



Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-090-3	01/21/2019	HSO	HRPP Policy Committee	Page 1 of 8

### 1. PURPOSE

1.1. Informed consent is one of the primary ethical requirements underpinning *human research*; it reflects the basic principle of respect for persons outlined in the *Belmont Report*. Informed consent is not a single event but an ongoing process, designed to provide potential *research participants* with sufficient information to make a fully informed, autonomous decision about research participation. This *policy* describes the ethical and regulatory requirements for the consent process, and the criteria for waiver or alteration of consent and waiver of documentation of consent.

### 2. DEFINITIONS

- 2.1. **Consent Process:** is an active ongoing process that involves more than the documentation of consent. The process involves an information exchange and on-going communication that takes place between the investigator(s) and the prospective participant.
- 2.2. **Informed Consent:** is the agreement to participate in research expressed by an adult person (or by the **legally authorized representative (LAR)** for a child or for an adult with cognitive impairment, based on sufficient information and adequate opportunity to consider voluntary participation. Also referred to as **legally effective informed consent**.
- 2.3. **Adult:** a person who by virtue of attaining a certain age is regarded in the eyes of the law as being able to manage his or her own affairs. For the purposes of this policy, adult status is defined by the laws governing the location where the research will take place. In Georgia, an adult is an individual who is 18 years of age or older.
- 2.4. **Exculpatory Language:** as it applies to informed consent, is any written or verbal communication which has the general effect of freeing or appearing to free an individual or an entity from malpractice, negligence, blame, fault, or guilt.
- 2.5. **Public Benefit or Service Program:** a program that delivers a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).

### 3. POLICY

- 3.1. This policy applies to all non-exempt research (i.e., studies reviewed by the convened IRB or **expedited procedure**) except where otherwise stated.
  - 3.2. The process for obtaining consent, whether written or oral, must incorporate **all** of the following:
    - 3.2.1. Before involving a human participant in research, the investigator must obtain the informed consent of the potential participant or the participant's LAR, unless the requirement for consent has been waived or altered by the IRB.
-



Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-090-3	01/21/2019	HSO	HRPP Policy Committee	Page 2 of 8

- 3.2.2. Consent must be sought only under circumstances that provide the prospective participant or the LAR sufficient opportunity to discuss and consider whether to participate.
  - 3.2.3. Consent must be sought only under circumstances that minimize the possibility of ***coercion*** or ***undue influence***.
  - 3.2.4. The information provided during the consent process must be presented in language understandable to the participant or the LAR.
    - 3.2.4.1. Consent documents should be written in the language that the participant is literate in and at a readability level appropriate for the participants. Consent documents should be written in second person (You) as use of first person (I) can be interpreted as suggestive and can constitute undue influence over voluntariness. The IRB recommends that consent documents intended for the general population be written for an 8<sup>th</sup>- grade reading comprehension level; use of academic, legal, or scientific/technical terms is not appropriate for this level.
    - 3.2.4.2. If the participant/representative understands more than one language, the consent process should be conducted, whenever possible, in the preferred language of the participant/LAR.
  - 3.2.5. No informed consent may include any exculpatory language through which the participant or the LAR is made to waive or appear to waive any of the participant’s legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
  - 3.2.6. The prospective participant or LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate. Informed consent as a whole must present information relating to the research in sufficient detail, and the information must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective participant’s or LAR’s understanding of the reasons why one might or might not want to participate.
  - 3.2.7. When student educational records are involved, the requirements of the Family Educational Rights and Privacy Act (FERPA) that pertain to written permission must be applied.
  - 3.2.8. Only approved members of the study team may be involved in obtaining consent from potential participants as this activity constitutes engagement in research.
  - 3.2.9. The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purposes of screening, recruiting, or determining the eligibility of prospective participants for inclusion in the research without the informed consent of the prospective participant or the participant’s LAR if either of the following conditions is met:
-



Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-090-3	01/21/2019	HSO	HRPP Policy Committee	Page 3 of 8

- The investigator will obtain information through oral or written communication with the prospective participant or LAR, or
- The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

3.2.9.1. When either of the above conditions is met, investigators do not have to request waivers of consent for the purposes of screening, recruiting, or determining eligibility but do have to describe these activities in the application or protocol submitted to the IRB. The above does not negate the requirements of other rules, such as HIPAA, when applicable. It also does not negate the requirement to obtain consent, or a waiver of consent, before involving a participant in other research activities, including the use of a participant’s identifiable private information or biospecimens.

3.2.10. The IRB may approve a consent or parental permission procedure which does not include, or which alters, some or all of the elements of informed consent, or to waive the requirement to obtain informed consent if it finds and documents that: the research is not FDA-regulated, the research does not involve non-viable neonates, and **all** the following criteria are met:

- 3.2.10.1. The research involves no more than minimal risk to the participants.
- 3.2.10.2. The research could not practicably be carried out without the waiver or alteration.
- 3.2.10.3. The waiver or alteration will not adversely affect the rights and welfare of the participants.
- 3.2.10.4. Whenever appropriate, the participants or LARs will be provided with additional pertinent information after participation.

