SUBJECT: Education and Training: Investigators and Research Staff

POLICY: RA:HRPP:10.03

DATE EFFECTIVE:

I. POLICY

Children's National Medical Center (CNMC) requires all individuals who are considered "engaged in research" (see RA:HRPP:02.01 and 02.01P, *Human Subjects Research: Definitions and Determinations*) to complete training in human research protection issues prior to their involvement in human subjects research. The type and amount of training required is contingent upon the individual's role in the performance of the research.

CNMC requires evidence of continuing education in human subject protections every two years.

II. ACCOUNTABLE EXECUTIVE AND REVIEWER(S)

A. Accountable Executive: Chief Academic Officer/Institutional Official for the Federalwide Assurance
B. Department Responsible for Review: Office for the Protection of Human Subjects
C. Committee Responsible for Review: Institutional Review Board Executive Committee
Research Policy/Procedure Working Group

III. APPROVAL

Approved by:

IRB Executive Committee — 10/01/2009
Date

Research Policy/Procedure Working Group — _____
Date

_____ — _____
Mark L. Batshaw, M.D., Chief Academic Officer — Date

IV. APPLICABILITY

Areas where the policy and procedure applies: Children's Research Institute, Children's National Medical Center

Persons to whom the policy and procedure applies: Investigators, research staff

V. REVIEW OR REVISION DATE

Original:

VI. REFERENCES

AAHRPP Element(s):

Policies and Procedures: RA:HRPP:02.01 and 02.01P, *Human Subjects Research: Definitions and Determinations*

SUBJECT: Education and Training: Investigators and Research Staff

PROCEDURE: RA:HRPP:10.03P

DATE EFFECTIVE:

I. PROCEDURE

A. General

1. Children's National Medical Center (CNMC) recognizes the importance of having a strong, comprehensive educational program that ensures that individuals involved in the performance of human subjects research at CNMC understand the ethical principles and regulatory requirements related to the protection of human subjects. All individuals who are "engaged in research" (see RA:HRPP:02.01 and 02.01P, *Human Subjects Research: Definitions and Determinations*), including Principal Investigators, co-investigators, study coordinators/project managers, research assistants, nurses, laboratory technicians, clinic staff, and others who interact with subjects and/or their data as part of a research protocol, must complete certain educational requirements prior to their involvement in a study.

2. Because investigators and their staff members assume different roles and responsibilities in the conduct of human subjects research, the CNMC Office for the Protection of Human Subjects (OPHS) has developed training requirements that take into consideration the different roles assumed in the research project. OPHS and the Institutional Review Board (IRB) have determined that the type and amount of training required depends on whether or not there is actual intervention or interaction with subjects.

B. Collaborative Institutional Training Initiative (CITI)

Children's National Medical Center is a subscribing member of the Collaborative Institutional Training Initiative (CITI), a web-based training program in human research protections. Completion of CITI training is required before an individual may perform any research activities.

1. Who Must Complete CITI Training
    a) All Principal Investigators (PIs) on research protocols involving any intervention or interaction with research subjects or their data must complete the CITI training before they submit a protocol for IRB

review. This is a requirement regardless of whether or not the PI actually performs the research procedures.

b) All other CNMC employees who intervene or interact with research subjects (including obtaining informed consent) and/or their data also are required to complete the web-based CITI training program. This includes co-investigators, study coordinators/ project managers, research assistants, research nurses, laboratory technicians, and clinic staff members who perform research activities. Training requirements must be successfully completed before any individual may be included on a research protocol.

c) Any non-CNMC employees listed on a protocol who intervene or interact with research subjects (including obtaining informed consent) and/or their data are required to provide evidence of having completed human research protection training at another institution within the last 2 years. If such evidence is not provided, the individual must complete the CNMC-required CITI training if he or she is to remain on the protocol.

d) If a research project has recognized subcontracts or collaborator arrangements, and the subcontractors or collaborators are involved with human subjects or their data at an offsite location or another institution, personnel may either provide evidence of completing human subject training at another institution, or complete the CITI tutorial.

2. Human Subject Protection Training at Other Institutions

CNMC employees must complete the required CITI training in human research protections regardless of whether they completed other non-CITI training programs at another institution. Evidence of completion of CITI training through other institutions will be accepted provided that the training was completed within the past 2 years. Any additional CNMC CITI requirements not completed through another institution must be successfully completed before the IRB will review a protocol submission that includes the individual.

3. Required CITI Modules

There are three different module tracks in CITI: One for biomedical research, one for behavioral/social science research, and one for research limited to the analysis of data or laboratory specimens. Investigators and research staff are to choose the track that corresponds to the type of research in which they are engaged. More than one track may be applicable. The course requirements for each of the module tracks are shown in Table 1.

Table 1. CITI Course Requirements for the Biomedical Research, Social/Behavioral Research, and Data or Laboratory Specimens Only Research Modules

Biomedical Research	Social/Behavioral Research (SBR)	Data or Laboratory Specimens Only Research
Belmont Report and Course Introduction	Belmont Report and Course Introduction	Belmont Report and Course Introduction
History and Ethical Principles	Students in Research - SBR	History and Ethical Principles
Basic Institutional Review Board (IRB) Regulations and Review Process	History and Ethical Principles - SBR	Defining Research with Human Subjects - SBR
Informed Consent	Defining Research with Human Subjects - SBR	Informed Consent
Social and Behavioral Research for Biomedical Researchers	The Regulations and the Social and Behavioral Sciences - SBR	Basic IRB Regulations and Review Process
Records-Based Research	Assessing Risk in Social and Behavioral Sciences - SBR	Records Based Research
Genetic Research in Human Populations	Informed Consent - SBR	Genetic Research in Human Populations
Research With Protected Populations - Vulnerable Subjects: An Overview	Privacy and Confidentiality - SBR	Research with Protected Populations
Vulnerable Subjects - Research with Prisoners	Research with Prisoners - SBR	Vulnerable Subjects - Research Involving Minors
Vulnerable Subjects - Research Involving Minors	Research with Children - SBR	Vulnerable Subjects - Research Involving Pregnant Women and Fetuses in Utero
Vulnerable Subjects - Research Involving Pregnant Women and Fetuses in Utero	Research in Public Elementary and Secondary Schools - SBR	Group Harms: Research with Culturally or Medically Vulnerable Groups
Group Harms: Research with Culturally or Medically Vulnerable Groups	International Research - SBR	HIPAA and Human Subjects Research
FDA-Regulated Research	Internet Research - SBR	Conflicts of Interest

