

## **Protection of Human Subjects**

The University of Alabama at Birmingham has an approved Assurance of Compliance on file with the Department of Health and Human Services. The Assurance Identification Number is M1149. The Institutional Review Board Number is O1NR. Research by the trainees on this training grant that is not covered by their preceptor's protocol and IRB approval will be submitted for expedited or full IRB review, depending on the nature of the research. If a current trainee is participating in research involving human subjects under a currently covered protocol, the protocol number and date of last renewal is provided annually as part of the non-competitive progress report.

### **1. Risks to Human Subjects**

#### **1.a. Human Subjects Involvement, Characteristics, and Design**

Based on projects previously conducted by our T32 trainees and mentors, most projects for current and future trainees will involve human subjects, but will likely differ in terms of characteristics and study design. When applicable, each trainee will actively engage stakeholders (i.e. patients, physicians, payers, etc.) during each phase of the project including design and implementation.

#### **1.b. Sources of materials**

Based on projects previously conducted by our T32 trainees and mentors, data for each trainee's project may be both existing and original. Original data may be collected as part of a prospective trial through surveys or other data collection methods. Trainees may also use existing administrative databases (i.e. Medicare/Medicaid) as part of their research projects.

#### **1.c. Potential Risks**

Most of the projects conducted by T32 HSOER trainees are likely to be observational and present minimal risks to subjects in relation to importance of the knowledge that may be expected to follow from the studies. Projects are likely to impact the care of individual patients, and so would confer benefit to the individuals through this knowledge to be gained. The major risk for these studies will be the risk of breach of data confidentiality. To minimize this risk, any paper or electronic data linking study identification numbers, identifiers and health information will be kept secured and accessible only by authorized personnel working on a trainee's study. In summary, the significant potential benefits are substantial compared to the small risks associated with collecting and analyzing the data.

### **2. Adequacy of Protection Against Risks**

#### **2.a. Recruitment and Informed Consent**

Research by the trainees on this grant that is not covered by their preceptor's protocol and IRB approval will be submitted for expedited or full IRB review, depending on the nature of the research. When applicable, trainees will follow appropriate IRB procedures for obtaining informed consent. Based on projects previously conducted by our T32 trainees and mentors, recruitment will vary based on the study design. All participants that meet study eligibility will be recruited regardless of sex or minority status.

#### **2.b. Protection Against Risks**

The release of personal information is highly unlikely as data safeguards will be maintained throughout the study. To protect against the risk of loss of confidentiality we will use a secure system of file storage. Personal health information (PHI) will not be disclosed to other non-study personnel or used for any other purposes except as outlined in a trainee's study protocol. In no way will individual patient-level data be released to the public or cited in a publication. Data will not be released from which it will be possible to reconstruct the identity of any physician or patient. All data will be encrypted and held in a physically secure environment with access only on a "need to know" basis. Data intended for broader use will be free of identifiers that permit linkage to individual research participants and variable that could lead to the disclosure of the identify of an individual subject. We have substantial experience with implementing these methods successfully. All study personnel will sign strict confidentiality agreements.

### **3. Potential Benefits of the Proposed Research to Human Subjects and Others**

The types of projects conducted by our trainees have the potential to improve health care for patients, physicians, and health care systems and help reduce health care disparities especially in underserved

populations. Trainee projects also provide stakeholders to be active participants in all phases of the research project including design and implementation.

#### **4. Importance of the Knowledge to be Gained**

The importance of clinical and research knowledge that may be gained from trainee research projects is thought to outweigh the minimal risks that might affect participants. With involvement with stakeholders (i.e. patients, physicians, administrators, etc.), there is potential for these studies to improve health care.

#### **5. Data and Safety Monitoring Plan**

If a trainee's project requires a Data and Safety Monitoring Board, program leadership will assemble the board in conjunction with AHRQ officials.

#### **6. ClinicalTrials.gov Requirements**

Research projects that meet the requirements to be registered on ClinicalTrials.gov will be registered.

#### **7 Inclusion of Women and Minorities**

For research projects, the entire cohort of eligible patients, regardless of sex or minority status, will be included. Some projects will examine disparities in care among racial and ethnic groups. As such, some projects will purposely over-sample minority populations to ensure an adequate representation.

#### **8. Targeted Planned Enrollment**

Not applicable.

#### **9. Inclusion of Children**

Projects proposing children to be involved in research will undergo special population review and approval process by the governing UAB IRB. This IRB approval process complies with the Additional Protections for Children Involved as Subjects in Research Code of Federal Regulations.