

Template Version 2019

NSU Institutional Review Board/Ethics Review Committee

Review of a New Proposal Involving Human Subjects Research

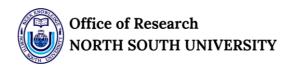
Primary Reviewer Template (see instructions on page three)

IRB/ERC Review Code: 2020/OR-NSU/IRB	
Primary Reviewer:	Designation:
Date of Review:	
Initial Checklist: The Proposal document contains. ☐ Scientific Merit Review approval document contains. ☐ Summary of the protocol. ☐ Detailed description of protocol procedu. ☐ Consent Document	nent included
Proposed Study has had review for scientific mer Yes No (if yes, identify school SRC and date of review	
School SRC: □SHLS; □SEPS; □SHSS	; □SBE; Date of SRC Review:
Purpose of Research Study:	
Summary (Background, number of arms, control	s, IND, etc.):
Sponsored Research: ☐ Yes ☐ No; <i>if "yes" ident</i> Name of Funding Agency:	ify sponsor(s):
PI/Co-PI(s): ☐ Qualified ☐ Not Qualified; Experience is: ☐ Adequate ☐ Inadequate	
Conflict(s) of Interest: ☐ Yes ☐ No; if "yes," ex	plain briefly below:
Study Population and Recruitment Practices: 1. 2. 3. 4.	
Includes vulnerable research subjects (e.g., children, ☐ Yes ☐ No	institutionalized population group, etc.):



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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: \square Yes \square No
Study has adequate procedures to protect vulnerable research subjects: \square Yes \square No
Informed Consent Document is adequate to the understanding of the research subjects: \[\sum \text{Yes} \sum \text{No}; \((if "no" provide suggestions and/or questions for principal investigator below) \]
Research subjects will be informed about research results: \square Yes \square 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) <i>If direct benefits to the research subjects explain briefly:</i>
Risk/benefit analysis (risks to research subjects are minimized and reasonable in view of potential benefits identified): ☐ Yes ☐ No; <i>provide brief comments below:</i>
Eventuality plan in place in case of adverse event and/or serious adverse event: $\hfill Yes \hfill No \hfill NA$
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.