



Graduate and Professional Schools Institutional Review Board (GPS IRB)
Animal and Human Subjects Research Compliance (AHSRC) Office

REVIEW RATING SYSTEM AND FORM

Guidelines for Review of Study Activities

After the Open Meeting and On-Site Review, the Reviewer(s) will evaluate the study activities in five major categories. Below are general guidelines for interpretation of major and minor violations:

Major violations are considered serious, may place participants at additional risk, and likely involve gross negligence. Major violations likely require formal corrective action by the PI and the study team. Major violations include:

- **RECRUITMENT:** Use of materials that were not IRB approved, or significant deviations/exceptions to the recruitment protocol without IRB notification.
- **CONSENT:** Failure to obtain written consent (and assent) from all subjects, failure to file consents appropriately/confidentially
- **DATA PROTECTION:** Failure to secure data as described in protocol, identifying information not separated from de-identified information, deviations/exceptions that to data protection procedures without IRB notification, breach of confidentiality without IRB notification
- **CHANGES TO STUDY PROTOCOLS AND FORMS:** Major changes to any study procedures without IRB notification, significant altering of any forms without IRB notification
- **HARM TO PARTICIPANTS/PARTICIPANT PROTECTION:** Unethical or negligent behavior by any study members that might potentially harm the participant or increase their risks from what was described in the consent form and protocol, Significant complaints about study activities by participants without IRB notification, lack of proper debriefing of participants or major deviations from the approved debriefing protocol (if applicable)

Minor violations may be expected to occur occasionally. Minor violations are not likely to place subjects at additional risk and do not rise to the level of gross negligence. Depending on the type of minor violations, the Reviewer(s) may provide PI education and/or require formal follow-up. Minor violations include:

- **RECRUITMENT:** Minor deviations to recruitment protocol that do not raise risk or coercion of participants

- **CONSENT:** Not systematically providing participants a copy, having untrained personnel review consent forms only cursorily, a few consent forms missing from files, consents filed in same file drawer as master list linking personal information to de-identified data
- **DATA PROTECTION:** information accessed by more researchers than originally planned, personal information not separated from de-identified data, minor deviations from approved data protection plan
- **CHANGES TO STUDY PROTOCOL AND FORMS:** Minor changes to procedures and forms (e. g., correcting typos, updating graphics, adding contact information) that are not likely to increase risk to participants
- **HARM TO PARTICIPANTS/PARTICIPANT PROTECTION:** Minor participant complaints (e.g., that the survey is too long, that the time required was different than what was explained on the consent) that are not likely to increase risk to participants, minor deviations from the approved debriefing protocol that are not likely to increase risk to participants (if applicable)

Rubric for Ratings

The following guidelines are used to evaluate the protocol performance found in an audit in the above described areas.

Exceptional (3)

Evidence of superior source documentation, data quality, protocol compliance and regulatory compliance. No formal PI response required.

Satisfactory (2)

- Few minor violations noted. Formal PI response is not needed, but may be subsequent to additional PI education (and assurance of PI understanding and plan to implement improvements) during the course of the AHSRC review process.

Needs Improvement (1)

- Several minor violations and at least one major violation noted. Written response may be required to address some of the violations, and additional PI education will be provided during the course of the AHSRC review process with assurance of PI understanding and plan to implement improvements.

Unacceptable (0)

- Many minor violations and/or several major violations noted. Formal PI written response is required to address any major violations, and certain study activities may be temporarily suspended.

AHSRC Review Ratings, Comments, and Follow-Up Steps

Name of PI:
Protocol ID/Title:

Name of Reviewer:
Date:

Domain	Rating (0-3)	Comments/Feedback	Follow-up Steps
Recruitment			
Consent			
Data Protection			
Changes to Study			
Participant Protection			
Overall Rating			