*Office Use Only:*

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

**Exemption Category:**

**Status update due**:



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)

IRB Protocol Application:

Secondary research for which consent is not required

## Exemption Category 4 and Expedited Category 5

This application is for secondary research uses of identifiable private information OR identifiable biospecimens which were collected for some other “primary” or “initial” activity. If any member of the research team will interact or intervene with the participant to prospectively gather data or specimens, do NOT use this application.

Title of Project:

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:

Co-Investigator:  Dept. name:

Campus address/phone:  Email address:

Role in this research:

1. **REVIEW CATEGORY**

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

**[ ]  Exempt Category 4 –** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

[ ]  i. The identifiable private information or identifiable biospecimens are publicly available;

1. Describe the publicly available source of the data and how one gains access to the data or specimens. Include any information on whether permission is required to access the data, or any Terms of Use that apply.

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*For more examples of publicly available data sources, please see* [*SOP 7.1 Exempt Determinations*](https://www.ndsu.edu/research/integrity_compliance/irb/procedures/)*.*

[ ]  ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

1. Describe how the information or specimens will be recorded so that the identities of the human subjects may not be readily ascertained.

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[ ]  iii. The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under HIPAA, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b);

**NDSU is NOT a HIPAA Covered Entity (CE), therefore this exemption category may NOT be used unless the research will take place at a covered entity and that entity determines through their IRB procedures that the exemption applies or NDSU formally enters into a** [**Business Associate Agreement**](https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html) **with the CE.**

![MCSY00871_0000[1]]()Attach documentation that HIPAA Authorization for the release of information was obtained OR documentation from the CE’s Privacy Officer that a waiver of authorization was granted by the Privacy Board**.**

[ ]  iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with **specified privacy standards**.

1. Please provide the name of the Federal department or agency for which the research is being conducted:

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1. Describe which privacy standards apply to the information collected:

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**[ ]  Expedited Category 5 –** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

***This category applies if information or biospecimens are not publicly available, AND codes or links to identifiers will be maintained (even temporarily) by the research team.***

* If consent will not be obtained, complete and submit the *Informed Consent Waiver, Alteration or Exception Request*.
1. **SUMMARY OF ACTIVITIES**
2. 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 yourarea of research. Area-specific jargon should be avoided or explicitly explained.

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2. Describe what data or specimens will be obtained or recorded. For data, include a list of field names or variables, the date range of the files/records, the number of records, etc. For identifiable biospecimens, include a description of codes or potential identifiers, the type(s) of biospecimens to be utilized.

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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. What is/was the primary or initial purpose of data/biospecimen collection?

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

[ ]  Yes – describe how the information or biospecimens may be accessed by the public:

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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.

6. Who is the owner of the data, records or biospecimens?

 **[ ]** NDSU – Dept. or Office:

**[ ]** Other entity – Name\*:

***\*Contact the*** ***NDSU IT Security Officer*** ***regarding data storage/security procedures for electronic access, storage and transfer of Protected Health Information (PHI); forward documentation of approval to the IRB.***

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

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8. 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.*

1. **PRIVACY AND CONFIDENTIALITY**

***NOTE****: 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 | [ ]  Audio recordings of participants |
| [ ]  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, if any.

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5. How long will any links between identifiers and code be maintained? [ ]  N/A

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6. Could any disclosure of the data 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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7. Describe how personally identifiable research data will be shared among research team members, collaborators, etc.

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8. In what format(s) will data be maintained during the life of the study (e.g. paper, digital, electronic)?

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9. Where will data be stored (include both paper/hardcopy records and digital/electronic files)?

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10. What security provisions will be taken to protect the data (e.g. password protection, encryption, etc.)? Fore more information on security procedures please see the ‘[Confidentiality and Data Security Guidelines for Electronic Research Data](https://www.ndsu.edu/research/integrity_compliance/irb/resources/).’

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11. Final disposition: Please describe at what point in time will PII and deductive identifiers be removed from the dataset and/or the records retention plan for the research records:

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1. **CATEGORY OF PROTECTED HEALTH INFORMATION (PHI)** **[ ]  N/A**

***NOTE:*** *Complete this section when accessing medical records.*

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 for more information on Data Use Agreements.

