Loyola University Chicago
Health Sciences Division
Maywood, IL

Human Subject Research Project Start-Up Guide

This Start-Up Guide is intended to guide you through the process of designing a research project and outlining the steps to gain the necessary approvals.

- ## Getting Started:

Once you have generated an idea and feel further investigation is warranted, **perform a literature search** to obtain more in-depth information and to make sure there are not conclusive findings already in the literature. Loyola librarians are very helpful in conducting literature searches and can be reached at http://library.luhs.org.

If you wish to continue the project after a preliminary literature search, you will need to find a suitable faculty mentor in that area of expertise. Once you have found a mentor and discussed your plan with them, a more targeted literature investigation is usually necessary. You must also determine who will serve in the important role of Principal Investigator (PI). Only Loyola faculty members are allowed to serve officially as the Principal Investigator.

- ## Protection of Human Subjects Certification:

Before the Institutional Review Board (IRB) can consider your project, you and anyone involved in the project must obtain and maintain appropriate education regarding the protection of human subjects and the responsible conduct of research. Completion of this training assures the IRB that you have basic knowledge regarding the conduct of human research.

Loyola University Chicago Health Sciences Campus subscribes to the Collaborative Institutional Training Initiative (CITI) to fulfill this requirement. This mandated education is for any personnel involved in the design, conduct, or reporting of a clinical trial including:
* Principal Investigator   * Fellows
* Collaborators   * Research Coordinators
* Residents   * Medical Students

The Loyola University Chicago Health Sciences Campus CITI Program includes the following **required** courses:
> **Basic Course** in the Protection of Human Research Subjects
> - Biomedical Focus
>   OR
> - Social and Behavioral Focus
>   OR

- Data or Lab Specimens Only – this option is restricted to personnel working with data and/or specimens only with NO human subject interaction.
    OR
- Refresher Course (required every 2 years)

Health Information Privacy and Security Course (HIPS)
- Biomedical Focus
    OR
- Social and Behavioral Focus

Responsible Conduct of Research Course (RCR)
- Biomedical Focus
    OR
- Social, Education, Behavioral Research Focus

Additional Courses Include:

Conflict of Interest, Stage 1 (COI) – The Conflict of Interest Course is *REQUIRED* for investigators that currently have or will have Public Health System (PHS) funding. PHS agencies include: NIH, FDA, CDC, AHRQ, HRSA, IHS, SAMHSA, and ATSDR.

Good Clinical Practice Courses (GCP)
- GCP Course for Clinical Trials Involving Drugs (ICH-Focused)
- GCP Course for Clinical Trials Involving Devices
- GCP Course with US FDA Focus

The Humans Subjects Research Core Courses will require 4-6 hours to complete. You are encouraged to use multiple log-on sessions. The minimum "passing" aggregate score is **80%**. A running tally is compiled in the Grade Book.   If you want to improve a score on a quiz, you may repeat any quiz in which you did not score 100 % correct.

To Register and Begin the Courses:

Current CITI Users: If you are currently a CITI user with another institution, please use your current CITI log-in information and:
- Select the option, "**Click Here to Affiliate with a Participating Institution**"
- Select **Loyola University Chicago <u>Health Sciences Campus</u>** from the Participating Institutions drop-down menu
- Complete your new membership profile with your Loyola information
- Click Submit
- Proceed to "**Course Selection**" below.

New Learners to CITI: If this is your first time at the CITI Course site you must register for the course.   Click on the "**Register Here**" link.
1. Choose your institutional affiliation – Select "**Loyola University Chicago <u>Health Sciences Campus</u>**" from the Participating Institutions drop-down menu.
2. Choose a Username and Password – If you have one, please use your Loyola ID as your Username. Your password will be your choice.
3. Complete a Security Question and Answer

4. Enter your First and Last name.
5. Enter your email address(s)
6. Answer the question regarding CME/CEU credits
7. You may either skip or answer this question regarding Professional Certification.
8. Answer question regarding Course Survey question. Answering the question is required, but your participation in the survey is not.
9. On the next screen, enter your member information.
10. You will then be taken to the Course Selection page.

