Date Received

IRB Protocol #:



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>

**IRB Protocol Form: Exempt Categories**

Application to Conduct Research Involving Human Participants

1.Title of Project:

2. Principal Investigator: Dept. name:

*(PI must be an NDSU faculty or staff member; graduate students must list their advisor as PI)*

Campus address/phone:  Email address:

Role in this research:

3. Co-Investigator:  Dept. name:

Campus address/phone:  Email address:

Role in this research:

4. Research team:*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.,** **Affiliation** | **E-mail Address** | **Role in Research** | **Training date (IRB office only)** |
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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 for information and a link to the CITI online training.*
* ***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 documentation of this training.***

5. Project dates: Indicate the anticipated start date *(may state ‘after IRB approval’)* and end dates for research procedures involving human subjects: *(Note that start date must allow sufficient time for IRB review and approval; no research procedures involving human participants may begin prior to obtaining notification of IRB approval.)*

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

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| **Exemption Screening Questions***A ‘yes’ response to any of the questions below indicates the project is not eligible to be certified as exempt, and requires either expedited or full board review.* |

1. [ ]  Yes [ ]  No Will the research specifically recruit pregnant women, fetuses, prisoners, cognitively impaired individuals, economically or educationally disadvantaged individuals?

2. [ ]  Yes [ ]  No Will the research involve survey or interview procedures with children (under 18 yrs of age)?

3. [ ]  Yes [ ]  No Will the research involve the observation of children in settings where the investigator will participate in the activities being observed?

4. [ ]  Yes [ ]  No Will the research involve an intervention, an attempt to influence or change participants’ behavior, perception, or cognition?

5. [ ]  Yes [ ]  No Will a drug, biological product, medical device, or other product regulated by the FDA be used in this project?

6. [ ]  Yes [ ]  No Will data collection include sensitive information (illegal activities, or sensitive themes such as sexual orientation, or behavior, undesirable work behavior, or other data that may be painful or very embarrassing to reveal)?

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| **Project Description***Use plain language, avoiding technical terms, acronyms or jargon, unless explained. The description should be understandable to any person unfamiliar with the area of research.*  |

1. Purpose and goals of the research:

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2. Method and procedures: *Explain in detail what subjects will be asked to do or what information will be collected about them, and when or how often research procedures will be conducted. Provide a timeline or schedule of events, if applicable. May provide as a separate attachment, with numbered pages.*

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3. Performance site(s): *Indicate the location(s) where research procedures will be conducted.*

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| **Exemption Categories***Federal regulations define 6 categories of Exempt Research. A research project may qualify if all parts of the research fall within 1 or more of these categories.**NDSU policy requires the IRB to certify all exempt research before the research may begin. The IRB will make the final determination as to level of review in order to protect the rights and welfare of participants.*  |

Check all that apply, and answer applicable questions:

[ ]  **Exemption category #1: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:**

**[ ]  research on regular and special educational instructional strategies, or**

**[ ]  research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.**

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

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**1b.** Describe the normal educational practices to be used:

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***Note****:*

* *This category may include children under 18 years of age (*![MCSY00871_0000[1]]()*Complete the ‘Children in Research’ Attachment)*
* *If students’ academic records will be used for research, the investigator is responsible for compliance with FERPA. Use of academic records for research generally requires a signature from the student (or parent, if student is a minor). More information may be found at:* [*http://www.ndsu.edu/general\_counsel/ferpa/*](http://www.ndsu.edu/general_counsel/ferpa/)*.*

[ ]  **Exemption category #2: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior for which subjects cannot be identified directly or through coded identifiers, or, if they can be identified, disclosure of their information/responses outside of the research project would not reasonably place the subjects at risk of criminal or civil liability, or be damaging to their financial standing, employability, or reputation.**

(Mark as applicable):

 **[ ]  Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) for which the subjects cannot be identified, or release of the information would not be harmful to the subject.** *(This category* ***may*** *include children; attach the ‘Children in Research Attachment.’)*

  **[ ]  Research involving the use of survey procedures or interview procedures or observation of public behavior for which subjects cannot be identified, or release of the information would not be harmful to the subject.**  *(This category is* ***not*** *applicable to children, except for observation of public behavior where the researcher does not take part in the activities being observed.)*

**2a.** Will data collection include any information which may directly or indirectly identify participants, (including codes or links to identifiers)? [ ]  No [ ]  Yes\*

**NOTE:**

* *Even if names will not be collected, it may be possible to identify an individual simply by collecting certain demographics or other unique information about participants that would allow their identity to be deduced, especially within a small sample size, or specific group of individuals.*
* *Check ‘yes’ if a coded link will be held by any party, at any point in the research, even temporarily)*

\*If ’yes’, is there any potential for harm to participants if confidentiality were to be breached? *(\*Harm means any disclosure (intentional or unintentional) of the participant’s responses outside the research could reasonably place the participants at risk of criminal or civil liability or can be damaging to the participant’s financial standing, employability, or reputation.)*

 [ ]  No [ ]  Yes\* *(if ‘yes’, project is not eligible for exemption under this category)*

