Office of Research
NORTH SOUTH UNIVERSITY

NSU Institutional Review Board/Ethics Review Committee

Detailed Reviewer Template for IRB/ERC Protocol Review

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

Introduction, Specific Aims, and Background	**Yes**	**No**
Are the specific aims of the proposed research clearly specified?		
Are there adequate preliminary data to justify the research?		
Is there appropriate scientific justification for this research protocol?		
Scientific Design	**Yes**	**No**
Is the scientific design adequate to answer the research question?		
Are the objectives likely to be achieved within a given time frame?		
Is the scientific design (i.e., randomization; placebo controls; Phase 1, 2, or 3) described and adequately justified?		
Inclusion/Exclusion Criteria for Research Subjects	**Yes**	**No**
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 subjects appropriate for the question being asked?		
Is the principle of distributive justice adequately incorporated into the inclusion and exclusion criteria for the research protocol?		
Is subject selection equitable?		
Recruitment of Research Subjects	**Yes**	**No**
Are the methods for recruiting potential subjects well defined?		
Are the location and timing of the recruitment process appropriate?		
Is the individual performing the recruitment appropriate for the process?		
Are all recruitment materials submitted and appropriate?		
Are there acceptable methods for screening subjects before recruitment?		
Research Procedures	**Yes**	**No**
Are the rationale and details of the research procedures accurately described and acceptable?		
Is there a clear differentiation between research procedures and standard (medical) care?		
Are the individuals performing the procedures appropriately educated?		
Is the location of where the procedure will be performed acceptable?		
Are there adequate plans to inform research subjects about specific research results if necessary (e.g., clinically relevant results, risk of depression, risk of suicide, incidental findings, etc.)?		
Drugs, Biologics, and Devices	**Yes**	**No**
Is the status of the drug, biologic, or device described and appropriate (investigational, new use, government approved) within indications of use?		
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 device described and appropriate?		
Data Analysis and Statistical Analysis	**Yes**	**No**
Is the rationale for the proposed number of research subjects reasonable?		
Are the plans for data and statistical analysis defined and justified, including the use of stopping rules and end points?		
Are there adequate provisions for monitoring data, e.g., a data safety monitoring board (DSMB)?		
Potential Risks, Discomforts, and Benefits for Research Subjects	**Yes**	**No**
Are the risks and benefits adequately identified, evaluated, and described?		
Are the potential risks minimized and likelihood of benefits maximized?		
Is the risk/benefit ratio acceptable for proceeding with the research?		
If children are involved, is there a regulatory category of risk/benefit applicable and identified, such that all relevant criteria for this category are adequately addressed?		

Compensation and Costs for Research Subjects	**Yes**	**No**
Is the amount or type of compensation or reimbursement reasonable?		
Are there adequate provisions to avoid out-of-pocket expenses by the research subject(s), or is there sufficient justification to allow subject(s) to pay?		
If children or adolescents are involved, is it clear who receives the compensation, and is this appropriate?		
Privacy and Confidentiality	**Yes**	**No**
Are there adequate provisions to protect the privacy, and ensure the confidentiality, of the research subjects?		
Are there adequate plans to store and code the data?		
Is the use of identifiers or links to identifiers necessary?		
Are identifiers or links to identifier information adequately protected?		
Informed Consent/Assent	**Yes**	**No**
Are all the elements of prior, explicit, informed consent contained in the consent document?		
Is the process of obtaining prior, explicit, informed consent adequately described?		
Is consent/assent required?		
Is waiver or modification of consent reasonably to be approved?		
Other Issues	**Yes**	**No**
Are adequate references (relevant research literature; *in vivo*/animal models results, prior studies, etc.) provided to support and otherwise warrnat the proposed research?		
Should a follow-up review occur next? If so, when? (specify date):		
Should follow-up reviews be scheduled at intervals? If so, when? (specify dates):		

Reviewer Name: _____ Member Status _____

Signature: _____ Date: _____

Reference:

The above template is adapted from the content of Robert Ambur, Elizabeth A. Bankert, *Institutional Review Board: Member Handbook*, 3rd Edition (Sudbur, MD/USA: Jones and Bartlett Publishers, 2011)