Sir Lester Bird Medical Centre

Institutional Review Board

Instructions and Application Document

Contents

1. Introduction .....Page 3
2. Institutional Review Board (IRB) application instructions.....Page 4
3. Documents required for review.....Page 5-6
4. Application form.....Page 7-11
5. Required Documents Checklist .....Page 14

Introduction

The Sir Lester Bird Medical Centre Institutional Review Board (SLBMC-IRB) approves and oversees all research within the institution. It ensures the safety of research subjects and the integrity of the research involving humans. The Board evaluates scientific methods, procedures, and ethical concerns. SLBMC adheres to ethical standards set by the International Council for Harmonisation – Good Clinical Practice (ICH-GCP) and the World Medical Association's Declaration of Helsinki.

Scientific Soundness is evaluated on the following criteria:

1. Problem: Definition-Hypothesis
2. Specific Aims
3. Background- Literature and Previous Work
4. Significance - Impact of Proposed Research
5. Design & Methodology
6. Statistical Tools

Ethical Soundness will be evaluated on the following criteria:

1. Privacy, Confidentiality, and Data Management
2. Risk Assessment and Management
3. Benefits
4. Subject Recruitment
5. Informed Consent

Institutional Review Board application instructions

a) Applications must be submitted on the prescribed application form or electronically to the following email address irb@msjmc.org . The sections to be completed can be found on Pages 7-11.

b) All relevant core documents (see Section B below for a list of the documents for review) must be submitted along with the completed application form for review.

c) The application form and all core documents must be submitted in English.

d) Applicants shall submit research proposals for review prior to the start of recruitment of participants, formal data collection, access to data or human specimen collection. Failure to comply will result in administrative consequences.

e) Applicants must seek approval for conducting pilot studies.

f) Supplementary information or changes to the core documents should be submitted to the IRB within two weeks of the date when the request for review was made. Applicants requiring additional time must formally write to the Chairperson outlining justifications for the required extension.

g) Applicants seeking to make changes to an approved research protocol must submit university/hospital approved proposed changes to the IRB for approval.

h) Proposals will be acknowledged within three working days. The IRB meets on the first Friday of each month. Review decisions will be emailed to applicants and SLBMC Management by the Chairperson or secretary.

Documents required for review

1. Completed and signed application form.

2. The protocol for the proposed research project together with supporting documents and appendices.

3. Current curricula vitae of the principal investigator(s).

4. Any regulatory clearance (if applicable).

5. Statements of conflicts of interest (if applicable)

6. Plans for publication and knowledge sharing

7. Disclosure of all previous decisions (including those leading to a negative decision or modified proposal) by other IRBs or regulatory authorities for the proposed study, whether in the same location or elsewhere, and indication of the reasons for previous negative decisions and modification(s) to the proposal made on that account.

8. Any other information relevant to the study e.g. consent forms, data capture instruments, advertisement, participant information sheets, questionnaires, adverse event sheets etc.

9. When the research involves:

    a. An experimental product (such as a pharmaceutical or medical device under investigation), an adequate summary of all safety, pharmacological, pharmaceutical, and toxicological data available on the study product, together with a summary of clinical experience with the study product to date (e.g. recent investigator's brochure, published data, a summary of the product's characteristics) must be submitted.

10. The extraction and/or use of clinical specimen, justification for the use of specimen and a summary of safety related issues must be presented.

Application form

Section 1: Basic information

Title of the proposed research:

Reason for research:

- ☐ Fulfillment of Academic Obligations
- ☐ Grant project
- ☐ Quality Improvement/ local audit
- ☐ Research project

Name and contact details of Primary Investigator:

Name

Address

Telephone number

Email address

Institutional Affiliation

Co Investigator(s) (if investigator will be on site):

Name

Address

Telephone number

Email address

Institutional Affiliation

Section 2: Project Details

a. Please fill the section below.

Title	
Hypothesis	
Aim	
Objectives (SMART)	
Population	
Methodology	
Sample Size	
Statistical tools	

Risks. Indicate what you consider the risks to participants to be, and indicate the precautions to be taken to minimize or eliminate these risks. If any monitoring procedures are needed to ensure the safety of participants, describe them.

Recruitment: Describe how participants will be recruited and how informed consent will be sought from participants or from the participants' legally authorized representatives. Use additional sheets as needed.

Conflict of Interest: Do any investigators or co-investigators have a conflict of interest?

- ❑ Yes. If yes, please explain in the space provided below.
- ❑ No.

Proposed start date (dd/mm/yyyy)_____

Proposed end date (dd/mm/yyyy)_____

b. Provide the research/dissertation protocol. The protocol must include:

- An introduction and background information on the research topic
- A clear statement of the objectives of the research proposal
- The justification for the research (This should include a review of the current knowledge from the literature on the topic, with an explanation why this project is necessary, and how it will contribute to the overall knowledge in this area in Antigua and Barbuda)
- A detailed description of the methods.
- Procedures for obtaining informed consent, including statements that the researcher/s will read the informed consent form to the participant or his/her legal guardian and that s/he understands its content before the seeking of consent. A copy of the informed consent form, recruitment posters and any questionnaires to be administered.
- Plans to protect the confidentiality and anonymity of participants.
- Plans for the dissemination of findings.
- Relevant references (i.e. literature citation)

- ❑ I certify that the information furnished concerning the procedures to be taken for the protection of human participants is correct. I will seek and obtain prior approval for any modification in the protocol or informed consent document, and will report promptly any unexpected or otherwise significant adverse effects encountered in the course of this study.

- ❑ I certify that all individuals named as consultants or co-investigators have agreed to participate in this study.

- ❑ Upon completion, I will provide a copy of the completed research to the SLBMC-IRB.

_____

Date and Signature of Principal Investigator

_____

Date and Signature of Co Investigator

Required Documents Checklist

- □ Completed application form with signature of principal investigator.
- □ Curriculum Vitae (with photograph) of Principal Investigator.
- □ Research/project protocol with accompanying data extraction forms, questionnaires, informed consent forms etc.
- □ Letter of Ethical Approval from the university if the investigator is a student.
- □ Letter of Permission from the Medical Director or the Director of Administration if the principal researcher is not a student and is employed at SLBMC. Approval from the identified directors depends on the subject matter (clinical or administrative) of the research. Should an ethical issue arise during the research process; the project will be stopped by the IRB.
- □ Any other information that may be requested by the IRB.

Applications will not be reviewed unless:

1. **A formal research protocol/dissertation protocol has been submitted along with supporting documents (questionnaires, data extraction templates etc)**
2. **The IRB Application Form has been signed by the Principal Investigator. If the Principal Investigator is not stationed at Sir Lester Bird Medical Centre, the IRB Application must be cosigned by the on-site investigator(s).**