BayCare

POLICY & PROCEDURE

Title:	**Policy Number:** BC-IRB-409
ELEMENTS OF INFORMED CONSENT	**Page:** 1 of 2
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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Approved by: Ed Rafalski, SVP, Chief Strategy & Marketing Officer **Signature:** DocuSigned by: Edward Rafalski 1C605CA03849475...	

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 "**Elements of Informed Consent** " Policy ("**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 required basic and optional elements of the Informed Consent Form.

PROCEDURE:

A. Elements of the Informed Consent Form:

1. The Institutional Review Board (IRB) verifies the required disclosures are included in the informed consent, so they are provided to each subject or legally authorized representative (LAR) in accordance with legal and regulatory required elements of informed consent. The IRB determines whether additional disclosures are required for inclusion in the consent process.
2. Researchers use the informed consent form template with the required sections and language for preparing consent forms. The consent form template contains the required elements of consent. In multi-site research, other templates are acceptable, provided all required elements and applicable additional elements are included. A request for waiver or alteration of some or all of the elements can be requested by the researcher and the waiver approved by the IRB. In addition, the IRB requires that consent forms be written in the second person.
3. The following are the basic required elements:
   - An explanation of the purpose of the proposed research.
   - The expected duration of the subject's participation.
   - A description of the procedures.
   - Identification of which procedures are experimental(this element can be omitted for minimal risk studies which are not funded by Health and Human Services(HHS).
   - A description of reasonably foreseeable risks or discomforts subjects may encounter and a statement that some applicable risks are currently unforeseeable.
   - A description of possible benefits(if any) to the subject and others which may be reasonably expected. State that if it is an experimental treatment or procedure, no benefits can be guaranteed.
   - A disclosure of alternative procedures or treatments (if any) available and advantageous to the subject, including the choice not to participate in the research (his element may be omitted for minimal risk studies which are not funded by HHS
   - A statement describing the manner and extent(if any), confidentiality of records identifying the subject will be maintained, a statement that the IRB and other entities may inspect the records., If the research is Food and Drug Administration (FDA)-regulated, include that the FDA may inspect the records.

- For greater than minimal risk research, an explanation regarding the compensation or medical treatments available if injury occurs, what they consist of, or where further information may be obtained.
- A description of any reimbursement, including the schedule of payments or that there is no reimbursement provided
- Information regarding who (generally the principal investigator (PI) or study staff) to contact for answers about the research and in the event there is a research-related injury, and separately list the BayCare Institutional Review Board (IRB)Human Research Protection (HRPP) Office is named for questions concerning the subject's rights to provide input, comments, or complaints.
- A statement indicating the subjects' participation is voluntary, refusal to participate will not involve penalty or loss of benefits to which the subject is entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is entitled.
- If the research involves a collection of identifiable private information or identifiable biospecimens, one of the following statements must be included as appropriate:
  - A statement indicating how identifiers are removed and 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 from the subject or LAR.
- A statement indicating that even if identifiers are removed, the subject's information or biospecimens collected as part of the research will not be used or distributed for future research studies.

FDA regulated trials require the following statement is included in the consent form:

"*A description of this clinical trial will be available on https://www.clinicaltrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."*

4. The following additional elements of informed consent are added to the consent form, when appropriate:
   - If the research involves an investigational drug or device or involves procedures for which the risk profile is not well known, a statement that the particular treatment/procedure may involve risks to the subject (or to the embryo or fetus, if the subject becomes pregnant) that are currently unforeseeable.
   - When there are known circumstances under which the subject's participation may be terminated by the PI or sponsor, list the anticipated circumstances under which the subject's participation may be terminated by the PI, with or without the subject's consent.
   - When there are additional costs to subjects, over and above standard of care, include a description of additional costs for which the subject will be responsible that may result from participation in the research study.
   - When there is a likelihood that abrupt termination from the research is likely to result in adverse events to the subject, include a description of the consequences of a subject's decision to withdraw from the research and procedures for orderly and safe termination of participation by the subject.
   - When there is likelihood that interim findings might indicate increased risk and a reasonable person would wish to reconsider participation, include a statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.
   - The approximate number (*correct: 10, about 300, up to 670; incorrect: unknown, cannot be determined, 20-30, a dozen*) of subjects involved with the study, totally and at BayCare.
   - For research involving biospecimens, a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subjects 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.
   - Other additional information may be required by the IRB.