[ ]  **Exemption category #3:** **Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b2) of this section if:**

**[ ]  the human subjects are elected or appointed public officials or candidates for public office; or**

**[ ]  federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.**

**[ ]  Exemption category #4: Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if:**

**[ ]  these sources are publicly available, or**

**[ ]  the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or indirectly through identifiers linked to the subjects.** *(This category may include children.)*

*Additionally, to qualify under this category, all of the following must apply:*

* *all records/data/specimens existed (were ‘on the shelf’) before this research was proposed*
* *the research will not involve prospective collection (e.g. use of ‘left-over’ or ‘extra’ specimens collected going forward, or information that will be added to a record or dataset)*

**4a.** Will coded links to identifiers (e.g. Medical Record numbers, study ID numbers, lab numbers, or any HIPAA identifier) be accessed by any member of the NDSU research team at any time during the course of the research?

 [ ]  No. This is not considered to be human subjects research. Stop here.

 [ ]  Yes: Will codes be recorded by the research team?

[ ]  No

[ ]  Yes *(project not eligible for exemption; complete the IRB Protocol form for expedited or full review)*

**4b.** Are the data, documents, records or specimens to be used freely available to the general public?

[ ]  No. ![MCSY00871_0000[1]]() Attach documented permission from the owner(s) allowing the use for this research.

[ ]  Yes - describe how the public may access the data, including web address, if applicable:

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**4c.** Will the study involve use of human blood, tissues, or specimens?

[ ]  No

[ ]  Yes – Project also requires approval from the Institutional Biosafety Committee. If an *NDSU employee will handle human blood/tissues/specimens, participation in NDSU’s Bloodborne Pathogen Program is also required; more information is available at:* [*www.ndsu.edu/ibc*](www.ndsu.edu/ibc)*.*

**4d.** Provide a complete description of the specific data, documents, records or specimens to be studied. If specimens are to be studied, please also indicate if any associated health information will be collected. If selecting a subset of data, indicate how individual records/specimens will be chosen or selected:

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* Attach a data collection sheet listing column headings, if applicable.

**4e.** Will members of the research team record or retain (even temporarily) any information that could potentially identify an individual with the data, documents, records or specimens? *(Includes both direct identifiers – e.g., names, address, personal ID numbers; as well as indirect identifiers – e.g., demographic information within a small and/or well defined population sample, HIPAA identifiers, or other information that could be used to deduce the identity of an individual)*

[ ]  No [ ]  Yes *(project not eligible for exemption; complete the IRB Protocol form for expedited or full review).*

**4f.** Indicate the source, original purpose, and date(s) of collection of the data, documents, records or specimens, if known:

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**4g.** Indicate what individuals were originally told regarding the use and confidentiality of their information, records or specimens *(*![MCSY00871_0000[1]]()*provide original consent form, contract/agreement, or letter, as applicable)*: [ ]  Unknown

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*\*****Note****: If proposed secondary use is inconsistent with the original agreement with individuals, the IRB may require expedited or full review, as well as informed consent.*

**4h.** Were the data, documents, records or specimens collected as part of research previously approved by another IRB?

 [ ]  No

 [ ]  Yes: Indicate IRB:

***Note:***

* *Access to some types of data or records may be restricted (e.g., medical records) by additional laws that protect an individual’s privacy. Contact the NDSU HIPAA Privacy Officer (*NDSU.HIPAA@ndsu.edu) *if research will involve access to individuals’ private health information (PHI) held by NDSU.*
* ***If research is limited to use of existing data, documents, records, or specimens, skip to the ‘Privacy and Confidentiality’ section of this form.***

**[ ]  Exemption category #5:**  **Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and which are designed to study or evaluate public benefits or services.** (e.g., evaluation of public benefits programs: Medicare, Public Assistance).*(Note that this category may only be used with projects conducted under federal authority, and usually does not apply to academic research projects. See OHRP guidance for more information:* [*http://answers.hhs.gov/ohrp/categories/1564*](http://answers.hhs.gov/ohrp/categories/1564)*)*

**[ ]  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, by the Food and Drug Administration or approved by the Environmental Protection Agency or the food Safety and Inspection Service of the US Dept. of Agriculture.** *(This category may include children less than 18 years of age;* ![MCSY00871_0000[1]]()*attach the Children in Research Attachment).*

**6a.** Describe the samples to be used in the research, and explain how they meet the above criteria:

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| **Proposed Participants, Recruitment and Informed Consent** |

1. Describe proposed participants *(include the approximate number, any relevant characteristics, and describe how they will be selected, identified, contacted, and/or recruited)*:

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* Attach a copy of any oral script, advertisement, announcement or preliminary invitation that will be used.

2. Explain procedures for obtaining consent\* from participants *(who will seek consent, in what setting and time frame, etc)*:

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 *\*The informed consent process for ‘exempt’ projects may involve providing the required elements to participants by use of an oral script, handout/information sheet, cover letter, or email; a signature is not usually required. If applicable, prepare an assent document for minors under age 18, as well as a parental permission form. Templates may be found on the ‘*[*Forms’*](http://www.ndsu.nodak.edu/research/institutional_review_board/forms.html) *page of the website and additional examples may be found on the ‘*[*Resources’*](http://www.ndsu.nodak.edu/research/institutional_review_board/resources.html) *page.*

* Attach a copy of the consent document, hand out, or oral script.

