Date Received

Description: cid:3365659872_46747

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

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**Continuing Review Report**

***Use this form to: request a continuation of IRB approval if a protocol which is currently active (enrolling or recruiting participants, providing study interventions, or collecting data from research participants which is not a part of routine clinical care. If study remains open for data analysis of identifiable private information or identifiable***

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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: |
| Human Subjects Training:  (IRB office only) | Human Subjects Training:  (IRB office only) |

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| **I. Project Status** |

1. Expected end date of research:

2. Current research procedures involve:

Recruiting participants

Providing research intervention(s)

Ongoing data collection

Ongoing analysis of identifiable data

Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

3. Is the project currently externally funded?  No  Yes

If yes, source of current funding: FAR#      

Current Funding period: Start date:       End Date:

**3a. 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.**

**4. 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 or include the* [*Add, Delete or Change Personnel Form*](http://www.ndsu.edu/research/integrity_compliance/irb/forms/)*.*

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| **Name, Dept.,**  **Affiliation** | **E-mail**  **Address** | **Design** | **Recruit** | **Consent** | **Intervene** | **Data**  **Analysis** | **Training**  **date**  **(IRB office)** |
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| **II. Project Summary** |

1. Brief summary of the progress of the research to date:

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1. Are any of the research procedures or conditions no longer active, i.e., have portions of the study been completed? If so, please describe:

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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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#### ****A. Participants****:

1. How many participants have completed the study in the last year (or since last report):      .
2. How many total participants have completed the study (since initial approval):      .
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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#### B. 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 or additional risk(s) been discovered 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** |

As the Principal Investigator, I certify 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
* IRB approval will be obtained prior to implementing changes in the research protocol, 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.

*C:\Users\Kristy.Shirley\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\VGGU6D80\MC900239185[1].wmf 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:  Continuation Approved  Approved, Project remains open for:  Data analysis, including analysis of identifiable private information or specimens, or  Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care  Complete/Inactive  Retain records until ­­­­­­\_\_\_\_\_\_\_  IRB Signature: Date: |
| Reviewed by the Full Board - meeting date \_\_\_\_\_\_\_\_\_\_\_\_\_\_  Expedited Review – Category: ­\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Current approval period expires:  Next Report due\*: |