SOP 603D: Communication with Research Participants

1. POLICY

Communications received from prospective or current research participants shall be promptly 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, comments, or complaints related to their participation will be directed to the HRPP Director or to a designee who is unaffiliated with the research project.

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

Specific Policy

1.1 Prospective Participant Request for Information

All communications from prospective participants shall be directed to the HRPP Director or designee for review.

1.2 Current Research Participants

1.2.1 The HRPP and IRB Staff shall notify the HRPP Director or designee of participant correspondence pertaining to concerns or problems a participant encountered while participating in a research project promptly.

1.2.2 The HRPP Director or designee shall receive and maintain the information in a manner that is secure and confidential.

The HRPP Director or designee may direct the participant to other University officials who are unaffiliated with the research project so that the participant may discuss concerns specific to the officials’ duties.

1.2.3 The HRPP Director or designee shall report research participant allegations that suggest research noncompliance or scholarly misconduct to the Director of Compliance as described in SOP 903: Noncompliance/Scholarly Misconduct. In the absence of the HRPP Director or designee, the HRPP and IRB Staff shall promptly forward all such communication from participants to the Director of Compliance.

2. Scope

This SOP applies to all human participant research.

3. Responsibility

3.1 The HRPP and IRB Staff are responsible for promptly directing all research participant communication to the HRPP Director.

3.2 The HRPP Director or designee is responsible for documenting all participant complaints received.
3.3 The HRPP Director or designee is responsible for promptly addressing potential or current research participant communications, notifying the Director of Compliance, HSC Vice President for Research, and OHRP as necessary.

3.4 The Norman Campus Senior Vice President and Provost or the HSC Vice President for Research is responsible for addressing noncompliance and/or scholarly misconduct allegations 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: Protocol Deviations and Unanticipated Problems
   SOP 903: Non-Compliance/Scholarly Misconduct

6. Attachments

   None

7. Process Overview

   7.1 If the HRPP or IRB staffs receive communication from a prospective, current or former research participant, they shall notify the HRPP Director or designee promptly. If an individual presents to the IRB office, the IRB will provide direct access to HRPP Director or designee.

   7.2 The IRB will maintain the confidentiality of any prospective or current participant communication(s).

   7.3 For participant correspondence that involves research projects that are covered under FDA regulations, the HRPP Director or designee 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. The HRPP Director works with the Compliance Officer of the FDA, as required.

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

   7.5 The HRPP Director documents communications with participants, directs the participants to appropriate University officials and federal agencies as indicated, and retains the documentation of all communications on file at the HRPP Office.

APPROVED BY: ____________________________ DATE: 08/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016