3.2.11. The waiver request described in section 3.2.10 is required for all non-exempt studies that involve deception or incomplete disclosure. See Policy and Procedures: Deception or Incomplete Disclosure. Other examples may include studies involving medical chart review and secondary data analysis.

3.2.12. Use of “passive” or “opt-out” consent can only be approved if a waiver or alteration has been proposed and meets the criteria in section 3.2.10.

3.2.13. **For research under the Common Rule:**

3.2.13.1. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant or LAR 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.

3.2.13.2. Key information includes, but is not necessarily limited to, the following:



Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-090-3	01/21/2019	HSO	HRPP Policy Committee	Page 4 of 8

- The fact that consent is being sought for research and that participation is voluntary;
- The purposes of the research, the expected duration of the prospective participant's participation, and the procedures to be followed in the research;
- The reasonably foreseeable risks or discomforts to the prospective participant;
- The benefits to the prospective participant and/or to others that may reasonably be expected from the research; and
- Appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the prospective participant.

3.2.13.3. Ideally, the key information is presented within the first page to page and a half of the consent materials.

3.2.13.4. The IRB may approve a request from an investigator to waive the requirement for informed consent, or to omit or alter one or more basic or additional elements of consent for research involving Public Benefit and Service Programs, if it finds and documents that both of the following are applicable:

- The research or demonstration project is to be conducted by or participant to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: a.) Public benefit or service programs; b.) Procedures for obtaining benefits or services under those programs; c.) Possible changes in or alternatives to those programs or procedures; or d.) Possible changes in methods or levels of payment for benefits or services under those programs; and
- The research could not practicably be carried out without the waiver or alteration.

3.2.13.5. The IRB may approve a consent or parental permission procedure which does not include, or which alters, some or all of the elements of informed consent, or the IRB may waive the requirement to obtain informed consent if it finds and documents that: the research is not FDA-regulated, the research does not involve non-viable neonates, and **all** the following criteria are met:

- The research involves no more than minimal risk to the participants.
  - The research could not practicably be carried out without the waiver or alteration.
  - If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.
-



Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-090-3	01/21/2019	HSO	HRPP Policy Committee	Page 5 of 8

- The waiver or alteration will not adversely affect the rights and welfare of the participants.
- Whenever appropriate, the participants or LARs will be provided with additional pertinent information after participation.

3.2.13.6. The waiver request described in the above section (3.2.13.5) is required for all non-exempt studies that involve deception or incomplete disclosure. See Policy and Procedures: Deception or Incomplete Disclosure. Other examples where a waiver request may be appropriate include studies involving medical chart review and secondary data analysis.

3.2.13.7. Use of “passive” or “opt-out” consent can be approved only if a waiver or alteration has been proposed and meets the criteria in section 3.2.13.5.

3.2.13.8. Documentation of informed consent is required in all cases, unless the IRB has approved a waiver of the requirement to document informed consent per 45 CFR 46.117(c). See Policy and Procedures: Documentation of Informed Consent.

#### 4. SPECIFIC CONSIDERATIONS IN INFORMED CONSENT

4.1. Informed consent must be obtained from:

4.1.1. The participant when the participant is an adult capable of providing consent.

4.1.1.1. When the targeted population may include adults with cognitive impairment, there must be an adequate plan for the assessment of the capacity to consent.

4.1.2. The LAR when the participant with diminished capacity to consent. See Section 2.1 of *Policy and Procedures: Legally Authorized Representatives for Adults with Diminished Consent Capacity and for Children*.

4.1.2.1. The IRB must have specifically approved the protocol to allow the enrollment of adults unable to consent.

4.1.2.2. LARs are to be well informed regarding their roles and obligations to protect incompetent participants or participants with impaired decision-making capacity. They must also be told their obligation is to try to determine what the prospective participant would do if competent, or if the prospective participant’s wishes cannot be determined, what they think is in the incompetent participant’s best interest.

4.1.3. One or both biologic or adoptive parents (parental permission) and the **child** (assent) when the participant is a child, or in the absence of a parent, a person other than a parent authorized under applicable law to consent on behalf of the child to general medical care.

