SOP		
Department	**Title**	**Dates**
Research Integrity and Protection	Informed Consent for Research	Effective: 10/25/17
		Approved: 10/23/17
Policy ID		Last Revised: n/a
IRB-SOP-901		Expiration: n/a

PURPOSE

This document establishes the process to obtain informed consent from a participant in human subject research. It does not address the topics of documentation of informed consent, additional considerations or requirements for certain populations or circumstances such as parental permission, assent from children, obtaining consent from subjects lacking decisional subjects or obtaining consent under emergency circumstances.

SCOPE

This SOP applies to all non-exempt human research studies conducted at Ascension Wisconsin facilities, .

DEFINITIONS

Consent: Consent refers to an agreement to participate in a certain action after thoughtful consideration.

Coercion: Pertaining to unacceptable participant recruitment methods which involve duress, undue inducement or indirect pressure. One example of an environment conducive to coercion involves the recruitment of employees by their employer for human participant research.

Exculpatory Language: As it applies to informed consent, any written or verbal communication through which a research participant (or his/her legally authorized representative) is asked to waive or appear to waive any of the participant's legal rights or to release (or appear to release) the investigator, sponsor, institution or its agents from liability for negligence.

Legally Authorized Representative (LAR): A person authorized either by statute or by court appointment to make decisions on behalf of another person. In human subject research, an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

Undue Influence: Excessive or inappropriate reward or other incentive in which a person is induced to act otherwise than by their own free will or without adequate consideration of the consequences.

PROCESS

1. **Requirements for Informed Consent**
   - **1.1.** Researchers are required to obtain the legally effective informed consent of each subject or their LAR, for all non-exempt human subject research, unless the IRB approves a consent procedure which does not include, or which alters, some or all of the elements of consent. All relevant requirements and in the FDA regulations in 21 CFR 50.20, 50.25, 50.27 and 56.111 that are applicable to the consent process and the consent document must be satisfied.
   - **1.2.** In general, informed consent must:
     - Be obtained in circumstances that minimize the possibility of coercion and undue influence;
     - Utilize language understandable to the subject;
     - Not waive or appear to waive subjects' rights;

- Include each of the required elements and applicable additional elements of informed consent describing the research and the nature of research participation as required by Federal regulations; and
- Use the appropriate Ascension Wisconsin IRB Informed Consent template language when enrolling subjects at Ascension Wisconsin sites.

2. Informed Consent Process

2.1. The Principal Investigator (PI) is responsible for describing the informed consent process in the IRB application.

2.1.1. The description of the process should include who will obtain informed consent, where the process will take place, and how it will be determined that the subject or LAR understood the information.

2.1.2. Informed consent is a process, not only obtaining a signature on a consent document. The PI should describe the process for ensuring an active ongoing process that involves an information exchange and on-going communication that takes place between the researcher and the prospective subject.

2.1.3. Additionally, when it is expected that some or all of the subjects may be considered to be from a vulnerable population, the description must take into account any additional process or safeguard required.

2.2. Investigators must also submit all informed consent documents (full written documents, oral scripts, a list of talking points, videos, comprehension materials, any type of comprehension or assessment aids, and short forms) in their application for review.

2.3. Unless specifically waived by the IRB, informed consent is documented in writing through the use of the current IRB-approved informed consent form signed and dated by the subject or by the subject's LAR prior to enrollment or participation in the research project.

2.4. The PI must ensure that informed consent is obtained through the IRB-approved process and the IRB approved version of the informed consent information, document or materials are used when obtaining consent , prior to subject involvement in any research activities, including screening procedures. Any changes to the consent form or process must be submitted as an amendment and reviewed and approved by the IRB prior to implementation.

3. Elements of Informed Consent

3.1. Investigators are responsible for incorporating the elements of informed consent as required by Federal Regulations into each informed consent, regardless of the type of consent process, including written consent documents, verbal scripts or information handouts.

3.2. The information provided in the informed consent documents must be in a language understandable to the subject (target population). Technical and scientific terms should be adequately explained using common or lay terminology. Drugs, devices and procedures should be described consistently throughout the documents and explained in simple language. It is generally recommended that consent forms or material be written at a sixth to eighth-grade reading level.

3.3. The informed consent document or information must begin with a concise and focused presentation of the key information that is most likely to assist the subject/representative to understand the reasons why one might or might not want to participate in the research.

