

*Office Use Only:*

**IRB Protocol #:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date Received**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Exemption Category(ies)** \_\_\_\_\_\_\_\_\_\_\_

**Limited IRB Review?** \_\_\_\_\_\_\_\_\_\_\_\_

Research Integrity & Compliance
Institutional Review Board
**office:** Research 1, 1735 NDSU Research Park Drive, Fargo, ND 58102
**mail:** NDSU Dept. #4000, PO Box 6050, Fargo, ND 58108-6050
**p:** 701.231.8995 **f:** 701.231.8098 **e:** ndsu.irb@ndsu.edu **w:** [www.ndsu.edu/irb](file:///C%3A%5CUsers%5Ckristy.shirley%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CTemporary%20Internet%20Files%5CContent.Outlook%5CDownloads%5Cwww.ndsu.edu%5Cirb)

IRB Protocol Application for Exemption: Primary Research

## Exemption Categories 1, 2, 3, 5, and 6

*\*PI must be faculty or staff member. For graduate research, advisor must serve as PI.*

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| Title of Project:       |
| Principal Investigator:       | Co-Investigator:       |
| Department:       | Department:       |
| Email Address:       | Email Address:       |
| Phone:       | Phone:       |

1. **PROJECT DESCRIPTION:**
2. **Purpose and goals of the research:**

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1. **Methods and procedures:** Describe in detail what subjects will be asked to do, what information will be collected about them, and when or how often research procedures will be conducted. For complex or multi-phase studies, a separate attachment describing the methods may be included which contains graphics, tables, timelines or schedule of events.

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1. **Research site(s):**

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1. **Project Dates:** Indicate the expected start date and end dates for the research procedures which will involve human subjects:

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| **Anticipated start date:       or after IRB Approval****Anticipated end date:** |

1. **EXEMPTION CATEGORIES:**

Check the category or categories which apply and respond to the questions within that exemption section:

**[ ]  Exemption Category 1:** Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

1. Describe the established or commonly accepted educational setting of the research:

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1. Could the research adversely impact student achievement in anyway?

[ ]  No [ ]  Yes, The study does not qualify under this category.

1. Could the research adversely impact the assessment of educators who provide instruction?

[ ]  No [ ]  Yes, The study does not qualify under this category.

1. Does the research involve a comparison of a proven educational technique to a novel technique?

[ ]  No [ ]  Yes, The study does not qualify under this category.

**[ ]  Exemption Category 2:** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met (Select one):

[ ]  2(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;

[ ]  2(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;

[ ]  2(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 § \_\_.111(a)(7). This category may NOT be applied to research with children.

 **Screening Criteria: *(Must be completed for Exemption Category 2)***

1. Does the research involve minor participants?

[ ]  Yes [ ]  No

1. If yes to a), does the research involve surveys?

[ ]  Yes [ ]  No

If yes, to a) and b), **Exemption Category 2** does not apply. Complete the IRB Protocol Form for expedited review.

1. Does the research involve an intervention? [ ]  Yes [ ]  No

*Intervention* is defined as, “manipulations of the subject or the subject’s environment that are performed for research purposes.”

If yes, Exemption Category 2 does not apply.

**[ ]  Exemption Category 3:** Research involving *benign behavioral interventions\** in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

[ ]  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; or

[ ]  (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 § \_\_.111(a)(7).

**\* Benign behavioral interventions** are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

1. Describe the benign behavioral intervention:

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If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

1. Does the research involve deception? [ ]  Yes [ ]  No
2. If so, will subjects prospectively agree to be unaware of or misled regarding the nature of the research? [ ]  Yes [ ]  No

If yes to b), but no to c), the research will not qualify under this category. Please complete the IRB Protocol Form for expedited review.

1. Does the research involve minors? [ ]  Yes [ ]  No

If the research will involve minors, the research does not qualify under this category.  Use the IRB Protocol Form.

**[ ]  Exemption Category 4:** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens.

Screening Criteria:

1. Will you collect both primary and secondary data about the same individuals?
[ ]  Yes [ ]  No. If yes, the research will not qualify for Exemption under this category.
2. Are you collecting only secondary data, with no direct interaction or intervention with human participants? [ ]  Yes [ ]  No.  Please use the IRB Application for Exemption: Secondary Research for which consent is not required.
3. Do you have two distinct participant groups: one from which data is being collected through interaction or intervention, and one for which secondary data is being collected (e.g. through a retrospective chart review).
[ ]  Yes [ ]  No. ![MCSY00871_0000[1]]() Attach the Additional Materials Attachment detailing the secondary data to be used.

