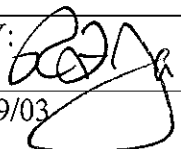


**ARKANSAS CHILDREN'S HOSPITAL RESEARCH INSTITUTE
LITTLE ROCK, ARKANSAS**

SUBJECT: Training in the Protection of Human Subjects in Research	DATE: 11/26/07	PAGE: 1 of
	APPLICATION: Hospital/ACHRI	DISTRIBUTION:
	APPROVED BY: 	ACHRI/MD-9-08
RECOMMENDED: ACHRI Administration	Supersedes: 7/29/03	

Purpose

The purpose of this policy is to define the Human Subject Protection educational requirements for investigators, key personnel, and others involved in human subject research conducted on the ACH/ACHRI campus.

Policy

Recognizing the complexity of the federal, state, and campus policies and regulations created to adequately protect the rights of human subjects in research, ACHRI and UAMS have adopted the mandatory education program outlined below for all IRB members, Principal Investigators, and all key research staff having contact with human subjects, human subject data, or biological specimens. Key research staff may be defined as those persons whose responsibilities may include, but are not limited to, day-to-day protocol decision-making related to the study conduct; subject recruitment, selection and eligibility; clarification of the complexities of the protocol to the subject and others; collecting subject information; and entering data.

Re-certification is required every two years after completion of the initial educational program requirement.

Scope

The requirements of this policy apply to the following individuals:

1. All Investigators and persons participating in the conduct of human subject research, including faculty, residents, and students.
2. Faculty Supervisors of student investigators who submit a human subjects protocol to the IRB for review and approval.
3. Persons responsible for, but not limited to, day-to-day protocol decision-making related to the study conduct; subject recruitment, selection and eligibility; clarification of the complexities of the protocol to the subject and others; collecting subject information; and entering data.

4. Research Coordinators, Research Nurses, and Research Assistants/Associates
5. Members of the UAMS IRB
6. Any others who conduct or have incidental contact with research on the Arkansas Children's Hospital/Arkansas Children's Hospital Research Institute campus

Definitions

PRINCIPAL INVESTIGATOR

As the leader of the investigational team, this individual is responsible for conducting the research and ensuring the safety and welfare of the study subjects.

KEY RESEARCH PERSONNEL

Individual involved in the design and/or conduct of research which involves human subjects and whose responsibilities are delegated by the Principal Investigator. This includes anyone who conducts or has incidental contact with research on the Arkansas Children's Hospital/Arkansas Children's Hospital Research Institute campus. This specifically includes but is not limited to the following personnel: Research Associates, Research Assistants, Research Coordinators, Research Nurses, Sub-Investigators, Specialty Nurses, Office Personnel, and other personnel whose job responsibilities may include but are not limited to the day-to-day protocol decision-making related to the study conduct; subject recruitment, selection and eligibility of subjects; clarification of the complexities of the protocol to the subject and others; collecting subject information and entering research data.

INCIDENTIAL CONTACT PERSONNEL

Individual whose main purpose is not research but may come in contact with a research project while performing their regular job duties. These personnel would include, but are not limited to, clinical staff who do not have direct involvement in the conduct of research procedures and students conducting chart reviews as determined by the IRB.

Accepted Educational Programs

Completion of one of the following educational programs will meet mandatory ACHRI and UAMS requirements for investigators and key personnel involved in human subject research.

All staff who conduct or assist in research must take either Biomedical or Social & Behavioral Courses

1. Successful completion of the Collaborative Instructional Training Initiative (CITI) course. Researchers should register with the CITI program at www.citiprogram.org and affiliate with either ACHRI or UAMS (preferably both). Researchers will then enroll in one of the Human Subject Protection Learner Groups appropriate to their research discipline:
 - a. Biomedical Research Investigators

The Biomedical Course is appropriate for persons whose research involves drugs, devices, and surgical/ invasive procedures.
 - b. Social & Behavioral Research Investigators

The Social & Behavioral course is relevant to those disciplines and is not appropriate for investigators whose research involves drugs, devices or surgical/invasive procedures.

For staff who have only incidental contact with research:

c. Incidental Research Contact & Students

The Incidental Research Contact module is relevant to those whose main purpose is not research but may come in contact with a research project while performing their regular job duties. Personnel who would take this course include clinical staff who do not have direct involvement in the conduct of research procedures and students conducting chart reviews as determined by the IRB.

For IRB Members:

d. IRB Members

The IRB Members module is relevant to those currently serving on the IRB per UAMS IRB policy.

Undergraduate and High School Students:

e. Students conducting no more than minimal risk research

The Students module is available to undergraduate and high school students who are performing no greater than minimal risk research as part of their normal class work.

General Information

The HIPAA for Research course previously given has now been included in all CITI modules. A separate training course in HIPAA is no longer required. The HIPAA course is a short overview of the researcher and key research personnel responsibilities for confidentiality, use and disclosure of Public Protected Health Information obtained during research. UAMS and ACH each have additional institutional privacy policies and may require additional training on HIPAA.

On a case-by-case basis, the UAMS IRB Director and the Office of Research Compliance Director will consider other programs to determine if they meet these educational requirements.

Persons should save a copy of all certificates of completion and should forward a copy of the certificate(s) to the IRB.

Deadline for Compliance

Effective September 4, 2007, all persons to whom this policy applies must have documentation of one of the acceptable courses listed above for Human Subject Protection. **Grandfather Clause: Those who have taken the UAMS Online Human Subject Protection and HIPAA training, and whose training will expire between September 5, 2007 and September 3, 2009 will be allowed to complete the CITI program when their current training expires.

Penalty for Noncompliance

Persons without appropriate training may be subject to one or more of the following the disciplinary actions:

1. ACHRI will not submit the IRB required ACHRI sign-off letter to the UAMS IRB on the Principal Investigator's behalf.
2. All research accounts will be frozen.
3. Research support services will be suspended.
4. Suspension of investigational drug dispensing, which would require IRB notification.
5. Notification sent to the Investigator's department chair regarding non-compliance.
6. And, any additional actions taken by UAMS or ACHRI, for non-compliance to this policy.

Re-certification

Re-certification will be required every two years through one of the methods below:

- Completion of the web-based refresher modules at www.citiprogram.org
- Other programs may be an acceptable alternative to the above courses. Please contact the Office of Research Compliance if this is chosen as an option.

For More Information

Questions concerning this policy should be directed to the ACHRI Regulatory Compliance Specialist at 501-364-7373.

Other Contact Numbers:

UAMS: IRB Director: 501-686-8845