

Institutional Review Board

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**Protocol Deviation Report**

Protocol #:  Title of Project:

Principal Investigator:

Report submitted by:       Date:

You may email the completed document to the NDSU IRB at ndsu.irb@ndsu.edu. For questions regarding the completion of this document, please contact the IRB office at 701.231.8995.

1. Describe the protocol deviation:

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1. When did the deviation occur?

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1. What occurred to result in the protocol deviation?

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1. Describe the steps taken to avoid recurrence of the deviation?

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1. Describe potential impacts on participant rights or welfare and/or the privacy and confidentiality of participants?

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1. Explain why this occurrence does or does not affect the integrity of the research data:

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 Attach any documentation or communication relevant to the review of the protocol deviation (e.g. recruitment announcements or emails, consent forms, etc).



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| For IRB use only:[ ]  No Follow-Up necessary.[ ]  Follow up needed. Please explain:IRB Signature/Date: |