# Institutional Research Review Board Application Form
## FOR FACULTY AND STAFF RESEARCH

***Please complete this form and attach brief responses to the issues raised, keeping in mind that the primary concern is the potential risk—physical, emotional, or other—to participants, as well as the protection of their rights.*** *Provide copies of all surveys, questionnaires, consent forms or other documents to be used in the inquiry.* ***The Institutional Research Review Board (IRRB) must have enough information about the transactions with the participants to evaluate the risks of participation. Assurance from you, no matter how strong, will not substitute for a description of the transactions.***

***Submit all questions and complete application forms and all supporting materials via email to IRRBMailbox@nl.edu***

**PLEASE PRINT**

**Name(s):** _____

_____

_____

**College:** ☐ CPS ☐ NCE ☐ Library ☐ Staff Dept: _____

**Campus:** _____

**Home Address:**

**Phone:**
Home: _____
Work: _____
Cell: _____

**NLU E-Mail Address:** _____

**Research Title:**

**Anticipated Data Collection Start Date*:** _____
*This project cannot begin until IRRB has issued it's approval.

**In addition to completing the information above and the signature form on page 2, address each of the following explicitly and separately in an attached narrative:**

***For all projects:***

1. Briefly describe the purpose of your study, in non-technical terms, what the participants will be asked to do, and what the processes and procedures for data collection are. Append relevant instruments (i.e., protocols, questionnaires, surveys, focus group questions, interview questions, etc).
2. Describe any potential risks or benefits (emotional, physical, social, political, or economic) to your participants.
3. Give the anticipated ages, gender, and number of participants, and explain how and where they will be recruited.
4. Describe the procedures for obtaining assent or informed consent as provided for the Code of Federal Regulations, section 46.116. Append the informed consent form and any other forms used. If you are using video an additional consent form is needed. If you are working with minor children you must provide assent as well as parental consent forms.

***For Non-Exempt Projects Only, please additionally describe the following:***

5. If minors are involved, describe the procedures for obtaining consent to participate from the minors capable of giving consent, as well as the procedures to obtain parental or guardian consent.
6. If risk is involved, explain how the knowledge to be gained and/or the benefits to the research participants from the proposed research justify any risks the participants might incur.

7. Explain what, if any, support services will be provided in the event of harm to a participant.

# SIGNATURE PAGE

## Certification

I certify that I have read and understand the policies and procedures for research projects that involve human participants and that I intend to comply with University Policy. I understand that all non-exempt projects require annual review. Significant changes in the study protocol need to be submitted on a Change of Status Of Continuing Research Form for review prior to those changes being put into practice.

**Signature of Researcher(s):** **Date**:

**Check one of the following, indicating the category into which this research falls according to Title 45, Code of Federal Regulations, Part 46:**

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101

❑ Project is exempt.
**Cite exempt category number from page 3: _____**

*Note: This project **MUST** receive formal clearance in the form of a verification of Exemption letter from the IRRB chair **PRIOR** to the start of data collection.*

❑ Project is referred for expedited review.
**Cite expedited category number from page 3: _____**

❑ Project is referred for full IRRB review.
*All research requires the full review of the IRRB unless it meets criteria specified on page 3 of this form.*

**Approval Signature**

_____

**Signature of IRRB Chair:** **Date**:

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# CATEGORY STATUS

## Exempt Status

When the involvement of human participants in research falls only in one of the following categories, such research is exempt from the Federal Human Subject Review Policy. The declaration of exemption, together with accompanying documentation, is filed with the IRRB.

Categories (**CHECK THE ONE THAT BEST APPLIES):**

☐ Research in common educational settings, involving normal or special educational practices. (Category Number: 46.101b 1)

☐ Research involving educational tests, surveys, interviews, or observation unless confidentiality cannot be maintained or disclosure places the participants at risk. (Category Number: 46.101b 2)

☐ Research involving elected or appointed public officials or candidates for office, even when confidentiality cannot be maintained or disclosure places the participants at risk. (Category Number: 46.101b 3)

☐ Research involving the study of existing data either publicly available or recorded by the researcher(s) in a manner that maintains confidentiality. (Category Number: 46.101b 4)

☐ Institutional or organizational research designed to improve service or benefits when approved by the agency's head. (Category Number: 46.101b 5)

## Expedited Review

Expedited review by the IRRB Chair and a designated member of the IRRB will suffice for research proposals meeting either of two criteria AND falling into one of the categories below:

**Criteria (CHECK THE ONE THAT BEST APPLIES):**

☐ Research involves no more than minimal risk. (Category Number: 46.110b 1)

☐ Minor changes are proposed in previously approved research. (Category Number: 46.110b 2)

**Categories (CHECK THE ONE THAT BEST APPLIES):**

☐ The collection of biological specimens or data for research purposes by noninvasive means. (Category Number: 63 FR 60364-60367F 1-4)

☐ Research involving materials (data, documents, records, or specimens) collected solely for non-research purposes (such as medical treatment or diagnosis). (Category Number: 63 FR 60364-60367F 5-6)

☐ Research employing survey, interview, program evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from review.) (Category Number: 63 FR 60364-60367F 7)

## Full Review

All research requires the full review of the IRRB unless it meets criteria specified on page 3 of this form.

*If you cannot determine which review method or category number applies to your project, contact a member of the IRRB. Members and their contact information can be found on the IRRB website by emailing IRRBMailbox@nl.edu.*

## *REQUIRED ELEMENTS*

An informed consent form must be developed for each data collection activity that involves the use of Human Participants (i.e., interviews, focus groups, observations) and must be included with the application packet.

To ensure that participation is voluntary, be sure that the participant is not coerced or influenced by relations of power to the participant. This can especially be an issue with vulnerable populations—prisoners, students, and disabled persons. This may extend to researchers who serve in a supervisory and evaluative capacity in relationship to the participants.

If a participant is under the age of eighteen, the consent of a parent or guardian is required. If a participant over the age of eighteen, and is disabled and unable to give consent, the consent of a legal guardian is required.

If participants speak a language other than English, the assent and consent forms must be submitted in English and in the second language.

You cannot assume that, because a person is participating, s/he has given consent. It must be explicit and in writing.

**PLEASE NOTE**: Before collecting your data, you should secure **two** copies of the signed consent form (a copy for you and the participant), and a letter of agreement from the cooperating institution or organization, if applicable.

The informed consent form must include **ALL** of the following:

1. A statement identifying the researcher's affiliation with National-Louis University, if appropriate.

2. A clear and concise description of the purpose of the study in language that the participant can understand.

3. An identification of the anticipated risks (physical, emotional, social, political, economic) and benefits to the participant.

4. A description of the procedures you will follow: what is expected of participants, what they will be required to do, what data will be collected and how it will be used, and the time required for participation.

5. A statement regarding the voluntary nature of participation and the right to withdraw at any time without negative consequences.

6. An explanation of how confidentiality will be protected. If you are using audio or video that will be viewed outside the research, explain this on your form.

7. A statement regarding the protection of the audio and visual recordings of the participant and field notes. Identify who, if anyone will have access to the tapes, transcripts and field notes. Identify where these will be held and how they will be secured. Identify what will happen to recordings upon the completion of the study.

8. An offer to make available the results of the research in some form.

9. An explanation of whom to contact for answers to questions about the research project

and participant rights. This should include the name, title, work, address, telephone number and NLU email of the researcher and if the researcher is a student the primary advisor / program chair as well as the IRRB Chair.