**Application for Review of Research**

Institutional Review Board Human Subjects Research

Northwest Missouri State University

**Instructions:**

This form is intended for submission of a request for review of your research project by the Institutional Review Board (IRB) at Northwest Missouri State University. It is recommended that you download, read, and review the *Northwest IRB Submission Guide* prior to beginning your application.

There are three levels of review which your project may be submitted under: ***exempt, expedited,*** and ***full review.*** For more detail on the difference between each level, including differences in estimated review time, see Section 5 of the Northwest IRB Submission Guide.

To qualify for an ***exempt review***, your project must fit under one of eight categories of human subjects research outlined by the Department of Health and Human Services (HHS). To qualify for an ***expedited review,*** your project must fit under one of the nine categories outlined by the Office for Human Research Protections (OHRP). For more details on these categories, see [45 CFR 46.104](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1104) of the Code of Federal Regulations, the [1998 OHRP Expedited Review Categories](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html), or the [IRB Exempt and Expedited Categories](https://www.nwmissouri.edu/fsenate/irb/exempt-expedited.htm) section of the Northwest IRB website.

Note that to qualify for an exempt or expedited review, your project must **both** fit under a listed category **and** be considered no more than minimal risk to subjects. For more on this, see the Northwest IRB Submission Guide.

You can also submit this document for *Secondary Review* if your project was previously approved as exempt or expedited. A secondary review means that your project has already been approved by the Northwest IRB but that approval has expired, or that your project was approved by another institution’s IRB. To submit this document for a secondary review, complete sections 1, 2, and 7 and attach all materials that were reviewed in your previous approval.

**Submission Instructions:**

This form must be completed and submitted, along with all required supplementary documents, through email to [IRBNWMS@nwmissouri.edu](mailto:IRBNWMS@nwmissouri.edu).

Some sections only apply for certain types of projects. Only complete those sections that are relevant to your project. Further instructions are provided in each section to help explain when certain sections are required.

You must receive approval prior to collecting new research data or accessing pre-existing data.

**SECTION 1: PROJECT INFORMATION**

**All** projects must complete this section.

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

**2. Project Title:** Click or tap here to enter text.

**3. Principal Investigator(s):**

Principal Investigator 1

Name: Click or tap here to enter text.

Address: Click or tap here to enter text.

Email: Click or tap here to enter text.

Affiliation/Department: Click or tap here to enter text.

Principal Investigator 2 (delete if only 1 PI; copy this section to add more PIs as needed)

Name: Click or tap here to enter text.

Address: Click or tap here to enter text.

Email: Click or tap here to enter text.

Affiliation/Department: Click or tap here to enter text.

**4. Is the PI a student?**

Yes

No

**5. Faculty Advisor (if PI is a student):**

Name: Click or tap here to enter text.

Department: Click or tap here to enter text.

Office: Click or tap here to enter text.

Email: Click or tap here to enter text.

**6. Has This Project Been Previously Approved by an IRB?**

Yes, by the Northwest IRB (Approval Code: Click or tap here to enter text.)

Yes, by another institution (enter name of institution: Click or tap here to enter text.)

No

**7.** **Other Researchers:**

On the following page, list the names, email addresses, affiliations, and statuses of any other researchers who will interact with subjects or otherwise have access to the data from this project. If all researchers are already listed on the previous page, leave this section blank. If you need additional space for more researchers beyond that given, you can add more lines.

Additional Researcher 1

Name: Click or tap here to enter text.

Email: Click or tap here to enter text.

Affiliation/Department: Click or tap here to enter text.

Status: This researcher would best be described as a Choose an item.

If you chose Other above, explain: Click or tap here to enter text.

Additional Researcher 2

Name: Click or tap here to enter text.

Email: Click or tap here to enter text.

Affiliation/Department: Click or tap here to enter text.

Status: This researcher would best be described as a Choose an item.

If you chose Other above, explain: Click or tap here to enter text.

Additional Researcher 3

Name: Click or tap here to enter text.

Email: Click or tap here to enter text.

Affiliation/Department: Click or tap here to enter text.

Status: This researcher would best be described as a Choose an item.

If you chose Other above, explain: Click or tap here to enter text.

Additional Researcher 4

Name: Click or tap here to enter text.

Email: Click or tap here to enter text.

Affiliation/Department: Click or tap here to enter text.

Status: This researcher would best be described as a Choose an item.

If you chose Other above, explain: Click or tap here to enter text.

