

## Guidance Document – Human Subject Protection (HSP) Training

### 1. What is the required Human Subject Protection (HSP) training that I need to complete if I am conducting a research project involving human participants?

You are required to complete a HSP training if you will engage in any research related activity involving human participants including surveys, interviews, interventional studies (etc.), use of human tissue/biospecimen or access to personal health information.

- Prior to September 27, 2018, the LAU IRB was requiring that you complete the training through the National Institute of Health (NIH) for the “Protection of Human Participants in Research”. The LAU IRB will still honor the NIH Certificate of Completion if it is still valid until December 2019. (Certificate validation is a period of 3 years from the date noted on the certificate).
- If you do not have a valid NIH, you will now be required to take the training through the Collaborative Institutional Training Initiative (CITI) Program. You can access the CITI Training from the LAU IRB website under [Education and Training](#) or directly through [CITI Home page](#)

### 2. How do I register for the CITI Training?

In order to register for the training, please go to the [CITI Home page](#). The following [link](#) will assist you in registering with CITI. You can also follow these steps:

- Click on “Register” in order to register as a new User
- Select “Lebanese American University (LAU)” as Your Organization Affiliation
- Follow the steps to create you user name and password
- You have the option to request Continuing Educational (CE) credits for a fee, you can opt out and amend that at a later date
- You will then complete Organization specific details about your school affiliation and role in research
- Please keep record of your Username and Password
- Last step (Step 7), you will be asked to select the course or courses you wish to take. Please refer to Question 3 below.

### 3. Which CITI Courses will I be required to complete?

The Courses provided to you are based on the learner groups identified by the LAU IRB. Please select the learner group that best fits your research / discipline under Question 1. (You can select a course from Question 2. and Question 3. only if it applies to you)

*Question 1. Human Subjects Research. Please choose one learner group in this section based on your role and the type of human subject activities you will conduct*

***There are 3 Learner Groups/Courses that applies to Research involving Human Participants:***

- ***IRB Exempt Research*** – only for researchers applying to the LAU IRB for their research project that fits one of the exempt criteria or is part of an IRB Classroom project application that fits exempt criteria. Otherwise the researcher must complete the training under either

*the Biomedical Researcher Learner group of the Social Behavioral Educational Researcher Learner Group*

- **Biomedical Researcher**
- **Social Behavioral Educational Researcher**

#### 4. How many modules are in each Learner Group / Course?

Each course has Required Modules (R), Elective Modules (E) and Optional Modules (S).

- LAU IRB selected those modules that are **Required** per Learner Group/Course and these are mandatory to be completed
- In addition, LAU IRB selected for some Learner Groups /Courses **Elective Modules**, please check your Learner Group/Course to see if such modules are provided and how many are mandatory. You have the option to select the E modules you would like to complete and you have a minimum requirement to complete to be able to get your certificate
- LAU IRB has provided for Learner Groups /Courses **Optional Courses**, which you might find beneficial. These are not required to be completed for you to be able to get your certificate.

#### 5. Good Clinical Practice (GCP) Modules

We are also making available through CITI the Good Clinical Practice (GCP) modules **only if required by the sponsor or funding agencies for studies under (FDA Submission, ICH Good Clinical Practice)**. These modules have concentrations under U.S. FDA Focus or ICH GCP Focus.

#### 6. Does LAU IRB accept any other HSP certification?

The LAU IRB office will still accept NIH Certificate of Completion, if it is still valid, along with your IRB submission until December 2019. You will not be required to take CITI if your NIH is valid, for those applying for their research projects between now and December 2019.

Other types of HSP training will be assessed on a case by case basis when all relevant information are provided to the LAU IRB Office.

#### 7. Does my CITI certificate expires?

The CITI certification is valid for a period of 3 years. Every 3 years, individuals who have completed the CITI *Basic Human Subjects Protection* course must complete the CITI *Refresher Human Subjects Protection* course.

For Students who completed the *Student IRB Exempt Research*, will be required to take the *Basic Biomedical Researcher* or *the Basic Social Behavioral Educational Researcher* if they are no longer students or if they will be involved in Non-exempt research projects.

#### 8. Whom should I contact if I have any questions?

You can contact the LAU IRB Office at ext. 2546 or by email at [irb@lau.edu.lb](mailto:irb@lau.edu.lb)