*Office Use Only:*

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



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 FORM**

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:

Highest earned degree and field of study:

3. Co-Investigator(s):  Dept. name:

Campus address/phone:  Email address:

Specify role in this research:

Highest earned degree and field of study:

4. Review Category:

 [ ]  Expedited review *(*![MCSY00871_0000[1]]() *Include the ‘Expedited Review Categories’ attachment)*

 [ ]  Full board review

1. **PROJECT DESCRIPTION:**

1. Purpose and goals of the research:

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2. Method and procedures:

2a. In nontechnical language, describe your research design (observational, experimental, descriptive, etc.) and how these methods will answer the research question(s). Include, what participants will be asked to do and/or what information will be collected about them. Specify when or how often research procedures will be conducted. Provide a timeline or schedule of events, if applicable.

*(*![MCSY00871_0000[1]]()*May provide as a separate attachment, with numbered pages.)*

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2b. If this research is taking place in a school, clinic or hospital setting, list all procedures that would be performed or activities that would take place if there was no research involved.

[ ]  N/A

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2c. Will any online/electronic resources be utilized for recruitment, data collection or storage?

[ ]  No

[ ]  Yes. If yes, describe what online/electronic software products will be utilized.

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**NOTE**: Software licenses are subject to review and approval by the NDSU VP for Information Technology. See the [Software and Online Services License Review](https://www.ndsu.edu/its/software/license_review/) website for more information.

3. Project/performance site(s): Specify where the research will be conducted.

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**NOTE:** If you are conducting your research off site at another institution, health care organization or school, project/performance site approval is required prior to beginning the research.

4. 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:** |

5. Research design and analysis plan: Describe the sampling plan, the sample size or study group(s), planned data analysis, and the power of any planned statistical tests *(if applicable).*

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6. Additional materials: Will the research involve use of data, documents, records or specimens that have already been collected (pre-existing) from individuals, or will be collected solely for non-research purposes?

[ ]  No

[ ]  Yes: ![MCSY00871_0000[1]]() Complete the *‘Additional Materials Attachment’.*

**II. RECRUITMENT:**

1. Research participants and recruitment methods:

1a. What is the age range of potential participants?

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1b. Which of the statements below describes the recruitment strategy (If both apply, select both).

[ ]  A. Potential subjects will self-identify based on response to an advertisement, flyer, presentation or respondent driven sampling.

Describe recruitment procedures including where/how recruitment notices will be displayed. If research involves targeted recruitment sampling describe who will send recruitment messages and in what format:

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![MCSY00871_0000[1]]() Attach a copy of any oral script, advertisement, announcement or invitation that will be used.

[ ]  B. Potential subjects will be recruited based on information contained in private/protected records (e.g. medical records, educational or employment records).

If B, Explain how the researcher has legitimate access to these records. Identify who will make initial contact with potential participants.

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2. Inclusion/Exclusion criteria, if applicable: [ ] N/A

2a List the criteria for subject INCLUSION in the study:

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 2b. List the criteria for subject EXCLUSION in the study:

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3. Vulnerable populations: Indicate if individuals from any of the following groups will be specifically targeted:

[ ]  minors (under age 18) - ![MCSY00871_0000[1]]() *Complete the ‘Children in Research Attachment’.*

[ ]  prisoners - ![MCSY00871_0000[1]]() *Complete the ‘Prisoners in Research Attachment’.*

[ ]  pregnant women, fetuses or neonates

[ ]  cognitively impaired individuals

[ ]  economically disadvantaged persons

[ ]  educationally disadvantaged persons

[ ]  N/A - None of these groups will be specifically recruited.

If any vulnerable populations will be recruited, indicate what additional safeguards will be implemented to protect participants’ rights and welfare:

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4. Compensation: Will incentives be offered for the research (e.g., gifts, payment, reimbursement, services, extra/course credit, drawings, etc.)?

[ ]  No, proceed to question 5.

[ ]  Yes.

4a. Indicate the type of compensation and the maximum value a participant may receive during the course of his/her participation. If compensation to someone other than the participant (e.g. parent, institution allowing research to be conducted at their facility, etc.) is planned, please describe this here.

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4b. When will compensation be provided? Include whether payment for multiple visits is prorated and provide the compensation schedule.

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*The IRB recommends compensation be pro-rated, rather than awarded only on completion of the study whenever possible.*

4c. Will partial payments be provided to participants who withdraw prior to completing the study?

[ ]  No.

[ ]  Yes.

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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*NOTE: If research will involve compensating students with extra or course credit, specify the amount of credit, and what non-research alternatives (equal in time and effort) are available to the students for earning this credit.*

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

[ ]  No

[ ]  Yes - describe the relationship, and explain 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 do, and provide justification for use of class time for research (![MCSY00871_0000[1]]() Attach course syllabus, when applicable):

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**III. INFORMED CONSENT**

1.Who will conduct the consent process?

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2.Explain the process for obtaining informed consent from participants, their parent/guardian, and/or legally authorized representative.

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![MCSY00871_0000[1]]()Attach as applicable: informed consent, parent/guardian permission, and child/youth assent documents*.* Templates and examples may be found on the [IRB website](http://www.ndsu.edu/irb).

