BayCare

POLICY & PROCEDURE

Title: **GENERAL REQUIRMENTS for the INFORMED CONSENT PROCESS and POSTING of the INFORMED CONSENT FORM**	**Policy Number:** BC-IRB-408 **Page:** 1 of 4
SPONSORED BY: Sponsored Programs and Research Committee	**Issued for:** All BayCare, including without limitation: Bartow Regional Medical Center BayCare Alliant Hospital BayCare Wesley Chapel Hospital Mease Countryside Hospital Mease Dunedin Hospital Morton Plant Hospital Morton Plant North Bay Hospital South Florida Baptist Hospital St. Anthony's Hospital St. Joseph's Hospital Winter Haven Hospital
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This policy is developed as a guideline to address general circumstances. There may be certain instances in which the exercise of professional judgment and/or discretion by the health care provider warrants taking other actions.

This **GENERAL REQUIREMENTS for the INFORMED CONSENT PROCESS and POSTING of the INFORMED CONSENT FORM** Policy applies to BayCare Health System, Inc., and any of its affiliated entities, including those entities listed above (collectively, "**BayCare**").

SCOPE:

BayCare Human Research Protection Program

PURPOSE:

To outline general requirements for the Informed Consent Process and posting of the Informed Consent form.

PROCEDURE:

General Information:

It is the policy of the BayCare Institutional Review Board (IRB) Office that investigators will not involve human beings as subjects in research unless the investigator has obtained the legal informed consent of the subject or the subject's legally authorized representative (LAR). Exception to this policy requires the IRB grant a waiver of the informed consent requirement. Unless waived by the IRB, consent is documented using an approved, written consent form. The form is signed, dated, and time stamped by the prospective subject or the prospective subject's LAR. *Note: research personnel may not fill in the date and time on the subject's signature line*.

Informed consent is a process, not just a consent form, by which the research study is thoroughly explained by the researcher to the potential subject. The requirement to obtain informed consent is both a legal obligation and an ethical obligation. Documentation of informed consent is accomplished using a consent form. Prior to enrolling subjects in a research activity, researchers are required to obtain legal informed consent from a potential subject or their LAR.
The consent document includes the basic elements of informed consent, and the additional elements of informed consent as applicable.

Informed consent begins with a concise and focused presentation of the key information most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. Present this part of the informed consent in an organized way and with sufficient detail relating to the research that facilitates comprehension. *A key informed section is required for all non-exempt research studies using a consent form longer than 3 pages.*

The investigator seeks informed consent under circumstances that provide the prospective subject or, when approved by the IRB, the subject's LAR, sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
If the investigator has a preexisting personal or professional relationship with a prospective subject, the responsibility for the consent process be delegated to another qualified member of the study team, wherever

possible, to avoid the possibility of undue influence to participate in the research. The information given to the subject/LAR is in language understandable and not higher than *the 8th school grade readability level* to the subject/LAR.

Provide the prospective subject/LAR with information that a reasonable person would want to have to make an informed decision about whether to participate, and an opportunity to discuss that information.

No informed consent (oral or written) includes exculpatory language through which the subject/LAR 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, the institution, or its agents from liability for negligence.

Any consent form used to enroll subjects in a research protocol is reviewed and approved by an IRB prior to enrollment. In addition, the IRB may request to observe the informed consent process to verify adequate consent when the research involves particularly vulnerable populations.

Informed Consent forms are required to be consistent with state laws and federal regulations regarding content. The informed consent requirements stated in this policy are not intended to preempt any applicable federal, state, or local laws that require additional information to be disclosed for legal informed consent.

