

## UH Human Studies Program

### Investigator & Key Personnel Training Requirements on the Protection of Human Subjects for New Exempt (effective date 01-15-2013) and Non-Exempt Research Projects

Effective date 09-04-2012

#### I. Effective Date Training Requirements

\*\* To see the breakdown of what courses to take, see below

Training requirements described in sections I-III will be effective on Tuesday, September 4, 2012. These requirements will be implemented for **new non-exempt research** proposed for IRB approval after this date. These requirements are not retroactive: Training certificates are not required with IRB continuing review/renewal applications for research initially approved prior to 9-4-12.

It is required that investigators complete the on-line training prior to submitting their application for IRB initial approval. Study activities may not commence until final IRB approval, with no conditions, is documented in a letter to the principal investigator from the UH Human Studies Program.

Retraining is required at three-year intervals.

Links to the NIH and CITI on-line training programs can be found on the UH IRB website.

#### II. Training Requirements for Key Personnel on NIH-funded Research

The National Institutes of Health (NIH) requires researchers who will be involved in NIH-funded human subjects research to complete a training requirement approved by the grantee institution. These requirements apply to all "key personnel," which the NIH defines as the Principal Investigator(s) and other individuals responsible for the design or conduct of NIH-funded research.

As a condition of receiving NIH research awards, UH is required to have a policy that complies with the NIH requirement.

#### **What is the UH Training Policy for NIH-funded Research?**

UH offers 2 options for meeting the NIH training requirement.

**Option 1:** UH faculty and staff who meet the NIH definition of "key personnel" have the option of completing the NIH on-line training course at:

<http://crt.nihtraining.com/login.php>.

Upon successful completion of this module, the trainee will be able to print out a certificate of completion. A copy of this certificate must be provided to the Human Studies Program, preferably with the application for IRB approval of a new study.

**Option 2:** Alternatively, NIH key personnel can complete the CITI training for investigators as described in section III below.

### III. Training Requirements for Investigators on non-NIH Non-Exempt Research Projects

The principal investigator(s) and co- or sub-investigators on all non-NIH research operating under the approval of a UH IRB must complete the appropriate on-line training module offered by the CITI (Collaborative Institutional Training Initiative) Program. Completion of CITI training by investigators is required as a condition of receiving approval by a UH IRB to perform research.

Completion of the RCR (Responsible Conduct of Research) CITI training does not satisfy the requirement for training in the protection of human subjects.

For instructions on how to select your CITI training courses, go to:

[http://www.hawaii.edu/irb/html/training\\_citi\\_howto.php](http://www.hawaii.edu/irb/html/training_citi_howto.php).

It takes between 4 and 6 hours to complete a CITI basic training course. The course can be completed in segments. You can exit and re-enter the system at any time. The system will keep track of all completed modules.

Successful completion of the CITI training program requires an 80% average on the quizzes for all modules required for your learner group. Upon successful completion of your training modules, you will be able to print a training completion certificate.

To renew your CITI certification before the three-year expiration, complete the CITI refresher course offered in your on-line CITI curriculum.

### IV. Training Requirement for Exempt Research Projects (effective 1-15-2013)

UH students and UH faculty members involved in exempt research must complete CITI training, effective January 15, 2013, prior to receiving approval from UH IRB to conduct their study. Research advisors of UH students conducting exempt projects must also complete the same curriculum as their students in order to be well equipped with the essential research knowledge to effectively advise their students. Investigators for exempt research will select the 'Student and Advisors – Class Projects' Learner Group. Go to

[http://www.hawaii.edu/irb/html/training\\_citi\\_howto.php](http://www.hawaii.edu/irb/html/training_citi_howto.php) for detailed instructions. It may take between 1-2 hours to complete the CITI basic training course for exempt study researchers.

Investigators conducting research that involves existing data or human specimen will need to complete the ‘Research with data or laboratory specimens- ONLY.’

If you have already completed either the Biomedical Research for Investigators learner group or the Social and Behavioral Research for Investigators learner group, you do not need to complete the requirement for exempt research projects.

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Type of study/ Role	IRB	Learner Group	Good Clinical Practice Course	HIPS
Investigators and key personnel (i.e., study coordinators obtaining informed consent) conducting <b>non-exempt studies</b>	Biomedical	Biomedical Research Investigators	Only if working on clinical trial, choose one: (1) medical devices; (2) investigational drugs; (3) US FDA Focus for both medical device and drug	If working on health-related study, choose Information for Clinicians; otherwise, choose Information for Investigators
	Social and Behavioral	Social & Behavioral Research Investigators	n/a	Information for Investigators
	Cooperative	Biomedical Research Investigators	Only if working on clinical trial, choose one: (1) medical devices; (2) investigational drugs; (3) US FDA Focus for both medical device and drug	If working on health-related study, choose Information for Clinicians; otherwise, choose Information for Investigators
Investigators, and their research advisors if applicable, conducting studies approved under <b>exempt review</b>		Students and advisors – Class Projects	n/a	Information for Students or Instructors
Investigators conducting research with <b>existing data or specimen</b>		Research with data or laboratory specimens – ONLY	n/a	Information for Students or Instructors