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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**Attachment: HIPAA Data**

*Please complete this form if you intend to use/disclose protected health information (PHI) in your research. PHI is health information transmitted or maintained in any form or medium that: identifies or could be used to identify an individual; is created or received by a healthcare provider, health plan, employer, or healthcare clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual*

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| **Section I - Description of Medical Records** |

1. Medical or healthcare provider holding the records *(covered entity)*:

NDSU – Dept. or Office:

Other entity – Name\*:

2. Briefly summarize the collection, use and sharing of PHI for this study.

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| **Section II – Category of PHI** |

1. Will any of the following [HIPAA Identifiers](https://privacyruleandresearch.nih.gov/pr_08.asp) 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 from 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 from 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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| **Section III - 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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***\*Questions on HIPAA requirements may be submitted to*** [***NDSU.HIPAA@ndsu.edu***](http://www.ndsu.nodak.edu/research/institutional_review_board/documents/NDSU.HIPAA@ndsu.edu) ***including questions on data security standards for use, transfer and storage of PHI. In addition, the NDSU IT Security Officer (701-231-5870) must approve data security procedures for electronic access, storage and transfer of PHI; forward documentation of approval to the IRB.***