BC 10.160 - Research Subject Recruitment

I. POLICY:

The recruitment phase of a research study is frequently difficult and challenging. Successfully recruiting subjects involves developing and implementing a well-coordinated plan that may require the efforts of the entire research team. Under federal regulations, the Institutional Review Board (IRB) must review and approve methods used to recruit subjects to ensure that the methods are not coercive and that the confidentiality and privacy of potential subjects are protected. Therefore, every protocol should describe how potential subjects are identified, approached, and consented. It should indicate if third parties (calling centers/centralized screening centers) are involved in the recruitment of subjects.

II. PURPOSE:

The purpose of this policy is to define the requirements for recruiting research subjects at any Baystate Health affiliated entities. It applies to approving the recruitment material, enrolling the PI's own patients, employees and students as well as identifying potential subjects through Private Medical Information and advertising.

III. SCOPE:

This policy applies to all employees, medical staff, associate professional staff, teachers, students, residents, fellows, volunteers, contractors, consultants, agents, and others associated with BH who are involved in Research or any professional scholarly activities at any BH affiliated entities including but not limited to: Baystate Medical Center ("BMC"), Baystate Wing Hospital ("BWH"), Baystate Franklin Medical Center ("BFMC"), Baystate Noble Hospital (BNH), and the University of Massachusetts Chan Medical School – Baystate.

IV. DEFINITIONS:

Coercion is the practice of persuading someone to do something by using force or threats. Coercion will generally involve physical force. No relationship between the two individuals need exist for coercion to occur.

Subject selection means the process of identifying potential research subjects based on specific inclusion or exclusion criteria.

Recruitment is a component of the consent process. The process of distributing or presenting information that describes the research project and eligibility criteria so that a prospective subject may consider enrollment.

Undue influence means influence by which a person is induced to act otherwise than by their own free will or without adequate attention to the consequences. Undue influence will generally involve mental pressure in which one person takes advantage of the unequal relationship they have with the other person (e.g., supervisor/employee, doctor/patient, etc.).

V. PROCEDURE:

A. Recruitment Material

Selecting appropriate recruitment methods depends on the study design and eligibility criteria. The IRB review will follow BH Human Research Protection Program SOPs and assure that the

material is accurate not coercive or unduly optimistic, creating undue influence on the subject to participate. The content of recruitment materials should be limited to the information that prospective subjects need to determine their eligibility and interest.

Research teams need also be aware that any materials for public display or dispersion that bear the Baystate name and/or logo must be approved by Marketing & Communications. The principal Investigator is responsible for securing and documenting this approval.

Once approved by the IRB, an advertisement cannot be altered or manipulated in any way without prior IRB approval.

Directory listings of research such as ClinicalTrials.Gov are not considered advertisements and therefore, do not require IRB review and approval if the listing is limited to the following basic trial information: title, purpose of the study, protocol summary, basic eligibility criteria, study site location(s), and how to contact the study site for further information.

B. Recruitment of Subjects from the Investigator's Patient Population

When recruiting potential subjects from among their own patients, still requires IRB review and approval of the recruitment process before recruitment begins. Investigators must consider the possibility that their patients may feel obligated to participate because they are being asked by their treating physician. For the investigator, maintaining a dual role as investigator and treating physician may create subtle conflicts and ethical tension, while for the patient/subject it may create some uncertainty.

Investigators should reinforce with their patients that participation is voluntary, that they do not have to participate, and the decision not to participate will not affect their care, now or in the future.

Investigators proposing to recruit their own students, employees or patients as research subjects should justify in the protocol the necessity for the inclusion of the dependent subject. In addition, the IRB must closely scrutinize the precautions in place to prevent the appearance of coercion in the recruitment of subjects.

C. Recruitment of Subjects Identified through Private Medical Information

Recruitment efforts frequently target individuals known to have a specific medical condition. Medical records, patient registries, clinical databases, and referrals from treating physicians can be useful resources to identify potential subjects; however, it is essential to take special precautions to ensure that patient privacy is protected and that the individual patient is appropriate to participate in the research.

