SOP: 603D
COMMUNICATION WITH RESEARCH PARTICIPANTS

1. POLICY

Communications received from research participants shall be directed to the HRPP Director for prompt response. The HRPP Director shall provide a safe, confidential, and reliable means for participants, whether past, present, or prospective, to voice concerns or questions regarding their participation in a research project or to request information regarding a research project.

Participants who have questions or comments related to their participation will be directed to an informed individual who is unaffiliated with the research project.

When findings from a research project indicate that participants may be at increased risk that was not anticipated at the time of study initiation, the IRB shall request the Investigator to provide written notification to current and past participants regarding those developments and verify their willingness to continue participation, if applicable.

Specific Policy

1.1 Prospective Participant Request for Information

- 1.1.1 Regardless of the mode of communication (letter, telephone call, or email), all research participant communications shall be directed to the HRPP Director or designee for review.
- 1.1.2 The HRPP Director shall process requests for information, if possible, based on the ability of the IRB database to generate such data.

1.2 The HRPP and IRB Staff shall forward phone calls or correspondence immediately to the HRPP Director or designee when the correspondence pertains to concerns or problems a participant encountered while participating in a research project.

- 1.2.1 The HRPP Director or designee shall receive and maintain the information in a manner that is safe and confidential.
- 1.2.2 The HRPP Director or designee shall direct the participant to an informed individual who is unaffiliated with the research project so that the participant may further discuss specific concerns.
- 1.2.3 The HRPP Director or designee shall report research participant communications to the Director of Compliance, if applicable.

1.3 In the absence of the HRPP Director or designee, the IRB Staff shall immediately forward all communication from participants to the Director of Compliance.

2. Scope

This policy applies to all human participant research.

3. Responsibility

The IRB Staff is responsible for immediately directing all study participant communication to the HRPP Director.

The HRPP Director is responsible for immediately addressing communications, notifying Director of Compliance as necessary, and notifying OHRP as necessary.

The Director of Compliance is responsible for addressing serious concerns of Investigator/study staff issues raised by research participants.

4. Applicable Regulations and Guidelines

45 CFR 46.116,
21 CFR 50.25

5. References to Other Applicable SOPS

SOP 407, Unanticipated Problems Involving Risks to Participants or Others and Protocol Deviations
SOP 901, Quality Improvement Program
SOP 903, Non-Compliance/Scholarly Misconduct.

6. Attachments

None.

7. Process Overview

7.1 If the IRB receives written communication from a research participant, the IRB forwards it to the HRPP Director or designee immediately.

7.2 If the communication is verbal, the IRB will record the information in such a way as to protect the identity of the caller, if the caller wishes to remain anonymous. If the communication is via the telephone, the IRB will direct the call to HRPP Director or designee immediately. If an individual presents to the IRB office, the IRB will provide direct access to HRPP Director or designee.

7.3 The HRPP Director notifies the Compliance Officer of the FDA and/or requests site evaluation as required in SOP 407, Unanticipated Problems Involving Risks to Participants or Others and Protocol Deviations; or SOP 903, Non-Compliance/Scholarly Misconduct, as applicable.

7.4 The HRPP Director, in conjunction with the Compliance Officer as required, works to resolve participant issues.

7.5 The HRPP Director documents communication with participant, directs the participant to appropriate federal agencies as indicated, and retains the communication on file at the IRB Office.

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

NEXT ESTABLISHED REVIEW DATE: MAY 2012