I. INTRODUCTION -- The Protection of Minors Policy sets forth guidelines and requirements for the protection of minors (individuals under 18 years of age) who are involved in University programs and activities, including research activities, and for University faculty, staff and students who are involved in such programs and activities. This document provides an overview of the requirements of the Policy as they apply to human subjects research involving minors. For purposes of this document, “human subjects research involving minors” means projects or protocols in which individuals under the age of 18 are research subjects. (This document does not replace the Protection of Minors Policy. Nor does it address circumstances when individuals under the age of 18 who are not full-time Georgetown students assist with research—please contact the Office of Compliance and Ethics for questions about such situations.)

II. POLICY REQUIREMENTS OVERVIEW-- The Policy contains three main requirements applicable to those who participate in research involving minors:

1. Reporting of Known or Suspected Abuse or Neglect: Anyone who knows, suspects, or receives information indicating that a minor has been abused or neglected, or who has other concerns about the safety of minors must make a report to the Office of Compliance and Ethics. In the case of an emergency, one should immediately call Georgetown’s Department of Public Safety.

2. Training and Education Requirements: Anyone participating in human subjects research involving minors must read the “Working With Minors Guidelines,” which include basic information on the warning signs of child abuse or neglect, “do” and “don’t” tips for working with minors, and information on how to report concerns or raise questions, and must sign a certification attesting that they have read and understood this information. The Guidelines are available in eRIC, along with an electronic certification form. Additional training may be required depending upon an individual’s role in the human subjects research involving minors.

3. Background Check Requirement: Certain individuals are required to clear a criminal background check prior to participation in human subjects research involving minors. They are: a) the program director or supervisor (generally the Principal Investigator); b) anyone who stays overnight with minors; and c) those who are regularly alone with minors (unaccompanied by other adults). The University will conduct an individualized assessment if a criminal background check reveals information that could potentially affect one’s suitability for these roles. Prior convictions shall not automatically disqualify a person from participating in research involving minors, and except as required by law, criminal background checks conducted pursuant to the Protection of Minors Policy will be used only for purposes consistent with this Policy and will otherwise be kept confidential (with records maintained separately from an individual’s personnel or student file).

III. SPECIFIC ISSUES RELATED TO HUMAN SUBJECTS RESEARCH INVOLVING MINORS -- The principal issue that arises in applying the Protection of Minors Policy in the context of human subjects research involving minors is the question of when researchers are required to report suspected abuse or neglect they become aware of in their research and what they must tell research subjects about this requirement.

The obligations associated with the goal of protecting minors from abuse or neglect and the obligations associated with confidentiality in research may at times to be in tension. On the one hand, treating information gathered from human subjects as confidential, presenting data and results in a de-identified manner, and other measures to protect information are important for obtaining research subject consent, as
well as for the conduct and integrity of the research itself. On the other hand, guarantees of confidentiality provided to human research subjects are never absolute, and in the context of human subjects research involving minors, considerations relating to the potential vulnerability of those under 18 and the moral and legal obligations to protect them from abuse or neglect affect the promises a researcher can make and the actions he or she must take when information about abuse or neglect surfaces. Researchers must take seriously their reporting obligations and ask for help from the IRB Office and/or the Office of Compliance and Ethics if they are uncertain about what to do.

**Mandated Reporter Law** --In addition to the reporting requirements of the University’s Protection of Minors Policy, District of Columbia law (and that of most other states) requires individuals in certain occupations and professions, classified as “mandated reporters,” to report known or suspected abuse or neglect of minors they encounter in their professional capacity. Among other categories of mandated reporters, DC Law requires “physicians,” “psychologists,” “mental health professionals,” “registered nurses,” and “social service workers,” to report “known or suspected mental or physical abuse or neglect of a child known to [them] in [their] professional capacity” to either the Metropolitan Police Department (by calling 911) or to the DC Child and Family Services Agency (CFSA) through the CFSA Hotline. The Office of Compliance and Ethics, in consultation with the Office of University Counsel, can help answer questions about the mandated reporter law.

