BayCare

POLICY & PROCEDURE

Title: **SUBJECT PARTICIPATION, RECRUITMENT, and SCREENING**	**Policy Number:** BC-IRB-410 **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 **SUBJECT PARTICIPATION, RECRUITMENT, and SCREENING** 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 requirements for subject's participation, recruitment, and screening.

PROCEDURE:

A. General requirements for subject's recruitment.

1. Recruitment materials meet the brand standards of BayCare and are approved by the Institutional Review Board (IRB).
   - Brand Standards can be found at: https://baycare1.sharepoint.com/sites/MAR/Shared Documents/Forms/AllItems.aspx?id=%2Fsites%2FMAR%2FShared Documents%2FBayCare Brand Guide%2Epdf&parent=%2Fsites%2FMAR%2FShared Documents
2. The information in recruiting materials represent the earliest components of the informed consent process.
3. The IRB reviews the scientific merit and protection of subjects from unnecessary research risks and evaluates protocols for equitable and non-discriminatory subject recruitment. When inclusion is inappropriate with respect to the safety or well-being of the subjects or the purpose of the research, justification for exclusion of particular groups requires approval. The IRB considers the scientific and ethical justification for exclusion of classes of persons who might benefit from the research and determine if exclusion is justifiable and allowable.
4. The IRB application includes the description of the proposed study population, the number of participants to be enrolled, and the procedures used for recruitment. Materials used to recruit participants are reviewed and approved by the IRB, including written advertisements and the amount of participants' stipends.

B. Pre-screening

1. If the proposed research includes a pre-screening process asking for personal and sensitive health information to determine eligibility for the study the IRB must evaluate:
   - Questions asked to determine if procedures are in place for protecting the privacy and confidentiality of the information collected.
   - Whether the description of potential risks and benefits is presented in a fair and balanced manner.
   - When incentives are offered, the types of incentives that are offered, that the trial is voluntary, and other subject protection issues.

C. Recruitment Plan

1. The Principal Investigator (PI):
   - Provides a recruitment plan in the initial application, including a description of the proposed recruitment method(s), any advertisements, other recruitment materials or payment arrangements.
   - Specifies the method(s) and frequency of contacts to engage a prospective subject.
   - Describes the extra protections for prospective subject populations that may be vulnerable to coercion or undue influence.
   - Describes the source of prospective subjects.
   - Determines that recruitment methods, advertisements, payment arrangements are not misleading, inaccurate, exculpatory, or violate the equitable selection of subjects; and do not place prospective subjects at risk of coercion or undue influence.
   - Protects subject privacy and confidentiality
   - Considers a prospective subject's stress level or health status.
   - Considers the timing of recruitment discussions with a prospective subject, for example, in relation to a subject receiving a diagnosis and the readiness of a prospective subject to understand information being discussed.

2. The PI submits copies of recruitment materials including:
   - Printed materials
   - Media advertisements including website and social media postings
   - A copy of the audio/video file or the text / script for taping/broacasting.
   - If final copies of recruitment or advertising materials are not available at the time of initial IRB submission, draft versions are permissible until the final copy becomes available for IRB review and approval prior to use or dissemination.
   - Recruitment letters, phone or e-mail scripts.
   - Telephone call scripts.
   - Direct advertising intended to be seen or heard by potential subjects.
   - Payment arrangements, if applicable

D. Advertisements

1. IRB review and approval of the information and mode of advertisements to recruit subjects for a research study is required. Limit information to what is needed by a potential subject to determine if they are eligible and interested in participating, including:
   - The name and address of the investigator and/or research facility.
   - The condition or disease that is the focus of the research.
   - The purpose of the research referencing that the study is investigational.
   - If any, a brief list of potential benefits of participation.
   - A summary of criteria for eligibility to participate.
   - The time and other commitments required of the subject.
   - The location of the study and the office to contact for further information.
   - If any, the reimbursement for time, travel, etc. will be given.
   - The statement: “This study has been approved by The BayCare Institutional Review Board.”

2. Advertisements **do not** contain:
   - Emphasis on the amount of reimbursement that subjects will receive by bolding or using large fonts.
   - Exculpatory language where the subjects are required to give up some of their rights.
   - A guarantee for a favorable outcome or benefits.
   - Promoting that subjects will be receiving medical treatment at no cost (free medical treatment)
   - Explicit or implicit claims of equivalency or superiority to other standards of treatments or safety and efficacy.
   - Wording that the study involves “new treatment”, “new medication, or “new drug” without an explanation that the treatment is investigational.
   - Claims, explicitly or implicitly, about the drug, biologic or device under investigation that are inconsistent with FDA labeling.

3. When following FDA regulations the IRB reviews and determines that advertisements do not allow compensation for participation in a trial, including a coupon good for a discount on the purchase price of the product after approval for marketing.

E. Advertisement Materials Posted on Websites

1. IRB review and approval of listings of clinical trials on the internet is not required when the system format limits the descriptive information provided to basic trial information, such as: the title; purpose of the study;

protocol summary; basic eligibility criteria; study location(s); and how to contact the site for further information. Examples include clinicaltrials.gov and baycare.org.

2. Information exceeding the basic trial information, such as descriptions of clinical trial risks and potential benefits or solicitation of identifiable information, requires IRB review and approval.

