IRB: FREQUENTLY ASKED QUESTIONS

1. **How do I determine if my proposal needs to go through Full IRB Review, Expedited IRB Review, Exempt IRB Review, or no Review at All?**

   Please review the definitions of exempt, expedited, and full reviews contained in the website Overview. Then, using the Canvas guide, review your proposed project using the Is My Project Research flowchart. After reviewing the flowchart, if you are still unsure as to how to complete the Application Cover Page, please check with the instructor for your research seminar. The instructors work closely with IRB and can help you determine which review category to check. If further clarification is needed, please contact the Chair of the IRB Committee.

2. **What is the difference in the IRB process for a Full IRB Review versus an Expedited IRB Review?**

   In the Full Review, all members of the IRB read, review, and discuss the proposal at the next scheduled IRB Committee meeting. Approval is granted by a majority vote. In an Expedited Review, one member of the IRB Committee is assigned to read, review, and approve the proposal and reports such to the IRB Committee at the next scheduled IRB Committee meeting. In the event of a conflict of interest, an alternate IRB member is designated by the chair of the IRB Committee.

3. **What is the required timing for submitting a proposal for review?**

   Fall 2024 proposals must be submitted by November 15, 2024.

   Spring 2025 proposals must be submitted by March 28, 2025.

4. **How quickly can I expect a response from the IRB?**

   You can generally expect a response within 3 weeks following the regularly scheduled meeting following the date you submitted your proposal. If there is a delay, you will be notified as soon as possible.

5. **What happens if I need to submit a proposal and obtain a response in a different time frame than that listed above?**

   Although we expect all submissions to follow the timeline outlined above, we do understand that occasionally unforeseen circumstances arise. This includes proposals submitted by faculty and for student research that is not linked to degree completion requirements. In such a case, please contact the Chair of the IRB directly. The Chair will contact the other members of the IRB to determine their availability, and every effort will be made to accommodate your needs, although no guarantees are given.

6. **Does Spacing or Font matter*?***

   Generally speaking, single spaced, 12 pt non serif fonts such as Aptos are preferred. However, please consult with the research seminar professor regarding their specific preference.

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7. **How do I contact the IRB Chair or other committee members?**

   If you have questions the instructor for your research/thesis seminar cannot answer, please contact either the Chair of the IRB Committee using Canvas in-mail or the email address listed below:

   Michael Drexler, PhD, CPRP,
   Chair, NDNU IRB Committee
   Faculty, Psychology Department
   School of Psychology
   mdrexler@ndnu.edu

8. **What should I do if I want to modify my research project after it's been approved by the IRB?**

   Changes to your original approved IRB proposal must first be discussed with your research course instructor. A Modification application (Research Modification Form) must be submitted via the IRB Canvas guide portal for all proposed modifications/changes to exempt and currently approved research protocols. The IRB must approve the modification(s) before you can begin, or resume your research study.

   Examples of modifications include but are not limited to: research data collection methods, consent forms, assent form, permission forms, verbal scripts, advertisements, changes in testing instruments, change in risk level, change in participant population, investigators, etc.

9. **What if my research is exempt and with the modifications it will still be exempt?**
   Even if your research is exempt, you must notify the IRB as the IRB is responsible for the final determination of whether the research continues to be exempt, or if the category has changed due to the modification.

   If you would like to make changes to your approved IRB research proposal, the first step is to review the changes with your faculty research instructor. Once discussed, fill out the Research Modification Form and submit it to the Chair of the IRB via the IRB Canvas Guide portal. Exempt modifications will be reviewed by the Chair of the IRB or their designee within five business days.

10. **What if the modifications change my research from exempt to expedited or full review?**
    If your original research protocol was exempt, and with the modifications is determined to be non-exempt, you will need to complete and submit a new IRB proposal Research Modification Form under the expedited or full category.

11. **What if my research was approved as expedited or full review and I want to modify my original proposal?**

    If you would like to make modifications to your approved expedited or non-exempt IRB Proposal, first review the changes with your faculty research instructor. Complete the Research Modification Form and submit it to the chair of the IRB. Modifications will be

reviewed by the chair of the IRB or designee, with the goal of a response within five business days.

