

Title:	Research Participant Concerns and Complaints
Last Approval Date:	11/16/18
Previous Approval Dates:	None
Standard Operating Procedure:	7

7.1 Purpose

NC State University is committed to protecting the rights, safety, and welfare of research participants. Consistent with this commitment, NC State's Institutional Review Board (IRB) has established these expectations and procedures for handling questions, concerns or complaints from participants or third parties involved in research studies. This Standard Operating Procedure (SOP) addresses how complaints, concerns, and suggestions reported to the NC State IRB are addressed.

For purposes of this SOP, a participant concern or complaint means an expression of dissatisfaction by the participant (or their representative) that may or may not involve a breach in human subjects' rights or research ethics. Participants may choose to report concerns or complaints to the research study team, to a third party, or to the IRB Office.

7.2. Policy

All complaints, concerns, or suggestions regarding the conduct of human subject research by NC State University researchers may be brought to the attention of the NC State IRB Office. Research participants can express their concern, complain, or ask a question about a research study.

Complaints, concerns, and questions may be raised by past, present, and potential research participants, family members, designated spokespersons, or anyone else associated with the research project. All complaints, concerns, and questions can be provided to the IRB by phone, in writing via e-mail, in writing via mail, or in person.

Participants will have their complaint, concern, or question resolved in a timely manner. The NC State IRB office will follow its established procedures (see section 7.3.c) to resolve all complaints or concerns.

1. All complaints received regarding human subjects research conducted under the jurisdiction of the NC State IRB will be investigated and resolved.
2. Complaints that are reported are considered sensitive issues and the relevant information and the identities of individuals named in a complaint will be handled appropriately and confidentially to the greatest extent possible.
3. Complaints that indicate that a research participant's rights, safety or welfare may have been adversely affected, or were at risk of being adversely affected, shall be promptly reported to the IRB Office. Substantiated claims will be brought to the IRB Chair or IRB Full Board. Substantiated complaints may be further investigated through a directed review, and actions will be taken as deemed appropriate by the IRB, including reporting to sponsors and federal agencies.
4. A complaint that is determined to involve noncompliance, an unanticipated problem, or an adverse event will be promptly reported to the appropriate institutional officials, the Office for Human Research Protections (OHRP) and the Food and Drug Administration (if applicable) following necessary federal regulations and University policy.

7.3. Procedure for Receiving and Responding to Complaints, Concerns, or Suggestions

Complaints, concerns, or suggestions may be submitted to the IRB Office, the IRB Chair, IRB Full Board Members, the Principal Investigator, other researchers on the study, or individuals or offices within the University.

Participant complaints or concerns may be made to the IRB Office by phone, email, postal mail, or the NC State IRB Office [Website](#).

When a complaint is:

1. Submitted to general NC State faculty, staff, or student: When an issue is raised with someone from the general NC State population, the NC State affiliate should contact the PI for the research. If the NC State affiliate does not have enough information or is uncomfortable contacting the PI for the project, they may instead contact the NC State IRB Office.

2. Submitted to the Research Team: When an issue is raised with someone from the research team, they should contact the PI for the research. If the research team member is uncomfortable contacting the PI for the project, they may instead contact the NC State IRB Office.
3. Submitted to the PI: When an issue is raised with the PI for the project, the PI for the research should aim to resolve the issue efficiently, effectively, and completely. If the issue is significant in nature, the PI should contact the NC State IRB Office.
4. Submitted to an IRB Full Board Member: When an issue is raised with someone from the NC State Full Board, the Full Board member should contact the IRB Office or IRB Director.
5. Submitted to the IRB Full Board Chair: When an issue is raised with the NC State IRB Chair, the chair should contact the IRB Director to aid in information gathering and decision making.
6. Submitted to the IRB Office: When an issue is raised with the IRB office, the IRB Director will gather information from the participant, the research team, the PI, and other stakeholders. If appropriate the IRB Director will consult with the IRB Chair and the Director for Regulatory Compliance. Once the issue is identified and clarified, the IRB Director will resolve the issue or bring the issue to the Full Board for review.

A. Principal Investigator Responsibilities

The principal investigator (“PI”) is responsible for answering all questions, addressing all concerns, and responding to all complaints raised by participants . The name and contact information of the investigator responsible for the research is required in all NC State consent documents. If there is more than one PI on the project, each PI is equally responsible for complying with this SOP.

