# Standard Operating Procedures

<table>
<thead>
<tr>
<th>SOP #407.0</th>
<th>TITLE: Participant Concerns/Complaints</th>
<th>Effective Date: 10/15/2015</th>
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</thead>
<tbody>
<tr>
<td>Revision 0</td>
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<tr>
<td>Approved By:</td>
<td>Signature</td>
<td>Date 10/23/2015</td>
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<td>OIRB Director</td>
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<td>Approved By:</td>
<td>Signature</td>
<td>Date 11/18/15</td>
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<td>IRB Chair</td>
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## PURPOSE
To describe the procedures for handling concerns, complaints, or questions received regarding a research study involving human participants.

## REVISIONS FROM PREVIOUS VERSION
None

## 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 study may raise concerns, complaints, or questions about a research project by telephone, in writing (including email), or in person to the OIRB or AVPRC. The Associate Vice President for Research Compliance (AVPRC) is responsible for investigating concerns, complaints, and questions from participants and any improprieties involving researchers or their staff. The AVPRC may designate this responsibility. The AVPRC or designee will investigate concerns in a timely manner, assuring the protection of human subjects, and the IRB will hold researchers accountable to applicable regulations.

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](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, AVPRC.

## PROCEDURE
Concerns/Complaints/Questions

1. A research participant or anyone with a concern, complaint, or question regarding a research study involving human subjects may raise the concern, complaint, or question with the OIRB and/or
AVPRC. Upon receipt of a concern, complaint, or question, the AVPRC or designee gathers the following information from the complainant as appropriate:

- Participant's (or complainant's) name, address, email and phone number (This information is NOT MANDATORY, and an individual may report an incident anonymously; however, the AVPRC or designee advises the individual that a thorough review may not be possible, and that, without this information, follow-up responses to the individual are not feasible.);
- Study protocol title (or acronym) and the name of the PI;
- Date(s) of the incident, and;
- An explanation of the concern, complaint, or question.

2. The AVPRC or designee will assure the complainant the issue will be reviewed. The AVPRC or designee will explain the limits of confidentiality.

3. The AVPRC or designee address the concern, complaint, or question 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. The AVPRC or designee will convey the information regarding the concern, complaint, or question to the OIRB Director, the IRB Chair, and the PI of the study at issue, as appropriate, in a timely manner.

5. The AVPRC 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 AVPRC or designee will notify the IRB for immediate action pending formal inquiry. The AVPRC or designee will report concerns, complaints, or questions involving serious issues immediately to the IRB Chair, the OIRB Director, 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 AVPRC or designee will bring issues involving noncompliance to the attention of the IRB Chair, the IRB, and the OIRB Director. (See Research Noncompliance SOP.)

8. The AVPRC 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, in collaboration with the AVPRC 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, the AVPRC, or designee(s) may resolve the issue without bringing it to the IRB for a vote. The IRB Chair, the AVPRC, or designee(s) 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. IRB or COI Committees) for consideration in their committees;
- Details and recommendations forwarded to the appropriate department chair 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, ard;
- 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)