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 information to individuals in the community about research involving humans, what constitutes ethical research, and who to contact with questions about research. The University shall accomplish this purpose through:

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.

B. Internet Web Site

The HRPP shall maintain an internet web site as a resource for prospective, current, or former research project participants. 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’ web pages may also be included in the website.

C. Educational Activities

HRPP shall make available educational activities for the community. Educational activities shall be announced to the community on the IRB website. The curriculum of the educational activities shall be developed to foster an understanding of research within the community.

1.2 The HRPP Director, the HRPP Education Coordinator, and the Quality Improvement Specialist shall periodically evaluate the Participant Outreach Program activities and implement improvements as necessary.

2. Scope

This SOP applies to all human research projects.

3. Responsibility

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 the outreach participants’ feedback to the Director of Compliance.

The Director of Compliance is responsible for addressing serious concerns of research misconduct raised by research participants participating in the Participant Outreach Program.

4. Applicable Regulations and Guidelines

45 CFR 46.116
45 CFR 56.108(b), 56.113
5. References to Other Applicable SOPS
   SOP 701: Consent Process and Documentation

6. Attachments
   None

7. Process Overview
   7.1 Information contained in the informed 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 IRB website information is maintained by the HRPP Director or designee.
   7.3 Feedback from participants received by the HRPP or IRB staff is directed to the HRPP Director. The HRPP Director notifies the Director of Compliance as indicated.
   7.4 The HRPP Education Coordinator makes available educational activities for the community. Educational materials are provided free of charge.

APPROVED BY:_______________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020