Additional Researcher 5

Name: Click or tap here to enter text.

Email: Click or tap here to enter text.

Affiliation/Department: Click or tap here to enter text.

Status: This researcher would best be described as a Choose an item.

If you chose Other above, explain: Click or tap here to enter text.

Additional Researcher 6

Name: Click or tap here to enter text.

Email: Click or tap here to enter text.

Affiliation/Department: Click or tap here to enter text.

Status: This researcher would best be described as a Choose an item.

If you chose Other above, explain: Click or tap here to enter text.

**SECTION 2: REVIEW LEVEL, CATEGORY, AND EXPLANATION**

All projects must complete this section.

**Instructions:**

Select the level of review that you believe your research project qualifies under and provide a brief (1-3 sentence) explanation as to why you believe your project fits under this category. If your project qualifies for exempt or expedited review, select which category the project fits. For full descriptions of each level and category see IRB website.

**1. Additional Protections**

Check the box next to any of the populations listed below that will be involved in your research. If none of the groups listed below will be involved in your research, select “None of the Above.”

Children

Prisoners

Pregnant Women, Human Fetuses, and/or Neonates

None of the Above

If your research involves children, it may qualify for exempt review under any category except 2-III and 3, or may qualify under expedited or full review. There are also special criteria for research with children to qualify for categories 2-I and 2-II. If your research involves prisoners or pregnant women, human fetuses, and/or neonates, please contact the Northwest IRB prior to submitting your application.

**2. Level of Review**

Select what level of review you believe your project should receive.

Choose an item.

**2a. Exemption Category**

If you believe your project qualifies for an exempt review, select which of the eight [exemption categories](https://www.nwmissouri.edu/fsenate/irb/exempt-expedited.htm) your project qualifies under. You should only choose one category and should leave this question blank if you chose an expedited or full review.

Choose an item.

**2b. Expedited Category**

If you believe your project qualifies for an expedited review, select which of the nine [expedited categories](https://www.nwmissouri.edu/fsenate/irb/exempt-expedited.htm) your project qualifies under. You should only choose one category and should leave this question blank if you chose an exempt or full review.

Choose an item.

**3. Explanation**

In the space below, provide a brief (1-3 sentence) explanation as to why you believe your project fits under the level and category you chose. If your research involves children as subjects and you chose exemption category 2, you should also explain why you believe your research fits the special criteria for exemption category 2 research with children.

Click or tap here to enter text.

**4. Additional Information**

If your project fits under Exemption Categories 2, 3, and 4, or Expedited Category 1, additional information is necessary to determine whether your project qualifies. If you chose one of these categories for your project, respond to the appropriate question below. If you chose any other category, you should skip the remaining questions in this section.

**4a. Exemption Category 2**

Select which of the three subcategories below apply to your project (choose 1).

I. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.

II. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

III. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

**4b. Exemption Category 3**

At least one of the items below must be true for your project to qualify as exempt under category 3. Check all that apply to your project.

A. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.

B. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

C. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

**4c. Exemption Category 4**

At least one of the items below must be true for your project to qualify as exempt under category 4. Check all that apply to your project.

A. The identifiable private information or identifiable biospecimens are publicly available.

B. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.

C. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b).

D. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501.

**4d. Expedited Category 1**

Projects that fit this category must meet one of the following criteria. Check the one that applies to your project.

A. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required.

B. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

**SECTION 3: PROJECT DETAILS**

All projects should complete this section unless they are being considered for secondary review.

**1. Purpose and Rationale**

Provide a brief (1-2 paragraph) overview of the background for your research project, explaining the rationale behind your project and any research questions, predictions, or hypotheses that will be examined.

Click or tap here to enter text.

**2. Will your research involve data collection, or will you access pre-existing data?**

My research involves data collection.

You should complete all questions in this section as well as section 4 of the document. If using adult subjects, you must submit a consent form of your own, or one modeled after the Informed Consent Statement Template. If using child subjects, you must submit a permission form and assent form.

My research involves accessing a pre-existing data set.

If using pre-existing data, you may skip questions 3-5, 7-10, and 12-17 of this section as well as section 4 of the application.

In addition, please provide information in the space below about how you will access the data, including any permission granting access, where the data is hosted, and whether the data will be anonymized prior to you receiving it.

Click or tap here to enter text.

**3. Overview of Procedures**

Provide a detailed explanation of the procedures to be followed in your project. This explanation should have enough detail that a reviewer could re-create your entire research design based solely on the answer you provide here.

