

UNIVERSITY OF KENTUCKY

MANDATORY RESEARCH EDUCATION REQUIREMENTS

Human Subjects

Initial human subject protection (HSP) training: All personnel involved in human subject research must complete one of the two options below:

- **Collaborative Investigator Training Initiative (CITI):** readings and test online
 Instructions at http://www.research.uky.edu/ori/ORIForms/42-CITI_instructions.pdf
 Contact: Crystal McClure, Office of Research Integrity – 257-9428 or cdmay1@email.uky.edu
- **Protecting Study Volunteers in Research a.k.a. (Dunn & Chadwick):** book with online test
 Instructions at http://www.research.uky.edu/ori/ORIForms/43-Dunn_Chadwick_inst.pdf
 Contact: Stephanie Morris, Office of Research Integrity – 257-0582 or samo222@uky.edu

Continuing HSP training: Continuing education in HSP must be completed at least every three years. There are several options for renewing your HSP training:

- **CITI web based human subjects protection training (refresher course option):** Enter the CITI website and register as a UK user. The course is a synopsis of the main biomedical or social/behavioral modules that are required as initial training. Web address: <https://www.citiprogram.org/default.asp>
- **VA Good Clinical Practice and Human Subjects Protection web based modules** (submit certificate of completion) Web address: www.citiprogram.org
- **Attendance at the UK annual human subject protection conference,** (submit certificate of attendance).
- **Attendance of an equivalent human subjects protection conference** (ex. PRIM&R) within the last six (6) Months (this does not include an isolated session on human subjects protection as part of a conference on another subject matter). Submit certificate of attendance.
- **NIH human subjects protection program web-based training** (only qualifies as a refresher course and not for initial human subjects protection training). Submit certificate of completion. Web address: http://cme.cancer.gov/c01/intro_01.htm

Animal Care & Use

All personnel involved with the use and care of animals involved in research are required to complete initial training and continuing education. Depending on the species and/or proposed procedures, additional specialized training may be required. Please refer to the guidelines at the following link.

- **IACUC Policies & Procedures Training and Continuing Education**
 Web address:
http://www.research.uky.edu/ori/univet/resources/sop/IACUC_106_Training%20and%20Continuing%20Education%20Requirements.pdf

Fiscal Compliance Training for Clinical Trials that Involves Third-Party Billing

All staff and faculty who serve as principal and sub-investigators, budget preparers, clinical coordinators, clinical research associates, budget managers, departmental business managers and chairs participating in clinical research trials that involve third-party billing

- **Fiscal Compliance in Clinical Trials Education Program**

http://www.mc.uky.edu/ukcro/fiscal_man_page.htm

Classroom to be announced

Contact: Rebecca Scott, 323-1478 or rmwalt00@email.uky.edu

Sponsor/ Investigator Mandatory Training

All individuals who functioning as the investigator and sponsor for a FDA regulated trial (drug or device).

- **[Sponsor-Investigator web-based training description](#)**

Title: ORI000-NC: Sponsor-Investigator Clinical Trials with FDA Regulated Products

On-line modules and exams (drug or device specific) located on [UK's blackboard website](#). Contact: Belinda Smith, ORI Education Specialist, 323-2446 or belinda.smith@uky.edu

Environmental Health and Safety

The University requires safety training classes to be completed before beginning certain types of work. These requirements apply to all individuals involved in the covered work, including faculty, staff, students, post-docs, visiting researchers, and volunteers. To find out what classes you need to take, consult the Training Checklist.

- **Training checklist for Research Grants and Contracts**

Web address:

<http://ehs.uky.edu/checklist.html>

Classes are grouped under their respective EH&S departments on the training schedule including,

- Occupational Health and Safety (Chemical Hygiene/Lab Safety, Bloodborne Pathogens, Hazard Communications, etc);
- Biological Safety (Biological Safety, Bloodborne Pathogens for Researchers, Autoclave);
- Environmental Management (Hazardous Waste, DOT/IATA);
- Radiation Safety (Basic, Advanced, Laser Safety); and
- University Fire Marshal (Fire Extinguisher Use).

- **Training Schedule**

Web address:

<http://ehs.uky.edu/classes.html>

Veterans Affairs Medical Center

University of Kentucky researchers who utilize VA facilities, recruit VA patients for UK studies, or who have joint appointments must complete mandatory education in any area applicable to the research being conducted. These VA requirements are in the following areas: Human Subjects, Animal Care and Use, Occupational Health and Safety, Hazardous Materials Management, Radiation

Safety, and Fire and Safety. For specific information, contact Lena Molen at the VA Research Service Office, 281-4927.

OPTIONAL EDUCATION RESOURCES

(Not mandated by UK but may be required by sponsor or funding agency)

Responsible Conduct of Research

The [National Science Foundation \(NSF\)](#) has implemented training in Responsible Conduct of Research as an integral part of preparation and development of current and future scientists. RCR training is also a requirement for various other funding opportunities such as postdoctoral fellowships.

- **UK CITI Curriculum RCR Training – choose from:**
 - Biomedical RCR
 - Social and Behavioral RCR
 - Physical Science RCR
 - Humanities RCR
 - Administrators RCR
 - Engineers RCR

For instructions refer to the RCR training section of [CITI Instructions](#)

Good Clinical Practice

Some industry sponsors of clinical trials require investigators to be trained in Good Clinical Practice (GCP) guidelines. UK CITI curriculum includes GCP training modules under optional trainings.

- **UK CITI Curriculum Optional GCP Training (English and Spanish)**

For instructions refer to the optional training section of [CITI Instructions](#)

Compiled by Ada Sue Selwitz and Jennifer Harris, Office of Research Integrity Updated 9-24-09
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