NJCU Institutional Review Board

Email: IRB@njcu.edu

**Investigator’s Checklist for IRB Submission**

Please make sure that your application is complete prior to submitting it to the NJCU IRB. Please save the entire application and all supporting documents in one file using a file format such as DoeJ\_ddmmyy\_ver\_1.pdf. Please make sure that your file name includes your full name and please do not use “final” in the file name, as there may be revisions of the original application. Please be certain that your consent form (or procedure), if applicable, includes all of the information provided below.

All applications must be submitted by the NJCU faculty or staff member listed as the Principal Investigator (PI). Neither students nor external researchers may submit an application. (For all students, a faculty/staff member must serve as the PI. All external researchers must have an NJCU faculty/staff member as a sponsor.)

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

**Application**

[ ]  Completed and signed Proposal Submission Form

[ ]  Protocol Summary (5-page limit) that identifies the research question and describes methods

[ ]  Copies of data collection instruments that coincide with the study described in the Protocol Summary

[ ]  Recruitment materials (as applicable)

[ ]  Consent document(s) or the rationale for deviation from written consent

[ ]  Certificate of training in protection of human subjects from the Collaborative Institutional Training Initiative (CITI Program) (<https://about.citiprogram.org/>) for **all** researchers involved in the project. A separate guidance is available on CITI certification programs.

Please ensure that **all consent forms** are written for a general audience; are specific to subjects (and/or their parents/guardians); identify the researcher, the researcher’s position, and his/her institution; and:

[ ]  Describe the study and the procedures (activities, duration, and/or audio, photographic, or videotaping\*) in lay terms

[ ]  Clearly state that there are no benefits or known risks or clearly explain the precautions that will be taken if there are risks (Monetary payment does not constitute a benefit.)

[ ]  Include a statement that participation is voluntary and that all subjects have the right to skip any questions or activities and to opt out at any time without penalty

[ ]  Provide the names of all contact persons for the study, including the Principal Investigator and, for external researchers, the NJCU sponsor

[ ]  Include this statement: “If you have questions about your rights as a participant in this study, please contact Dr. Ashok Vaseashta, chair of the NJCU IRB, at (201) 200-2453 or avaseashta@njcu.edu.

[ ]  Include a statement of confidentiality\*\*

[ ]  Have places for signatures and the date.

\* Furthermore, for any study using audio, photographic, or video recordings, the researcher must also completely explain the use of these recordings, the plan for their storage, and also, if and how this information will be protected and disseminated.

\*\* If the research project is planned to deviate from complete anonymity, the researcher may include a waiver to use the names of respondents, but the researcher must specify how all data will be used and disseminated.

Please expect acknowledgement of your submission within 5 working days. If there is no acknowledgement, please email kresch@njcu.edu and avaseashta@njcu.edu.

**NJCU Institutional Review Board Application for**

**Review of Research Project**

Email all materials in one file to: IRB@njcu.edu and kresch@njcu.edu.

|  |
| --- |
| **FOR OFFICE USE ONLY – Please do not provide any information in this box** |
| Date Complete Application Submitted  |  |
| Review Type | Expedited Full Exempt  |
| Principal Investigator\* |  |

\* **For all student research, the faculty advisor is the Principal Investigator.**

**Date of Submission**: Click or tap to enter a date.

**Name (PI)/Sponsor Submitting Application:**

**Application Type**: [ ] Original [ ]  Previously Approved

|  |  |
| --- | --- |
| Proposal Title | Click here to enter Proposal Title. |
| Proposed Start Date | Click to enter a date. |
| Anticipated Duration of Research | Click here to enter anticipated duration. |
| CITI Certification by all researchers (Certificates must be attached.) | Click here to select. |

# Type of Research

[ ]  Student/Classroom project

[ ]  Faculty research project

[ ]  Staff research project

[ ]  External researcher project (All external researchers must have an NJCU faculty/staff sponsor.)

# NJCU Investigators (Please list additional investigators as necessary)

Name: Click here to enter Name.

Department: Click here to enter Department.

Telephone number: Click here to enter Telephone number.

Email address: Click here to enter Email address.

**Co-Investigator** (including student researchers)

Name: Click here to enter Name.

Department: Click here to enter Department.

Telephone number: Click here to enter Telephone number.

Email address: Click here to enter Email address.

**Co-Investigator** (including student researchers)

Name: Click here to enter Name.

Department: Click here to enter Department.

Telephone number: Click here to enter Telephone number.

Email address: Click here to enter Email address.

**Co-Investigator** (including student researchers)

Name: Click here to enter Name.

Department: Click here to enter Department.

Telephone number: Click here to enter Telephone number.

Email address: Click here to enter Email address.

*\**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 below.

# External Investigators

Name: Click here to enter Name.

Department: Click here to enter Department.

Telephone number: Click here to enter Telephone number.

Email address: Click here to enter Email address.

Name: Click here to enter Name.

Department: Click here to enter Department.

Telephone number: Click here to enter Telephone number.

Email address: Click here to enter Email address.

Name: Click here to enter Name.

Department: Click here to enter Department.

Telephone number: Click here to enter Telephone number.

Email address: Click here to enter Email address.

Name: Click here to enter Name.

Department: Click here to enter Department.

Telephone number: Click here to enter Telephone number.

Email address: Click here to enter Email address.

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

Name: Click here to enter Name.