[ ]  i. The identifiable private information or identifiable biospecimens are publicly available;

1. Describe the publicly available source of the data and how one gains access to the data or specimens. Include any information on whether permission is required to access the data, or any Terms of Use that apply.

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*For more examples of publicly available data sources, please see* [*SOP 7.1 Exempt Determinations*](https://www.ndsu.edu/research/integrity_compliance/irb/procedures/)*.*

[ ]  ii. 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;

1. Describe how the information or specimens will be recorded so that the identities of the human subjects may not be readily ascertained.

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[ ]  iii. The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under HIPAA, 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);

[ ]  iv. 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 **specified privacy standards**.

1. Please provide the name of the Federal department or agency for which the research is being conducted:

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1. Describe which privacy standards apply to the information collected:

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**[ ]  Exemption Category 5:** Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

**NOTE**: Exemption under Category 5 is only permitted upon Federal Agency approval AND after being published on a federal website.

**[ ]  Exemption Category 6:** Taste and food quality evaluation and consumer acceptance studies:

[ ]  (i) If wholesome foods without additives are consumed,

or

[ ]  (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

**[ ]  Exemption Category 7:** Storage or maintenance for secondary research for which broad consent is required.  **NDSU is not currently set up to use this exemption. category at this time.**

**[ ]  Exemption Category 8:** Secondary research for which broad consent is required.  **NDSU is not currently set up to use this exemption category at this time.**

1. **PARTICIPANTS, RECRUITMENT AND INFORMED CONSENT**
2. Describe the proposed participants:

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1. Recruitment: Describe recruitment procedures. Include how participants will be initially identified, approached or contacted regarding the research and in what setting.

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* *Please provide a copy of any recruitment materials, advertisements, flyers, text of emails, etc. which will be used.*
1. Describe procedures for informing participants about the research and how they will actively indicate their agreement to participate.

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* *Please provide a copy of the oral script, information sheet, etc. which will be used.*
1. Will information be purposely withheld from participants or will subjects be misled regarding the nature of the research?

[ ]  No [ ]  Yes If yes, please describe:

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1. Compensation/Incentives: Will participants or others be offered incentives for the research (e.g., gifts, payment, reimbursement, services, extra or course credit, or other incentives for participation)? [ ]  No [ ]  Yes.
2. If yes, please describe the amount of compensation, alternative ways to earn compensation (i.e., in cases of course/extra credit), and when compensation/incentives will be awarded.

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*Please see SOP 9.1 Consent process (Section 3.0) for additional information on appropriate recruitment strategies.*

1. Alternatives: Describe any alternatives available to those who choose not to participate (if applicable). [ ]  N/A

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6. Dual relationships: Does the investigator, co-investigator, any member of the research team, or anyone else assisting with the research have an authority relationship (e.g., instructor/student, employer or supervisor/employee, physician/patient, or other) with potential participants?

[ ]  No

[ ]  Yes\* - describe the relationship, and indicate how the research will be conducted to avoid undue influence on participants:

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7. Will any aspect of the research be conducted in a classroom setting during class time?

[ ]  No

[ ]  Yes - describe what those who choose not to participate will be doing, and provide justification for use of class time for research (![MCSY00871_0000[1]]() attach course syllabus):

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8. Will all participants, their parents/guardians and/or their legally authorized representative (as applicable) be fluent in English?

[ ]  Yes

[ ]  No - explain how informed consent will be obtained, and ![MCSY00871_0000[1]]()provide a copy of the translated documents to be used:

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9. If research will be conducted at an international site, indicate the investigator’s familiarity with the culture and cultural norms, and how the research may affect an individual’s standing in their community: [ ]  N/A

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1. **INSTRUMENTS**
* Provide the questionnaire(s), survey instrument(s), list of interview or focus group questions.
1. **PRIVACY AND CONFIDENTIALITY**

1. Privacy: Describe the conditions under which interaction with the subjects will occur (e.g., consent discussion occurs in a private room). Explain how these conditions adequately address the PRIVACY interests of subjects:

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2. Personally identifiable information: Will the researchers obtain any personally identifiable information (PII) from or about participants (e.g. names, addresses, telephone numbers, etc.)?