Course Selection:
1. You will be presented with 5 questions or options to enable you to enroll in the **Learner Group** appropriate to your role in human subject research.
2. Select 1 Learner Group for each question: Question 1 (Basic Course), Question 2 (HIPS), Question 3 (GCP) OPTIONAL, Question 4 (RCR), Question 5 (COI).
3. After you click submit, you will be given the opportunity to affiliate with a VA Medical Center. Answer **"Yes"** or "**NO**" and **Submit**.
4. The next page is the **Main Menu**. This page lists the courses you have chosen.
5. *If you are affiliated with another institution*, the software will sum the requirements of both institutions so that you need not retake modules common to the requirements of both institutions.
6. You may "**Add a course or update your learner groups**" if needed. This link will take you to the enrollment questions and permit you to change your "**Learner Group**" by providing new responses to the enrollment questions.

To Complete Courses:
1. The red link (**Enter** or **Re-Enter**) will permit you to Begin/Continue the Course.
2. Please complete the Integrity Assurance module presented at the top. The system will allow you to start taking the courses after completing it.
3. Complete the required modules and associated quizzes.
4. When you complete all Required Modules in your curriculum, you will be shown a link to "**Optional Modules**" in the Optional Course Catalog. You may return to the course site at a future time to review these modules.
5. When you complete all required modules successfully, you may print your completion report through the link: "**Print**" in the **Learner's Menu**

Proof of Certification: You may print or download a **Course Completion Report** as evidence that you have met institutional requirements. You may return to the course site in the future to obtain a copy of the completion report.

- **Drafting the Proposal:**
Formulate and modify a research proposal based on your literature search and discussion with your mentor. The proposal typically contains a Research Protocol and, depending on the protocol, may also include an Informed Consent Document (ICD) and a budget.

Protocol: Several web sites provide sample protocols for clinical research available at no charge, such as:

http://www.nia.nih.gov/NR/rdonlyres/57864169-734F-4B05-9DC0-A7B2E38C5A55/0/ProtocolTemplate_11_12_2007_Final.doc

For submission to the Loyola IRB, every protocol must include the following:
- an abstract (which is used by IRB members as a quick and easy summary of your proposal),
- an introduction that includes the hypothesis(es) and specific aim(s) of the study with description of the rationale for undertaking the study,
- the experimental design,
    - the performance sites should be listed in the resources and environment section to indicate where the study will occur (list all clinical sites and/or laboratories), and
    - the institutions and research personnel that plan to evaluate subjects or data should be included in this section of the proposal,
- an overview description of the consent process (if human consent if required),
- an evaluation of benefits and risk/discomforts, adequacy of protection against risks, inclusion and exclusion criteria, resources and environment, duration of recruitment,
- schedule of events,
- plans for dissemination (publication) and other goals (i.e., submission of grant applications in the future)
- a list of supporting references.

Informed Consent Document: For protocols that require an Informed Consent Document (ICD), the protocol should provide details about the consent process. The IRB will need assurance that your research team will be able to adequately describe the project to the potential research participants in clear language. Participants must have an opportunity to ask questions and decline participation, or withdraw from the study at any time.

A template to be used when developing your consent document is available in both .pdf and as a Word document on the Loyola IRB website.
http://www.stritch.luc.edu/research_services/content/institutional-review-board

The ICD should provide information in layperson's language. The ICD should contain a balanced evaluation of benefits and risks/discomforts that participants may experience during the proposed research. Any type of evaluation, questionnaire, procedure or physical risk needs to be addressed. The adequacy of protection against risks should also include the potential risk of lost confidentiality despite efforts to keep research records confidential to the fullest extent. To minimize this risk, every subject should be assigned a subject ID which would accompany any research sample or record. The subject ID should be constructed in such a way that it cannot be deciphered. A master list of the ID numbers should be kept in a secure (locked) cabinet with access restricted to a person who is not directly involved with the study.

Once your proposal is finished, ask your mentor to review and clear it for submission to the IRB for approval. It is a violation of Federal Regulations and Loyola's own policies for any human research investigation to be conducted without initial and on-going approval by the IRB. Initially approved projects must undergo a periodic re-review of the project.

- **Preparing for Submission**
  Prior to submission to the IRB, you will initiate a "routing form" which is essentially a cover letter letting the Office of Research Services know your planned research activities. By initiating a routing form, you will be issued an LU (Loyola University) number, which will be used for all future correspondence about this protocol with the IRB.