4.1.3.1. The IRB must have specifically approved the protocol to allow the enrollment of children.



Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-090-3	01/21/2019	HSO	HRPP Policy Committee	Page 6 of 8

- 4.1.3.2. The **principal investigator** must determine the appropriate age of consent for research, even if the participant is considered to be an adult for purposes of medical treatment. This will be determined by the laws governing the location where the research will take place. (e.g., the legal age of consent in Georgia is 18.)
- 4.1.3.3. The only exceptions to this requirement would be if the state considers the participant to be an adult, such as in the case of emancipated child. See Section 2.2 of *Policy and Procedures: Legally Authorized Representatives for Adults with Diminished Consent Capacity and for Children*.
- 4.1.3.4. Assent must be sought from the child unless the IRB has waived this requirement for **either** of the following reasons.
- The child is incapable of providing assent (due to age or condition); **or**
  - The intervention holds out the prospect of direct benefit to the child, and the intervention is available only in the context of the study. In these two situations, permission from parent(s) is sufficient.
- 4.1.3.5. Permission is obtained from both parents unless: one parent is deceased, unknown, incompetent, or not reasonably available; only one parent has legal responsibility for the care and custody of the child; or the IRB has specifically approved the protocol to allow the permission of one parent regardless of the status of a second parent.
- 4.1.3.6. If a child participant attains the age of consent while the research is ongoing/research activities continue (e.g., collection of data, analysis of **individually identifiable** data), the investigator must seek the informed consent of the now-adult participant in order to continue his/her inclusion in the project, unless the IRB has approved a waiver of the requirement to obtain informed consent.

## 5. PROCEDURES: Investigators

- 5.1. The investigator(s) must ensure that research participants provide informed consent prior to participating in research, unless the requirement for informed consent is waived or altered.
  - 5.2. The project submission must describe the detailed process for obtaining consent: how, where and when consent will be sought, the language understood by the prospective participant or the LAR (if not English), the language used by those obtaining consent (if not English), and the study team member(s) who will be responsible for obtaining consent.
  - 5.3. The consent process should:
    - 5.3.1. Invite and answer the participant's questions.
    - 5.3.2. Give the participant sufficient time to discuss taking part in the research study with family members, friends, and other care providers, as appropriate. Invite and encourage the
-



Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-090-3	01/21/2019	HSO	HRPP Policy Committee	Page 7 of 8

participant to take the written information home to consider and discuss the information and the question of whether to participate with family members and others before making a decision.

5.3.3. Be conducted in a language understandable to the participant.

5.3.4. When appropriate, include a process to determine whether **all** of the following are true, and if not, to either continue the explanation or determine that the participant is incapable of consent (Note: If the study is a clinical trial and the investigator is not a physician or physician extender, the study physician or physician extender may assist with these steps):

5.3.4.1. The participant understands the information provided.

5.3.4.2. The participant does not feel pressured by time or other factors to make a decision.

5.3.4.3. The participant understands that there is a voluntary choice to make.

5.3.4.4. The participant is capable of making and communicating an informed choice.

5.3.5. Provide objective information and avoid statements that imply that compensation or treatment is never available when the participant has questions about treatments or compensation for injury.

5.3.6. Stop if a participant indicates that he or she does not want to take part in the research study.

5.4. The participant and the individual obtaining consent must sign and date the consent document unless the IRB waives the requirement for written documentation of the consent process. See *Policy and Procedures: Documentation of Informed Consent*.

5.4.1. Participants who are unable to read or write can provide documentation of consent by making a mark in place of a signature on the consent document, when consistent with any applicable local law.

5.5. Provide a copy of the signed document to the participant.

## 6. PROCEDURES: Institutional Review Board

6.1. The IRB Staff and, when applicable, additional IRB member/s assigned to review the project or who attend the convened meeting, will evaluate the described consent process/es and submitted materials to ensure that the required and appropriate additional elements of disclosure have been included in the information that will be presented to the potential participants and that the process meets regulatory and ethical criteria as described in this policy. The elements must be appropriate and sufficiently complete, and the use of templates and suggested verbatim language or by investigator-created language equivalent in meaning to the verbatim template language is highly recommended.

6.2. If a waiver or alteration of the elements of informed consent or a waiver of the requirement to document informed consent has been requested by the investigator, the IRB Staff and, when



<b>Number:</b>	<b>Date:</b>	<b>Author:</b>	<b>Approved By:</b>	<b>Page(s):</b>
UGAHRP-090-3	01/21/2019	HSO	HRPP Policy Committee	Page 8 of 8

applicable, additional IRB member/s assigned to review the project or who attend the convened meeting will determine if the justification is adequate to grant the waiver. They will then document their findings via the appropriate checklists. The documentation must explain why the IRB judged that each criterion was met for the specific protocol and may reference other parts of the submission to supplement the justification provided by the investigator.

### 7. MATERIALS

- 7.1. Checklist: Informed Consent Elements
- 7.2. Checklist: Waiver or Alteration of the Consent Process
- 7.3. Checklist: Waiver of Written Documentation of the Consent Process

### 8. REFERENCES

- 8.1. Belmont Report
- 8.2. 21 CFR §50.20, 50.25
- 8.3. 45 CFR §46.116
- 8.4. Policy and Procedures: Deception or Incomplete Disclosure
- 8.5. Policy and Procedures: Documentation of Informed Consent
- 8.6. Policy and Procedures: Exempt Determination
- 8.7. Policy and Procedures: Legally Authorized Representatives for Adults with Diminished Consent Capacity and for Children

Revision History:  
09/19/2014: REV0 New Document  
06/29/2017: REV1  
10/18/2017: REV2  
01/21/2019: REV3