[ ]  No (Proceed to question 3).

[ ]  Yes:

2a. Identify which of the direct identifiers below will be obtained:

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| [ ]  Full Names | [ ]  Initials | [ ]  Photographs of participant in which s/he is identifiable |
| [ ]  Telephone numbers | [ ]  Email Address | [ ]  Video(s) of participant |
| [ ]  Birthdate | [ ]  Postal Address | [ ]  Audio Recording |
| [ ]  Any ID# (e.g. EMPLID, Student ID, etc.)       |
| [ ]  Other:       |

2b. How long will the PII be maintained?

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2c. Why is it necessary to maintain direct identifiers:

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2d. Describe the coding system that will be used to protect against disclosure of these identifiers.

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2e. How long will the link between identifiers and code be maintained?

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2g. Could identification of participants or their responses place them at risk of: [ ]  criminal liability, [ ]  civil liability, or be damaging to their: [ ]  financial standing, [ ]  employability, [ ]  insurability, [ ]  reputation, or be [ ]  stigmatizing? [ ]  N/A

2h. Explain how the researcher will mitigate these risks (e.g. limiting access to identifiers, obtaining a Certificate of Confidentiality from NIH, etc.)

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 ![MCSY00871_0000[1]]()If a Certificate of Confidentiality is obtained, provide a copy to the IRB

 once available.

3. Will any demographic information be collected which could lead to a deductive disclosure of participant(s) identities? If so, how will participant privacy be addressed?

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4. In what format(s) will the data originate (e.g. paper, digital, electronic media, video, audio or photographic)?:

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5. Describe how personally identifiable research data will be shared among research team members, collaborators, etc.

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6. In what format(s) will data be maintained during the life of the study (e.g. paper, digital, electronic media, video, audio or photographic)?

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7. Where will data be stored (include both paper/hardcopy records and digital/electronic files)?

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8. What security provisions will be taken to protect the data (e.g. password protection, encryption, etc.)? More information on security procedures can be found in the ‘[Confidentiality and Data Security Guidelines for Electronic Research Data](https://www.ndsu.edu/research/integrity_compliance/irb/resources/).’

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9. Are there potential ethical or legal circumstances when it would be necessary to break confidentiality (e.g., requirements for mandated reporting or other professional obligations to report)?

[ ]  No

[ ]  \*Yes –describe:

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\* This must be disclosed in the consent document(s).

10. Final disposition: Please describe at what point in time will PII and deductive identifiers be removed from the dataset and/or the records retention plan for the research records:

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1. **OTHER INFORMATION:**

1. External Interests. Does any investigator responsible for the design, conduct or reporting of the project (including their immediate family members) have a financial, personal or political interest that may conflict with their responsibility for protecting human participants in NDSU research?

Financial, personal or political interests related to the research (the sponsor, product or service being tested, or a competing product or service) may include:

* compensation (e.g., salary, payment for services, consulting fees)
* intellectual property rights or equity interests
* board memberships or executive positions
* enrollment or recruitment bonus payments

Refer to *NDSU Policy 151.1, External Activities and Conflicts of Interest, and NDSU Policy 823, Financial Disclosure – Sponsored Projects* for specific disclosure requirements.

[ ]  No – As PI, I attest that I have conferred with my co-investigators and key personnel and confirmed that no financial, personal or political interests currently exist related to this research.

[ ]  Yes – Describe the related financial, personal or political interests, and ![MCSY00871_0000[1]]() **attach documentation of COI disclosure and review** *(if applicable).*

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*For more information, see SOP 6.2, Conflict of Interest in Human Research, Investigator and Research Team.*

2. Funding: Has an external agency or sponsor agreed to provide funding to NDSU for the project?

[ ]  No

[ ]  Yes- PTF #: FAR00Agency or Sponsor\*:

 ![MCSY00871_0000[1]]() *Attach* ***complete*** *copy of final grant application, agreement or contract.*

2a. Were external funds made available for the project prior to IRB approval (via the IRB pre-screening process?) [ ]  No [ ]  Yes:

2b. Does the grant, agreement or contract related to this project include multiple human subjects research activities that are ***not*** described in this IRB protocol?

