Research Policies and Procedures

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I. PROTECTION OF THE RIGHTS AND WELFARE OF STUDY SUBJECTS

Authority of the IRB

1. Institutional authority - To comply with federal regulations regarding research involving human subjects, an Institutional Review Board is necessary to review research involving Boone Hospital Center (BHC). Through a partnership with Washington University in St. Louis IRB, research will be reviewed. Washington University will have the authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by 21 CFR Parts 50 and 56 (FDA) and 45 CFR Part 46 (HHS).

2. Scope of IRB authority - The IRB will review clinical investigations involving drugs, biological products, and medical devices used in the context of patient care at BHC or related facilities, as well as any other research involving patients, families, or staff, as required by federal regulations.
   a. The IRB has the authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by these policies.
   b. The IRB has the authority to suspend, place restrictions, or terminate approval of research activities that fall within its jurisdiction that are not being conducted in accordance with IRB requirements (noncompliance) or that have been associated with unanticipated problems. Any suspensions or termination of approval will include a statement of the reasons for the IRB’s action and will be reported promptly to the investigator, to appropriate institutional officials, and, through the appropriate channels, to the FDA or OHRP, as applicable.
   c. In addition, Boone Hospital Center administrative team has the authority to place restrictions on the types of investigational protocols it will consider for approval, for instance, excluding from review Phase I studies or studies involving highly vulnerable patient populations.

Purpose of the IRB

The purpose of IRB review is to ensure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in research. To accomplish this purpose, the IRB will endeavor to:
1. Protect the rights and welfare of patients receiving medical care at BHC and involved in investigational studies that take place at the hospital or related BHC facilities. This will include patients who are enrolled in studies that take place at other facilities, but who may require continuation of study treatment at the hospital if admitted for medical care.

2. Ensure the validity and appropriateness of investigational studies that take place at the hospital or related BHC facilities, including clinics, home health agencies, or the Wellaware program, and that involve BHC physicians, staff, patients, or family members as research personnel or study subjects.

3. Additionally ensure the validity and appropriateness of investigational studies proposed and/or conducted by individuals affiliated with BHC, regardless of their use of BHC facilities, whenever there is a concern about the rights or welfare of human subjects.

To accomplish this purpose, the IRB uses a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure the following:

1. Risks to study subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits (if any) to subjects and to the importance of the knowledge that may be expected to result.

3. Selection of subjects is equitable.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative and will be documented in accordance with, and to the extent required, by federal regulations unless the IRB has approved a waiver of consent in compliance with federal regulations.

5. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of the subjects.

6. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of protected health information and research data.

7. Appropriate additional safeguards have been included in the study to protect the rights and welfare of subjects who are members of a vulnerable group, as defined in III (F) of this policy.

IRB Responsibilities

a. By reviewing investigational protocols prior to the onset of research and by providing continuing review of ongoing studies, the Washington University IRB safeguards the public welfare, thus contributing to the best interest and benefit of all concerned.

b. This IRB acknowledges that it bears responsibility for overseeing research involving human subjects covered in this policy, including continuing review of research.
c. This IRB acknowledges its responsibility for complying with federal, state or local laws as they may relate to such research.
d. This IRB encourages and promotes constructive communication among the members of the IRB, department heads, research investigators, clinical staff, human subjects, institutional officials, and others concerned as a means of maintaining a high level of awareness for safeguarding the rights and welfare of human subjects.
e. This IRB will consider additional safeguards in research when that research involves prisoners, fetuses, pregnant women, children, individuals institutionalized as mentally disabled, other potentially vulnerable groups and human in vitro fertilization.
f. Research activity at BHC will follow entirely the policies of the Washington University IRB, available at Washington University HRPO Website:


2. BHC Responsibilities

a. The BHC administrative team will assure that each entity or individual involved in conducting or reviewing human subject research at BHC is aware of the most current IRB policies.

b. The Boone Hospital Center administrative team will conduct periodic quality analysis of research covered by these policies at intervals appropriate to the degree of risk, but not less than once per year, and will have authority to observe or have a third party observe the consent process and research activities.
II. BHC ADMINISTRATIVE REVIEW

1. All research affiliated with Boone Hospital Center should undergo the process of Administrative Review and Approval. This includes a thorough review, by senior administrators, to assess the budgetary concerns, legal aspects and overall biomedical facets of the research who, after doing so, will grant approval for the research to be conducted within BHC facilities.