3.4. Basic Elements of Informed Consent

3.4.1. In seeking informed consent, the following information must be provided to each prospective subject, unless the IRB approves a waiver or alteration of the element:

- A statement that the study involves research
- An explanation of the purpose of the research
- The expected duration of the subject's participation
- A description of the procedures to be followed
- Identification of any procedures which are experimental, if applicable, including a description of drugs or devices and stating whether any are investigational

- A description of any potential risks or discomforts to the subject
- A description of any direct or potential benefits to the subject or to others that may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject, when applicable
- A statement that describes how confidentiality will be protected and maintained and who has access to the data
- For research that involves more than minimal risk, explanations as to whether any compensation and any medical treatments are available if injury occurs and, if so, what this consists of, or where further information may be obtained
- A statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which he or she is otherwise entitled
- A description of compensation or study reimbursement for participants, if applicable
- An explanation of whom to contact in the case of a research-related injury to the subject
- An explanation of how to contact the research team for questions, concerns, or complaints about the research
- An explanation of how to contact someone independent of the research team for questions, concerns or complaints about the research, questions about the subject's right to obtain information, or to offer input
- A statement that 1) the subject's information or biospecimens collected as part of the research will not be used or distributed for future research studies, even if identifiers are removed, OR 2) identifiers might be removed from private information or biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent *(this required element is optional until transition to the revised Common Rule)*

3.5. Additional elements

3.5.1. When appropriate, the following elements of information should also be provided to each prospective subject:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), that are currently unforeseeable.
- Any additional costs to the subject that may result from participation in the research.
- Anticipated circumstances under which the subject's participation may be terminated by the researcher without regard to the subject's consent.
- The consequences of a subject's decision to withdraw from the research, if withdrawal could result in adverse events, and the procedures for orderly termination of participation by the subject.
- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation, will be provided to the subject.
- The approximate number of subjects involved in the study.
- A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

3.6. Requirements of the Food and Drug Administration (FDA)

3.6.1. Description that if they decide to stop being in the study, or are removed from the study, or the study is stopped, the data collected about them up to that point will remain part of the study and may not be removed from the study database.

3.6.2. Statement that the FDA may have access to the study data and records.

3.6.3. If the study is posted on ClinicalTrials.gov, as a required or voluntary posting (U.S.C. 282(j)(1)(A)), the FDA requires that the following statement be provided to subjects in most clinical trials as an element of the consent process, without alteration: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

3.7. Other Requirements

3.7.1. There may be additional requirements associated with specific federal and state agencies and regulations. For example, there may be state reporting requirements (e.g., child abuse, elder abuse, domestic violence) that are relevant to the research and should be explained to the subjects.

3.7.2. When planning to conduct research outside of the state of Wisconsin, researchers are responsible for being aware of, and complying with, any consent requirements of other states or countries.

3.8. Institutional Requirements

3.8.1. Investigators are required to use the Ascension Wisconsin IRB Consent Form Template in their development of a consent form for use in research studies conducted at Ascension Wisconsin. In rare cases, the IRB Chair or designated review may grant an exception to this requirement.

3.8.2. The Ascension Wisconsin IRB may require additional elements including, but not limited to:

- A conflict of interest disclosure (COI). This should be included when the IRB determines it is necessary to disclose a real or potential COI for the investigator or institution.
- The source of any external funding for the research.
- Statement that information may be placed in the medical record.
- Description of a federal Certificate of Confidentiality, if applicable.

3.8.3. The Ascension Wisconsin IRB may require additional information is provided when it is determined to meaningfully add to the protection of the rights and welfare of subjects.

3.9. Prohibited Elements

3.9.1. The informed consent documents may not contain any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the Investigator, the sponsor, or its agents from liability for negligence.

3.9.2. No unproven claims of effectiveness or certainty of benefit, either implicit or explicit, may be included in the informed consent documents.

3.9.3. Typically, the HIPAA authorization is required to be a separate document and the IRB will not approve a consent form that incorporates the HIPAA authorization; in rare cases the IRB Chair or designated reviewer may make an exception to allow this. Additionally, consent forms created prior to the effective date of this policy do not need to be modified to meet this requirement.

4. Waivers of Consent Requirements

4.1. The IRB may approve a consent procedure which does not include, or which alters some or all of the elements of informed consent if the IRB determines and documents that the following apply:

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

4.1.1. Waivers or alterations of informed consent, as described above, are granted for FDA regulated studies, pursuant to the FDA Guidance: IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects.

4.1.2. Additional requirements for waiving consent

4.1.2.1. Public Demonstration projects. The IRB may consider a waiver of the consent process for Public Demonstration projects if the IRB finds that the research or demonstration project is to be conducted by, or is subject to, the approval of state or local government officials, and is designed to study, evaluate, or otherwise examine: public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or 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.

4.1.2.2. Planned emergency research. Research involving planned research in life-threatening emergent situations where obtaining prospective informed consent has been waived for some or all of the potential research subjects, as provided by 21 CFR 50.24. The research plan must be approved in advance by FDA and the IRB, and publicly disclosed to the community in which the research will be conducted.