F. Use of Social Media for Recruitment

1. Social media (e.g. Twitter, Facebook, YouTube, etc.) requires review and approval by the BayCare Communications team.
   - New projects proposing use of social media require a statement from the PI in either the IRB application or the research project proposal indicating approval by BayCare's Communications.
   - Investigators from outside institutions for which the BayCare IRB is the IRB of record, will include documentation of review and approval by the relying organization for the use of social media, or documentation that such review and approval is not required by the institution within the IRB application.

G. Non-English Speaking Prospective Subjects who are Not Specifically Targeted for the Research Project (see below for targeted non-English speaking subjects).

1. If enrollment of a prospective non-English speaking subject is considered when a research project does not specifically target this population, the BayCare investigator is required to:
   - Have an independent medical interpreter provide an oral explanation (in-person or by phone) of the entire content of the English version of the approved consent document to the prospective subject or the subject's legally authorized representative (LAR).
   - In addition, use the BayCare IRB's written Short Form/ Authorization to Use and Disclose Protected Health Information form, stating that the elements of informed consent were presented orally. The short form is translated into a language understandable to the subject.
   - Provides a witness, who is conversant in both the English language and the language of the prospective subject, to the oral presentation. The medical interpreter may serve as the witness.
   - Verifies that the prospective subject or their representative has signed the translated Short Form/Authorization to Use and Disclose Protected Health Information form.
   - Verifies that the witness has signed both the translated Short Form and a copy of the English consent document.
   - Verifies that the person obtaining consent has signed a copy of the English consent document.
   - Provides a copy of the translated Short Form to the prospective subject or the prospective subject's representative.
   - Provides a copy of the English consent document to the prospective subject or the prospective subject's representative.

H. Non-English Speaking Prospective Subjects who are Specifically Targeted for the Research Project

1. If a research project targets non-English speaking persons of a specific language, then all printed study materials that are provided to the subject are translated in that language and approved by the IRB prior to enrolling potential subjects.
   - Submit English versions of the documents to the IRB for review and approval.
   - Send the final, approved English versions to BayCare's vendor for written translation services for translation into the intended targeted population's language.
   - Investigators at outside institutions for which the BayCare IRB is the IRB of record obtain translation of the documents by either an external translator or by using the translation services available within the relying institution and per institutional policy. Submit the translated documents to the IRB via the IRB electronic system with the translation service's Certificate of Authenticity.

I. Guidelines for the Use of Interpreters

1. BayCare investigators utilize a BayCare interpreter or BayCare-contracted telephone interpreter when obtaining informed consent for research from a non-English speaking prospective research subject or the subject's legally authorized representative.

2. Investigators at outside institutions for which the BayCare IRB is the IRB of record utilize the translation services available within the relying institution and per institutional policy.

3. Study team members designated to obtain consent and fluent in the language of the prospective research subject may serve as interpreters. Telephone interpreting is permissible when an interpreter is unavailable for a face-to-face encounter, unable to arrive within a reasonable amount of time, or when institutional translation services do not have an interpreter or team members for a requested language. Telephone interpreting is used as a back-up, not as a replacement for an in-person interpreter.

4. At BayCare, family members and friends may not serve as interpreters during the research consent process except in an emergency situation and only until an institutional or contracted telephone interpreter is available. However, adult family members or friends may serve as interpreters if the prospective research subject declines institutional interpreter services AND if the use of that person does not compromise the effectiveness of care or violate confidentiality.

5. The investigator requests a BayCare interpreter be present when a family member or friend is interpreting. Minor children may not serve as interpreters for the research consent process. With IRB approval, an interpreter contracted by the investigator for the purpose of a specific study may be utilized. Institutional approval may also be required.

J. Payment/ Reimbursement of Research Subjects

1. Research subjects may receive payment of participation, not as a benefit, but as reimbursement for time and effort. Payments to subjects in research are fair and equitable.

2. During the initial review of a research protocol, the IRB is required to review both the amount of compensation proposed and the method and timing of disbursement that neither are coercive or present undue influence. The IRB determines if the amount is reasonable and not so large as to unduly induce participation.

3. Guidelines to assist investigators in determining a reasonable amount of compensation to research subjects and place boundaries on what is and is not "reasonable" are available. The "reasonableness" of forms of payment are based on the time involved, the inconvenience to the subject, reimbursement for expenses incurred while participating, and not so large as to constitute a form of undue influence.
   a. The guidelines are:
      - For studies involving more than one visit/session, compensation accrues as the study progresses, rather than contingent on the subject completing the study.
      - Unless it creates undue inconvenience or undue influence, compensation to subjects who withdraw from the study are made at the time they would have completed the study, had at the time they withdraw.
      - Describe the amount of compensation and any prorating or scheduling of payments in the informed consent document.
      - Finder's fees and bonus payments are not permitted.

K. Individual or Institutional Recruitment Incentives

1. The following are prohibited:
   - Payments to medical providersin exchange for referrals of potential participants.
   - Payments designed to accelerate recruitment that are tied to the rate or timing of enrollment ("bonus payments") unless they are judged not to interfere with providing prospective participants with sufficient opportunity to consider whether to participate and do not increase the possibility of coercion or undue influence on investigators or participants.