

PARKVIEW HEALTH	INSTITUTIONAL REVIEW BOARD MANUAL
Policy & Procedure Title: Training Requirements for Individuals Involved in Human Subject Research	
Category: IRB Administrative Process	

I. Policy Statement

Parkview Health Institutional Review Board (PH IRB), in accordance with the Terms of Assurance of its Federalwide Assurance (FWA), demonstrates its commitment to the protection of the rights and welfare of Human Subjects in Research by ensuring that all individuals and applicable Researchers who are reviewing, conducting, or supporting Research demonstrate and maintain continuing knowledge of and comply with the ethical principles and regulatory requirements governing the protection of Human Subjects in Research.

II. Definition of Terms

Researchers: All individuals who are involved in the conduct of Human Subject Research, in either biomedical or social and behavioral Research, regardless of affiliation with Parkview Health.

This includes, but is not limited to:

- Principal Investigators, Sub-Investigators, Study Coordinators
- Any individuals who participate and exercise judgement in the preparation and content of any study or regulatory documents
- Subcontractors, consultants, residents, students, and all other non-Parkview Health personnel involved in Research being conducted at Parkview Health
- Any other individual who is a contributor to the conduct of a Research protocol, including retrospective studies, which involves intervention or interaction with Human Subjects in Research and/or their information, as appropriate.

Research: A systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Human Subject: A living individual about whom an investigator conducting Research obtains:

- Data through intervention or interaction with the individual, or
- Identifiable private information

Identifiable private information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Intervention: Both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the Subject or the Subject's environment that are performed for Research purposes.

Origination Date: 04-2010	Source: PH IRB
Revision Date(s):	Authorized by: Institutional Official

PARKVIEW HEALTH	INSTITUTIONAL REVIEW BOARD MANUAL
Policy & Procedure Title: Training Requirements for Individuals Involved in Human Subject Research	
Category: IRB Administrative Process	

Interaction: Communication or interpersonal contact between investigator and Subject.

III. Procedure

Training Requirements

- A. To fulfill the requirement for Human Subject Research training at Parkview Health, all Researchers and PH IRB Members and Staff must complete the specified education modules provided by the Collaborative Institutional Training Initiative (CITI), located online at <http://citiprogram.org> with an overall passing score of 80%.
- B. Since Researchers and others involved in the reviewing, conducting or supporting of Research assume different roles and responsibilities when conducting Human Subject Research, PH IRB has identified, within the CITI program, learner groups with role-related training requirements. Researchers and others will be assigned to an appropriate learner group during CITI registration at <http://citiprogram.org> and subsequent affiliation with Parkview Health.
- C. If more than one learner group is applicable to a Researcher, i.e., the Researcher is both an IRB Member and a Biomedical Researcher, all applicable learner group courses must be completed. Learner groups are designed such that any duplicate modules will be required to be taken only once.
- D. Credit for CITI training modules completed at another institution will be transferable to the PH IRB learner group courses.
- E. Upon completion of the CITI ***Protection of Human Research Subjects*** training course, a certificate of course completion will be emailed directly to the Parkview Health CITI Administrator via the CITI coordinating center as verification of the individual's course completion. Documentation of completed Human Subject Research training will be retained by the PH IRB Office.
- F. Documentation of completed Human Subject Research training must be submitted to the PH IRB Office **prior** to PH IRB consideration of a Research submission. PH IRB may refuse submissions that do not include documentation of Human Subject Research training for all Researchers listed as participants in the conduct of the study.
- G. The above CITI training requirement will become fully effective on **May 1, 2011**. After this date, PH IRB will only accept documentation of Human

Origination Date: 04-2010	Source: PH IRB
Revision Date(s):	Authorized by: Institutional Official

PARKVIEW HEALTH	INSTITUTIONAL REVIEW BOARD MANUAL
Policy & Procedure Title: Training Requirements for Individuals Involved in Human Subject Research	
Category: IRB Administrative Process	

Subject Research training that has been obtained through successful completion of the specified curriculum within the CITI program with an overall passing score of 80%. Prior to this date, completion of the National Institute of Health (NIH) and the Office of Human Research Protections (OHRP) sponsored Human Subject Research Protection training tutorials will continue to be accepted as evidence of Human Subject Research Protection training. These tutorials can be found at <http://phrp.nihtraining.com/users/login.php?l=3> (NIH) and <http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp> (OHRP). Documentation of individual completion of the NIH and OHRP tutorials must be submitted to the PH IRB Office in accordance with the requirements listed above.

- H. Other sources of training will not be accepted after May 1, 2011.
- I. Review of new study submissions and continuing review of all open studies by PH IRB will be dependent upon the timely fulfillment of this requirement.

Ongoing Training Requirements

- A. All Researchers and individuals who are reviewing, conducting, or supporting Research in the conduct of Human Subject Research must complete the CITI Refresher Course in Human Subject Research Protections with a passing score of 80%. This renewal of certification is required no less frequently than every **three** (3) years beginning with the original certification and every renewal thereafter. This can be accomplished through completion of the CITI Refresher Course assigned to the appropriate learner group located online at <http://citiprogram.org>.
- B. As a means of facilitating the ongoing Human Subject Research training requirement, the CITI system and/or PH IRB Office will forward reminders to current CITI certified Researchers at approximately 180 days, 90 days, and 30 days prior to the date the current certification is due to expire.
- C. If a Researcher has not completed the required Refresher Course within a sixty (60) day grace period following the original or refresher certification expiration date, the appropriate learner group Basic Course must be repeated in accordance with the requirements listed above.

Additional Protections – Principal Investigator’s (PI) Role

- A. The PI is responsible for assuring all study personnel complete the appropriate PH IRB learner group courses in the CITI program.

Continuing Education Credits

- A. PH IRB has purchased the CITI program and is responsible for the annual fee for maintaining the program. PH IRB is providing this training

Origination Date: 04-2010	Source: PH IRB
Revision Date(s):	Authorized by: Institutional Official

PARKVIEW HEALTH	INSTITUTIONAL REVIEW BOARD MANUAL
Policy & Procedure Title: Training Requirements for Individuals Involved in Human Subject Research	
Category: IRB Administrative Process	

opportunity to all Researchers who are reviewing, conducting, or supporting Research within the Parkview Health system at no cost to the Researchers.

- B. Although not required by PH IRB, CME/CEU credits are available from the University of Miami, School of Medicine (creators of the CITI program) after completing the required number of modules in the CITI Biomedical, IRB Member, or Social Behavioral courses and the CITI Good Clinical Practice (GCP) course. NOTE: This may require completing other modules in addition to those required by PH IRB.
- C. **The fee associated with obtaining the CME/CEU credits is the responsibility of the Researcher. PH IRB will not pay for or reimburse fees for obtaining CME/CEU credits.**
- D. For more information or to download the CITI CME/CEU Request Form, please visit the CITI website (<http://www.citiprogram.org/>). Click on the "CME/CEU" link on the Main Menu page or at the bottom of any page.

PH IRB reserves the right to require additional training for Researchers working with Human Subjects in Research when it is deemed necessary.

IV. References

- A. U. S. Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP), Federalwide Assurance (FWA) For the Protection of Human Subjects
<http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm>
- B. Basic HHS Policy for Protection of Human Research Subjects - Definitions, [45 CFR 46.102](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102)
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102>

Origination Date: 04-2010	Source: PH IRB
Revision Date(s):	Authorized by: Institutional Official