3. Will all subjects consent for themselves?

[ ]  Yes

[ ]  No – If No, indicate below who, when appropriate will provide consent:

[ ]  Parent/Guardian

[ ]  [Legally authorized Representative](http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/) (LAR)

4. Will all participants (and/or their parents/guardians or LAR, as applicable) be fluent in English?

[ ]  Yes

[ ]  No - explain how informed consent will be obtained. ![MCSY00871_0000[1]]() Attach a copy of the translated consent *(may submit once IRB has approved English version)*:

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5. Will research be conducted at an international site(s)?

[ ]  No

[ ]  Yes - Indicate site(s) and investigators’ familiarity with the culture/cultural norms, whether or not the different cultural context presents any problems or risks that need to be addressed, and how those issues will be handled:

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6. Is a waiver of the signature requirement requested? *Participants will be provided with all of the elements of consent, but their signature will not be required. Active agreement will be obtained in another manner.*

[ ]  No

[ ]  Yes – If yes, check the statement below that applies to justify waiving documentation of consent. If neither statement applies, researcher may not request waiver of documentation:

[ ]  The only record linking the subject and the research would be the consent form and the principal risk of the research would be the potential harm from a breach of confidentiality (the IRB may allow an option to sign or decline).

[ ]  The research presents no more than minimal risk and includes no procedures for which written consent is normally required outside the research context.

[ ]  If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

6a. Explain why obtaining signed consent would be outside the cultural norm and provide and explanation of the alternative mechanism for documenting informed consent.

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7. Withholding information or use of deception: Will the research involve withholding information about the research from participants prior to their involvement, or involve any use of deception?

[ ]  No

[ ]  Yes - ![MCSY00871_0000[1]]() Attach the ‘*Informed* *Consent Waiver or Alteration Request*’ and a copy of the debriefing.

8. Is a waiver of the consent process requested? *Active agreement to participate will not be obtained.*

[ ]  No

[ ]  Yes - ![MCSY00871_0000[1]]() Attach the ‘*Informed* *Consent Waiver or Alteration Request*.’

**IV. RISK AND BENEFITS**

1. Risks: Indicate all potential risks of harm/discomfort to participants or others:

[ ]  Physical

 [ ]  Psychological/emotional distress or discomfort

 [ ]  Financial impacts/employability

 [ ]  Privacy/Confidentiality

[ ]  Stigmatization/Reputational

[ ]  Legal implications/Criminal or civil liability

[ ]  Other -

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2. Protection against risks: Describe precautions you will take to minimize each of the potential risks identified above:

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3. Describe what steps will be taken if participants experience serious injury, distress, discomfort or decompensation during research participation: [ ]  N/A

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4. Risk category: Categorize the amount of risk involved in the research.

 *‘Minimal risk’: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

[ ]  No more than minimal risk

[ ]  A minor increase over minimal risk\*

[ ]  More than a minor increase over minimal risk\*

4a. If more than minimal risk, indicate what provisions will be taken to monitor the data collected to ensure the safety of subjects, and report unanticipated problems involving risks to subjects or others.

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**\* Research involving more than minimal risk must be reviewed at a convened IRB meeting.**

5. Benefits and risk-benefit analysis: Describe any potential benefits to participants (e.g. educational experiences, access to services, etc.) and/or society in general.

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 *NOTE: Compensation or incentives for participating should not be described here*, *but filled out under the Recruitment section, question 4*

6. Is the study a [Clinical trial as defined by NIH](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html):

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

[ ]  No

[ ]  Yes

ClinicalTrials.gov Registration: Clinical trials funded in whole or in part by the NIH or that are conducted with FDA-regulated drugs, biologics or devices must be registered at clinicaltrials.gov.

More information can be found in the FAQs at: <http://clinicaltrials.gov/ct2/manage-recs/faq>.

Some journals require registration of clinical trials in a public trials registry such as clinicaltrials.gov at or before the time of first subject enrollment in the trial. For more information see [the ICMJE website](http://icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html).

7. Use of human blood, tissues, or specimens:

[ ]  No

[ ]  Yes – Project also requires review/approval from the Institutional Biosafety Committee ([www.ndsu.edu/ibc](file:///C%3A%5CUsers%5Ckristy.shirley%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CTemporary%20Internet%20Files%5CContent.Outlook%5CDownloads%5Cwww.ndsu.edu%5Cibc)).

8. Investigational use of a drug, biological product, medical device, or other product regulated by the FDA:

[ ]  No

[ ]  Yes -![MCSY00871_0000[1]]() Attach additional information regarding risks and FDA approval status.

![MCSY00871_0000[1]]() If applicable, complete and attach the “*Use of Drugs and Biological Products*” or “*Investigational Use of Medical Devices*” form(s).

**V. INSTRUMENTS:**

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

**VI. 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 (link) 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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2f. 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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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, Certificate of Confidentiality, etc.)

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 ![MCSY00871_0000[1]]()If a Certificate of Confidentiality has been obtained or applies (NIH automatically provides for its awards), provide a copy to the IRB once available.

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

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

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

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7. 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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8. 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).

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

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**VII. 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) #:

[ ]  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 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/REC 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.*

**VIII. 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. Departmental support must be indicated by the chair/head via NDSU Email.