1. PIs are responsible for ensuring that complaints are handled in a thorough, timely and respectful manner.
2. PIs who receive any complaints or concerns that are more than minor are required to report such incidents to the NC State IRB.
 - a. As a study investigator, the PI and their staff are obligated to make a good faith effort to promptly respond to — and to try to resolve — any study-related concern or complaint you receive or of which you are aware.
 - b. A complaint/concern is significant if it may adversely impact a participant’s or a potential participant’s safety, rights or welfare. Additionally, any complaint/concern that requires a change to the study protocol or consent form is considered significant.
 - c. Minor concerns do not adversely impact a participant’s or a potential participant’s safety, rights or welfare and they do not require changes to the study protocol.
3. Participants should not be penalized for raising a concern, complaint, or question.
4. PIs should address the complaint in a timely manner and communicate its resolution to the complainant.
5. PIs must document significant complaints received from participants or third parties and their resolution and report them to the IRB Office.
6. When, despite best efforts, the PI is unable to resolve a complaint, the complaint should be reported to the NC State IRB. PIs are expected to act in good faith and cooperate with the IRB in order to resolve participant complaints or concerns.
7. Throughout the implementation of the research, PIs are responsible for:
 - a. Including contact information for the PI and the NC State IRB office in the IRB-approved informed consent document. Participants may contact the PI directly or the IRB about their rights as a research participant or with any questions or concerns about the study. Participants may contact the IRB office if they wish to speak with someone other than the study researchers.
 - b. Answering any and all questions of the research participants and providing contact information if future questions or concerns arise.
 - c. Responding as quickly as possible to any questions, concerns, or complaints received from participants or any other individuals before, during, and after study implementation.
 - d. Reporting complaints or concerns that involve potential risks to participants or others, that results in a change in the risk-potential benefit profile of the study, or cannot be resolved by the PI/research staff, to the NC State IRB
 - e. Considering and evaluating any suggestions that participants may have, and make improvements to their research and associated processes as appropriate.

8. Any complaint or concern received and resolved by the PI that does not involve risk to participants or others, or does not change the risk-potential benefit profile of the study should be submitted in a summary format to the IRB during the renewal process.

B. IRB Responsibilities

The NC State IRB Director is responsible for managing complaints received by the IRB Office. The IRB Chair will consult with the IRB Director as needed to resolve complaints. To the extent possible, the IRB Office will maintain privacy of the complainant where privacy is a concern or when requested by the complainant. In order to manage the complaints, the IRB Director is responsible for the following:

1. The IRB Director, as a designee of the IRB Chair, is responsible for communicating with the complainant and for conducting the initial investigations of all concerns and complaints brought to the attention of the IRB regarding research being conducted by NC State.
2. The IRB Director will gather information from the participant (or others) regarding the participant complaint or concern.
3. The IRB Director will investigate the complaint or concern using records provided by the participant and from the IRB Office's records.
4. The IRB Director will inform the principal investigator of the complaint and request a response to the issues raised in the complaint.
5. The IRB Director will work with the principal investigator, the IRB Chair, or the Director for Regulatory Compliance in order to resolve the complaint.
6. The IRB Office will address the complaint in a timely manner and communicate its resolution to the complainant.
7. The IRB Office will maintain records of complaints and their resolution, and a copy will be retained with the applicable protocol.
8. Should the complaint or concern result in an allegation of noncompliance or result in the suspension or termination of the research, the IRB will follow the procedures outlined in the NC State Noncompliance Policy.

C. IRB Procedures

Concerns and complaints, whether verbal or in writing, that are received by the IRB Office will be processed in accordance with the following:

- 1) **Confidentiality.** All complaints and concerns will be handled in a confidential manner, and all information will be kept as confidential as possible to the extent allowed by law.
- 2) **Complaint Information.** Upon receipt of a complaint or concern from a research participant or other individual, the IRB Director will determine urgency of complaint and obtain and record the following information, as appropriate:
 - a) Complainant's name and contact information (i.e., address, phone number, email address).
 - i) If the complaint is made anonymously, the same procedures will be followed, but without complainant information.
 - ii) If a written report is forwarded to the IRB Full Board, the complainant's name will not be disclosed.
 - b) Research protocol IRB number and name of Principal Investigator, if applicable.
 - c) A detailed description of the complaint or concern.
 - d) Whether the complainant has contacted the Principal Investigator/research staff, if applicable, or anyone else regarding the concern.
 - e) The complainant's proposed resolution of the complaint or concern, if the complainant has such a proposal.
 - f) The IRB Director will formally acknowledge receipt of the complaint or concern with the complainant either in writing.
 - g) Initial Inquiry. The IRB Director will conduct an initial inquiry and review to confirm and/or substantiate the complaint or concern.

