NMIMR-SCIENTIFIC AND TECHNICAL COMMITTEE
Reviewer's Checklist for Research Protocols

STC Paper #_____ Title: _____

1. INTRODUCTION, SPECIFIC AIMS AND RATIONALE	**YES**	**NO**	**N/A**
a. Are the specific aims clearly specified?	_____	_____	_____
b. Are there adequate preliminary data to justify the research?	_____	_____	_____
c. Is there appropriate justification for the research?	_____	_____	_____

Comments:

2. SCIENTIFIC DESIGN	**YES**	**NO**	**N/A**
a. Is the scientific design adequate to answer the question?	_____	_____	_____
b. Are the objectives achievable within a given time period?	_____	_____	_____
c. Is the scientific design (i.e. randomization; placebo controls; Phase 1, 2, or 3) described and adequately justified?	_____	_____	_____

Comments:

3. INCLUSION/EXCLUSION CRITERIA	**YES**	**NO**	**N/A**
a. Are inclusion and exclusion criteria clearly specified?	_____	_____	_____
b. If women or children are included or excluded is this justified?	_____	_____	_____
c. Is the choice of research participants appropriate for the questions being asked?	_____	_____	_____

Comments:

4. RECRUITEMENT OF PARTICIPANTS **YES** **NO** **N/A**

a. Are the methods for recruiting potential participants well defined? _____ _____ _____

b. Are the location and timing of the recruitment process acceptable? _____ _____ _____

c. Is the individual performing the recruitment appropriate for the process? _____ _____ _____

d. Are all recruitment materials submitted and appropriate? _____ _____ _____

e. Are there acceptable methods for screening participants before recruitment?_____ _____ _____

Comments:

5. RESEARCH PROCEDURES **YES** **NO** **N/A**

a. Are the rationale and study procedures accurately described and acceptable? _____ ____ _____

b. Is there a clear differentiation between research procedure and standard of care? ____ ____ _____

c. Are the individuals performing the procedures appropriately trained? _____ ____ _____

d. Are there adequate plans to inform participants about research results? _____ ____ _____

Comments:

6. DRUG, BIOLOGIC AND DEVICES **YES** **NO** **N/A**

a. Is the status of the drug described and appropriate _____ _____ _____
(new use of a Ghana FDA-approved drug, or an FDA-approved drug within approved indications)?

b. Are the drug dosage and route of administration appropriate? _____ _____ _____

c. Are the drug or device safety and efficacy data sufficient to warrant the proposed phase of testing? _____ _____ _____

d. Is the significant risk or non-significant risk status of the devised described and appropriate? _____ _____ _____

Comments:

7. DATA ANALYSIS	**YES**	**NO**	**N/A**
a. Is the rationale for the proposed number of participants reasonable?	_____	_____	_____
b. Are the plans for data and statistical analysis well defined and justified, including the use or stopping rule endpoints?	_____	_____	_____
c. Are there adequate provisions for monitoring data (DSMB)?	_____	_____	_____

8. REFERENCES	**YES**	**NO**
a. Are there adequate references?	_____	_____

Comments:

9. ANY OTHER COMMENT

Recommendation: a) approve _____ b) disapprove _____ c) defer _____

Reviewer's Name and Signature: _____ Date: _____