SOP: 603E
PARTICIPANT OUTREACH PROGRAM

1. POLICY

The University shall provide educational information to the community through an outreach program concerning human research in general and specifically the human research participant program of the University.

Specific Policy

1.1 The purpose of the Participant Outreach Program is to provide updated information to individuals in the community about research involving humans, what constitutes good clinical research, and who to contact with questions about research. The University shall accomplish this purpose through:

A. Contact Telephone Number
B. Internet Web Site
C. Educational Workshops

A. Contact Telephone Number
The IRB shall require that all participants receive a contact telephone number in their informed consent documents as well as a statement about who to contact with questions concerning research participant rights. The format of this section is included in the Consent Form Template located on the IRB website.

B. Internet Web Site
The IRB shall maintain an internet web site as a resource for study participants, whether prospective, current, or former. The web site shall provide a range of educational information from the history of research involving human participants to current research opportunities available. Links to other entities may also be included in the website.

C. Educational Seminars
HRPP shall conduct educational seminars for the community. Educational seminars shall be announced to the community on the IRB internet website. The curriculum of the seminars shall be developed to foster an understanding of research within the community.

1.2 The HRPP Director, the IRB Education Coordinator, and the Quality Improvement Coordinator shall evaluate the Participant Outreach Program activities on an annual basis and implement improvements as necessary.

2. Scope

These policies and procedures apply to all human research submissions.

3. Responsibility

A designated IRB staff member is responsible for managing and updating the IRB Outreach Website as indicated by HRPP Director. This designated IRB staff member is responsible for handling comments regarding the website, according to the content of the comments received, and presenting the comments to the HRPP Director.

The HRPP Director is responsible for providing support and direction for the management of the IRB Outreach Website and for acting on comments of outreach participants, whether positive or negative. The HRPP Director will provide feedback to the Director of Compliance.

The Director of Compliance is responsible for addressing serious concerns of investigator/study staff issues brought up by research participants participating in the Participant Outreach Program.

4. Applicable Regulations and Guidelines

45 CFR 46.113

45 CFR 56.108(b), 56.113

5. References to Other Applicable SOPS

SOP 701, Consent Process and Documentation.

6. Attachments

603E-A Web-Based Site for Study Participants

7. Process Overview

7.1 Information contained in the consent documents is reviewed per SOP 701, Consent Process and Documentation, to assure that contact numbers are available to participants in the case of injury or for questions regarding being a research participant.

7.2 Internet website information is maintained by the HRPP Director or designee.

7.3 Feedback from participants received in the IRB is directed to the HRPP Director. The HRPP Director notifies the Director of Compliance as indicated.

7.4 The IRB Education Coordinator schedules educational seminars for the community. Seminars and educational materials are provided free of charge.

APPROVED BY:_____ **DATE: 09/01/2009**

NEXT ESTABLISHED REVIEW DATE: MAY 2012