Office of Research
NORTH SOUTH UNIVERSITY

NSU Institutional Review Board/Ethics Review Committee

Review of a New Proposal Involving Human Subjects Research
Primary Reviewer Template *(see instructions on page three)*

IRB/ERC Review Code: 2019/OR-NSU/IRB-No._____

Primary Reviewer: _____
Name & Faculty Rank/Discipline/Member Status

Date of Review: _____

Initial Checklist: ***The Proposal document contains the following components:***

_____ Scientific Merit Review approval document included
____ Summary of the protocol
____ Detailed description of protocol procedures (with supporting materials)
____ Consent Document

Proposed Study has had review for scientific merit *with approval*:
_____ Yes _____ No *(if yes, identify school SRC and date of review approval; if not, discontinue review)*

School SRC: ____ SHLS; ____ SEPS; ____ SHSS; ____ SBE; Date of SRC Review: _____

Purpose of Research Study:

Summary (Background, number of arms, controls, IND, etc.):

Sponsored Research: _____ Yes _____ No; *if "yes" identify sponsor(s):*

_____

PI/Co-PI(s): _____ Qualified/ _____ Not Qualified; Experience is: _____ Adequate _____ Inadequate

Conflict(s) of Interest: _____Yes _____ No; if "yes," explain briefly below:

Study Population and Recruitment Practices:

1.
2.
3.
4.

Includes vulnerable research subjects (e.g., children, institutionalized population group, etc.):
___Yes ___ No

Research subject recruitment is adequate: _____ Yes _____ No (explain briefly who, where, how recruited):

Payment or reimbursements involved: _____ Yes _____ No

Subject selection is likely to be equitable: _____ Yes _____ No

Study has adequate procedures to protect vulnerable research subjects: _____ Yes _____ No

Informed Consent Document is adequate to the understanding of the research subjects:
_____ Yes _____ No; *if "no" provide suggestions and/or questions for principal investigator below:*

Research subjects will be informed about research results: _____ Yes _____ No

Risk to research subjects is: _____ (1) minimal; _____ (2) moderate; (3) _____ high

Investigator's protocol minimizes risk to research subjects: _____ Yes _____ No

Potential benefits: _____ Direct to research subjects; _____ Indirect (altruistic)

If direct benefits to the research subjects explain briefly:

Risk/benefit analysis (risks to research subjects are minimized and reasonable in view of potential benefits identified): _____ Yes _____ No; *provide brief comments below:*

Eventuality plan in place in case of adverse event and/or serious adverse event:
____ Yes ____ No ____ NA

Confidentiality: Provisions to protect research subject privacy and confidentiality are adequate:
_____ Yes _____ No

Data Oversight:
(a) There is adequate provision for data safety and monitoring: _____ Yes _____ No
(b) Rules for halting research are explained and sufficiently detailed: _____ Yes _____ No

Additional Comments:

Basic Instructions to Primary Reviewer on Order of Review

1. *Read the consent document.*
   Note that the consent document should explain aspects of the study to potential research subjects in lay (not technical) language. It should provide a reasonably clear introduction to the research protocol. You should at this time read the document to orient yourself about the overall design of the research proposed.
2. *Read the protocol summary.*
   Read the summary and assure yourself that the investigator has summarized the important aspects of the study in a way that facilitates IRB full committee review.
3. *Read the full protocol and supporting material.*
   Read the protocol and supporting materials to understand with a view to prior studies that are applicable to the study and that validate the research procedures outlined in the protocol (e.g., animal model studies done; safety studies done; efficacy studies done; rationale for a human study; phased clinical trial information; etc.). Assess whether there is evidence of detailed inclusion/exclusion criteria being met, recruitment procedures including advertisements, etc.
4. *Read the consent document again.*
   On this second reading of the consent document, record any suggested corrections or questions for the principal investigator.