2. Medical Review: Every study that involves Boone Hospital Center entirely or only through study-related tests or procedures has to be approved by a Senior Medical Authority, such as the Chief Medical Officer (Dr. Robin Blount), Chief Nursing Officer (Monica Smith), or, if requesting deferral to an outside IRB oversight, by the Medical Director for IRB matters at BHC (Dr. Michael Hauan). A discussion with the CMO/CNO to inform them about the planned research should take place through a phone call, email communication or an appointment. A copy of the research protocol or a summary of research should be available if necessary, along with an indication that budgetary and legal approval have been secured.

3. Budgetary Review
   a. Research coordinators and investigators should work with their sponsor to assemble a budget review of the overall profitability of their study as well as some of the Revenue and Expense metrics related to them.

4. Legal Review
   a. After the budget has been approved by the Boone Hospital Center VP of Finance (Barry Chambers) or Director of Finance (Brian Winn), researchers should submit the study for legal review. Included in this submission should be
   
   b. The approved budget,
   
   c. Clinical Trial Agreement (CTA),
   
   d. A list of procedures from the protocol to be performed at BHC. In some cases, a Facility or Service Use Agreement may be necessary, and
   
   e. Confidentiality agreements.

5. Senior Approval
   a. Every study submitted to the Washington University IRB requires an assurance document be signed by a Boone Hospital Center VP or President, such as the Chief Medical Officer or Chief Nursing Officer. A discussion with the CMO/CNO to inform them about the planned research should take place through a phone call, email communication or an appointment. A copy of the research protocol or a summary of research should be available if necessary, along with an indication that budgetary and legal approval have been secured.
b. In case of a single or blinded study involving experimental drug or devices, an unblinding process should be in place and the information about key contact personnel should be easily accessible to assure the safety of human research participants in the case of an emergency.

c. The signed document will be returned to you as indication of senior approval.

III. REQUEST FOR USE OF AN ALTERNATIVE IRB (central IRB)

COOPERATIVE RESEARCH

1. Cooperative research refers to multi-site studies that involve more than one institution. BHC may waive direct oversight of a study in favor of permitting oversight by another institution as set forth below.

2. BHC investigators participating in multi-site studies are fully responsible for safeguarding the rights and welfare of human participants and for complying with WU IRB policy.

3. To rely upon the review of an alternative IRB, the investigator must formally request that BHC approves the use of another IRB as the IRB of record.
   a. This request must demonstrate to the satisfaction of the BHC IRB Medical Director that a satisfactory alternative mechanism for assuring the protection of human subjects is available (e.g., review by a central IRB).
   b. Requests must include the study materials usually required for IRB review as well as a model informed consent form.
   c. All requested information about the alternative IRB must be supplied. This must include, at a minimum, the name of the alternative IRB and proof of their accreditation.
   d. The alternate IRB should have adequate knowledge of community attitudes, information on conditions surrounding the conduct of the research, and the continuing status of the research to assure fulfilling federal requirements.
   e. The application form for the use of a central IRB can be obtained from the BHC IRB website https://www.boone.org/IRB
   f. The application along with the documents listed below should be sent to BHC Clinical Research Office for review by the appropriate parties. BHC staff must be informed of:
      i. Study title
      ii. Principal investigator
iii. Study protocol/Summary of study protocol

g. Those by whom the use of a central IRB is permitted will receive a signed letter detailing the agreement.

4. Once a waiver for the use of a central IRB has been approved by BHC a Request to Rely form must be submitted to the Washington University School of Medicine IRB through myIRB. The Request to Rely should be approved by the WU IRB prior to submitting the IRB application to the central IRB.

RESEARCH PERFORMED AT OTHER INSTITUTIONS

1. BHC is not responsible for research conducted at another institution by non-BHC employees and/or that does not involve the use of the IRB partnership with Washington University. Individual PIs who choose to use central IRBs must accept responsibility for ensuring the safety and welfare of all human subjects who participate in the proposed research, in accordance with FDA regulations, 45 CFR 46 and HIPAA regulations.