MANDATORY TRAINING IN THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

All individuals involved in the design and conduct of research with human subjects are required to undertake training in the protection of human participants *before* commencing any proposed research activity involving human subjects regardless of whether the study is funded or non-funded research.

The conduct of human subjects research is not limited to <u>direct</u> interaction with subjects. Environments where researchers are working with subject data that are identifiable or potentially identifiable (for example, where a subject code key exists) are also included within training guidelines. Therefore, the training requirement is not only applicable to Principal Investigators and other senior personnel, but may also extend to staff and student assistants. Careful attention also is required for issues related to conflict of interest that might affect both the research and the reporting of it.

All personnel involved with human subjects research are strongly encouraged to undertake the training regardless of whether they fall within or outside of the mandatory training pool. Becoming certified under this program is an excellent training opportunity. Any individual who plays any role in these types of research endeavor will benefit. The courses themselves can also easily become part of a research course curriculum.

Importantly, submission of proof-of-training completion reports by the Principal Investigator(s) and other appropriate project personnel must be included with proposals submitted to the HSIRB for review; the Principal Investigator must submit to the Board proof of training completion for any individual who joins an approved project during its life before that person may commence work with subjects or identifiable data.

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CURRENT **Mandatory Training Requirements, in effect through January 31, 2016**
Either complete the National Institute of Health's training program or complete the CITI training curriculum (see below); the NIH training module can be found at:

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http://phrp.nihtraining.com/users/login.php.

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Note: Any proposal approved prior to January 31, 2016 will continue to be covered under the NIH training program or optional CITI training for the duration of the research project and any subsequent required annual continuation reviews.

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NEW **Mandatory Training Requirements, effective February 1, 2016**
Effective February 1, 2016, mandatory training requirements are met by completing the Collaborative Institutional Training Initiative at the University of Miami (CITI) training program in Human Subjects Research for all new proposals submitted for review, regardless of previous NIH mandatory training completed.

To access the CITI training curriculum:
- Go to https://www.citiprogram.org

- Create an account for yourself, if you don't have one already established
- Select Touro College New York as your institution
- Log in
- Under Main Menu, click on Touro College of New York Courses
- Click on Select Curriculum or Add a Course depending upon whether you have previously started the training process
- Under Select Curriculum, click on View Instructions Page; after reading the instructions return to the original menu
- Under Question 1, click on "Biomedical Research Investigators"
- Leave Questions 2, 3, and 4 blank
- Hit submit; the next window will take you to the curriculum: "Biomedical Research - Basic"
- Click on the course title; you will be taken to the curriculum course module listings to begin your training

Biomedical Research – Basic: Required Modules & Supplemental Modules:
- There are two unit listings under the curriculum, "Required Modules" and "Supplemental Modules."

- All researchers must complete the full set of "Required Modules" listed.

- Additionally, please carefully review the "Supplemental Modules" listed; select modules in this list must be completed if your research project involves any such areas of human subjects research (for example, international research or research involving prisoners, among other topics).

Time to Complete. Completion of each course may generally take up to 30 minutes. Courses can be taken over time until the curriculum is completed.

Validity of Training.   Completion of the required curriculum training and completion of any supplemental course is valid for three years.

Certificates:
- Upon completion of the required modules you will be able to generate a Coursework Requirements Report via the Reports header on the CITI website. That certificate must be submitted to the HSIRB as part of your proposal if the basic curriculum is sufficient for the project proposed.

- *However*, if the project proposed involves subject areas that appear only among the supplemental course offerings, a listing of supplemental courses completed does not appear on the Coursework Requirements Report, but rather only appears on the Coursework Transcript Report. Please submit that report as part of your proposal when appropriate.

- Approval of your proposal is subject to receipt of the reports confirming completion of all necessary training for the research project under review.

Special Notes:

- If you have successfully completed any of these courses while at Touro within the past three years, they will be counted towards your certification of training.

- If you have completed any of the courses within the past three years at another institution, follow the affiliation instructions. This earlier completion should allow you to carry forward those completion credits towards your Touro certification of training.

- *Some disciplines allow for CEU credit for CITI courses. Please click on the My CEUs header and read this material before commencing your curriculum. You must select this option and pay for the credits before you start your training program or you will not receive those credits.*

The HSIRB welcomes any constructive feedback you wish to provide about the new training program as part of our ongoing efforts to improve IRB processes. If you have any questions about the new CITI training program, please feel free to contact Dr. Joseph Indelicato, Chair, at joseph.indelicato@touro.edu, Dr. June Kume, Vice Chair, at june.kume-kick@touro.edu, or Glenn Davis, Director of the Office of Sponsored Programs, at glenn.davis5@touro.edu.