Include a copy of your approved IRB proposal, highlighting the content that you would like to change, and label it "CURRENT IRB." Next, add the new pages with the proposed modifications; highlight the new proposed changes and label it "PROPOSED CHANGES." You can also use the "track changes" feature to show the proposed changes (if it is easy to follow).

Sign the proposal form and have your faculty research instructor sign. If the proposal was expedited and the research will continue to be expedited, the research instructor may submit it to the chair of the IRB for expedited review. Either the Chair, or the Chair's designee, will review the proposal. If there is any question about the proposal and the Chair or designee will not approve it as expedited, the proposal will be submitted for review by the full IRB committee at the next committee meeting (see IRB dates).

Modifications to an approved expedited review that change the category to full review will be submitted for review by the full IRB committee at the next committee meeting (see IRB dates).

Modifications to proposals that were approved as full review will be submitted for review by the full IRB committee at the next committee meeting (see IRB dates).

Submit modification forms and accompanying material to the chair of the IRB.

12. What do I do when I have completed or end my research? Do I need to notify the IRB when I complete or terminate my research protocol?

Yes! The completion or termination of a research protocol is a change in activity and must be reported to the IRB. Using the resources within the Canvas Guide, please fill out and complete the Research Completion Form at the close of your study. You will need to attach an abstract summary of your study along with the form.

Please submit the Research Completion Form and your Abstract Summary to your Principal Investigator (faculty research instructor), who will submit it to IRB

A final report to the IRB signifies the closure of all files and provides information that may be used by the IRB in the evaluation and approval of related studies.

NOTE: Closure of a study means that no further data collection will be performed. Please note you, as the principal investigator, are required to keep your research data for a minimum of three years. If the research is published, the principal investigator is required to keep the data for a minimum of seven years post publication.

13. What do I do if I have unanticipated problems or issues with participant safety and well-being?

The best answer to this question starts with establishing a collective understanding of what might represent an unanticipated problem versus an unexpected adverse event versus an adverse event versus a serious adverse event, as they are addressed differently. Accordingly, using federal Office of Human Protection guidelines, an:

Unanticipated Problem involving risks to participants or others includes any incident, experience, or outcome that meets all of the following criteria:

- Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- Related or possibly related to a participant's participation in the research; and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, legal, or social harm) related to the research than was previously known or recognized.

Unexpected Adverse Event includes any adverse event occurring in one or more participants in a research protocol, the nature, severity, or frequency of which is not consistent with either:

> (1) the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol-related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or
> (2) the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the participant's predisposing risk factor profile for the adverse event.

Adverse Event includes any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participant's participation in the research, whether or not considered related to the participant's participation in the research. Adverse events may also be psychological in nature.

- *Possibly related to the research:* There is a reasonable possibility that the problem, event, incident, experience or outcome may have been caused by the procedures involved in the research.

Serious Adverse Event includes any adverse event temporally associated with the participant's participation in research that meets any of the following criteria:

- results in death;
- is life-threatening (places the subject at immediate risk of death from the event as it occurred);
- requires inpatient hospitalization or prolongation of existing hospitalization;
- results in a persistent or significant disability/incapacity;
- results in a congenital anomaly/birth defect; or
- any other adverse event that, based upon appropriate medical judgment, may jeopardize the participant's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

For additional information, please consult:
Government Regulations: Office of Human
Protections: www.hhs.gov/ohrp/policy/advevntguid.html
Applicable Regulations: 45 CFR 46.103(5) 21 CFR 56.108(b)

Submit form to IRB and cease research until the IRB notifies you to continue or to alter your research design.

14. What should I do if I have concerns about misconduct occurring in any ongoing research?

All institutional members will report observed, suspected, or apparent research misconduct to NDNU's IRB Chair. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, they may meet with or contact the IRB Chair to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically. For further information, please read the Belmont Report (1979).

Notre Dame de Namur University expects professional and ethical behavior from all participants in institutionally sponsored activities. Research misconduct includes the willful or unintentional failure to follow appropriate IRB guidelines, policies, and procedures at NDNU. The IRB Committee will do its best to disseminate information about policies, procedures, guidelines, and timelines; ultimately, the responsibility rests with the party or parties engaging in research, including faculty in charge of oversight of students. In addition, the IRB Committee will work with the deans to ensure that IRB information is appropriately disseminated to affected parties. Failure to comply may result in disciplinary action via the Provost's Office.