Department: Click here to enter Department.

Telephone number: Click here to enter Telephone number.

Email address: Click here to enter Email address.


# Data Sources

1. Number of participants: Click here to enter # of participants.
2. How was this number determined (e.g., power analysis)? Click here to enter text.
3. Does this project require the collection of new data? [ ]  Yes [ ]  No

3A. If yes, how will participants be selected or recruited (<4-5 sentences)?

Click here to enter text.

3B. Will subjects participate on a fully voluntary basis? [ ]  Yes [ ]  No

3C. Will subjects be compensated for their participation? [ ]  Yes [ ]  No

3D. If yes, please briefly describe the compensation:

Click here to enter text.

1. Does this project make use of human tissue or cell lines: [ ]  Yes [ ]  No
2. Briefly describe the research methodology(ies) to be used in this study (e.g., focus group, participant observation, survey, experiment). (<4-5 sentences)

Click here to enter text.

1. Does this project use data that have already been collected for a non-research purpose or by another researcher? [ ]  Yes [ ]  No

6A. If yes, what is the source of the data? (3-4 sentences)

Click here to enter text.

6B. Are the data accessible in the public domain? [ ]  Yes [ ]  No

6C. If no, does the data include information that would allow identification of individuals, either directly or indirectly? [ ]  Yes [ ]  No

6D. If yes, please explain briefly how participant confidentiality will be safeguarded. (3-4 sentences)

Click here to enter text.

# Participant Risks

1. 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

7A. 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. (4-5 sentences).

Click here to enter text.

1. 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. (<3-5 sentences)

Click here to enter text.

# Potentially Vulnerable

1. Human Research Subject Populations – Please check if your research involves vulnerable populations:

Physically/Mentally Challenged Individuals: [ ]  Yes [ ]  No

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

9A. If anything in Question #9 is checked **yes**, please briefly explain how the rights of this (these) population(s) will be protected. (<4-5 sentences)

Click here to enter text.

# Informed Consent (Please attach your consent form(s).)

1. Consent form must contain the following in lay terms:

|  |  |
| --- | --- |
| 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 discomfort: | [ ]  Yes [ ]  No |
| Any benefits to them or to others from the research:  | [ ]  Yes [ ]  No |
| The extent to which confidentiality will be maintained: | [ ]  Yes [ ]  No |
| Whom to contact for information about the research participants’ rights and any research-related injury: | [ ]  Yes [ ]  No |

10A. If the answer to anything in Question 10 was checked no, please briefly explain why the research requires an alteration of the standard elements of informed consent.

Click here to enter text.

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

[ ]  Signature on a written consent document

[ ]  Signature on a document to be read to the participants and witnessed by another party

[ ]  E-signature on an electronic form/survey

[ ]  Written documentation of informed consent will not be obtained because one of 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 participate, including risks associated with the loss of privacy, are no greater than those ordinarily encountered in daily life and the research involves no procedure for which written consent is normally required outside of the research context.

1. Who will obtain the informed consent from the participants?

[ ]  Principal Investigator

[ ]  Co-Investigator

[ ]  Sponsor (in cases where the Principal Investigator is not affiliated with NJCU)

[ ]  Other

[ ]  Not applicable

1. Please include your protocol summary (5-page maximum) and your recruitment materials (as applicable). You are provided space to do this at the end of this application. Please see *APPENDIX A. Protocol Summary.*

# External Reviews and Funding

1. Has this protocol been reviewed by an Institutional Review Board or Human Subjects Review Committee at any other institution(s)? [ ]  Yes [ ]  No

If yes, at what institution(s)?

Click here to enter institution(s).

1. What is its status? [ ]  Approved [ ]  Rejected [ ]  Pending (or provisionally approved)
2. Has this protocol been submitted for federal funding? [ ]  Yes [ ]  No

16A. If yes, list the agency or organization:

Click here to enter agency or organization.

Submission Date: Click here to enter a date.

Funding Start Date: Click here to enter a date. [ ]  Anticipated [ ]  Actual

Contact Person: Click here to enter Contact Person.

Contact’s Telephone Number: Click here to enter Contact’s Telephone #.

1. Has this protocol been submitted for any other types of funding: [ ]  Yes [ ]  No

17A: If yes, list the agency or organization:

Click here to enter agency or organization.

Submission Date: Click here to enter a date.

Funding Start Date: Click here to enter a date. [ ]  Anticipated [ ]  Actual

Contact Person: Click here to enter Contact Person.

Contact’s Telephone Number: Click here to enter Contact’s Telephone #.

# Proof of CITI Certification

Please provide documentation of current CITI 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/We certify that I/we 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.



\***Instructions for signatures**: First, save your application file and then open it.

Sign the document by right clicking on the signature line and selecting “Sign.” **DO NOT SAVE** the file, **simply CLOSE IT**. The signature will be automatically saved. If applicable, send the file as an email attachment to the next signatory. Every subsequent signatory must also follow these instructions.

Please submit the completed application, checklist, and accompanying documents as one document or PDF file to IRB@njcu.edu and kresch@njcu.edu.

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

**APPENDIX A. Protocol Summary\*; Surveys, including recruitment materials as applicable; and consent forms.**

Please note: The protocol summary (5-page maximum) should only include the central elements of the project such as the rationale, objectives, methods, populations, and period.

Click here to enter your Protocol Summary.