- **Creating a Routing Form**
  Log in to the Loyola Information Portal (Loyola.wired). Select Research Channel and, when the new window appears, select "New Routing Form," in the left hand menu. Below is what you will see. Notice the tabs at the top of the window. You can work with any tab as you get the appropriate information to complete the tasks within that tab.

Enter the Principal Investigator's name (last name first); then select all the Research Activities related that apply to the proposed study. If you are unsure, ask your mentor or call the IRB (x64608).

Select a funding mechanism. Depending on what type of funding mechanism is chosen, different windows, such as Research and Funding Types, may appear. **Save** all work before moving to the next screen.

Click over to the General Information Sub-Tab and fill in the required fields denoted by a red asterisk. The LU# will automatically appear. A Primary Contact Person must be entered. Enter the Short Project Title and the Full Project Title. The Primary funding source will appear on this screen if the project is being funded. The funding source due date is the submission date, if applicable.

The Keywords sub-tab must also be filled out. Be sure to save every screen before moving on.

The abstract must next be uploaded to the Abstract Sub-tab.

The next Tab is for Personnel Entry. Each faculty/staff member listed on the research study must be added under the personnel tab. The percent effort of each person must be entered. Every person listed in the Personnel Tab will be sent a Conflict of Interest form once the Routing Form is submitted.

For the Core Facilities tab, select any of the facilities the project will require.

The Required Approvals tab is next. This is where the IRB application should be submitted.

The Principal Investigator must submit the Routing Form. The Chairman of the Department of the Principal Investigator has an opportunity to disapprove the Routing Form, although this rarely occurs.

- **IRB Submission:**

The IRB has a blank worksheet available with all the information necessary for submission. The worksheet is only available once an LU# has been assigned (as described above). Once you have an LU#, click on the tab required approvals.

Click on IRB application. In the middle column are the blank worksheet and the Informed Consent Document Template.

IRB Application
By filling out the worksheet mentioned earlier, this step will be much easier. Every tab must be addressed. All applicable information must be entered into the appropriate tab. The Review/Submit tab is where the Protocol and Informed Consent Document must be uploaded. Any documents used for study purposes must be uploaded to this section, whether it is a telephone questionnaire, screening document, or a self rating measure.

Institutional Review Board

LU number **107769**   Status **NEW**
Title **test test**
Principal Investigator **Halaris, Angelos**

General ✔	Co-Investigators	Diseases/Objectives	Procedures	Drugs
Treatments	Financial	Alternatives	Benefits/Risks	Recruitment
Devices	Participants	Study Design		Marketing
Consent	Importance	Competing	Info Security	**Review/Submit**

Department   **Psychiatry and Behavioral Neurosciences**
Division

Attached Documents (desc.)

   none

   » To electronically submit Informed Consent and/or other supporting documents, click: [Upload Document]

General

Protocol Source

Contents   Grant Application   **NO**

                  Questionnaires, Inventories **NO**

                  Retrospective   **NO**

The Marketing tab is important for subject recruitment. Anything posted or submitted for print must be approved by the IRB. There is a Marketing Request Document on the application. It should be downloaded, completed and uploaded.

Institutional Review Board

LU number **107769**   Status **NEW**
Title **test test**
Principal Investigator **Halaris, Angelos**

General ✔	Co-Investigators	Diseases/Objectives	Procedures	Drugs
Consent	Importance	Competing	Info Security	Review/Submit
Treatments	Financial	Alternatives	Benefits/Risks	Recruitment
Devices	Participants	Study Design		**Marketing**

If this project is a clinical trial that you would like posted on the LUHS websites or otherwise marketed, submit a document in MS Word format describing the proposed marketing, including:

- Layperson Title of Trial
- Purpose of Trial (for laypersons)
- Eligibility and Exclusion criteria (for laypersons)
- Treatment description (for laypersons)
- Enrollment and Contact phone numbers
- Marketing audience (Internal/External)

This information will be reviewed by the Marketing Department.
Click here to view/download a document template.

Document	[ ]	Browse...
Description	Marketing Request document	
	Upload	

Once every tab has had the appropriate information added, it can be found under the Review/Submit tab where the documents were uploaded. Everything should undergo one last review before scrolling to the bottom of the Review/Submit tab and clicking "Submit." If you do not select "Submit", the application will not reach the IRB for review.

