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:///%5C%5Cad.ndsu.edu%5Cshared%5CVPRCATT%5CShared%5CIRB%5CReview%20and%20Approval%5CCONTINUING%20REVIEW%5Cwww.ndsu.edu%5Cirb)

**Continuing Review or Completion Report Form**

***Use this form to: 1) request a continuation of IRB approval if a project is currently active (recruiting subjects, collecting data, or analysis of identifiable data), or 2) report completion of a project.***

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| **Protocol Information** |

Protocol #:  Original approval date\*:

Title:

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| --- | --- |
| Principal investigator:   | Co-investigator:       |
| Department:       | Department:       |
| E-Mail/Campus Address:       | E-Mail/Campus Address:       |

*\* Complete and submit an updated protocol form & relevant attachments every 5 years following approval. Protocol records must be updated every 5 years by completing a new protocol form and any relevant attachments, and including it with this report. Use the most recent version of the forms on the IRB website at:* [*http://www.ndsu.nodak.edu/research/institutional\_review\_board/forms.html*](http://www.ndsu.nodak.edu/research/institutional_review_board/forms.html).

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| **Project Status** |

[ ]  Ongoing and currently active, Expected end date of research:

 [ ]  Complete, abandoned or inactive

Source of current funding: FAR#       [ ]  Not funded

Current Funding period: Start date:       End Date:

**Has a progress report been filed with the funding agency since last review?**

**[ ]  No** **[ ] Yes,** ![MCSY00871_0000[1]]() **Attach copy of final grant application(s), and/or recent report to funding agency.**

**Research team:** *List all individuals involved in the research (project design/oversight, 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. or affiliation:  | Specify role in research:  | Email Address | Training date: (IRB Use only) |
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| **Project Summary** |

1. Brief summary of results to date:

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1. List research site(s):

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1. List presentations or publications that have resulted from this research since the last review:

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#### **Participants**:

1. How many participants have completed the study since last review:      .
2. How many participants have completed the study since first review:      .
3. Will more participants be recruited?

**[ ]** No

**[ ]** Yes\* – Indicate approximately how many:

![MCSY00871_0000[1]]() **Attach a copy of current consent form(s), and any recruitment materials.**

1. Informed Consent: A copy of the approved informed consent form has been signed by each of the participants in the study, and retained for your records. Has this requirement been met?

**[ ]** Yes

[ ]  N/A, waiver approved

**[ ]** No – explain:

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1. Have any potential participants declined to participate, or withdrawn from the research?

 **[ ]** No

 **[ ]** Yes - explain:

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1. Summarize any complaints about the research (and their resolution) since the last review?

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#### Risk/Benefit Ratio:

1. Summarize any unanticipated problems (even if previously reported) or adverse events that have occurred since the last review:

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*Unanticipated problem: an unanticipated problem that involves risks to subjects or others is any incident, experience, or outcome that meets all the following criteria:*

* *is unexpected (in terms of nature, severity, or frequency) given the characteristics of the subject population and the research as described in the IRB approved protocol and consent document(s)*
* *is related, or possibly related to participation in the research*
* *suggests the research places subjects or others at greater risk of harm (physical, psychological, economic, or social harm) that previously known or recognized*
* *may not have resulted in actual harm to subjects, but may only represent increased risk of harm (ie., physical, psychological, social, economic, legal).*

*Adverse event: any untoward or unfavorable medical occurrence (physical or psychological) in a human subject, including any abnormal sign, symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to their research participation. Such events may have already been expected to occur with a certain frequency and severity, and previously identified as potential risks in the protocol form, and consent document(s).*

1. Has any new information resulted from the study or any literature, that would affect the risk/benefit ratio for new subjects (or for those currently or previously enrolled)?

**[ ]** No

**[ ]** Yes –explain, and indicate how this has been/will be addressed with future, current, or previously enrolled participants:

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| **Investigator’s Assurance** |

The signature below certifies that:

* information provided in this report is complete and accurate
* each individual involved as a 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
* the research will be conducted according to the approved protocol
* changes will receive IRB approval prior to implementation, unless necessary to prevent immediate serious harm to participants
* all unanticipated problems involving risks to participants or others will be promptly reported to the IRB.

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**Principal Investigator signature, date**

*![C:\Users\Kristy.Shirley\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\VGGU6D80\MC900239185[1].wmf]()In lieu of a written signature, submission of this report via the Principal Investigator’s NDSU email constitutes an acceptable electronic signature.*

- - - - - - - - - -FOR IRB USE ONLY - - - - - - - -

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| Project is: [ ]  Approved for continuation [ ]  Complete/Inactive [ ]  Archive after ­­­­­­\_\_\_\_\_\_\_ IRB Signature: Date: |
| Reviewed by: [ ]  Full Board - meeting date \_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ ]  Expedited review, category # \_\_\_\_\_\_\_Current approval period expires: Next Continuing Review/Completion Report due\*: *Note that the IRB office will typically remind the investigator a few weeks prior to the due date; however, timely submission of the report is the PI’s responsibility.*  |