Click or tap here to enter text.

**4. Video/Audio Recording**

Will your project involve the recording of subjects through audio and/or visual recording?

Yes

If yes, you must submit the Audio/Visual Consent Form along with your application. If you prefer, you may instead incorporate this information into your informed consent statement.

No

**5. Risk**

Provide a list of any foreseeable risks that subjects may encounter by participating in your project. Keep in mind that risks may include things that are unlikely to occur and things that seem of relatively low harm. Examples of risk include (but are not limited to) physical trauma, pain, allergies, side effects of medication, deception, loss of privacy, loss of legal rights, psychological distress, and coercion.

Click or tap here to enter text.

**5a. Level of Risk**

Would you consider the foreseeable risks associated with this project to be no more than minimal risk (risks that are no greater than those regularly encountered in everyday life)?

I believe my project is of no more than minimal risk.

I believe my project is of greater than minimal risk.

If so, you must submit your project for full review.

**5b. Risk Mitigation**

For all risks listed above, please explain how risks will be mitigated through the project. Mitigation strategies can include procedures that will be followed, resources that will be made available to subjects, debriefing forms, and explanations that will be included in the consent form.

Click or tap here to enter text.

**6. Materials/Stimuli**

Provide a brief (1-3 sentence) explanation of each material/apparatus that will be used in your project. This includes anything subjects will interact with (e.g. videos, images, machines) as well as anything for which data will be recorded (surveys, physiological indicators, interview questions, etc.). If you are using pre-existing data, provide details about each question and/or variable included within the data.

Note: Copies of all materials/stimuli discussed in this section should be included with your submission.

Click or tap here to enter text.

**7. Will your research involve subjects ingesting any substances (drugs, dietary supplements, food, beverages)?**

Yes

If yes, you must submit the *Ingested Substances and Dietary Supplements Form* along with your application. In addition, you must submit the *Informed Consent with Ingested* *Substances* document or incorporate this information into your overall informed consent.

No

**8. Will This Study Be Conducted Online?**

Yes

If so, you must attach a link to the actual survey subjects will complete with your submission (see section 7 below for a space to link your survey).

No

**9. Study Location**

Provide details on where data collection for your project will take place, being as specific as possible. If you will use multiple locations, each should be discussed. If you will need permission to collect data from a particular location, evidence of this permission should be included with your submission. If your study will be conducted electronically, provide details on where the survey will be hosted and how participants will be contacted.

Click or tap here to enter text.

**10. Data Collection Start/End Date**

If you are collecting new data as part of your project, provide estimated dates at which you will start and end data collection. Note that you cannot begin collecting data until your project is approved, so your start date may not be prior to your application submission.

Estimated Start Date: Click or tap to enter a date.

Estimated End Date: Click or tap to enter a date.

**11. Anticipated Sample Size**

Provide an estimation of the number of anticipated subjects for this project. If you are using pre-existing data, provide the number of subjects within the data set.

Click or tap here to enter text.

**12. Recruitment Strategy**

Explain in detail how you will recruit subjects for your project. If recruitment materials (flyers, emails, posters, etc.) will be used, these should be included with your submission.

Click or tap here to enter text.

**13. Compensation**

Provide an explanation of any compensation subjects may receive for participating in your study. Your explanation should detail what the compensation consists of (money, course credit, etc.), the amount of compensation ($20, 2 points, etc.), the source of the compensation (research grant, university funds, etc.), and what subjects must do in order to qualify for compensation. If your project will not involve compensation, please write “Not Applicable.”

Click or tap here to enter text.

**14. Will your research involve children as subjects?**

Yes

If yes, you must complete section 5 of this application.

No

**15. Will your research involve prisoners as subjects?**

Yes

Please contact the chair of the Northwest IRB prior to submitting your application.

No

**16. Will your research involve pregnant women, human fetuses, or neonates?**

Yes

Please contact the chair of the Northwest IRB prior to submitting your application.

No

**17. Will your research involve a vulnerable population not specified in Q14-16 above?**

Vulnerable populations are those with higher than normal potential for coercion or undue influence who may participate in your research.

Yes

No

Please specify: Click or tap here to enter text.

**SECTION 4: INFORMED CONSENT**

Projects fitting under exemption categories 4, 7, or 8, or expedited categories 5 or 8 may skip this section. If your project involves research with children, complete this section as it pertains to your permission and assent forms.