The IRB holds a full board review once a month. The schedule can be found on the Research Portal at http://www.stritch.luc.edu/research_services/content/institutional-review-board

All attachments and documentation needs to be submitted by the deadline. The IRB meets approximately two weeks after the submission deadline. After reviewing your submission at their meeting, they can give Full Approval, Conditional Approval, Tabled, Disapproval, or No Action.

Full approval: For approved protocols, it is very important to remember that no changes in or deviations from an approved protocol can be made without prior approval of the IRB.

Conditional approval: If conditional approval is given, usually more information is required or small changes in the documents are to be made. The documents are to be re-uploaded to the IRB application in a reply. In the reply, describe line-by-line how the changes differ in the new document. The response to the conditional approval will be reviewed and if the conditions of approval are met, an approval will be issued. If these are minor administrative matters, the approval may occur prior to the next full board meeting.

Tabled: If a project receives a tabled action more information is required. The required documents and information are to be re-uploaded to the IRB application in a reply. In the reply, describe line-by-line how the changes differ in the new document. Respond to any issues raised in the IRB review. A project which was tabled has substantive issues and your responses and the changes made must be reviewed by the full board at a regularly convened IRB meeting.

Disapproval: A flawed experimental design that cannot be corrected will lead to disapproval. In the event of disapproval by the IRB, the project application is terminated. Issues identified in

the disapproval letter should be used to revise the research protocol. The project will then need to be resubmitted as a new application.

No Action: If a submission is incomplete or the information provided in not adequate for the IRB to conduct a review the project may receive a notice of No Action. If this occurs, the project will need to be resubmitted as a new application.

Once IRB full approval is granted, the research can begin. Remember: **No human research can be conducted without full and current IRB approval!** This requires that you maintain the study's approval status by completing your annual renewals. If you do not comply with the mandatory annual review and do not secure IRB renewal to continue with your study, the project will have to be suspended. If this happens, you must immediately stop all data collection. A suspension is usually temporary until the IRB requirements have been satisfactorily met and renewed authorization to continue your study has been issued. On certain rare occasions, a study may be terminated by the IRB for cause (such as serious or repeated protocol violations, safety concerns, or ethical reasons).

Protocol Amendments and Adverse Events
If you must make a change in an existing and approved Protocol or Informed Consent Document, you may not implement the change(s) without prior IRB approval. The change(s) should be made on the most recently approved version of the protocol and/or consent document. The "Track Changes" option in Microsoft Word should be turned on so that everything that is a deleted or added is highlighted. The version date of the document must be changed accordingly. The amendment is submitted by logging into the Loyola Information Portal. Click on the Research Channel, select the correct LU#, and go into the IRB Application. Click on the Amendment Tab and upload the appropriate documents.

You must wait until the IRB makes a decision about the new amendment before any action may take place. If the amendment is approved, the new changes in the protocol may begin. If there is a conditional approval, a reply must be made addressing the response made by the IRB. The IRB may also issue Disapproval or No Action to the amendment, in which case the changes may not be made to the Protocol or Consent form and a new amendment must be submitted that addresses the concerns raised by the IRB. When submitting an amendment or reply to a submitted amendment, the line-by-line changes that are made should be noted in the Amendment Description or Reply.

Adverse Events

The IRB must be notified PROMPTLY of all serious and any unanticipated adverse events associated with the project (or the device or the drug). Any event in the course of your research that is unexpected, or a deviation from a protocol, must also be submitted to the IRB as a New Adverse Event with any associated documents uploaded.

Annual Reviews

The IRB conducts a periodic re-review of every active research protocol. The typical re-review period occurs annually. The Principal Investigator and the Primary Contact for the project will receive notification through e-mail before the review is scheduled. On the IRB application form, there is a Project Census and questions associated with the research activities throughout the year. This must be completed before the scheduled review. The required documentation needed is in the e-mail. The current version of the Protocol and Informed Consent Document must be uploaded. Projects that have not been re-reviewed will be suspended until the re-review of the project is conducted.

Subject Recruitment

In all likelihood you will need to recruit subjects for your study (patients or healthy control subjects, or both). The IRB must receive and approve your proposed subject recruitment plan including fliers you may wish to post or advertisements you may wish to place with the news media.   Once approved by the IRB, any postings or distributions on or off campus must be routed through Loyola's Clinical Research Marketing System.

If you require help with any of the above procedural steps, you may contact the IRB office at ext. 64608.

With all best wishes for successful research!

The Office of Research Services