[ ]  No; all human subject activities are covered in this IRB protocol

[ ]  Yes; these activities will be covered in a future IRB protocol(s)**\***

[ ]  Yes; these activities have been covered by a previous IRB protocol(s): Protocol #

[ ]  Yes; these activities have been or will be reviewed by another IRB:

[ ]  Other; explain:

2c. As part of the funding agreement, are you required to share personally identifiable research data with members or agencies outside the research team. If so, attach or describe your Data Sharing Plan.

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***NOTE***:

* **The PI is responsible for obtaining IRB approval prior to initiation of any future human subjects research activities.**
* *To certify IRB approval of an award, the final funding proposal and the IRB protocol are compared to verify consistency with respect to human subjects activities.*
* *If external funds will be used for the project, Sponsored Programs Administration (SPA) requires internal approval of the proposal by submission of a Proposal Transmittal Form (PTF). Consult the SPA website (*[*www.ndsu.edu/spa*](file:///C%3A%5CUsers%5Ckristy.shirley%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CTemporary%20Internet%20Files%5CContent.Outlook%5CDownloads%5Cwww.ndsu.edu%5Cspa)*) for more information.*

3. Other institution(s): Are any outside entities engaged in this research (e.g., receiving a direct award, grant or contract to perform research, directing or supervising the research, intervening and/or interacting with participants for research purposes, obtaining informed consent, obtaining private identifiable information or specimens from any source for research purposes, or utilizing private information or human specimens for FDA regulated research)?

For additional information, please see the ‘NDSU Collaborative, Multi-Site or Off-site Research Worksheet’ available on the IRB ‘Forms’ page.

[ ]  No

[ ]  Yes – name entity or institution, contact person(s), and describe their role in the research:

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| **Name of outside entity or institution:****Contact person:****Their role in the research:** |

3a. Will the NDSU IRB serve as the IRB of record for these outside entities?

 [ ]  No, ![MCSY00871_0000[1]]() Attach documentation of IRB or other ethics committee approval.

 [ ]  Yes, ![MCSY00871_0000[1]]() Attach letter of permission cooperation which includes:

* + A brief description of the entity’s role in the research,
	+ Documentation of IRB training,
	+ IRB Authorization Agreement (IAA) OR Independent Investigator Agreement (IIA) as applicable.

4. Other IRB review: Is other IRB/Research Ethics Board review required (e.g. from a collaborating institution, research site, tribal board, or national research ethics board, etc.)?

 [ ]  Yes - name of IRB and status of the application:

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![MCSY00871_0000[1]]() Attach a complete copy of the protocol reviewed and the IRB/REC’s determination.

 [ ]  No.

***NOTE****: If permission letter(s) or approval(s) from sites or collaborator(s) are not immediately available, the IRB may approve the protocol provided that:*

*1) all other requirements are met, and*

*2) the documentation from the site(s) are forwarded to the IRB prior to initiating research that site.*

1. **PERSONNEL:**

*List all NDSU students, faculty or staff who will assist in the project (recruiting participants, obtaining informed consent, intervening or interacting with participants to obtain information/data, and/or handling identifiable information for research purposes). May provide as a separate attachment.*

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| Name, Dept. | Email Address | Duties | Training Date |
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* ***Note:*** *Investigators and all members of the research team are required to complete a course in the protection of human research participants every three years. Refer to the* [*IRB ‘Training’ page*](https://www.ndsu.edu/research/integrity_compliance/irb/training/) *for information and a link to the* [*CITI online training*](file:///C%3A%5CUsers%5Ckristy.shirley%5CDownloads%5Ccitiprogram.org)*.*
* ***The PI is responsible to ensure that any non-NDSU research team member is trained in the protection of human subjects; however, the IRB does not require submission of the documentation of training.***

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**SUBMISSION INSTRUCTIONS:** The Principal Investigator must submit via official NDSU Email with all applicable supplemental materials (e.g., recruitment notices, oral script/information sheet or consent document, questionnaires, etc.) and carbon copy the co-investigator(s) and the department chair/head or college dean.