NJCU Institutional Review Board Application for
Review of Research Proposal

Email: IRB@njcu.edu

FOR OFFICE USE ONLY			
File Number			
Review Type	Exempt ☐	Expedited ☐	Full☐
PI			

Date of Submission

Proposal type:
☐ Original ☐ Revised*

*If this is a revised application, there is no need to complete the remainder of this form. However, please describe in detail the changes that you have made in response to the IRB's concerns. _____

Principal Investigator	
Proposal title	
Proposed start date	
Anticipated duration of research	

Type of Research

☐ Student/Classroom project
☐ Faculty project
☐ Staff project
☐ External researcher project (All external researchers must have an NJCU sponsor.)

NJCU Investigators (Please list additional investigators as necessary.)

Principal Investigator (For all student research, the faculty advisor is the PI.)

Name _____
Department _____
Telephone _____
Email _____

Co-Investigator (including student researchers)
Name _____
Department _____

Telephone _____
Email _____

Co-Investigator(including student researchers)

Name _____
Department _____
Telephone _____
Email _____

Co-Investigator(including student researchers)

Name _____
Department _____
Telephone _____
Email _____

*Any NJCU investigator who plans to work on this project either with or for a Principal Investigator or a Co-Investigator at another institution must identify those investigators and their institutions.

External Investigators

Name _____
Title _____
Institution _____

Name _____
Title _____
Institution _____

Name _____
Title _____
Institution _____

Name _____
Title _____
Institution _____

Name _____
Title _____
Institution _____

NJCU Sponsor (if the researcher is not affiliated with NJCU)

Name _____
Department _____
Telephone _____
Email _____

Data Sources

Number of participants _____

How was this number determined (e.g., power analysis) _____

Does this project require the collection of new data? ☐ Yes ☐ No

If Yes: How will participants be selected or recruited? _____

Will subjects participate on a fully voluntary basis? ☐ Yes ☐ No

Will subjects be compensated for their participation? ☐ Yes ☐ No

If yes: Please briefly describe the compensation.

_____

Does this project make use of human tissue or cell lines? ☐ Yes ☐ No

Briefly describe the research methodology(ies) to be used in this study (e.g., focus group, participant observation, survey, experiment).

_____

Does this project use data that have already been collected for a non-research purpose or by another researcher?

☐ Yes ☐ No

If yes: What is the source of the data?

_____

Are the data accessible in the public domain? ☐ Yes ☐ No

If no: Are fields included that would allow identification of individuals, either directly or indirectly? ☐ Yes ☐ No

If yes: Please explain briefly how participant confidentially will be safeguarded

_____

Participant Risks

Will participants be exposed to any stresses (e.g., anxiety, pain, etc.) or physical harm (e.g., injury, infection, etc.) in connection with this research? ☐ Yes ☐ No

If yes: Please briefly explain what risks may be involved in the research, what specific steps will be taken to minimize and monitor the risk, and what will be done to compensate and/or treat participants who are harmed by the research.

_____

Does the research design require that participants be deceived? ☐ Yes ☐ No

If yes: Please briefly explain why deception is necessary and what steps will be taken to reduce potential harm from this deception.

_____

Potentially Vulnerable

Populations Will this research involve:

Physically/Mentally Challenged Individuals Young children (ages 0-13)	☐Yes	☐No
Older children (ages 14-17)	☐Yes	☐No
Senior Citizens (over age 65)	☐Yes	☐No
Pregnant Women	☐Yes	☐No
Prisoners	☐Yes	☐No

If yes to any of the above: Please briefly explain how the rights of this (these) population(s) will be protected.

_____

Informed Consent

Will participants be fully informed about:

The voluntary nature of their participation and the freedom to withdraw without penalty at any time	☐Yes	☐No
The purposes and procedures of the research	☐Yes	☐No
Any reasonably foreseeable risks or discomforts	☐Yes	☐No
Any benefits to them or to others from the research	☐Yes	☐No
The extent to which confidentiality will be maintained	☐Yes	☐No
The compensation and/or treatments available if injury occurs (This question need only be answered for research that involves risks.)	☐Yes	☐No
Whom to contact for information about the research participants' rights and any research-related injury	☐Yes	☐No

If the answer to any of the above is no, please briefly explain why the research requires an alteration of the standard elements of informed consent.

_____

How will participants' informed consent be documented? Please check all that apply.

☐ Signature on written consent document
☐ Signature on document to be read to the participants and witnessed by another party
☐ Written documentation of informed consent will not be obtained because one or more of the following criteria is satisfied (check all that apply):

☐ The only link between the subject and the research would be the informed consent documentation and the primary risk is loss of confidentiality.

☐ The risks to participants, including risks associated with the loss of privacy, are no greater than those ordinary encountered in daily life and the research involves no procedure for which written consent is normally required outside of the research context.

Who will obtain the informed consent from the participants?

☐ Principal Investigator
☐ Co-Investigator
☐ Sponsor (in cases where PI is not affiliated with NJCU)
☐ Other
☐ Not applicable

Please include your protocol summary (5 pages maximum) and your recruitment materials (as applicable).

External Reviews and Funding

Has this protocol been reviewed by an Institutional Review Board or Human Subjects Review Committee at another institution(s)? ☐ Yes ☐ No

If yes: At what institutions(s)?

_____

What is its status? ☐ Approved ☐ Rejected ☐ Pending (or provisionally approved)

Has this protocol been submitted for Federal Funding? ☐ Yes ☐ No

If yes: Agency or Organization: _____

Submission Date: _____

Funding Start Date: _____ ☐ Anticipated ☐ Actual

Contact Person: _____

Contact's Telephone: _____

Has this protocol been submitted for any other types of funding? ☐Yes ☐No

If yes: Agency or Organization: _____

Submission Date: _____

Funding Start Date: _____ ☐Anticipated ☐Actual

Contact Person: _____

Contact's Telephone: _____

Proof of NIH or CITI Certification

Please provide documentation of current CITI and/or NIH certification in human subjects research for all researchers involved in this project.

Certificate of Agreement

The signatures of all researchers involved in this project must be provided.

I certify that I agree to comply with the requirements of both NJCU and the Office for Human Research Protection (OHRP) of the United States Department of Health and Human Services as described in 45 CFR §46.

_____ _____

PI Signature Date

_____ _____

Co-PI Signature Date

_____ _____

Co-PI Signature Date

_____ _____

Co-PI Signature Date

_____ _____

Co-PI Signature Date

Please submit the completed application and accompanying documents as one document or pdf to IRB@njcu.edu and kresch@njcu.edu.

All applications must be submitted by the NJCU faculty or staff member who is serving as the Principal Investigator (PI). Neither students nor external researchers may submit an application.