Introduction to Clinical Research

Office of Research and Faculty Development

School of Dental Medicine

Stony Brook University

1. Team Building and Development

a. The Research Team

The research team consists of individuals who intervene or interact directly with human subjects (including the recruitment or consenting thereof), or who analyze data and/or tissue derived from humans for research purposes:

Principal Investigator (PI), co-Investigators (co-I's), Research Coordinator, Statistician, Administrative Reviewer, Scientific Reviewer, Advisor, Students, Residents, post-doctoral students.

Trainees: May not serve as Principal Investigators. They must have a faculty sponsor who fulfills the PI eligibility criteria and who will serve as Principal Investigator and faculty advisor on the study.

b. Responsibilities

(https://web.stonybrook.edu/research/humans-sop/Shared%20Documents/Section12.aspx)

1. Develop and conduct research that is in accordance with the ethical principles in the Belmont Report;
2. Develop a research plan that is scientifically sound and minimizes risk to the subjects;
3. Have sufficient resources necessary to protect human subjects, including:
   a. Access to a population that would allow recruitment of the required number of subjects
   b. Sufficient time to conduct and complete the research.
   c. Adequate numbers of qualified staff.
   d. Adequate facilities.

    e. A process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions.
    f. Availability of medical or psychological resources that subjects might require as a consequence of the research.
    g. Assure that all procedures in a study are performed with the appropriate level of supervision and only by individuals who are licensed or otherwise qualified to perform such under the laws of New York and SBU policies
4. Assure that all key personnel are educated in the regulatory requirements regarding the conduct of research and the ethical principals upon which they are based;
5. Protect the rights and welfare of prospective subjects;
6. Ensure that risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes
7. Recruit subjects in a fair and equitable manner
8. Obtain and document informed consent as required by CORIHS and ensuring that no human subject is involved in the research prior to obtaining their consent;
9. Have plans to monitor the data collected for the safety of research subjects;
10. Protect the privacy of subjects and maintain the confidentiality of data;
11. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, include additional safeguards in the study to protect the rights and welfare of these subjects;
12. Have a procedure to receive complaints or requests for additional information from subjects and respond appropriately;
13. Ensure that pertinent laws, regulations, and institution procedures and guidelines are observed by participating investigators and research staff;
14. Ensure that all research involving human subjects receives CORIHS review and approval in writing before commencement of the research;
15. Comply with all CORIHS decisions, conditions, and requirements;
16. Ensure that protocols receive timely continuing CORIHS review and approval;
17. Report unexpected or serious adverse events problems that require prompt reporting to CORIHS;
18. Obtain CORIHS review and approval in writing before changes are made to approved protocols or consent forms
19. Seek CORIHS assistance when in doubt about whether proposed research requires CORIHS review

c. Research Team Credentialing

(http://www.stonybrook.edu/research/orc/human-subjects.shtml)

i. Initial Education

- All Principal Investigators and members of their research team must: review core training documentation including the "SBU Standard Operating Policies and Procedures for Human Research Protection," and the "Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research,

- be familiar with the SBU HRPP website, and the availability of links and other information contained within, and

- complete either:

  the SBU-required Core Modules in CITI Course in the Protection of Human Research Subjects, and pass the required quizzes with a score of 80 or better,

  or

  a course in human research protections offered by the Office of Research Compliance (available for groups of twenty or more trainees). This option also requires completion of a CITI refresher course for the purposes of assessing competency with the course material, via a score of 80 or better on the required quizzes.

- Complete 'HIPAA in Research' training

ii. Recertification

All investigators and members of their research teams must meet SBU continuing education requirement every three years after certification of Initial Education for as long as they are involved in human subject research. There is no exception to this requirement. Acceptable training includes:

- the SBU-required CITI Refresher Modules (chosen in accordance with the criteria referenced above in Section 12.4.1.1, with a passing score on the required quizzes with a score of 80 or better.

or

- A refresher course in human research protections offered by the Office of Research Compliance (available for groups of twenty or more trainees). This

option also requires completion of modified CITI refresher course for the purposes of assessing competency with the course material, via a score of 80 or better on the required quizzes.

and

· Thorough review of all CORIHS Updates sent regularly from the Office of Research Compliance on guidance and hot topics pertinent to human subject protections

iii. The Collaborative Institutional Training Initiative

The Collaborative IRB Training Initiative (CITI): SBU offers access to the CITI program to all SBU faculty, staff, or students. Non-SBU investigators can use the CITI program if they are on file with CORIHS as an investigator on an IRB application (approved or pending).

The CITI web-based program is available at **http://www.citiprogram.org** , Investigators register under SUNY University at Stony Brook. After login, questions will be asked to assess what type of training is required based on:

1. The level of SBU training (initial, first renewal, second renewal etc.)
2. The type of research (biomedical, social behavioral, FDA etc.)
3. The role in the research activities (data/tissues only, interaction with subjects, etc)
4. Completion of the initial training through CITI will take approximately 4-6 hours, although the trainee can go back over multiple sessions to complete training.
5. The University of Miami (which provides the IT, administrative support, and home to the CITI program) issues CME/CEU credits for a fee. In order to qualify for CME/CEU credits, one must take and pass all required modules for the group you choose. Click the link for CME/CEU credits on the Learner's Menu for detailed information.

