Baptist Health South Florida

POLICY NO.: 200-5810-831.00
Administrative

POLICY TITLE: IRB Initial Review of Protocols

Responsible Department: Institutional Review Board

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Review Date:
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SUMMARY & PURPOSE:
In accordance with federal regulations governing human subjects research the Institutional Review Board (IRB) must conduct initial and continuing review of research at a convened meeting, except where expedited review is appropriate under the Department of Health and Human Services (DHHS) regulations.

POLICY:
This policy outlines the procedures which the IRB will follow for conducting initial review of research protocols and the documents that must be obtained for review and approval by the IRB.

SCOPE/APPLICABILITY:
This policy applies to Baptist Health and their employees, volunteers, workforce members, licensed health care professionals and medical staff members that may be involved in conducting research at Baptist Health.

PROCEDURES TO ENSURE COMPLIANCE:
The IRB Office will obtain the following documents for new IRB submissions:

- IRB application
- Certification of required human subjects research training for study personnel
- Certification of institutional requirements for study personnel
- Consent form (if applicable)
- Recruitment materials (if applicable)
- Complete copy of the sponsor's protocol (if applicable)
- Complete copy of the grant application (if applicable)
- For Investigator initiated studies a study proposal and/or protocol
- Investigator's drug or medical device brochure (if applicable)
- Instructions for Use for medical device (if applicable)
- Data collection forms (if applicable)
- FDA Form 1572 (if applicable)
- Sponsor's FDA letter or statement from the sponsor that the study is FDA approved
- Questionnaires/surveys/tests (if applicable)

- IRB fee payment for industry sponsored studies
- Documentation of Administrative Review/Facilitated Review/Pre-Review

The IRB Office will process the documents as follows:

- Review the documents for completeness
- Enter the information in the IRB database
- Prepare file folder
- Scan documents into share drive

The IRB Chair or his/her designee will determine for which of the following reviews the new protocol submission qualifies:

- Full Review
- Expedited Review
- Exempt Review

Full Board Review:

To make the required determination for IRB approval under DHHS 45 CFR 46.111 and/or FDA 21 CFR 56.111, at a minimum, the Board members will receive the following documents:

- IRB application
- Consent form (if applicable)
- Recruitment materials (if applicable)
- Instructions for use for medical device (if applicable)
- Questionnaire/Surveys/Tests

➢ Primary Reviewer:

A Primary Reviewer system is used for initial and continuing review of research. The Primary Reviewer will receive a complete copy of the protocol submission documents.

A complete copy of the protocol submission is available for the members at the IRB meetings.

The Primary Reviewer will complete and sign an IRB Reviewer Worksheet for each submission he/she reviews.

➢ Meeting Process:

The Principal Investigator or Sub-Investigator will attend the IRB meeting to present, provide additional information, or answer any questions which may arise. The Principal Investigator, Sub-Investigator, or study personnel cannot be present during the vote.

The IRB will discuss the protocol, the information presented, and any supporting documentation. The IRB may determine that it requires additional information or supporting documentation, or may require changes to the protocol materials or consent form prior to approving the protocol.

The IRB may require independent verification from sources other than the investigator. Independent verification may consist of review of the protocol by a consultant or verification by other means as determined by the IRB.

The IRB will grant approval for each study for specific time intervals not to exceed one (1) year. The IRB will also determine if the protocol requires review more often than annually. The factors to be considered in determining the appropriate frequency of review will include, but not necessarily be limited to:

1. the nature of the study;
2. the degree of risk involved; and,
3. the vulnerability of the study population

If the proposed research study is acceptable, the IRB will make the appropriate determinations under DHHS 45 CFR 46.111 and/or FDA 21 CFR 56.111 for review and approval of the proposed research, as well as any special determinations required for special or vulnerable populations (i.e. children), and document any associated discussions and findings in the minutes.

The IRB will notify the investigator in writing of its decision to approve or disapprove the protocol, or of modifications required to secure IRB approval of the research activity.

If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. Monthly reports of the list of approved studies are sent to the entities institutional officials.

Expedited Review:
Protocols that qualify for Expedited Review under 45 CFR 46.111 and/or 21 CFR 56.111 will be reviewed and approved by the IRB Chair or his/her designee. The protocols approved under Expedited Review will be listed on the IRB meeting agenda as required under 45 CFR 46.110(c) and/or 21 CFR 56.110 (c). The protocols approved under Expedited Review will be listed on the IRB meeting agenda. At the meeting IRB members may request to review the protocol or may suspend approval pending review at a convened meeting.

Exempt Protocols:
Protocols that qualify as Exempt under 45 CFR 46.101(b) will be reviewed and deemed to be Exempt by the IRB Clinical Research Manager or his/her designee. The protocols deemed to be Exempt will be listed on the IRB meeting agenda. At the meeting IRB members may request to review the protocol or may suspend Exempt status of the study pending review of the protocol at a convened meeting

SUPPORTING/REFERENCE DOCUMENTATION:

- Office for Human Subjects Research (OHRP)
- DHHS 45 CFR 46
- DHHS 21 CFR 56 FDA

RELATED POLICIES, PROCEDURES, AND ASSOCIATED FORMS:

- BHSF Administrative Policy: 200-5810-830-02 IRB Membership-Institutional Review Board
- BHSF Administrative Policy: 200-5810-830-03 Board Meetings-Institutional Review Board
- BHSF Administrative Policy: 200-5810--830.04 Board Meeting Minutes-Institutional Review Board
- BHSF Administrative Policy: 200-5810--831.03 Expedited Review-Institutional Review Board
- BHSF Administrative Policy: 200-5810--831.04 Exempt Review Procedures for new IRB Applications-Institutional Review Board
- BHSF Administrative Policy: 200-5810-833-03 Vulnerable Subjects-Institutional Review Board
- IRB Reviewer Checklist

ENFORCEMENT & SANCTIONS:
Enforcement of this policy will be performed by the Baptist Health South Florida Institutional Review Board (IRB).

Non-compliance by medical staff and credentialed allied health practitioners are subject to disciplinary action as outlined in the medical staff by laws and policies and enforced by the Medical Executive Committee and Board of Directors of the Baptist Health facility at which the research was conducted and/or where the staff member maintains privileges.

Violations of this policy by employees may be subject to disciplinary action in accordance with HR policy.