SOP 2.2.1 Informed Consent, Assent, Parental Permission and Documentation

General Description:

General Informed Consent:
The IRB requires researchers to conduct a legally effective informed consent process with each potential human research participant (or his or her legally authorized representative (LAR)) before the participant may be enrolled in a research study (45 CFR 46.116; 21 CFR 50.20). It is the ultimate responsibility of the Principal Investigator (PI) to ensure that informed consent is obtained from each human subject and that the consent process is conducted as detailed in the approved research protocol.

The Informed Consent process is an essential and continuous communication process between the prospective human subject and an investigator, and begins with the initial approach of a researcher to the potential subject, and continues through the completion of the research study. It is the process by which the research study is explained to the potential participant and the participant asks questions and then voluntarily agrees to participate in the research. The informed consent process should ensure that all critical information about a study is completely disclosed, and that prospective subjects (or their legally authorized representatives) adequately understand the research so that they can make informed choices.

The requirement of informed consent is founded on the principle of respect for persons, one of the three ethical principles governing human subjects research described in the Belmont Report. The informed consent process ensures that prospective participants understand the nature of the research in order to decide knowledgeably and voluntarily whether to participate. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate. While there are a few circumstances in which the IRB may grant a waiver (detailed in GMU SOP 2.2.2) or provide for an alternative to the informed consent process, obtaining legally effective informed consent is the standard for all research with human participants.

The IRB has the final authority as to the content of the consent form presented to the prospective study participants. The IRB may require that the form include, in addition to the information required by the regulations, information decided by the IRB to add significant and meaningful information for the protection of the participants' rights and welfare. The IRB also has the authority to observe, or to request a third party to observe, the consent process.

Assent:
Assent: agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research. An assent is typically paired with permission from a parent or guardian, and together they comprise the informed consent to participate.

Children (minors) are a vulnerable research population and, as such, require additional protections when they are potential research subjects. Subpart D of both 45 CFR 46 (DHHS), and 21 CFR 50 (FDA) require certain additional protections for children involved as subjects in research. The requirements of Subpart D apply to all non-exempt research involving children conducted under the auspices of George Mason University. The regulations require that adequate provisions be made for soliciting the assent of all children involved in research, when the children are capable of providing assent. In determining

whether children are capable of assenting, the ages, maturity and psychological state of the children should be taken into account.

In general, children should be given developmentally appropriate information about a research study in a language and manner that is understandable to them, given their age, maturity, and cognitive abilities.

For children aged 11-17 years: Children in this age group should be fully informed about the research and documented assent should be obtained. The child may either sign his/her own Assent Form or may verbally assent to participate in the study, but in either case, the information provided to the subject should be appropriate to the individual's age, maturity and developmental abilities. Assent must be obtained along with the consent of a parent or guardian.

For children aged 7-11 years: This age group should be fully informed about the research, using language appropriate to their age and maturity, and assent should be obtained from those deemed capable of making a meaningful decision. Assent should be obtained along with the consent of a parent or guardian.

For children under the age of 7: Typically, minors under 7 years old should provide oral assent. The oral assent script should be conversational and stated in such a way that is understandable and age-appropriate. Assent should be obtained along with the consent of a parent or guardian.

Parental permission:
Sections 408(b) and 55(b) of Subpart D require that adequate provisions be made for soliciting the permission of parents or guardian of each child involved in a research study. All of the requirements concerning informed consent apply to obtaining parental permission and the appropriate elements of consent must be included in a written informed consent document. The IRB may waive the requirement for obtaining parental permission as described in GMU IRB SOP 2.2.2.

Informed Consent of Non-English Speaking Subjects:
There may be circumstances when a subject is unable to read the full consent document (e.g. when a potential subject does not speak the language in which the consent document is written). Investigators must deliver all information regarding informed consent/assent to potential subjects or their LAR in the subject's native language(s) or one that the subject understands. The investigator must provide the IRB and prospective subjects a translated version of the consent/assent form. In cases of research studies that are deemed greater than minimal risk, a translator may be also be required to ensure effective communication.

