

Notre Dame de Namur University Institutional Review Board
Forms: Renewal/Continuation Form

Code of Federal Regulations 45CFR §46.109 (e) an IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but no less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

Instructions: Submit this form with the IRB Application Cover Sheet and one copy of the current project details, recruitment, and consent documents. **Please type online** using a different font than the one in this form, then print. **Signatures must be original and legible.** Incomplete applications will delay the review and re-approval of your project.

If a renewal application is not reviewed and approved by the expiration date, all human participants research activity on this project must cease. It is the Principal Investigator's responsibility to ensure that the renewal application is submitted to IRB no less than one month prior to the expiration date. (Expiration date is one year from original project review date).

Principal Investigator: _____ **E-mail:** _____
Student Investigator: _____ **E-mail:** _____
Project Title: _____
IRB Approval #: _____ **Current Expiration Date:** _____

1. Status (check all that apply):

- Inactive. Do you still plan to conduct the study? YES NO
This study is currently awaiting funding. No human participants research activities have occurred. YES NO
- Participant recruitment and/or interventions ongoing
- Data collection/subject interventions ended on (date): _____
- Open for data analysis only. Expected end date: _____

2. Participant Information:

- a) Total approved sample size: _____
- b) Total number of participants who have participated in study since its inception: _____
- c) Number of participants who have participated in study during the past year: _____
- d) Number of participants who withdrew from study voluntarily during the past year: _____
- e) Number of participants withdrawn from study by investigator or by choice during the past year: _____
- f) Number of participants to be recruited in the coming year: _____

3. Anticipated completion date of data collection: _____

4. If any participant voluntarily withdrew or was withdrawn from study during the past year, explain below:

5. Describe any difficulties encountered in contacting, recruiting, or gaining the consent of participants:

6. Describe any complaints about the research received during the past year:

7. Describe any serious adverse events, injuries to participants, or other unanticipated problems involving risks to participants or others during the past year:

8. Do you know of any findings outside of your study, recent literature, or other relevant information, especially about risks associated with the research, since the study last received IRB approval? YES / NO

If yes, please attach documentation. Documents attached

9. **ATTACH A BRIEF SUMMARY/REPORT of any study findings from past year (REQUIRED).**

10. **Proposed Study Amendments (If yes to any of the following, please attach explanation)**

- a) Does the contact information on your attached Application Cover Sheet reflect an address, email or phone number change from last year? YES / NO
- b) Does your Application Cover Sheet reflect any change in funding from last year? YES / NO
- c) Does your Application Cover Sheet reflect any change in key personnel and/or in the roles of these individuals? YES / NO
- d) Are there any modifications or additions to your approved *project* for the coming year? YES / NO
- e) Are there any modifications or additions to your approved *consent form(s)* for the coming year? YES / NO
- f) Are there modifications or additions to your approved *materials* (e.g., surveys, interviews) for the coming year: YES / NO

If more space is needed to answer any of the above items, attach a separate sheet. If you have any questions about your renewal/continuation, please contact the Chair of the IRB Committee.

Principal Investigator Signature: _____ **Date:** _____

Student Investigator Signature: _____ **Date:** _____