment; Part of the Consent Process

- Recruitment plans, “Public Service” announcements, ads and flyers are usually the beginning of the informed consent process.
- All recruitment plans and documents must be reviewed and approved by the IRB prior to implementation or display.



Loyola IRB Deadlines

- **IRB meetings**; 3rd Wednesday of the month
- **IRB Submission of New Projects**; 1st Friday of the month



Application Process; Initial Submission

- Electronic - begins with the routing form
- Items to submit –
 - ❖ Protocol (written research proposal)
 - ❖ Informed consent document
 - ❖ Data collection tools
 - ❖ Investigators brochure (for IND studies)
 - ❖ Any other relevant supporting documentation




Amendments

- Amendments are to be completed whenever there is a substantive change to the protocol or informed consent.
- Items to be submitted with an amendment include:
 - Protocol and /or ICD-both the redlined version and the new version (be sure to include the new version date)
 - Supporting materials



Adverse Protocol Reactions

- Documents to provide to the IRB:
 - ❖ Supporting documentation: Company revisions, Medwatches. (as appropriate)
 - ❖ Revised consent document: Use redline and strikeout options and change version date



Continuing/Periodic (annual) re-reviews

- Annual review notices are sent via email
- Documentation to submit includes the following:
 - ❖ Completion of review questions
 - ❖ Current approved consent document
 - ❖ Current approved protocol



Researcher Responsibilities

- Assure that all research personnel have passed the HS Protection test
- Respond to IRB in timely manner
- Keep copies for at least 3 years
- Obtain approval for changes
- Notify IRB immediately of any problems



IRB Staff / Contact Information

- ❖ Bernice Partacz, IRB Administrative Secretary at extension 66450
- ❖ Elaine Fluder MSN, Director Human Research Protections Program at extension 66198
- ❖ Kenneth C. Micetich MD, Chairman IRB
- ❖ Loyola IRB website:
http://www.meddean.luc.edu/res_serv/ors/human.htm