Date Received

Description: cid:3365659872_46747

Institutional Review Board

**office:** Research 1, 1735 NDSU Research Park Drive, Fargo, ND 58102

IRB Protocol #:

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

**IRB Application:**

**Research Involving Existing Records/Data/Specimens**

This application is for research involving data, documents, records (e.g.., academic, medical, etc.), or biological samples or specimens that have already been collected (pre-existing).

1. Title of Project:

2. Principal Investigator: Dept. name:

*(PI must be an NDSU faculty or staff member; graduate students must list their advisor as PI)*

Campus address/phone:  Email address:

Role in this research:

3. Co-Investigator:  Dept. name:

Campus address/phone:  Email address:

Role in this research:

4. Research team:*List any individual actively engaged in the research project (e.g. using or obtaining private identifiable information or specimens for research purposes). May provide as a separate attachment.*

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| **Name, Dept.,**  **Affiliation** | **E-mail Address** | **Role in Research** | **Training date (IRB office only)** |
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* ***Note:*** *Investigators and all members of the research team are required to complete a course in the protection of human research participants every three years. Refer to the IRB ‘Training’ page for information and a link to the CITI online training.*

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| **I. Risk Assessment – Level of Review Required** |

Depending on the specifics of the project, the study can be eligible for review as:

**Exempt Category 4 –** Research involving the collection or study of **existing** data, documents, records, pathological specimens or diagnostic specimens, if these sources are **publicly available** or the information is recorded by the investigator in such a manner that the **subjects cannot be identified** directly or through identifiers linked to the subjects.

OR

**Expedited Category 5 –** Research relying solely on information recorded in medical records collected exclusively for non-research purposes (such as medical treatment or diagnosis). Information will be recorded in such a manner that the subjects can be identified directly or through identifiers linked to the subjects (this would include collection of any of the 18 HIPAA identifiers).

OR

**Expedited Review Category 5 requiring full application –** Research involving materials (data, documents, records, or specimens) that **will be** collected solely for non-research purposes (such as medical treatment or diagnosis). Information will be recorded in such a manner that the subjects can be identified directly or through identifiers linked to the subjects **(This includes prospective collection of records/specimens – records that are NOT currently “on the shelf” at the time of the research proposal). – Please STOP HERE and complete the** [**IRB Protocol Form**](http://www.ndsu.edu/research/integrity_compliance/irb/forms/) **and relevant attachments.**

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| **II. Summary of Activities** |

1. What is the research question?State hypothesis or primary objective and the rationale for conducting the study. Use lay language or language understood by a person unfamiliar with *your* area of research. Area-specific jargon should be avoided or explicitly explained.

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2. Describe what data will be recorded, including: field names or variables, the date range of the files/records, the number of records, etc.:

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3. What is the source of the records?:

Medical records (HIPAA rules apply)

Academic records (FERPA rules apply; consult the Office of Registration and Records (ndsu.registration.records@ndsu.edu) for more information

Data

Documents

Human biological samples or specimens *(Also requires review and approval by the Institutional Biosafety Committee, and enrollment in NDSU’s Bloodborne Pathogens Program: See* [*www.ndsu.edu/ibc*](http://www.ndsu.edu/ibc) *for more information.*

Other records: Please specify :

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4. Are the materials available to the general public for un-restricted use?

Yes – describe public access and provide web address, if applicable: *(skip remaining questions on this form)*

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No - MCSY00871_0000[1] attach documented permission from the owner of the materials, HIPAA Privacy officer, and/or the responsible IRB allowing use in this research project. The permission should also describe any data use restrictions or provisions, and whether or not written authorization was obtained for release of the records.

5. Who is the owner of the data, records or specimens?

NDSU – Dept. or Office:

Other entity – Name\*:

***\*Contact the*** [***NDSU IT Security Officer***](mailto:theresa.semmens@ndsu.edu) ***(701-231-5870) regarding data storage/security procedures for electronic access, storage and transfer of PHI; forward documentation of approval to the IRB.***

6. How will the data/material be obtained, transferred, and stored for the project?

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7. What is the level of risk to subjects associated with this research study?

No Risk. Private identifiable data contained in the data set (including any of the [18 HIPAA identifiers](http://www.ndsu.edu/fileadmin/research/documents/IRB/operating_procedure/11x1UseofConfidentialRecords.pdf)) will not be recorded or stored. There will be no link. IRB staff will confirm that research meets **Exempt Category 4** eligibility.

Not greater than minimal risk. Private identifiable data from the record/dataset will be recorded, a link will be maintained. IRB staff will confirm that research meets **Expedited Review Category 5.**

8. Confirm the availability of the record/specimen at the time this application will be submitted.

Existing (already collected/ ‘on the shelf’)

What was the original purpose and date(s) of collection of these materials?

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Prospective collection – samples/data have not yet been collected. (**Please STOP HERE and complete the** [**IRB Protocol Form**](http://www.ndsu.edu/research/integrity_compliance/irb/forms/) **and relevant attachments.**).

