STANDARD OPERATING PROCEDURES

SCIENTIFIC AND TECHNICAL

COMMITTEE (stc)

Noguchi Memorial Institute for Medical Research

College of Health Sciences

University of Ghana

Legon

Background/Introduction

The Noguchi Memorial Institute for Medical Research Scientific and Technical Committee (NMIMR-STC) was established in the year 1982 with the mandate to examine the objectives, relevance, scientific quality and budgets of all research projects proposed and also review the progress of execution. An ancillary responsibility of the committee was to serve as a conference committee of the Institute.

Composition

Initially the composition of SOP was as follows:

Noguchi Representatives included:

- The Director of Noguchi (Chairman)
- Co-coordinators of projects
- All heads of Unit
- Two (2) members elected by the Research Fellows and Honorary Research Fellows of the Institute

Outside Representation included:

- Department of Animal Science, Faculty of Agriculture
- Department of Community Health, University of Ghana Medical School
- Department of Food Science, Faculty of Science
- Institute of Scientific Social and Economic Research (ISSER)

The committee met quarterly to review proposals submitted to it for review. The numerical strength of STC used to be twenty- two (22) including administrative staff.

Over the years, concerns had been raised regarding the large numbers of protocols required as part of submission process. For this reason, a proposal was put forward at a Faculty Board

Meeting held on 20th July, 2012 to re-constitute the STC. This was to enhance efficiency and effectiveness of the committee and also reduce the number of membership. This led to the current composition/membership which is as follows:

- Director of NMIMR(Chairman)
- Two (2) Professors elected by Fellows
- Four (4) Heads of Departments elected by Fellows
- Head of the Department of the Principal Investigator(s) [PIs]

Outside Representatives are as follows:

- Institute for Statistical Social and Economic Research (ISSER)
- A representative from the Medical School
- A representative from College of Basic and Applied Science

In attendance are the following:

- The executive secretary
- The Research Development Officer (Co-ordinator)
- Administrative Assistant

The numerical strength of STC now is 14 including administrative staff.

Co-opted Reviewers

- ✓ The STC at its discretion may invite scientists who are not members of STC but have expertise to function as co-opted reviewers of a project application to assist the STC in its review process. This will be done by the coordinator in consultation with the chairman of STC.
- ✓ These co-opted reviewers shall have access to all documents submitted to STC relevant to the specific project under review.
- ✓ They may participate at the deliberations and make recommendation on the project.

STC Application Requirements

A protocol submitted by PIs to the Scientific and Technical Committee (STC) must satisfy the following:

- 1 hard copy submitted to the office and a soft copy sent electronically to the co-coordinator through email address: stc@noguchi.ug.edu.gh
- Soft and hard copies of CVs of PIs and Co-PIs, should be (Abridged versions preferable/NIH standard)
- A cover letter signed by the Principal Investigator; for students signed by Supervisor/Head of Department.
- Consent Form for research participants attached to each proposal (use Noguchi Consent Form Template).
- STC submission form filled out and attached to each proposal.
- 1 copy of all supporting documents including questionnaire, interview guide etc.
- Proposal should be in **Times New Roman font,** have a **Font size of 12,** and **1.5 Spacing.**

Meetings

- The committee meets on the first Tuesday of every other month and operates on the academic year schedule.
- There shall be an agenda for every meeting which will include all protocols submitted for review and matters arising out of previous meeting.
- Members shall be notified of an upcoming meeting two weeks before the meeting and the materials submitted will be distributed early enough (at least two weeks) to allow ample time for the review of the protocols.
- A quorum shall consist of 50% majority.

Meeting Procedure

- The Chairperson (Director) shall chair the meeting. In his absence, a member nominated by members present
- A member assigned to respective protocols will lead discussion on his/her assigned protocol prior to invitation of the Principal Investigator.
- The PI shall make a brief presentation after which questions or comments will be posed by STC Members.
- The PI will then leave and a decision will be taken about the protocol.

Meeting Minutes

- The Coordinator shall prepare minutes of each meeting.
- The minutes will be in sufficient detail, and will include the following:
  - ✓ Date and venue of the meeting.
  - ✓ Attendance and absence.
  - ✓ Matters arising out of previous meeting.
  - ✓ Decisions reached on each research project application reviewed.
  - ✓ Reasons for requiring changes in a project, or disapproving or suspending a proposal.

Communicating STC Decisions to Applicants

- After the meeting, a correspondence will be sent to the applicant via e-mail within a maximum of five (5) working days.
- Such Correspondence will include the following:
  - o The name of the applicant.
  - o The date of the decision.
  - o The exact title of the proposal reviewed.
  - o The assigned STC number.
  - o A clear statement of the decision reached by STC.
  - o In case of unfavourable decision, any requirements by STC including suggestion for revisions should be clearly explained in writing to the applicant.

GUIDELINES FOR REVIEW OF SCIENTIFIC AND TECHNICAL ASPECT OF PROTOCOLS (STC CHECKLIST)

INTRODUCTION, SPECIFIC AIMS AND BACKGROUND/RATIONALE

- ✓ Are the specific aims clearly specified?
- ✓ Are there adequate preliminary data to justify the research?
- ✓ Is there appropriate justification for the research?

SCIENTIFIC DESIGN

- ✓ Is the scientific design adequate to answer the question?
- ✓ Are the objectives likely to be achievable within a given time period?
- ✓ Is the scientific design (that is randomization; placebo controls; Phase 1,2, or 3) described and adequately justified?

INCLUSION/EXCLUSION CRITERIA

- ✓ Are inclusion and exclusion criteria clearly specified and appropriate?
- ✓ If women, minorities, or children are included or excluded is this justified?
- ✓ Is the choice of research participants appropriate for the questions being asked?

RECRUITEMENT OF PARTICIPANTS

- ✓ Are the methods for recruiting potential participants well defined?
- ✓ Are the location and timing of the recruitment process acceptable?
- ✓ Is the individual performing the recruitment appropriate for the process?
- ✓ Are all recruitment materials submitted and appropriate?
- ✓ Are there acceptable methods for screening participants before recruitment?

RESEARCH PROCEDURES

- ✓ Are the rationale and details of the research procedures accurately described and acceptable?

Is there a clear differentiation between research procedure and standard of care

- ✓ Are the individuals performing the procedures appropriately trained, and is the location of performing the procedure acceptable?
- ✓ Are there adequate plans to inform participants about specific research results if necessary (clinically relevant results, incidental findings etc)?

DRUG, BIOLOGIC AND DEVICES

- ✓ Is the status of the drug described and appropriate (investigational, new use of an FDB-approved drug, or an FDB-approved drug within approved indications)?
- ✓ Are the drug dosage and route of administration appropriate?
- ✓ Are the drug or device safety and efficacy data sufficient to warrant the proposed phase of testing?
- ✓ Is the significant risk or non-significant risk status of the devised described and appropriate?

DATA ANALYSIS

- ✓ Is the rationale for the proposed number of participants reasonable?
- ✓ Are the plans for data and statistical analysis well defined and justified, including the use or stopping rule endpoints?
- ✓ Are there adequate provisions for monitoring data (DSMB)?

OTHER ISSUES

- ✓ Are there adequate references?

STC RECORD KEEPING/ARCHIVING

- ✓ Agenda of the STC meetings.
- ✓ Minutes of the STC meetings.
- ✓ Correspondence to applicants or concerned parties regarding application, decision and follow-up.
- ✓ All written documentation received from applicants for STC review.

- ✓ Electronic copies of STC documents