JUPITER MEDICAL CENTER

Policy Title: Submission of Research Protocol	**Date of Origin: 10/01/1997**
Site(s): JMC	**Type: Organization Wide**
Policy Owner: Jeanine Secor (Director of Clinical Research)	**Department(s): Clinical Research**
Review/Revise Due Date: 10/19/2018	**Date Approved: 10/19**/2015

Policy Statement

New research proposals at Jupiter Medical Center will undergo a thorough review process to ensure the expertise and qualifications of the Principal Investigator, the scientific merit of the study, and the study feasibility.

Purpose

To protect the rights, welfare and safety of all clinical research participants

Scope

The Principal Investigator and those whom are designated by the Principal Investigator. The Principal Investigator is ultimately responsible.

Definitions

CV – Curriculum Vitae
IND – Investigational New Drug
IRB – Institutional Review Board
NIH – National Institutes of Health
PI – Principal Investigator

Policy

A. Principal investigators shall be responsible for submitting to the IRB information regarding all research involving human subjects to include:
    1. **Consent Form**- A consent form or process is required for all protocols that pertain to human subjects.
    2. **Protocol**- To include quality of life and assessment forms.
    3. **Initial Review Submission Form** – signed by Principal Investigator.
    4. **Other materials** to be provided to subjects which are not included in the protocol, such as advertisements, questionnaires, diaries, etc.
    5. **Investigators Brochures, if appropriate**
    6. **Form 1572** (or 1571 form, if IND) with all resumes and professional licenses attached. FDA Website has the 1572 form if needed.
    7. **Certificate of Completion**, NIH internet course, “Human Participant Protections Education for Research Teams”; University of Miami CITI, or acceptable course for all investigators and study staff.
    8. Guidance for Industry Good Clinical Practices completion for all investigators and study staff.

9. CV for Principal Investigator and all investigators and study staff.
10. For expected costs, please see Clinical Research Department Schedule of Fees
11. **Circumstances under which an IRB fee waiver may be appropriate:**

    - Research conducted by JMC students and/or team members and research project is in alignment with a JMC program
    - Research that is investigator-initiated and research project that is in alignment with a JMC program
    - Emergency or compassionate use cases when life threatening- to be determined on a case by case basis when treated at JMC
    - Devices being regulated under a Human Device Exemption (HDE) that is in alignment with a JMC program
    - JMC IRB relinquishes oversight to another (outside) IRB.

12. If you wish to request a waiver of fees, see Request for Waiver of IRB Fees Form

B. The IRB Coordinator shall
    1. Submit the proposed research study information to the appropriate Jupiter Medical Center physicians or employees as noted in the Pre-IRB Review Policy, who shall review:
        a. the scientific merit of the study and its medical appropriateness in comparison to current standards for medical care;
        b. cost implications for the research subject and for Jupiter Medical Center;
        c. Operational demands the research study may place upon Jupiter Medical Center staff and/or departments.
    2. The IRB and the Pre-IRB review committee reserve the right to seek an outside opinion regarding a particular proposed study; especially if it is determined that a greater understanding and/or expertise is required. The cost for this outside review shall be borne by the PI/study sponsor. The PI will be notified of cost prior to review.
    3. Following this review, a summary of findings, comments, questions and/or concerns shall be submitted to the IRB Coordinator.
    4. This review shall be accomplished within a period not to exceed 2 weeks' time frame dependent upon cooperation by PI and study sponsor.

C. Upon Completion of pre-IRB review, PI will provide adequate copies of protocol, informed consent, and advertisements to the office of IRB for full IRB review within 3 weeks of the next IRB meeting.

Related Documents

A. Initial Protocol Review Form
B. Initial Investigational Device Protocol Review Form
C. Criteria for IRB Approval of Research
D. Clinical Research Department Schedule of Fees
E. Institutional Review Board - Schedule of Fees
F. Request for Waiver of IRB Fees Form

References

A. FDA Information Sheets, Guidance for Institutional Review Boards and Clinical Investigators; 1998 Update, Title 21, Part 50 Code of Federal Regulations (CFR); Title 21, Part 56 CFR; Title 45, Part 46 (DHHS) CFR.
B. Review Dates: 10/99, 01/01, 01/28/10, 06/13
C. Revision Dates: 04/99, 03/02, 01/06, 01/08, 01/09, 03/12, 01/15, 09/15
D. Contributing Author: IRB Coordinator, Director of Research, VP Ambulatory Services, Institutional Official

Approved by: Policy Committee, Judith Magalhaes (Vice President Outpatient Oper)	**Approve Date: 10/19**/2015