It is not appropriate for investigators to make the first contact with potential subjects identified through their private health information. Rather, active participation by the patient's primary/specialist health care provider in the recruitment process ensures that consideration is given to the appropriateness of an individual patient's participation in the research prior to recruitment and that the patient's privacy is respected. Research teams are encouraged to review the HRPP standard operating procedures which provide additional considerations and IRB requirements for review requirements.

D. Recruitment of potential subjects through Advertising

The text of all direct advertising for research subjects, i.e., advertising that is intended to be seen or heard by prospective subjects, must be reviewed, and approved by the IRB prior to distribution, posting, publication, or broadcasting. Direct advertising includes, but is not limited to newspaper, radio, TV, bulletin boards and the internet.

Unlike potential subjects identified through private medical information, those responding to advertisements have initiated the first contact and therefore, have implicitly given their permission to be contacted by study staff.

E. Recruitment of Employees and Students as Subjects

When students and/or employees are being recruited as potential subjects, researchers must ensure that there are additional safeguards for these subjects. The voluntary nature of their participation must be primary and without undue influence on their decision. Researchers must emphasize to subjects that neither their academic status or grades, or their employment, will be affected by their participation decision.

To minimize coercion, investigators should avoid, whenever possible, the use of their students and employees in clinical protocols involving procedures which are neither therapeutic nor diagnostic.

The Dean or equivalent must grant permission for research where students are the intended subjects. The Program Director must grant permission for research where residents are among the intended subjects. In most cases, permission from Chairs, Program Directors, Managers, or other leaders is necessary when staff from within their units of responsibility are among the intended subjects. This permission must be documented and included in the submission to the IRB. Electronic signature on the IRB application will in most instances suffice. Research teams are encouraged to review the HRPP standard operating procedures which provide additional considerations and IRB requirements for review requirements.

F. Persons with Impaired Decision-Making Capacity

The requirements in this section apply to all research involving persons with mental disabilities which may impact decision-making capacity or persons with impaired decision-making capacity regardless of funding source.

General Rule
Research involving persons with impaired decision-making capability may only be approved when the following conditions apply:

1. When only incompetent persons or persons with impaired decision-making capacity are suitable as research subjects. Competent persons are not suitable for the proposed research. The investigator must demonstrate to the IRB that there is a compelling reason to include incompetent individuals or persons with impaired decision-making capacity as subjects. Incompetent persons or persons with impaired decision-making capacity must not be subjects in research simply because they are readily available.

2. The proposed research entails no significant risks, tangible or intangible, or if the research presents some probability of harm, there must be at least a greater probability of direct benefit

to the participant. Incompetent people or persons with impaired decision-making capacity are not to be subjects of research that imposes a risk of injury, unless that research is intended to benefit that subject and the probability of benefit is greater than the probability of harm

3. Procedures have been devised to ensure that participant's representatives are well informed regarding their roles and obligations to protect incompetent subjects or persons with impaired decision-making capacity. Health care agents (appointed under the MA Health Care Proxy Law or similar law) and next-of-kin, or guardians, must be given descriptions of both the proposed research and the obligations of the person's representatives. They must be told that their obligation is to try to determine what the subject would do if competent, or if the subject's wishes cannot be determined, what they think is in the incompetent person's best interest.

VI. POLICY REFERENCES:

HRPP SOP Effective: October 28, 2022

VII. REGULATORY OR JOINT COMMISSION REFERENCES:

21 CFR 50.20, 50.25
21 CFR 56.111(a)(3);56.111(b)
21 CFR812. 20(b)(11)
Belmont Report, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research April 18, 1979
FDA Information Sheet-Recruiting Study Subjects-Information Sheet Guidance for Institutional Review Boards and Clinical Investigators
ICH 4.1.1.29

APPROVALS:

		Date:
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