A. IRB Submission and Review

1. The IRB reviews the application and related documents including (but not limited to) the research protocol, consent forms, scripts, recruitment and advertising materials, and participant stipend proposal. The IRB determines:
   - Whether the consent process is appropriate for the proposed research activities and any revisions to the consent process or document if necessary.
   - The amount of any stipend, ensuring the proposed method and timing of disbursement is not coercive or presents undue influence.
   - That the consent document accurately reflects the purpose, risks, benefits, procedures, and stipends as outlined in the research protocol, and that the consent document contains the required elements of consent disclosure.
   - That the documentation of informed consent is appropriate for the proposed research activities, the subject population and the level of risk.

2. The IRB verifies that:
   - The submitted research application and related materials are approvable.
   - Recruitment locations, recruitment methods, advertising materials and payment arrangements do not place subjects at risk of coercion or undue influence and promote equitable selection.
   - The consent process minimizes the possibility of coercion or undue influence and maximizes continued legally effective informed consent with an emphasis on assurances for vulnerable populations
   - The consent document has the requisite regulatory and institutional information and is written in language that is understandable to the research project population such as no higher than *the 8th school grade readability level*.
   - The consent documents accurately describe the risks and benefits initially approved, with any research project modifications, continuing review, and with the submission of reportable events or other safety-related information.
   - Any significant findings or alterations to the risks and benefits possibly related to the subject's willingness with continued participation is provided to the subject.

B. After IRB Approval

1. **Investigator Responsibilities – Enrollment.** During the enrollment phase of a research project, the investigator:
   - Adheres to the current IRB-approved research project approved consent form, and approved consent process plan.
   - Verifies delegated activities are performed by the authorized and qualified staff listed in the IRB application.
   - Submits proposed research project modifications and related or otherwise revised documents to the IRB for review and approval prior to use.
   - Documents and retains consent records.
   - Reconsents subjects when required.
   - Assesses a prospective subject's physical and emotional state to determine his/her capacity for decision making; stopping or rescheduling enrollment if a prospective subject is unable to discuss or comprehend due to their physical or emotional state, appear reluctant, or decline participation. The investigator (or their delegate) does not try to convince a prospective subject to participate in a research project.

- Considers the physical environment for conducting enrollment and utilizes a private area to avoid confidentiality concerns, avoids environments such as procedural rooms, waiting rooms with other patients nearby, exam rooms after being gowned, immediately before surgery or clinical procedures, or when prospective subjects are deprived of their glasses, hearing aids, clothing, or have been pre-medicated for a procedure.
- Conducts a conversation with the prospective subject regarding the research, using the consent document. The investigator (or their delegate):
  - ✓ Repeat important information to enhance subject recall.
  - ✓ Use plain, nonmedical language whenever possible.
  - ✓ Pause for clarification, questions and answers often.
  - ✓ Spend time listening to the prospective subject.

- Verbally remind the prospective subject that their decision to participate or not participate will not affect their clinical care.
- Provides private and ample time
- Depending on the subject population, enrollment requirements may include a medical interpreter, witness, advocate, parent(s), spouse or a LAR to be present to support the subject, communicate information, ensure impartiality of the discussion, contribute to documentation of the prospective subject's decision, and ensure the research project is discussed in a culturally and linguistically appropriate manner.
- Involvement of an LAR in the consent process requires preapproval by the IRB.
- Involvement of a witness in the consent process may require IRB pre-approval. The witness to informed consent is a licensed team member or other medical staff and will observe the entire consent process, sign the informed consent document, attest that the subject appears capable of making an informed decision, and given the opportunity to ask questions:
  - ✓ Non-English-speaking Prospective Subjects: A medical interpreter is used for communication assistance in the informed consent process, following the relevant hospital, clinic or ambulatory policy.
  - ✓ English-speaking, Illiterate Prospective Subjects: A person who speaks and understands English, but does not read and write or has low literacy, can be enrolled in a study by "making their mark" on the consent document. A witness will observe the entire consent process and sign the consent document.
  - ✓ English-speaking, Legally Blind Prospective Subjects: A person who speaks and understands English, but is unable to read due to blindness or other sight issues, can be enrolled in the study by making a mark or signing the consent with assistance. A witness will observe the entire consent process and sign the consent document.
  - ✓ English-speaking, Physically Unable to Sign Prospective Subjects: A person who speaks and understands English, but is physically unable to talk or write, can be entered into a study if (1) the person has decision making capacity, and (2) is able to indicate approval or disapproval to study entry. The consent form documents the specific method used for communication with the prospective subject and how the prospective subject communicated agreement to participate in the study. A witness observes the entire consent process and sign the consent document.