9. Specify what research participants were told regarding the use and confidentiality of their original information or specimen(s):  Unknown, or N/A

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MCSY00871_0000[1]Attach original consent form or letter, as applicable.

*\*Note: If proposed secondary use is inconsistent with the original agreement, the IRB may require investigators to seek permission for the secondary use from participants, or justify why this is not possible.*

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| **III. Privacy and Confidentiality**  *More information on data privacy and security can be found at* [*NDSU IT Security*](http://www.ndsu.edu/its/security/) *or by reviewing the* [*Confidentiality and Data Security Guidelines for Electronic Research Data*](https://www.ndsu.edu/research/integrity_compliance/irb/resources/)*.* |

1. Describe the method of transferring data from the owner to the investigator:

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2. Will any of the following direct identifiers below will be maintained):  N/A

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| Full Names | Initials | Photographs of participants |
| Telephone numbers | Email addresses | Video of participants |
| Birthdate | Postal Address | Other: |

3. Why is it necessary to maintain direct identifiers?  N/A

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4. Describe the coding system that will be used to protect against disclosure of identifiers.

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5. How long will the link between identifiers and code be maintained?  N/A

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6. Could any disclosure of the participant’s responses place the participant at risk of criminal or civil liability or could the disclosure be damaging to the participant’s financial standing, employability, or reputation?

No

Yes Explain how the researcher will mitigate these risks (e.g. limiting access to identifiers, obtaining

a [Certificate of Confidentiality](http://grants.nih.gov/grants/policy/coc/index.htm), etc.)?

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| IV. [**Category of Protected Health Information (PHI)**](http://www.hhs.gov/hipaa/for-professionals/special-topics/research/) **N/A**  **If the research will include access to medical records, complete the following section.** |

1. Will any of the following HIPAA Identifiers be obtained or recorded?

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| Names | All geographic subdivisions smaller than a state | All elements of dates (except year) for dates directly related to an  individual including date of birth, admission, discharge, date of death,  and all ages over 89 |
| Telephone numbers | Fax Numbers | Email Addresses |
| Social Security Numbers | Medical Record Numbers | Health plan beneficiary numbers |
| Account numbers | Certificate/license numbers | Vehicle identifiers and serial numbers |
| Device identifiers and  serial numbers | Web Universal Resource Locations; (URLs) | Internet Protocol (IP) addresses |
| Biometric identifiers including finger and voice prints | Full face photographs | Any other unique identifying number, characteristic, or code,  except as otherwise permitted. |

2. To access PHI for research purposes, approval must be obtained by one of the following methods:

*(Please check one)*

De-identified health information. De-identified Information is health information that cannot be linked to an individual. Research involving the use of de-identified PHI is exempt form HIPAA requirements. The HIPAA Privacy Rule lists 18 identifiers that must be removed from the health information **before** the researcher obtains the information for it to be considered not identifiable.

Written authorization will be obtained from each patient/subject for disclosure of their PHI.

NOTE: This authorization is NOT the same as the informed consent document. It is a separate document. **You must use an authorization developed or approved by the medical provider that will be releasing the protected health information.** Attach a copy of the approved document for our files.

[Review preparatory to research](http://www.hhs.gov/hipaa/for-professionals/faq/317/can-the-prepatory-research-provision-be-used-to-recruit-individuals-to-a-research-study/index.html): Preparatory work is when PHI is reviewed for the purpose of designing a research study or identifying potential subjects. No information may be removed from the records.

Research on decedent’s information: Decedent research is when PHI is collected form deceased (prior to the study) patients/subject’s records.

Limited data set agreement: A limited data set is a subset of information (PHI) that only contains the following identifiers linked to the subject: city, state, zip code, or elements of data such as date of birth, death or service. The other specific identifiers included in the list above may not be included in the health information that is being received by the research team. The use of a Limited Data Set requires a Data Use Agreement to be in place. The Data Use Agreement is a legal contract between the covered entity and NDSU (as the recipient). The Data Use Agreement will set out the permitted uses and ultimate disposition of the limited data set which was acquired from the covered entity.  Please contact the [Assistant Director for Business Development](mailto:joycelyn.lucke@ndsu.edu) for more information on Data Use Agreements.

Waiver of authorization is requested *(complete section below).*

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| **V. Waiver of Authorization  N/A** |

1. Explain how the research use of PHI will involve no more than a minimal risk to the privacy of individuals whose records will be used:

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1. I certify that:

there is an adequate plan to protect identifiers from improper use and disclosure (as described below)

there is a plan to destroy identifiers at the earliest opportunity, or  there is a health or research justification for retaining the identifiers, or is required by law

the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research which the use or disclosure of PHI would be permitted by the Privacy Rule

1. Explain why the research could not practicably be conducted without this waiver:

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1. Explain why the research could not practicably be conducted without access to and use of the PHI:

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1. Provide justification that the PHI being requested is the minimum necessary information needed to accomplish the objectives of the research:

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