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](http://www.ndsu.nodak.edu/research/institutional_review_board/documents/www.ndsu.edu/irb)

# Protocol Amendment Request Form

*Changes to approved research may not be initiated without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to participants.* Reference*:* [*SOP 7.5 Protocol Amendments*](http://www.ndsu.edu/fileadmin/research/documents/IRB/operating_procedure/7x5ProtocolAmendments.pdf).

*Examples of changes requiring IRB review include, but are not limited to changes in: investigators or research team members, purpose/scope of research, recruitment procedures, compensation strategy, participant population, research setting, interventions involving participants, data collection procedures, or surveys, measures or other data forms.*

|  |
| --- |
| **Protocol Information:** |

Protocol #:  Title:

 Review category: [ ]  Exempt [ ]  Expedited [ ]  Full board

Principal investigator:  Email address:

Dept:

Co-investigator: Email address:

Dept:

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 via the Principal Investigator’s NDSU email constitutes an acceptable electronic signature.*

|  |
| --- |
| **Description of proposed changes:** |

1. Date of proposed implementation of change(s)\*:

*\* Cannot be implemented prior to IRB approval unless the IRB Chair has determined that the change is necessary to eliminate apparent immediate hazards to participants.*

2. Describe proposed change(s), including justification:

1. Will the change(s) increase any risks,or present new risks *(physical, economic, psychological, or sociological)* to participants?

[ ]  No

[ ]  Yes: *In the appropriate section of the protocol form, describe new or altered risks and how they will be minimized.*

4. Does the proposed change involve the addition of a vulnerable group of participants?

Children: [ ]  no [ ]  yes – include the *Children in Research* attachment form

Prisoners: [ ]  no [ ]  yes – include the *Prisoners in Research* attachment form

Cognitively impaired individuals: [ ]  no [ ]  yes\*

Economically or educationally disadvantaged individuals: [ ]  no [ ]  yes\*

 \**Provide additional information where applicable in the revised protocol form.*

5. Does the proposed change involve a request to waive some or all the elements of informed consent or documentation of consent?

[ ]  no

[ ]  yes – ![MCSY00871_0000[1]]()Attach the *Informed Consent Waiver or Alteration Request.*

6. Does the proposed change involve a new research site?

[ ]  no

[ ]  yes

**If information in your previously approved protocol has changed, or additional information is being added, incorporate the changes into relevant section(s) of the protocol. Draw attention to changes by using all caps, asterisks, etc. to the revised section(s) and attach a copy of the revised protocol with your submission.** *(If the changes are limited to addition/change in research team members, research sites, etc. a revised protocol form is not needed.)*

|  |
| --- |
| **Impact for Participants (future, current, or prior):** |

1. Will the change(s) alter information on previously approved versions of the recruitment materials, informed consent, or other documents, or require new documents?

[ ]  No

[ ]  Yes - ![MCSY00871_0000[1]]() attach revised/new document(s)

2. Could the change(s) affect the willingness of *currently* enrolled participants to continue in the research? [ ]  No

[ ]  Yes - describe procedures that will be used to inform current participants, and re-consent, if necessary:

3. Will the change(s) have any impact to *previously* enrolled participants?

[ ]  No

[ ]  Yes - describe impact, and any procedures that will be taken to protect the rights and welfare of participants:

**- - - - - - - - - -FOR IRB OFFICE USE ONLY - - - - - - - -**

|  |
| --- |
| **Request is: [ ]  Approved [ ]  Not Approved** **Review:** **[ ] Exempt, category#: \_\_\_\_** **[ ] Expedited method, category # \_\_\_\_** **[ ] Convened meeting, date: \_\_\_\_\_****[ ] Expedited review of minor change** |
| **IRB Signature: Date:** |
| **Comments:**  |