4.1.2.3. Unplanned Emergency Research. For unplanned emergency use of a FDA regulated product for a single subject, the investigator is required to obtain informed consent of the subject or the subject's legally authorized representative as described in the *IRB SOP: Emergency Use of an Investigational Drug, Biologic or Device*.

4.1.2.4. In Vitro Diagnostic Device Studies. The FDA believes that it is possible in certain circumstances for IVD device investigations, under specific conditions conferring IDE exemption defined by 21 CFR 812.2(c)(3),to be conducted using leftover specimens obtained without informed consent when the study uses only leftover specimens for which the subject cannot be identified, the results of the investigational test are not communicated to/associated with the identified subject, concerns associated with privacy are minimized and the study does not pose new medical risks to subjects whose specimens are used. The IRB may waive the informed consent requirement in these cases, pursuant to the FDA guidance: Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable.

4.1.2.5. Department of Defense. The IRB may not waive the consent process for any research to be conducted under Department of Defense (DoD) regulations where the research is classified or if subject meets the DoD definition of an experimental subject. A waiver of the consent process for such DoD regulated research requires permission of the Secretary of Defense or Assistant Secretary of Defense for Research and Engineering.

4.1.2.6. Department of Education. For research subject to Department of Education regulations, the IRB will follow the requirements of the Family Educational Rights and Privacy Act (FERPA) when considering whether it may grant exceptions to parental/student consent to release of records for research. In addition, the Investigator must ensure the project complies with and follows the requirements set forth the Protection of Pupil Rights Amendment, for research seeking a waiver of consent involving students

4.2. An IRB may waive the requirement for the investigator to obtain a signed and dated consent document for some or all subjects, if it finds either:

- That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
- That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

4.2.1. When the research involves an FDA-regulated product, the IRB may waive written consent only for research as described above.

4.2.2. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

5. Additional Considerations and Requirements of the Informed Consent Process for Certain Populations

5.1. Legally Authorized Representative: See *SOP: Informed Consent Process for Research: Legally Authorized Representative (LAR)*

5.2. Adults with Decreased Decision Making Ability: See *SOP: Research Involving Adults with Decreased Decision Making Ability*

5.3. Children: See *SOP: Research Involving Children*

5.4. Non-English-speaking subject: See *SOP: Research Involving Subjects with Limited English Proficiency*

5.5. Subjects with Limited Literacy: The IRB expects researchers to consider the literacy level and distribution in the study population and to make appropriate accommodations to the consent process so that all consent requirements are addressed.

5.5.1. If an Investigator anticipates recruiting and enrolling subjects who may have limited or a lack of literacy, the Investigator must develop and describe in their submission their consent process for this subject population.

5.5.2. If the Investigator unexpectedly determines that a potential subject demonstrates limited or a lack of literacy when discussing the research project, the Investigator should:

- Identify a literate adult person to work with the potential subject and to serve as a witness to the consenting process. The individual may not be a part of the study team, but may be a family member.
- Read the entire consent document to the subject with the witness present and ask both the subject and witness to sign the form.
- Provide a copy of the signed informed consent document to the subject for future reference with the name and contact information for the study staff called out or highlighted.
- Be sure to document the process in their study records.

6. Observation of the consent process

6.1. The IRB has the authority under 45 CFR 16.109e and 21 CFR 56.109(f) to observe, or have third party observe, the consent process for research.

6.2. The IRB may consider observation of the consent process when it would be useful to ensure human subject protections for research, such as the following cases:

- The IRB has concerns that the consent process is not being conducted properly and wants to ensure that the consent process is appropriate and the approved process is being followed
- The IRB wants verification from sources other than the investigator that no material changes have taken place since prior IRB review
- The nature of the research indicates that the consent process can be improved through observation
- The research involves a vulnerable population or use of a highly risky or innovative procedure
- The research and/or consent process is conducted by an inexperienced investigator and/or research team

6.3. The IRB, Institutional Official or designee designates who conducts the observation. The IRB may have the observation conducted by IRB member(s), IRB/Research Integrity and Protection staff (typically the Research Education and Quality Management coordinator), or an independent person hired by the IRB, but paid for by the investigator's funds.

REFERNCES

45 CFR 16.109(e)
21 CFR 56.109(f)
21 CFR 812.2(c)(3)
FDA Guidance: "IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subject", 2017
FDA Guidance: "Guidance for Sponsors, Institutional Review Boards, and Food and Drug Administration Staff", 2006

RELATED MATERIAL

IRB SOP: Informed Consent Process for Research: Legally Authorized Representative (LAR)
IRB SOP: Research Involving Subjects with Limited English Proficiency
IRB SOP: Research Involving Children
IRB SOP: Research Involving Adults with Decreased Decision Making Ability
REQM SOP: Observation of the Consenting Process

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	10/23/2017	New- Initial Integration Update	J. Blundon