

Key Personnel Training Form Instructions

All NIH key personnel from Case Western Reserve University, University Hospitals of Cleveland, The MetroHealth System and the Louis Stokes CDVAMC must be trained via one of the following options:

Training Option #1: Protecting Study Volunteers in Research Examination, or

- The Responsible/Principal Investigator would provide his/her copy of the “Protecting Study Volunteers in Research” manual to each key personnel to read or provide a summary of the contents of the manual to all key personnel. Key personnel should take the examination contained at the back of the manual, fill out the Examination Answer Sheet, and return it for grading and certification of the results to the IRB office from which protocol approval has been given or will be sought.

Training Option #2: Website education, or

- Responsible/Principal Investigators may facilitate web-based training of key personnel by directing them to <http://tutorials.rgs.uci.edu/> or <http://ohsr.od.nih.gov/cbt/> or http://137.187.172.201/cbttng_ohrp/default.asp?CBTID=2 (as “Other”). Key personnel using this option should complete the tutorial at one of the sites.

Training Option #3: Responsible/Principal Investigator Education Checklist

- Responsible/Principal Investigators may use the Checklist below as a guide to training key personnel. If key personnel are trained using this option the Responsible/Principal Investigator should verbally convey all the topics listed below and document the time and date that this training occurred.

ETHICAL RESEARCH INVOLVING HUMAN SUBJECTS

- The necessity of conducting ethical human subject research.
- An overview of and opportunity to read the Belmont Report.
- Special concerns for protecting human subjects belonging to protected populations (if appropriate to the project).

INFORMED CONSENT

- Ethical background for requiring informed consent.
- Requirements of informed consent.
- Requirement for the documentation of informed consent.
- Discussion regarding the necessity of ongoing informed consent.

ORIENTATION TO FEDERAL AND INSTITUTIONAL REGULATIONS

- Explanation of human subject research. What is a human subject? What is research?
- Overview of the applicable regulations.
- Requirement to report unexpected instances of adverse harm to subjects.
- Explanation of basis upon which research may be suspended or terminated.

ISSUES SPECIFIC TO THE PROJECT

- The purpose of the project.
- Detailed discussion of what is expected of the volunteer subject.
- Explanation of how key personnel is expected to maintain the privacy of the subject and the confidentiality of the data.
- Explanation of what undue influence and coercion are.

NIH requires that investigator's obtain an institutional official's signature on a training letter. To obtain the signature, Responsible/Principal Investigators must submit the following items to the CWRU Office of Research Administration: **1) a completed Key Personnel Training Form (KPTF); 2) any outside certifications; 3) a copy of the grant page listing key personnel; and 4) a completed key personnel training letter** (template available at http://ora.ra.cwru.edu/main_human_subjects_protection_page.htm).

Key personnel outside of the above institutions should provide signed documentation from their academic institution that they have received appropriate training. This documentation should be attached to the KPTF. Outside key personnel who are not affiliated with an appropriate institution (e.g. consultant) should complete one of the internal requirements and sign the KPTF.

KEY PERSONNEL TRAINING FORM (KPTF)

GRANT INFORMATION:

(Print Full Grant Title)

(Print Full Grant Number, if known)

(Agency)

KEY PERSONNEL:

The personnel listed below attest that they have received human subject protections training as required by NIH policy prior to signing:

(Signature)

(Date)

(Print Name)

Training Option: (circle one) Option #1 Option #2 Option #3

***** ***** ***** ***** *****

(Signature)

(Date)

(Print Name)

Training Option: (circle one) Option #1 Option #2 Option #3

***** ***** ***** ***** *****

(Signature)

(Date)

(Print Name)

Training Option: (circle one) Option #1 Option #2 Option #3

IF MORE THAN THREE KEY PERSONNEL, ATTACH ADDITIONAL SHEETS IF NECESSARY

RESPONSIBLE/PRINCIPAL INVESTIGATOR:

I attest that the above key personnel have received human subject protections training as required by NIH policy:

(Signature)

(Date)

(Print Name)

(Department)

(Institution)

(Number of key personnel)

Documents for ORA:

Signed KPTC Outside Certifications

Key Personnel Grant Page

Training Letter