

# The Institutional Review Board “Working with the Institutional Review Board (IRB)”

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February 1, 2012

6:30 p.m. – 8:00 p.m.

Corboy Law Center 727 - Water Tower Campus



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# Welcome

- Introduction
- Who is familiar with the IRB?



# Familiar with these IRBs?

- IRB  $\neq$  Institutional Revision Board
- IRB  $\neq$  Inconsistent Review Board



# What is the IRB?

- Institutional Review Board
- A group of people dedicated to ensuring participants are treated appropriately and the study is properly carried out.
  - Responsible for ensuring the proposed research meets the regulatory requirements and the institution's policy.
  - Monitors the study to ensure any unexpected situations are properly addressed.
- A vital component of a human subjects protection program



# Who is on the IRB?

(46.107 IRB Membership)

- The IRB must be made up of at least 5 members.
- Must be “sufficiently qualified through experience and expertise... to promote respect for its advice and counsel in safeguarding” the subjects.
- Effort should be made to have a diverse membership.
- Include a member that is “not otherwise affiliated”.
- Have at least one member with scientific concerns.
- Have at least one member with nonscientific concerns.



# History



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# The Regulations

- Department of Health and Human Service  
“The Common Rule”
- The FDA
- The Belmont Report
- The Privacy Rule (HIPAA)



# When is IRB approval required?

- DHHS: prior to conducting human subjects research
- FDA: to conduct a clinical investigation
- LUC Policy: Prior to engaging in any human subject research (includes “confirmation of exemption”)





# “Human Subject”

***Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains**

- (1) Data through intervention or interaction with the individual, or
- (2) Identifiable private information.



# “Research”

***Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.**



# “Clinical Investigation”

(21 CFR Parts 50 and 56 )

- *Clinical investigation* means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies.



# Different Levels of Review

- Convened Review (“Full Review”)
- Expedited Review
- Exempt Review (does not require IRB oversight, but requires the IRB to confirm exemption)



# Which level of review is appropriate?

- First Determine Risk Classification:

- Minimal

- Greater Than Minimal

- Use the regulatory guidance and LUC policies

- Contact Andrew if you have a question.



# Minimal Risk

- **§46.102 (i)**

*Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*



# When can the IRB use expedited review?

**“Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.”**



- (1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
  - (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
  - (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  - (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
  - (b) from other adults and children<sup>2</sup>, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- (3) Prospective collection of biological specimens for research purposes by noninvasive means.
  - Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
- (4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
  - Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.





- (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)
- (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
- (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(2\)](#) and (b)(3). This listing refers only to research that is not exempt.)
- (8) Continuing review of research previously approved by the convened IRB as follows:
  - (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
  - (b) where no subjects have been enrolled and no additional risks have been identified; or
  - (c) where the remaining research activities are limited to data analysis.
- (9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.



# When can the IRB use expedited review?

## Loyola University Policy:

- **To be eligible for expedited review, research must involve “minimal risk” to participants.**
- **Studies using the following populations may not be reviewed under the expedited procedures:**
  - **Mentally Disabled**
  - **Participants with whom the researcher has another relationship which is of a supervisory or authoritarian nature (e.g., administrator-teacher, teacher-student, psychotherapist-client, supervisor-employee, doctor/nurse-patient, professional-client, parole officer-parolee)**

[http://www.luc.edu/irb/irb\\_VIIC.shtml](http://www.luc.edu/irb/irb_VIIC.shtml)



# Isn't my research "Exempt" from the IRB requirements?

Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
  - (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
  - (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
  - (i) the human subjects are elected or appointed public officials or candidates for public office; or
  - (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- (5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
  - (i) Public benefit or service programs;
  - (ii) procedures for obtaining benefits or services under those programs;
  - (iii) possible changes in or alternatives to those programs or procedures; or
  - (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- (6) Taste and food quality evaluation and consumer acceptance studies,
  - (i) if wholesome foods without additives are consumed or
  - (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.



# Isn't my research "Exempt" from the IRB requirements?

## Loyola University Policy:

- **Restrictions:** *Research cannot be exempt if any of the following are involved:*
  - prisoners, fetuses, pregnant women or human in vitro fertilization;
  - survey or interview techniques with minors;
  - research involving the observation of public behavior of minors if the researcher participates in the activities being observed;
  - the review of health care records or other archival data records if information is recorded in such a way that individuals can be identified or if the Investigator has access to a key that can be used to link the records to individuals
  - deception of participants; OR
  - procedures which expose participants to greater than minimal risk.

