

14.0 Participant Outreach Activities

14.1 Responsibility

It is the responsibility of the HRPP Director or designee to implement the procedures outlined below.

14.2 Outreach Resources and Educational Materials

In order to involve and inform current and future research participants in accordance with the Belmont principle of Respect for Persons, Pennington Biomedical Research Center HRPP maintains a “Research Participants” page on the HRPP website. This page provides resources for research participants. In addition, research participants are invited via the website to contact HRPP/IRB staff to provide feedback and/or obtain information about human subjects research and HRPP activities.

The following resources are provided to participants:

- Opportunity to submit concerns, trial information and receive feedback.
- Participant Brochure
- Links to government websites (e.g., OHRP, FDA, NIH)

14.3 Questions, Concerns and Complaints

All complaints, concerns and questions received by the IRB from any individual through the Concerns and Complaints Form or any form of communication will be acknowledged and forwarded to the appropriate individual within the Institution for handling and follow-up. While the IRB expects a prompt resolution, the time frame is dependent on the complexity of the complaint or concern.

Contact information for reporting complaints or concerns is provided in the informed consent, participant brochure and the HRPP website.

14.4 Periodic Evaluation

Pennington Biomedical Research Center periodically evaluates its outreach activities and makes changes when appropriate. These evaluations take place in an informal, ongoing manner. All IRB members, IRB Chair, IRB Staff and HRPP Staff will report both positive and negative feedback regarding outreach activities to the HRPP Director who will track the input and suggest changes be made to improve outreach activities. The HRPP Director will summarize the material annually in order to formally evaluate its outreach activities and determine:

1. The specific community outreach activities being used; and
2. Whether or not these community outreach activities have an evaluative component, and if so what, if any, changes in the outreach activities have resulted from these.