***Informed Consent of Cognitively Impaired Subjects*:**
Individuals who are considered cognitively impaired are those who have a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders), an organic impairment (e.g., dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests. – *IRB Guidebook, Chapter VI, special classes of subjects.*

In circumstances of individuals with diminished capacity, a legal representative must be present during the consent process, and can sign a consent form on the behalf of the participant. Definition of Legally Authorized Representative (per Virginia State Code) is available here: http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-162.16
– Virginia Code 32.1-162.16

Documentation of Informed Consent:
The consent form must be signed and dated by the participant or the participant's legally authorized representative prior to participant in a study-related activity. The IRB has authority to waive documentation of informed consent (as detailed in GMU IRB SOP 2.2.2). The participant must be given a copy of the consent form. The original signed consent form must be kept in a secure place at the PI's site for audit purposes.

Please see SOP 2.2.2 for information regarding informed consent waivers.

Procedures:

Informed Consent Process, Documentation and Approval

1. The PI submits an IRB application which includes a proposed informed consent procedure and written form prior to initiation of research. The IRB may waive the requirement for obtaining consent or the requirement for documenting informed consent as detailed in GMU IRB SOP 2.2.2.
    a. The IRB application must indicate which study personnel will participate in the informed consent process or individuals the PI will authorize to obtain informed consent on his/her behalf.

2. The GMU IRB provides informed consent templates, available on the irbnet.org website. Investigators should use the templates as a guide unless the IRB grants exceptions or a waiver. If the Mason template consent is used and the total length of the consent document is four pages or less, then the IRB considers the regulatory requirements of the summary statement to be met. If the consent form for a study is longer than four pages, the document must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. At a minimum, the consent should contain the nine required elements, the nine additional elements of informed consent (when applicable), and additional GMU-specific language requirements. A list of the required elements of consent can be found here: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html
    a. When usage of the MRI is included in the project, the MRI consent template must be used.

3. If the research involves vulnerable populations or sensitive issues, the investigator addresses additional regulatory and/or institutional requirements. The investigator may consult the IRB staff for guidance. The vulnerable populations and sensitive issues include, but are not limited to:

    - Research involving the participation of children;
    - Research involving individuals with impaired consent capacity;
    - Research activities directed toward pregnant women;
    - Research involving prisoners;
    - Research involving illegal behavior or other issues that have a high potential to impact participants' safety, freedom, employment, or relationships.

4. The IRB will assess the PI's description of the informed consent process to ensure that the process meets the general requirements of informed consent (i.e., consent be obtained from the subject or

subject's legally authorized representative; be in language understandable to the subject; be obtained under circumstances that allow the subject to adequately consider whether or not to participate; be obtained under circumstances that minimize coercion or undue influence; does not include language through which the subject is made to waive his/her legal rights or releases the investigator, sponsor, or institution from liability for negligence).

5. The IRB is responsible for reviewing the proposed informed consent document(s) to ensure that all applicable federal and GMU requirements are met.

6. Once the IRB approves the study, IRB staff will place an approval stamp on every page of the approved consent document, indicating the approval and expiration (if applicable) dates for use of the informed consent form. Investigators may only enroll subjects using informed consent/assent forms that have a valid "IRB approval" stamp unless the IRB grants a waiver from the requirement for informed consent or documentation.

    a. If the study includes documents approved by the IRB for use in the informed consent process, which are not signed by subjects under waiver of documentation/signature, (e.g., survey cover letters, web page cover letters, telephone scripts), forms will be stamped, indicating approval for use, but approval of use is also documented in formal approval correspondence provided to the researchers.

Posting of clinical trial consent form

1. For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the researcher conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.
2. If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (*e.g.* confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.
3. The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment and no later than 60 days after the last study visit by any subject, as required by the protocol.

References:

Cornell University Office of Research Integrity and Assurance IRB Human Participants Policy & Standard Operating Procedures http://www.irb.cornell.edu/policy/

Documentation of Informed Consent
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.117

General Requirements for Informed Consent (45 CFR 46.116)
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116

FDA requirements for Informed Consent
http://www.fda.gov/regulatoryinformation/guidances/ucm126420.htm#Informed%20Consent%20Process

FDA Informed Consent content requirements

http://www.fda.gov/regulatoryinformation/guidances/ucm126420.htm#Informed%20Consent%20Document%20Content

IRB Guidebook http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm

Required Elements of Informed Consent
1. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html

Research with Children (Subpart D)
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd

University of Kentucky IRB Standard Operating Procedures https://www.research.uky.edu/office-research-integrity/policies-guidance

Related Forms, Guidance, and SOPs:

- GMU SOP 2.2.2

Responsibility:

Principal Investigators
Research Team Members
IRB staff/Research Development, Integrity and Assurance office
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	January 21, 2019
Laurie Meamber	IRB Chairperson	January 21, 2019