2. **Investigator Responsibilities – Participation:** During the participation phase of a research project, it is the responsibility of the investigator (or their delegate) to:
   - Increase or enhance a subject's understanding of the research project.
   - Provide opportunities for subjects to ask questions; confirm participation or withdraw from the research project.
   - Remind the subject that research project team contact information is provided in the consent document and may be used for research project related questions.
   - Provide the subject with a medical contact for clinical issues.
   - Keep research project team contact names and telephone numbers up to date and submit the updated consent or other materials to the IRB for review and approval.
   - Notify the IRB when there are significant changes in the research project and/or when information about the research project provided up to that point is no longer sufficient for maintaining legally effective informed consent.
   - Verify the subject's willingness to continue in the research project.
   - Submit proposed changes to the consent process or consent document(s) to the IRB for review and approval prior to implementation.

3. **Investigator Responsibilities - Study Completion and Last Contact:** The informed consent process ends at the point of last contact with the subject. The investigator determines when the final communication with the subject is anticipated or scheduled.

C. Consent Process Plan

1. The investigator develops and maintains a detailed consent process plan in the IRB application. The following factors are considered:
   - Type of research being conducted, for example, biomedical research, behavioral/social science research, health services research.
   - Risk to subjects, including procedures, devices, drugs, or biologics.
   - Vulnerable categories of subjects, for example children; adults lacking decision-making capacity; prisoners; persons who are non-English speaking, economically or educationally disadvantaged, terminally ill, or students or employees of the organization.
   - Characteristics of subjects such as age or health status that may influence health literacy and the consenting process.
   - Need to inform subjects of significant or incidental findings resulting from the research.

2. The plan includes a description of the following:
   - The method(s) for obtaining informed consent, including the location, methods of communicating, and any related privacy needs as applicable.
   - Time amount planned for the consent process.
   - Method(s) for assessment of a subject's capacity to consent, as applicable.
   - Protections to reduce potential subjects' vulnerability to coercion or undue influence during the consenting process.
   - Additional safeguards for the specific population,as described in 5.1.3 including the need for a medical interpreter, LAR, witness, or advocate as applicable.
   - The waiting period between discussion, decision, and enrollment.
   - Study team members who will meet with the prospective subject and obtain informed consent. These individuals must be sufficiently trained, knowledgeable about the research project in order to answer questions posed by the subject and must have IRB approval to obtain consent.

D. Posting of Clinical Trial Consent Forms

1. Per federal requirements effective January 21, 2019, 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 awardee or the federal department or agency component conducting the trial on a publicly available federal website 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.

E. Obtaining a Legally Effective Informed Consent in an Urgent or Emergency Care Setting.

1. Individuals receiving urgent or emergent medical care are vulnerable often additional protections are required for the subject's consent to participate in research to ensure consent is voluntary and sought under circumstances that minimize the possibility of coercion or undue influence.

2. The IRB and investigator(s) consider each research subject's specific situation to make the determination to and documentation of consent, including:
   (a.) the expected medical condition of the prospective subject population.
   (b.) the nature of the research.
   (c.) adequacy of time for the potential subjects or their LAR to consider participation; and
   (d.) if the circumstances appropriate minimize the possibility of coercion or undue influence for obtaining informed consent.

3. In some cases, it is possible to obtain consent from a LAR or the Secretarial waiver of informed consent under federal statute may be applicable. If the research is regulated by FDA, the Secretarial waiver permits the research to be conducted under a comparable provision.