- 3) **Initial Determination.** If the complaint or concern is substantiated, the IRB Director will make an initial evaluation of the severity and type of the complaint or concern in order to determine whether the complaint or concern can be addressed and resolved at the administrative level, or must be reviewed by the IRB Full Board.
 - a) Complaints and concerns that do not involve potential risk to participants or others will undergo a review by the IRB Director in consultation with the IRB Chair. Any corrective action will be initiated by the IRB Direction in consultation with the IRB Chair.
 - b) Complaints and concerns that involve an attempt to unduly influence IRB chairs, IRB members, and IRB staff will be reviewed by the IRB Director and Director of Regulatory Compliance. Reports of undue influence that require disciplinary action will be forwarded to a higher level of supervisory authority for corrective action.
 - c) Complaints, concerns, or suggestions about the conduct of the study will be discussed with the Principal Investigator for consideration and evaluation and may potentially result in modifications to the study protocol.

- 4) **IRB Review.** If the IRB Director determines that the concern or complaint may involve potential risk to the participants or others, or may include suggestions of ways to improve the study, the IRB Director will submit a written report regarding the complaint, concern or suggestion to the IRB Full Board for review. Upon review, the IRB may take a range of actions, including, but not limited to, the following:
 - a) No action.
 - b) Approve continuation of research without changes with an expression of caution to the PI.
 - c) Require formal educational intervention for the researchers involved, that targets behaviors needing correction, for example: a training seminar.
 - d) Require minor or major changes in the research procedures and /or consent documents.
 - e) Modify the current approval period.
 - f) Require monitoring of research by the IRB or designated group.
 - g) Require monitoring of the consent process.
 - h) Require audits of other active protocols of the individual(s) involved.
 - i) Disqualify the individual(s) from conducting research involving human subjects at the institution
 - j) Determine if the data collected may or may not be used for publication.
 - k) Require that participants previously enrolled in the study be contacted and provided with additional information, be asked anew to provide additional consent, or both.
 - l) Notifying publishers and editors if manuscripts resulting from the research have been submitted or published.
 - m) Notify the appropriate IRB officials of partner institutions engaged in the research.
 - n) Report the issue to agencies and sponsors as appropriate.

- 5) **Notification.** The IRB/reviewer will notify the Principal Investigator of any required corrective actions. The IRB/reviewer may, but is not required to, inform the complaining participant of the proposed actions.

- 6) **Emergencies.** An emergency situation means a response by the police, paramedics, fire department, or University Communications is required or necessary, and may involve special situations involving severe, unanticipated risks to the participants. In emergency situations, the IRB Director will immediately notify the Director of Regulatory Compliance, the IRB Chair, and if appropriate the Office of General Counsel. In an emergency situation the IRB Director shall:
 - a) Talk with the participant(s) as requested or deemed appropriate to obtain all relevant information.
 - b) Document all information related to the incident.
 - c) Provide pertinent information and guidance to the researcher(s) that in order to help resolve or mitigate the situation.
 - d) Connect the researcher (or participants) with NC State's emergency staff including Environmental Health and Safety, University Police, Fire and Life Safety, Counseling Center, and/or the Office of Student Conduct.
 - e) Follow up with all parties once the situation is resolved including those in supervisory chain.

D. IRB Reporting Requirements

In accordance with federal law, NC State's IRB is required to report, to the appropriate federal department or agency head(s) and institutional official (45 CFR 46.103(b)(5) and 21 CFR 56.108(b)), all unanticipated problems involving risks to participants or others; any serious or continuing noncompliance; any suspension or termination of IRB approval; and the outcome of the IRB's actions to resolve these issues.

E. Whistleblower and Respondent Obligations and Protections Related to Research Misconduct

Some participant complaints or concerns may lead to an investigation regarding research misconduct. [NC State's Regulation for Research Misconduct](#) outlines all issues and expectations related to issues of Research Misconduct. NC State's administrative regulation requires reporting of observed, suspected, or apparent research misconduct. For more information regarding research misconduct, and a summary of obligations of and protection for whistleblowers see [insert hyperlink]