[http://www.luc.edu/irb/irb\\_VIIIA1.shtml](http://www.luc.edu/irb/irb_VIIIA1.shtml)



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# “Minor”

There is no set definition of minor, it depends on the type and context of the activity involved. I suggest referring to state regulations or professional standards (if they are documented).

However, the IRB generally goes with a minimum age of 18 years to be considered “majority”.



# What are the informed Consent requirements?

- Must be sought from the subject or the subject's legally authorized representative
- Allow time to make a decision
- Minimize possibility of coercion or undue influence
- Subjects/representative must be able to understand
- No exculpatory language



# Common Rule Requirements

## (What the IRB needs to determine)

- **(1) Risks to subjects are minimized:**
  - (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
  - (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- **(2) Risks to subjects are reasonable in relation to anticipated benefits**, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- **(3) Selection of subjects is equitable.** In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- **(4) Informed consent will be sought** from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by [§46.116](#).
- **(5) Informed consent will be appropriately documented**, in accordance with, and to the extent required by [§46.117](#).
- **(6) When appropriate, the research plan makes adequate provision for monitoring** the data collected to ensure the safety of subjects.
- **(7) When appropriate, there are adequate provisions to protect the privacy of subjects** and to maintain the confidentiality of data.



# Consent “Process” Requirements

Basic elements of informed consent. ... in seeking informed consent the following information shall be provided to each subject:

- (1) 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 which are experimental;
- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.





# Optional Elements

Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

- (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- (3) Any additional costs to the subject that may result from participation in the research;
- (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- (6) The approximate number of subjects involved in the study.



# The Consent Form

- The consent process must be documented
  - The form should include all elements above
  - However, it can be a “short form” with the approval of the IRB



# The IRB can permit alterations!

- Ultimately, the IRB must determine that the consent process is appropriate.
- With justification, the IRB has the ability to approve proposals that do not include full informed consent
  - Deception when necessary
  - “Emergency research”
- Consider the risk to benefit Ratio



# Waiver of Documentation

- Signed consent forms are not needed.
- An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
  - (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
  - (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
- In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.



# Waiver of Consent

- An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:
  - (1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
  - (2) The research could not practicably be carried out without the waiver or alteration.
- An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:
  - (1) The research involves no more than minimal risk to the subjects;
  - (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
  - (3) The research could not practicably be carried out without the waiver or alteration; and
  - (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.



# Institutional Revision Board

- According to the Common Rule the IRB can:  
“require modifications”
- 3 categories of required changes to a proposal the IRB makes
  - Necessary to fulfill the 7 criteria of the Common Rule
  - Necessary to meet another requirement
    - FDA regulations
    - Local laws
    - Institutional Policy
  - Personal preferences or recommendations



# Inconsistent Review Board

- The regulations do occasionally change.
- Changes to institutional policies.
- New IRB procedures and implementation of technology.
- Most often the focus of the IRB shifts:
  - Reactions to national or local events.
  - Changes in Membership



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**BREAK TIME**



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# The IRB Process and Requirements for Loyola University Students



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# IRB Requires CITI Training

*All personnel engaged in research with human subjects must obtain IRB certification by completing an on-line training course. The course, provided by the University of Miami, is called the Collaborative IRB Training Initiative (CITI) course. Completion of the CITI course quizzes with an overall score of 80 percent is required for certification. IRB certification is valid for three years and is required for IRB approval of a research project.*

[www.luc.edu/ors/pdfs/IRB/FLYERCITIinstruction.doc](http://www.luc.edu/ors/pdfs/IRB/FLYERCITIinstruction.doc)



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# Citiprogram.org

- Step 1: Set-up Profile
  - Indicate Loyola University Chicago as your institution
  - Please use your luc.edu email address
- Step 2: Complete required readings and quizzes
- Step 3: After 3-5 days check your date in CAP
- Step 4: Watch for renewal notice, must be redone at least every 3 years.
  
- Contact ORS with any problems.



# Support of a Faculty Sponsor

All Applications by LUC students must have a faculty sponsor who agrees to supervise the student and bear responsibility for the project. This applies to all projects that are being conducted for the purpose of a degree as well as to all independent research projects.

Note: Does not need to be a member of your dissertation committee. Does require current CITI training to be on file with ORS.