**Disclosure to Research Subjects** -- In designing a protocol for human subjects research involving minors, investigators must ensure that minor research subjects and their parent(s) or guardian(s) are aware of the obligations imposed on Georgetown researchers by the University’s Protection of Minors Policy and by District of Columbia law. Informed consents and other communications should be clear about the limits these obligations impose on confidentiality. Principal Investigators and others can obtain assistance and advice from the IRB Office, which will coordinate with the Office of Compliance and Ethics on issues relating to the Protection of Minors Policy and DC child protection law.

**What to Do When You Suspect Minor Abuse or Neglect** -- If you or other members of the research team become aware of information suggesting that a minor is the victim of abuse or neglect or is in danger of being abused or neglected, you should:

- Review the District of Columbia Child and Family Services Agency “Signs of Child Abuse and Neglect” document that is attached to this document.

- Determine whether you or the person who knows or suspects abuse or neglect is a “mandated reporter” under DC law. If you have questions about this, you or the IRB Office may contact the Office of Compliance and Ethics for help in making that determination and understanding your obligations.

- Report the known or suspected abuse or neglect to the Office of Compliance and Ethics by calling (202) 687-6493, or by email to protectionofminors@georgetown.edu

- Contact the Office of Compliance and Ethics if you have questions about a particular situation or what you should do. OCE will work with you and the IRB to determine the appropriate course of action, taking into account both the obligation to protect minors and the needs of the research.

**When to Contact the Office of Compliance and Ethics (OCE)** --(202) 687-6493 -- In addition to making reports of suspected minor abuse or neglect to OCE, researchers should call OCE when they have questions about the applicability of the Policy to their specific research activities or when they find themselves uncertain about what to do. OCE staff is available for confidential conversations about the Policy, including matters related to reporting, training, and criminal background checks. The Compliance Helpline is available for confidential and/or anonymous reporting of problems or concerns. See, [http://compliance.georgetown.edu/reporting/]
SUMMARY OF RESPONSIBILITIES OF FACULTY/STAFF/STUDENTS CONDUCTING HUMAN SUBJECTS RESEARCH INVOLVING MINORS

The following summarizes the responsibilities of Principal Investigators and others on the research team for human subjects research involving minors under the Protection of Minors Policy:

Principal Investigator Responsibilities:

1. Read “Working with Minors Guidelines: Information for Adults Participating in University-Run or Affiliated Programs Involving Minors.” The Guidelines are available in eRIC, along with an electronic certification form.

2. Submit the electronic Certification at the end of the Working with Minors document in eRIC. For ongoing research projects, the Working with Minors document must be read and a Certification must be signed and submitted to the IRB every three (3) years as part of the renewal process.

3. In eRIC, provide the names and net IDs of all members of the research team who will have interactions with minors as part of the protocol.

4. Require all research team members (including students or others who are involved in the research) to read the Working with Minors document and submit the Certification through eRIC.

5. Request a criminal background check. Requests for background checks should be sent to backgroundchecks@georgetown.edu, with WORKING WITH MINORS BACKGROUND CHECK REQUEST in the subject line. The following information must be included in your request:
   - The e-mail address of the engagee (the principal investigator and any study team members whose role requires a background check)
   - The engagee’s first and last names
   - The name of the research project/activity
   - The engagee’s supervisor’s name and contact information, if applicable
   - For purposes of charging the background check, the fund number, purpose number, and program number
   - Role at the University (Faculty, Other GU Employee, GU Student, Volunteer, Other)

Those who are undergoing background checks will receive an e-mail directly from HireRight, Inc., the University's background checking vendor, asking for information to complete the check. The entire process, from submission to result, generally takes 5-7 working days. The cost of the background check is $78.50 per check, plus any fees that may be charged by county jurisdictions (the fee amounts vary but are generally minimal). The checks will be billed through the consolidated billing process or by journal voucher. RX numbers are not recommended, as the approvals may cause delays.

See Appendix C of the Protection of Minors Policy regarding the frequency of background checks for Georgetown University employees and students:
https://georgetown.app.box.com/s/esmadkcpw3vmiekxy7fy

6. Report known or suspected abuse or neglect of minors to OCE (202-687-6493 or by email at mailto:protectionofminors@georgetown.edu) and contact OCE with questions if you have them.