Description: cid:3365659872_46747

*Office Use Only:*

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

Research Integrity & Compliance  
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](mailto:ndsu.irb@ndsu.edu) **w:** [www.ndsu.edu/irb](file:///C:\Users\kristy.shirley\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\Downloads\www.ndsu.edu\irb)

Informed Consent Waiver, Alteration or Exception Request

*Consent may not be waived for research regulated by the FDA.*

1. **REQUEST FOR WAIVER OR ALTERATION: (**§\_\_\_.116(f)(3))
2. Please indicate whether you are requesting to waive or alter the consent process.

**Request for Alteration**: The IRB may approve a consent procedure that omits some, or alters some or all of the Basic Elements (§\_\_\_.116(b)) or Additional Elements (§\_\_\_.116(c)) provided the IRB satisfies the below requirements. The IRB may not omit or alter any of the General Requirements for informed consent (§\_\_\_.116(a))

**Request for Waiver:** The IRB may waive the requirement for obtaining informed consent for research under §\_\_\_.116 (a) through (c). **If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens, and refused to consent, and IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.**

1. In order to waive or alter consent, the IRB must find and document the following. Please describe how your research meets each of the following criteria:
   1. The research involves no more than minimal risk to subjects:

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* 1. The research could not practicably be carried out without the requested waiver or alteration:

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* 1. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format:

N/A

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* 1. The waiver or alteration will not adversely affect the rights and welfare of the subjects:

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* 1. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation:

N/A

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1. **REQUEST FOR WAIVER OR ALTERATION FOR RESEARCH CONDUCTED BY OR SUBJECT TO THE APPROVAL OF STATE OR LOCAL GOVERNMENT OFFICIALS:**
2. Please indicate whether you are requesting to waiver or alter the consent process.

**Request for Alteration**: The IRB may approve a consent procedure that omits some, or alters some or all of the Basic Elements (§\_\_\_.116(b)) or Additional Elements (§\_\_\_.116(c)) provided the IRB satisfies the below requirements. The IRB may not omit or alter any of the General Requirements for informed consent (§\_\_\_.116(a))

**Request for Waiver:** The IRB may waive the requirement for obtaining informed consent for research under §\_\_\_.116 (a) through (c). **If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens, and refused to consent, and IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.**

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

Public benefit or service programs;

Procedures for obtaining benefits or services under those programs;

Possible changes in or alternatives to those programs or procedures; or

Possible changes in methods or levels of payment for benefits or services under those programs, and

1. Describe why the research could not practicably be carried out without the waiver or alteration:

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1. **EXCEPTION FOR SCREENING, RECRUITING OR DETERMINING ELIGIBILITY: (**§**\_\_\_.116(g))**
2. The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject’s legally authorized representative, if either of the following conditions are met:

(1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative.

(2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

1. Describe how private identifiable information collected during the screening process will be safeguarded (regardless of whether the individual was recruited to participate in the study).

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