# Degree Requirement Research

- **If the purpose of the research project is towards the completion of a Masters or Dissertation:**
  - The project must be approved by your committee before the project is submitted for IRB review. You must submit a copy of your Proposal Ballot that has been signed by your committee members to the IRB with your application for review.
  - PLEASE NOTE: The Graduate School requires IRB approval before approving a Thesis or Dissertation Proposal. After the committee members have approved the proposal, the committee members should sign the Ballot for the Approval of a Thesis/Dissertation Proposal. A copy of this form should be submitted both to the Graduate School and to the IRB. The IRB will notify the Graduate School when a student's protocol has received final IRB approval. After the Graduate School is notified that the student's protocol has received final IRB approval the Graduate School will approve the Thesis/Dissertation proposal, provided everything else is in order.



# Applying to the IRB

The entire IRB process is done online, using the CAP program.

You can access CAP from the IRB website:

[www.luc.edu/irb](http://www.luc.edu/irb)

Should be available anytime.



# Step 1: Create/Update Profile

- The CAP system uses your normal Loyola University ID and password, just like you use for Novell or LOCUS.
- The first time you log in, you may be asked to request permission from ORS, we will have your account opened within 2 business days.
- Once in CAP, use the link on the left called “Update Your Profile”, please check to make sure all information is correct (including your CITI training date).
- If you experience any problems, please contact Andrew or Pawel. Pawel is our department’s database manager and website expert.



## Step 2: Create Your Project

1. Click the “Start New Project” link.
2. Complete this page and click “Save” at the bottom.
3. Now you have created a file in the ORS database, you still need to create, submit, and get approval of your application to the IRB.





# Step 3: Create a New Application

- See Handout “Creating a New Application”

## Creating a New Application

### Instructions for Starting a New IRB Application in CAP

This guidance is intended to be used by investigators who intend to submit a new IRB application. Creating a project and starting a new application are two separate steps. Before an application can be submitted, a Project must be created in CAP. For guidance on creating a project, please see the Creating a Project user guide.

Institutional Review Board  
Loyola University Chicago  
6439 N. Sheridan Road,  
Suite 400  
Chicago, IL 60626-5309  
Phone: 773.508.2471  
irb@luc.edu



### Step 1: Login to CAP

- 1) Open your web browser and go to this address:  
<http://www.luc.edu/irb/CAP.html>
- 2) Enter your "Username" and "Password"
- 3) Click the "Login" Button.

### Step 2: Find the Project

- 1) Be sure you are at your "Welcome Page" by clicking on "Main" at the top menu. (see Figure 1, blue arrow)
- 2) Use the "Projects by PI" and "Projects by Sponsor" tabs to locate projects that list you as the Principal Investigator or Faculty Sponsor.
- 3) Select the project that you want to prepare an application for by clicking on the "View" link (see Figure 1, yellow arrow)
- 4) You should now be at the project information page.

### Step 3: Start a New Application

- 1) Scroll down to Section 3 (Project Applications) at the bottom of the project page.
- 2) Click on the "+ Start a New Application" link in Section 3.
- 3) A pop-up window will ask you to verify that you want to create an application ("Do you want to create a new application?"). Click OK.
- 4) You should now be on the application page.

CAP  
<https://compliance.luc.edu>



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# Step 4: Have Faculty Sponsor Review and Submit Application

- Only the Faculty Sponsor can electronically submit the application.
- You can request this in CAP.
- However, you should follow-up with your Sponsor.
- You will receive an email when the application is submitted.
- Please monitor the status in CAP.



# Step 5: Receive Feedback from IRB

- You may be asked to make modifications to your proposal or provide additional information.
- You will respond directly in the CAP application.
  - Revise the responses in the form.
  - Provide a response in the Comments section: you must enter a response to each comment.
- Your Sponsor will need to resubmit.



# Amending Your Approved Project

- Any changes need to be reported to the IRB
- If the change is to reduce risks to subjects it can be immediately implemented.
- All other changes should be submitted to and approved by the IRB first.
- You obtain approval by submitting an “Amendment Application” in CAP.



# Continuing Review

- IRB Approval typically lasts 1 year
- Continuation must be approved prior to expiration
- ORS recommends submitting the Continuing Review Application (in CAP) at least 45 days before the expiration date.
- Same process as Initial Application, but your application should be updated each year.



# Additional Resources

- Department of Health and Human Services has the regulations online:  
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>
- Human Subject Regulations Decision Charts:  
<http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>
- FDA Guidance:  
<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm>  
<http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm> (search for part 50)



# Contact Information

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# Tips for Graduate Students

Toby Dye, Ph.D.  
Chair of the IRB