3. Will the project purposely withhold some or all information about the research or involve deception?

[ ]  No

[ ]  Yes

 3a. Please provide justification for waivers of some or all of the elements of consent\*: [ ]  N/A

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 *\*Note:*

* *This is considered to be a request for a waiver of informed consent, and may be justified only if ethically acceptable; typical instances may include public observation, or use of de-identified existing data, records, or specimens, where the investigator/research team does not, or did not previously have access to participants’ names or identities.*
* *Research utilizing medical records may require a signed authorization from patients, and may not qualify for an exemption. The covered entity holding the records is responsible for ensuring compliance with HIPAA privacy rules.*

4. Compensation: Will participants or others, be offered incentives for the research (e.g., gifts, payment, reimbursement, services, extra/course credit, or other forms of compensation)? *Compensating participants for their time and effort may be appropriate if the amount of compensation does not cause undue influence to participate in a study. Compensation should also be pro-rated, rather than awarded only on completion of the study. If research will involve compensating students with extra credit, specify the amount of extra credit, and what non-research alternatives (equal in time and effort) are available to the students for earning extra credit.*

[ ]  No

[ ]  Yes - provide details of the compensation scheme:

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5. Alternatives to research participation: Describe any alternative procedures 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 *(and/or their parents/guardians, if 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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| **Instrument(s)***Provide the list of survey, interview or focus group questions, or oral history objective (may be provided as a separate attachment)* |

![MCSY00871_0000[1]]()Provide the questionnaire(s), survey instrument(s), list of interview or focus group questions, or oral history objective.

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| **Privacy and Confidentiality** |

1. Confidentiality: Describe whether or not participants will be promised confidentiality of their responses or information. Include who will have access to individual data and how results will be reported:

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2. Identifiable information: Will any information be collected (even temporarily) that could potentially identify an individual? *(This would include not only names, personal ID #s, address, video or audio recordings, or other direct identifiers, but also may include certain demographic or other unique information that could be used to deduce the identity of an individual.)*

[ ]  No

[ ]  Yes:

2a. Describe use of any identifying information, including codes or links to identifiers; and indicate why these are necessary for the research:

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2b. Indicate whether these identifiers, codes or links will be retained after data collection, and if they will be removed at some point:

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3. Video/audio tape recording\*: Will participants be recorded (e.g., audio, video)?

[ ]  No

[ ]  Yes - describe the type of recording and specify how they will be used, stored/secured, and their final disposition *(also provide this information to participants on the consent document)*:

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*\* Note that all recordings are considered individually identifiable.*

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| **Other Information** |

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

[ ]  No

[ ]  Yes- NDSU PTF #: FAR00 Agency or sponsor:

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

1a. Were external funds made available for the project prior to IRB approval (via the IRB pre-screening process?) [ ]  No [ ]  Yes:

1b. 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) #:

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

[ ]  Other; explain:

**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 requires internal approval of the proposal by submission of a Proposal Transmittal Form (PTF). Consult the* [*SPA website*](http://www.ndsu.nodak.edu/research/sponsored_programs_administration/) *for more information.*

2. 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)?

Additional information may be found in [SOP 2.3](http://www.ndsu.nodak.edu/research/institutional_review_board/procedures.html) ‘Collaborative, Multisite and Off-Site Research.’

[ ]  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:** |

2a. Will the NDSU IRB serve as the IRB of record for these outside entities?

 [ ]  No, ![MCSY00871_0000[1]]() Attach documentation of IRB/REC approval.

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

* + a brief description of the entity’s role in the research
	+ a statement that appropriate training will be completed prior to involvement of human subjects
	+ a statement that the project will be conducted according to the approved protocol and NDSU policy for protecting research subjects.

3. 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.*

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| **Investigator’s Assurance**  |

The signature(s) below certify that:

* information provided in this application is complete and accurate\*
* the principal investigator has the ultimate responsibility for protecting the rights, safety and welfare of human subjects and the ethical conduct of this research
* each individual listed as principal, co-investigator, or research team member has received the required human research protections education
* each individual listed as an investigator or member of the research team possesses the necessary experience for conducting research activities in their assigned role, and is aware of and will abide by NDSU policies and procedures for the protection of research participants
* research procedures with human subjects will not be initiated until approval has been obtained from the IRB Office
* the research will be conducted according to the protocol approved by the IRB, in accordance with NDSU policies and procedures

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**Principal Investigator signature, date**

**![MC900239185[1]]()** *Principal Investigators may submit applications and required supplemental materials electronically via their official NDSU Email account, by copying all co-investigator(s) and the department chair, dean, or director.*

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**Co-investigator(s) signature, date**

As Department Head/Chair, College Dean, or Division Director, I acknowledge that this research is in keeping with the standards set by our department/unit.

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**Chair, Dean or Director\* signature, and date:**

*\* If the PI or co-investigator is the Department Chair, the College Dean must sign.*