In order to conduct ethical human subjects research, HHS requires investigators to obtain ***informed consent*** from all subjects prior to their participation in research. To obtain consent, an **informed consent statement** with specific content is required for almost all human subjects research involving adults, and an **assent form** and **permission form** are required for human subjects research involving children.

The Northwest IRB requires that you obtain informed consent from adult subjects by adapting the ***Informed Consent Template*** to use with your project. This template can be downloaded from the Northwest IRB website. If your research involves child subjects, you should submit an assent form and a permission form instead. Currently, the Northwest IRB does not have templates for assent and permission forms; instead, please review the *Informed Consent, Assent, and Permission Information* on the IRB website and ensure that all necessary information is included.

Please check the relevant boxes below confirming that your informed consent documentation is included with this application and that it includes all necessary information.

**If Using Adult Subjects:**

I have adapted the Informed Consent Template from the Northwest IRB webpage for use with my research project, and I have attached the document along with my application.

**If Using Child Subjects:**

I have created an assent form for obtaining assent from my subjects which includes all relevant consent information as specified in the *Informed Consent, Assent, and Permission Information* webpage, and I have attached the document along with my application.

My assent form is written in language that is understandable given the age and reading ability of my subjects.

I have created a permission form for obtaining permission from the parent(s) or guardian(s) of my subjects which includes all relevant consent information as specified in the *Informed Consent, Assent, and Permission Information* webpage, and I have attached the document along with my application.

Please respond to the section below regardless of the age of your subjects.

**Signatures (For Human Subjects of Any Age):**

Proof of consent is required in the form of either written or electronic signatures for many categories of human subjects research. However, signatures are not required for exempt or expedited research **if any** of the following is true:

**A**. If responses would otherwise be anonymous and the primary risk to subjects would be harm from a breach of confidentiality.

**B.** If the project is no more than minimal risk and involves procedures where written consent is normally not required outside of the research context.

**C**. If the project has no more than minimal risk, subjects come from a cultural community where signing is not the norm, and the researcher has put into place an alternative mechanism for ensuring consent.

1. Will subjects in this study be asked to sign your consent/assent form, either on paper or electronically?

Yes

No

2. If you answered “No” to question 1, which of the criteria for waiving signed consent applies?

A

B

C

**SECTION 5: RESEARCH WITH CHILDREN AS SUBJECTS**

If your project does not involve research with children as subjects, you can skip this section.

**Instructions**

If some or all of the participants in your project will be children, HHS has special guidelines that your research must follow in addition to the information requested earlier in this document. Your responses to the following questions will ensure that your project is in compliance with these additional precautions.

**1. Risk and Exemption/Expedited Criteria**

Research with children can only be reviewed as exempt or expedited if it is of no more than minimal risk to the subjects and if the research fits one of the criteria detailed in section 2 of this document. Complete the following confirming you believe these to be true of your study.

This project is of no more than minimal risk to participants.

This project fits under the following exempt or expedited category: Choose an item.

If you selected Exemption Category 2, please also complete the following.

I am not submitting this project for Exemption Category 2-III (see section 2, question 3a).

The investigator will not be involved in the data collection or observation process.

If you are submitting your project for full review, please check the following instead.

I am submitting my project for full review.

**2. Justification for Use of Children**

Research with children is only allowed if using children as subjects is required to investigate the research questions of the study and using adults instead is not an option. In the space below, briefly explain (1-3 sentences) why it is necessary to use children as subjects in this project.

Click or tap here to enter text.

**3. Assent**

HHS requires all research with children to obtain the child’s assent to participate unless they are reasonably incapable of doing so. The Northwest IRB requires you to submit an Assent Form which you will use when obtaining assent. The assent form includes the same general information as an informed consent form as detailed in section 4 above, but must also be written in a language and reading level that subjects can comprehend. In addition, a procedure for obtaining assent must also be provided.

I have attached an assent form for this project which is written in language that subjects in this study should be able to comprehend (considering age, maturity, etc.).

**4.** **Procedure for Assent**

Please outline the procedure you will follow to obtain assent from your subjects. In your response, be sure to explain when and how subjects will provide assent, who will be present (parents, teachers, etc.), and any steps that will be taken to avoid coercing subjects to assent.

Click or tap here to enter text.

