OFFICE OF THE INSTITUTIONAL REVIEW BOARD

Standard Operating Procedures		
SOP #407.1 Revision 1	**TITLE: Participant Concerns/Complaints**	Effective Date: 3/1/2019
Approved By: OIRB Director	Signature 	Date 3/1/2019
Approved By: IRB Chair	Signature 	Date 3/1/2019

PURPOSE
To describe the procedures for handling concerns, complaints, or questions received regarding a research project involving human participants.

REVISIONS FROM PREVIOUS VERSION
Remove references to AVPRC and administrative corrections

POLICY
Research participants have a right to lodge a concern (allegation), complaint, or question and to be assured that the concern, complaint, or question is taken seriously and resolved in a timely manner. A research participant (past, current, or prospective), a designated spokesperson, family member, or anyone with a concern about a human research project may raise concerns, complaints, or questions about a research project by telephone, in writing (including email), or in person to the OIRB or IO. The OIRB Director or designee is responsible for investigating concerns, complaints, and questions from participants and any improprieties involving researchers or their staff. The OIRB Director or designee will investigate concerns in a timely manner, assuring the protection of human participants, and the IRB will hold researchers accountable to applicable regulations and policies.

An interested party may also raise a concern or complaint via the UNM Compliance Hotline at either https://secure.ethicspoint.com/domain/media/en/gui/42682/index.html or 1-888-899-6092. Each IRB approved informed consent document includes a telephone number to reach the Office of the IRB (OIRB); the toll free compliance hotline telephone number is also listed on the OIRB and University websites.

RESPONSIBILITIES
Execution of SOP: Researchers, IRB, OIRB, IO

PROCEDURE
Concerns/Complaints/Questions
1. A research participant or anyone with a concern, complaint, or question regarding a project involving human participants may raise the concern, complaint, or question with the OIRB and/or IO. Upon receipt of a concern, complaint, or question, the OIRB Director or designee gathers the information from the complainant as appropriate, using the Complaint Report.
2. The OIRB Director or designee will assure the complainant the issue will be reviewed and will explain the limits of confidentiality.
3. The concern, complaint, or question will be addressed in a confidential manner to the extent possible. The OIRB limits access to information concerning the issue to employees with responsibilities that require knowledge of the concern, complaint, or question.

4. Information regarding the concern, complaint, or question will be conveyed to the IRB Chair, and the PI of the project at issue, as appropriate, in a timely manner.
5. The OIRB Director or designee will promptly investigate the concern, complaint, or question; evaluate the alleged impropriety; and make every effort to correct the issue(s) at the administrative level.
6. If the alleged impropriety involves potential harm to participants or others, the Director or designee will notify the IRB for immediate action pending formal inquiry**.** The OIRB Director or designee will report concerns, complaints, or questions involving serious issues immediately to the IRB Chair, and the Institutional Official or their designee, and, if appropriate, the Office of University Counsel.
7. The OIRB and IRB will monitor any concerns, complaints, or questions that an individual may lodge for issues of noncompliance. The OIRB Director or designee will bring issues involving noncompliance to the attention of the IRB Chair and the IRB as appropriate (see Research Noncompliance SOP).
8. The OIRB Director or designee will manage the inquiry, preparing related correspondence, and maintaining documentation of the review as required by the university document retention policy.
9. The IRB Chair or designee ensures appropriate response to each concern, complaint, or question and reports the action(s) taken to the IRB. If the complaint, concern, or question is of a minor nature the IRB Chair or designee may resolve the issue without bringing it to the IRB for a vote. The IRB Chair or designee will refer major issues the IRB for action.
10. The IRB may take any of the following actions:
    - Further inquiry;
    - Seek legal counsel from the Office of the University Counsel;
    - Administrative action;
    - Details and recommendations forwarded to the appropriate committee chairs (e.g. COI Committee) for consideration in their committees;
    - Details and recommendations forwarded to the appropriate Department Chair, Center Director, and/or Dean for action as appropriate;
    - Details and recommendations forwarded to the Institutional Official for action;
    - Refer matters thought to rise to the level of research misconduct as outlined in Faculty Policy E40;
    - Details and recommendations will be forwarded to the appropriate officials at affiliated institutions for notification, action, and/or follow-up, if applicable, and;
    - Other actions as deemed appropriate, up to and including suspension or termination of the project.

REFERENCES

45 CFR 46.116(a)
21 CFR 50.25(a)