IRB Procedures

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Welcome

- Introduction

- Who is familiar with the IRB?

The IRB Process and Requirements for Loyola University Students

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

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Citiprogram.org

- Step 1: Log In
  - Use LUC Username and Password.
  - Should walk you through setup questions.
- 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.

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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

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 Outlook or LOCUS.

- The first time you log in, you might 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.

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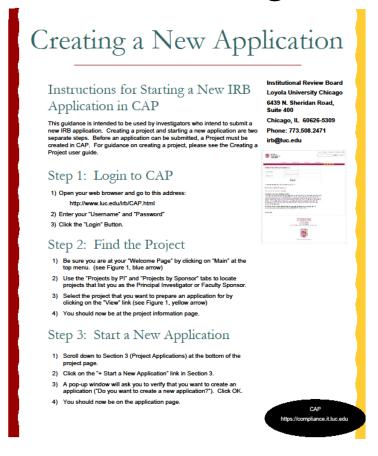
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Step 2: Create Your Project

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.

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Step 3: Create a New Application

- See User Guide "Creating a New Application"

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.

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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.

Get Notification of IRB Approval

- You can start your work with human subjects!

- Use the consent forms with the IRB approval stamp.

- *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.
(continue to follow all the LUC policies)

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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 (up to 2)
- 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)

- Academy of Criminal Justice Sciences – "Code of Ethics":
  http://www.acjs.org/page/Code_Of_Ethics

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