SOP 1.4.6 **Research Involving Sensitive Topics**

General Description:

Research involving potentially sensitive topics such as substance use/abuse, family violence/abuse, mental health issues, sexual behavior/preferences, or illegal behaviors may require additional protections and safeguards for participants. This policy provides additional information on research involving sensitive topics.

Policy:

1. If conducting research involving sensitive topics, the researcher should consider any necessary procedures to handle the possibility of a participant becoming upset during and/or after participation in the research and include that information in the IRB application and consent form if applicable.
2. Mason researchers are mandatory reporters and must report any suspicions of child abuse or neglect to the proper authorities. More detailed information about mandatory reporting can be found on Mason's Human Resources website. Participants must be informed about these requirements in the consent form. A template statement can be found in the consent instructions in IRBNet.
3. Mason researchers should also have a plan to deal with identifiable reports of harm to self or others if they are collecting this type of information. Relevant details should be included in the IRB application and consent form.
4. If a research project involves the collection of sensitive data, the consent form should generally include information about the subject of the research and the types of questions that will be asked so that participants are made aware.
5. Depending on the nature of the research, it may be appropriate for the researcher to provide participants with contact information for the student counseling center (or another appropriate counseling contact) in the informed consent form. In some cases, the researcher may want to provide the participants with a list of local counseling services to take with them in case they experience distress after participating in the research.
6. If a researcher conducting a project that involves the collection of sensitive data plans to recruit participants via snowball sampling, the IRB may require that the researcher provide his/her contact information for participants to give to other potential participants rather than asking participants for the names and contact information for other potential participants.
7. Student projects that meet the criteria of a classroom project that does not require IRB review may not involve the collection of data about sensitive topics.

Procedures:

1. If a research project involves collecting data about sensitive topics, the researcher should include information in the IRB application about any particular risks to participants based on the topic and how those risks will be mitigated.
2. The researcher should consider collecting data anonymously and if that is not possible, at least consider coding the data and storing the data without any identifiers and separately from any links to identifiers, including signed consent forms.
3. Template language that can be used in the consent form to inform the participant about risks and provide contact information for the counseling center is available in IRBNet.
4. If the researcher has concerns that asking the participant to sign the consent form may put them at risk, he or she can request a waiver of the requirement to obtain the participant's signature on the

consent form and provide justification for that request in the appropriate section of the IRB application.
5. The IRB will review the protocol in accordance with 45 CFR 46.
6. The IRB will determine that the researcher describes adequate provisions for mitigating risks to participants based on the collection of sensitive information.
7. The IRB will follow regular procedures for an exempt, expedited or full board review as necessary.
8. Some studies involving the collection of sensitive information may qualify for a Certificate of Confidentiality (CoC). In some cases, the IRB may require a CoC in order to approve the project.

Related Forms, Guidance, and SOPs:

- 1.3.4 Certificates of Confidentiality and Privacy Certificates
- 1.3.5 Classroom Projects
- 2.2.1 Informed consent, assent, parental permission, and documentation
- 2.5.1 Full board review
- 2.5.2 Exempt and expedited

Responsibility:

Principal Investigators
Research Team Members
IRB staff
Institutional Review Board

Approval and Version History:

Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

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Approved By	Title and Division	Date Approved
Aurali Dade	Associate Vice President, Research Development, Integrity and Assurance	May 24, 2017
Laurie Meamber	IRB Chairperson	May 24, 2017