Office of Research
NORTH SOUTH UNIVERSITY

*Template Version 2019*

# 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: 2020/OR-NSU/IRB-_____**

**Primary Reviewer:** Designation:

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):*

Name of Funding Agency:

**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: ☐ minimal; ☐ moderate; ☐ 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:**

☐ Approved ☐ Disapproved ☐ Conditional Approval ☐ Waived

**Signature of Primary Reviewer: _____**

## 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.