Biomedical Research	Social/Behavioral Research (SBR)	Data or Laboratory Specimens Only Research
HIPAA and Human Subjects Research	HIPAA and Human Subjects Research	
Workers as Research Subjects-A Vulnerable Population	Workers as Research Subjects-A Vulnerable Population	
Conflicts of Interest in Research Involving Human Subjects	Conflicts of Interest in Research Involving Human Subjects	
Good Clinical Practices (GCP)	Good Clinical Practices (GCP) (required if engaged in greater than minimal risk social/ behavioral research)	

a) Individuals engaged in biomedical research must also complete the CITI Good Clinical Practices (GCP) training.
b) Individuals engaged in social/behavioral research that presents greater than minimal risk to subjects (e.g., an intervention trial) must also complete the CITI Good Clinical Practices (GCP) training.
c) Individuals whose engagement in human subjects research is limited to chart/medical records review, discarded biological specimens, database inquires, and data analysis or statistical support should complete the CITI modules for "data or laboratory specimens only." They have the option of taking the GCP training module, but it is not required.
d) If at any time an individual's role or type of research changes, placing him or her in a different category of CITI training, the modules corresponding to the individual's new circumstances must be completed, as listed in Table 1 above.

4. Accessing CITI
   a) To start the CITI course, investigators and research staff should log onto the training site (http://www.citiprogram.org), register as a user, and select CNMC as their affiliate institution. (If already affiliated with another institution, individuals should also affiliate themselves with CNMC.) They then select the appropriate educational modules, read the text, and complete the quizzes. A minimum of 80% of the quiz items must be answered correctly to achieve a passing score on the module. Scores are automatically compiled in an online Grade Book. Complete instructions for using CITI are available on the IRB/OPHS intranet site under "Human Subjects Training."

b) Investigators and research staff are able to access the training activities they have completed from their CITI log in the "Learners Group" section and print out a certificate of completion for their own records, as necessary. It is not necessary

5. Continuing Education
    a) In addition to completing initial CITI human subject protections training, CNMC requires all individuals engaged in human subject research to complete continuing education every two years.
    b) The CITI web-based training has refresher modules. Investigators and staff will receive an email reminder from CITI to complete the refresher training for continuing education every two years.

6. Verification of Completion of CITI Training
    a) A staff member in the Office for the Protection of Human Subjects (OPHS) is assigned the role of Collaborative IRB Training Initiative (CITI) Administrator for CNMC. The Administrator has access to a database of training completion records for all CNMC users, and uploads updates onto the OPHS share drive for access by all OPHS staff on a weekly basis.
    b) Investigators are required to list on each new protocol application form all personnel who will be working on the study and their roles (e.g., obtain informed consent, intervene or interact with subjects, data analysis, review medical records, handle specimens, etc.). Changes in study personnel must be reported to the IRB using a Personnel Change Amendment.c) As part of the protocol regulatory pre-review, the IRB Regulatory Analysts check each member of the research team listed on the protocol application and their role against the CITI database to determine whether they have completed the appropriate training.
        i. If a Principal Investigator on the protocol has not completed the required initial or refresher CITI training, the protocol/continuing review will not be processed or approved until he or she has done so.
        ii. If a co-investigator or staff member listed on the protocol has not completed training, the PI will be informed as part of the OPHS pre-review. The co-investigator/ staff member must either complete the training or the PI must remove his or her name from the protocol before the OPHS processing of the submission can continu. If an individual is removed from the protocol, they may be reinstated after their training is completed, through the PI submission and IRB approval of a Personnel Change Amendment.

C. Other HRPP Education

The OPHS presents human subjects training opportunities to the CNMC research community on an ongoing basis. The topics presented represent opportunities to strengthen the knowledge and understanding of "hot topics" in the human subjects protections arena. Attendance at some of these training sessions may be mandatory.

D. Faculty/Departmental Staff Meeting Presentations

The IRB Chair, the Director of Research Regulatory Affairs, and the Education Manager are available to attend faculty and departmental staff meetings to present topics in human subject protections. Departments may request presentations on topics they feel would most benefit their faculty and staff. These presentations also provide faculty and staff with the ongoing opportunity to interact with the leadership of the IRB; to express issues, concerns, and problems; and to ask pertinent questions.

E. Individualized Training

OPHS staff members provide ongoing individualized training to members of the CNMC research community. Investigators are encouraged to seek the assistance of the OPHS staff when planning a protocol or when responding to IRB questions and concerns. OPHS staff members are trained to identify each requirement, describe what it is, and provide a rationale for why it is required. In this way, human subject protection training is continually reinforced. Research staff members also frequently contact OPHS staff for information on IRB submission requirements.

II. REVIEW OR REVISION DATE

Original:

III. REFERENCES

AAHRPP Element(s):

Policies and Procedures: RA:HRPP:02.01 and 02.01P, *Human Subjects Research: Definitions and Determinations*