Guideline for Research Proposal

The primary responsibility of the Institutional Review Board (IRB) is to safeguard the rights and welfare of human research participants. For that reason, the principal investigator must provide sufficient information for the IRB to determine that research participants will be adequately protected and that the research will be conducted in full compliance with Jersey City Medical Center IRB standards. In order to approve a research activity, the IRB must assure that **all** of the following requirements are satisfied:

1. **Introduction/Literature Review:**
    - Identify the problem and provide background information on the problem
    - Discuss the importance of your research
    - Discuss current research findings as it relates to the problem or research question
    - Describe how your research will add to the knowledge in this area
    - If applicable include a discussion of the conceptual or theoretical framework you will use
    - Use references and citations

2. **Research project and its objectives:**
    - State the purpose/objective/aims of your research.
    - State your research questions

3. **Methodology to be used, including type of study, number of subjects, subject inclusion and exclusion criteria, tests, and statistical analyses**
    - Describe Methodology
    - Appropriateness of research methodology to the field of study and the objectives of the research
    - Study Design
        - Describe in detail how the study will be conducted
        - Indicate the steps taken to answer identified research questions
        - Indicate inclusion and exclusion criteria
    - Sampling:
        - Describe how sample will be selected (i.e. random sample, convenience sample etc)
        - If applicable, describe characteristics of the sample by gender, race/ethnicity, socioeconomic status, or other relevant group membership
        - Expected sample size and justification
    - Instruments:
        - Outline instruments to be used (surveys, scales, interview protocols, observation grids)
        - If instruments have previously been used, identify previous studies and findings related to reliability and validity
        - If instruments have not previously been used, outline procedures you will follow to develop and test their reliability and validity
        - Written permission by author to use tool

- Data Collection
    - Outline the general plan for collecting the data. This may include survey administration procedures, interview, medical record review or observation procedures
    - Describe your plans for maintenance and disposal of the data in a way that keeps the data private
    - Discuss how patient confidentiality will be maintained
- Data Analysis
    - Specify the procedures to be used, and label them accurately (e.g., ANOVA, ethnography, case study, grounded theory).
    - Describe how the data will be evaluated in relation to each of the objectives
    - Communicate precise intentions and reasons for these intentions
    - Discuss how results will be interpreted

4. Appropriateness of subject selection criteria and techniques.

- How will you assure that participants are not in any way coerced to participate
- Describe how you will recruit participants. Include any information about the use of incentives if relevant
- If your research includes vulnerable participants, state the rationale for their inclusion
    - (Vulnerable participant populations include children, prisoners, people with developmental disabilities, members of politically disadvantaged groups and anyone else who might not be completely free or able to refuse participation in your research)

5. Risks to research subjects and how risks, if any, will be minimized

- Describe any potential risks of physical, emotional, financial or social harm to participants
- Describe your methods for minimizing the risk of harm
- Specify any factors that would cause you to stop your research due to physical or emotional stress on the part of participants
- Discuss how treatment will be provided if harm should occur
- If there are no risks of harm, this must be stated and explained
- Anticipated Benefits
    - State any anticipated direct benefits to these participants.
    - State any anticipated benefits to society-at-large or others (e.g., the academic literature)

6. How consent will be obtained, and by whom

- Attach any relevant forms
- Discuss process for obtaining consent
    - All participants obtaining consent must obtain NIH training. Provide copies of training certificates

- Use the template provided in the IRB packet, modify to included specific information regarding the study
- Discuss how patient confidentiality will be maintained

7. **How treatment and/or compensation will be provided to research subjects if harm occurs**
    - Discuss process
    - If there are no risks of harm, this must be stated and explained

8. **How costs of the research are to be funded. Specify possible costs to subjects, Jersey City Medical Center, or to Liberty Health**

9. **Summary discussion of expected results**
    - Predict the significance of the study and expected outcomes. This may closely relate to aims

10. **Completed Chair/SVP Approval Statement**
    - Use form provided
    - Must be signed

11. **A statement indicating that a report will be submitted to the IRB annually, or more often if required**

12. **Investigator credential**
    - Identification of all co-investigators
    - including their institutions and possible conflicts of interest

13. **Name and address of the individual or institution to be notified if the proposal is approved by the IRB, requires modification, or is not approved.**

14. **Copies of completed Assurance Training Certificate. Visit website to obtain certification through modular training: http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp**
    - Copies must be provided for Investigators and Co-investigators