**5. Permission**

In addition to assent, investigators must obtain permission from parents or guardians. Signed permission forms from at least one parent/guardian are required and must be obtained prior to collecting data from a given subject. Permission forms should include any information that would be included on a typical informed consent as discussed in section 4 of this document. Unlike projects using adult subjects, permission forms must be signed even if the project is reviewed as exempt or expedited.

I have attached a permission form for this project.

**6. Procedure for Permission**

Please outline the procedure you will follow to obtain permission from parents/guardians. In your response, be sure to explain how permission forms will be distributed and collected.

Click or tap here to enter text.

**SECTION 6: ADDITIONAL CIRCUMSTANCES**

This section includes issues that may or may not apply to your project. Read through each issue and determine if it applies; if it does not apply, you can skip the section.

**Deception**

Some research projects require the use of deception regarding the true purpose of the study. In cases of deception, informed consent may be altered such that participants are not given all information until after their participation is complete, but only if all of the follow are true. If you are using deception in your project, check the following boxes to indicate they are true.

The research is of no more than minimal risk to subjects.

This project would be impossible without the use of deception.

Altering consent will not affect the rights or welfare or the subjects.

Subjects will be given all pertinent information after completing the study.

If your project will use deception, respond to the questions below and check the boxes confirming the attachment of necessary supplementary documents.

I have attached the altered consent form that will be given to participants.

I have attached a debriefing form that outlines the true nature of the study.

**1.** Why is deception and alteration of consent required for this project?

Click or tap here to enter text.

**2.** What specific information will be withheld from subjects until after completing the study?

Click or tap here to enter text.

**3.** At what point will participants be fully informed about the true nature of the study?

Click or tap here to enter text.

**4.** Describe the procedure by which subjects will be debriefed and told the true nature of the study.

Click or tap here to enter text.

**Debriefing**

Some research projects require a debriefing of subjects following the study. Generally, debriefing is only necessary for projects that involve deception and alteration of consent or for projects that may have caused some form of harm (e.g., depressive states) to subjects.

If your project will use a debriefing procedure, respond to the questions below and check the boxes confirming the attachment of necessary supplementary documents.

I have attached a debriefing form that will be given to all participants.

**1.** If your project will use debriefing, why is a debriefing necessary for this project?

Click or tap here to enter text.

**2.** Briefly describe the debriefing procedure that will be followed.

Click or tap here to enter text.

**SECTION 7: CONFIRMATION AND SIGNATURE**

All projects must complete this section.

**Projects Involving Collection of New Data**

I confirm that, in addition to this document, I have attached the following:

Copies of All Materials/Apparatus/Stimuli Used in Project

Informed Consent Template (if using adult subjects)

Assent Form (if using child subjects)

Permission Form (if using child subjects)

Audio/Visual Consent Form (if data collection involves audio/visual recording)

Completion Certificate(s) for CITI Training for each PI, researcher, and faculty advisor

**Projects Involving Pre-Existing Data**

Document Outlining Variables Included in Dataset

Documentation of Permission to Access Data (if necessary)

Completion Certificate(s) for CITI Training for each PI, researcher, and faculty advisor

**Secondary Reviews**

If this project has been previously approved, I have also attached:

All Documents from Prior IRB Submission

Evidence of Prior IRB Approval

This will typically take the form of an approval letter for your project from the IRB.

Completion Certificate(s) for CITI Training for each PI, researcher, and faculty

**Additional Documentation**

I have also attached each of the following documents, each of which are only necessary if they apply to my project:

Ingested Substances and Dietary Supplements Form (see Section 3.6)

Informed Consent with Ingested Substances Template (see Section 3.6)

Link to Online Materials (Surveys, Consent Forms, etc.; see Section 3.7)

Provide a link to any online materials here: Click or tap here to enter text.

Documentation of Approval for Data Collection (see Section 3.8)

Recruitment Materials (Email Templates, Flyers, etc.; see Section 3.11)

Debriefing Form (see Section 6)

**Signatures**

All applications must include an electronic or written signature on the application form. If you are a student researcher, you should also send the application form to your faculty advisor for review; they will also need to sign and date the form before you submit it.

I affirm that all materials submitted are accurate and represent the documents as they will be used in this project, and that the statements I have made herein are truthful to the best of my knowledge.

Principal Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_

Faculty Advisor Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_

(if applicable)

All materials should be submitted electronically to the Northwest IRB email address ([IRBNWMS@nwmissouri.edu](mailto:IRBNWMS@nwmissouri.edu)). Any necessary supplementary documents should be included as attachments to your electronic submission.