2. Scientific Protocol

Prepare the following sections pertaining to the research proposal

a. Hypothesis statement
b. Specific questions (Aims) to test hypothesis
c. Choose study design
d. **Protocol Template for submissions to IRB (CORIHS)**

- TITLE
- INVESTIGATORS

A. SPECIFIC AIMS
B. BACKGROUND AND SIGNIFICANCE
C. PRELIMINARY STUDIES
D. RESEARCH DESIGN AND METHODS
   1. Rationale/overview
   2. Research Site
   3. Study sample
   4. Screening
   5. Procedures
E. STATISTICS
F. FUNDING STATUS, DETAILS
G. HUMAN SUBJECTS RESEARCH PROTECTION FROM RISK
   1. Risk to Subjects
   2. Adequacy of Protection Against Risks
   3. Potential Benefits of Proposed Research to the Subjects and Others
   4. Importance of the Knowledge to be Gained
H. DATA SAFETY MONITORING PLAN (for more than minimal risk studies)
I. LITERATURE CITED

3. Institutional Compliance

i. Office of Clinical Trials
(http://www.stonybrook.edu/research/osp/contracts.shtml#clinicaltrials-tab)

Administers the overall process, including confidentiality agreement, protocol review, contract and study initiation; forms; fees; contact persons:

1 PI reviews Non-Disclosure Confidentiality Agreement form sponsor and send to the Office of Clinical Trials for review
2 Contact the Office of Technology Licensing & Industrial Relations (only if PI is a co-inventor)
3 Investigator & Sponsor develop protocol
4 Develop budget w/sponsor - -> consult Department Chair & send to Ms. Leigh Gentilcore
5 Receive approval from Office of Sponsored Programs before proceeding forward

ii. Office of Sponsored Research
(http://www.stonybrook.edu/research/osp/)
Includes contract process, application forms and procedures; contact persons; fees:

1. Sign contract (Office of Clinical Trials forwards to Sponsor)
2. Start COEUS application (online)
3. IRB: SBU's IRB is CORIHS (Committee on Research involving Human Subjects) http://www.stonybrook.edu/research/orc/humans/IRBNet%20for%20SBU%20BNL%20Researchers.pdf

a. submission deadlines; application forms and procedures; contact persons; fees
b. Register with IRBnet.org. Go to http://www.irbnet.org (see Appendix I)
c. Complete IRB checklist

i. CORIHS Submission Requirements (New, First Time Submissions) - see Appendix II
ii. CORIHS Submission Requirements (Continuing Reviews, Regular & Five-Year Submissions) - See Appendix III

d. Sponsor forwards fully executed agreement to Office of Sponsored Programs

i. Award is established
ii. CORIHS approved
iii. Study begins

3. Gathering Preliminary Data – Pilot Studies – Retrospective Study Design
    a. See http://www.statsdirect.com/help/basics/prospective.htm
    b. Retrospective study designs usually fall under IRB exemption status

4. Prospective Experimental Design

    a. Prospective study designs usually fall under IRB expedited or full committee review status.
    b. Speak with Dr. Kyrkanides to discuss your need for statistical support.
    c. DSMB (Data Safety Monitoring Board) / DSMP (Data Safety Monitoring Plan): Review Appendix V for DSMP instructions and format.

5. What does your signature mean!

Certification of Principal Investigator

Your electronic signature that will accompany the IRBNet electronic submission for IRB approval of this activity certifies that the research activity described in these forms and supporting materials will be conducted in full compliance with Stony Brook University's Policies and Federal regulations governing human subject research. Furthermore, I will:

- Promptly report any revisions or amendments to the research activity for review and approval by CORIHS prior to commencement of the revised protocols, with the only exception to this policy being those situations where changes in protocol are required to eliminate apparent, immediate hazards to the subject,
- Promptly report any unanticipated problems or serious adverse events affecting risk to subjects or others,
- Assume full responsibility for selecting subjects in strict accordance with the inclusion/exclusion criteria outlined in the application materials,
- Ensure that only CORIHS-approved, stamped consent forms will be used for studies in which consent form(s) have been approved for the research activity, and
- Ensure that all personnel involved with human subjects, or human data and/or biological specimens during the course of this research activity are trained in the Protection of Human Subjects and HIPAA in Research, in full accordance with SBU policy on this matter.
- Ensure that no member of my study team will be involved in any aspect of the study for which s/he has not been trained, or conduct any procedure in which s/he has not been certified/licensed.

Certification of Study Team members

Your electronic signature certifies that:

- I am fully cognizant of the details of the protocol, and will conduct all aspects of the study as approved by CORIHS
- I will promptly report to the Principal Investigator any unanticipated problems or serious adverse events affecting risk to subjects or others
- I will not be involved in any aspect of the study for which I have not been trained, or conduct any procedure in which I am not certified/licensed.

6. Sign off procedure

On IRBNet.org, the study Principal Investigator or designee will invite all members of the study, as well as the Chair of the Department and the following members of the Clinical Research Review Committee as "Reviewers":

- Dr. David Paquette
- Dr. Julio Carrion
- Dr. Dolores Cannella

During sign off, all study members, one of the Clinical Research Review Committee members and the Department Chair have to sign off on IRBNet.org