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

1. **WAIVER OF HIPAA AUTHORIZATION**
2. 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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1. **OTHER INFORMATION:**

1. External Interests. Does any investigator responsible for the design, conduct or reporting of the project (including their immediate family members) have a financial, personal or political interest that may conflict with their responsibility for protecting human participants in NDSU research?

Financial, personal or political interests related to the research (the sponsor, product or service being tested, or a competing product or service) may include:

* compensation (e.g., salary, payment for services, consulting fees)
* intellectual property rights or equity interests
* board memberships or executive positions
* enrollment or recruitment bonus payments

Refer to *NDSU Policy 151.1, External Activities and Conflicts of Interest, and NDSU Policy 823, Financial Disclosure – Sponsored Projects* for specific disclosure requirements.

[ ]  No – As PI, I attest that I have conferred with my co-investigators and key personnel and confirmed that no financial, personal or political interests currently exist related to this research.

[ ]  Yes – Describe the related financial, personal or political interests, and ![MCSY00871_0000[1]]() **attach documentation of COI disclosure and review** *(if applicable).*

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*For more information, see SOP 6.2, Conflict of Interest in Human Research, Investigator and Research Team.*

2. Funding: Has an external agency or sponsor agreed to provide funding to NDSU for the project?

[ ]  No

[ ]  Yes- PTF #: FAR00Agency or Sponsor\*:

 ![MCSY00871_0000[1]]() *Attach* ***complete*** *copy of final grant application, agreement or contract.*

2a. Were external funds made available for the project prior to IRB approval (via the IRB pre-screening process?) [ ]  No [ ]  Yes:

2b. Does the grant, agreement or contract related to this project include multiple human subjects research activities that are ***not*** described in this IRB protocol?

[ ]  No; all human subject activities are covered in this IRB protocol

[ ]  Yes; these activities will be covered in a future IRB protocol(s)**\***

[ ]  Yes; these activities have been covered by a previous IRB protocol(s) #:

[ ]  Yes; these activities have been or will be reviewed by another IRB:

[ ]  Other; explain:

2c. As part of the funding agreement, are you required to share personally identifiable research data with members or agencies outside the research team. If so, attach or describe your Data Sharing Plan.

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***NOTE***:

* **The PI is responsible for obtaining IRB approval prior to initiation of any future human subjects research activities.**
* *To certify IRB approval of an award, the final funding proposal and the IRB protocol are compared to verify consistency with respect to human subjects activities.*
* *If external funds will be used for the project, Sponsored Programs Administration requires internal approval of the proposal by submission of a Proposal Transmittal Form (PTF). Consult the SPA website (*[*www.ndsu.edu/spa*](file:///C%3A%5CUsers%5Ckristy.shirley%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CTemporary%20Internet%20Files%5CContent.Outlook%5CDownloads%5Cwww.ndsu.edu%5Cspa)*) for more information.*

3. Other institution(s): Are any outside entities engaged in this research (e.g., receiving a direct award, grant or contract to perform research, directing or supervising the research, intervening and/or interacting with participants for research purposes, obtaining informed consent, obtaining private identifiable information or specimens from any source for research purposes, or utilizing private information or human specimens for FDA regulated research)?

For additional information, please see the ‘NDSU Collaborative, Multi-Site or Off-site Research Worksheet’ available on the IRB ‘Forms’ page.

[ ]  No

[ ]  Yes – name entity or institution, contact person(s), and describe their role in the research:

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| **Name of outside entity or institution:****Contact person:****Their role in the research:** |

3a. Will the NDSU IRB serve as the IRB of record for these outside entities?

 [ ]  No, ![MCSY00871_0000[1]]() Attach documentation of IRB or other ethics committee approval.

 [ ]  Yes, ![MCSY00871_0000[1]]() Attach letter of permission cooperation which includes:

* + A brief description of the entity’s role in the research,
	+ Documentation of IRB training,
	+ IRB Authorization Agreement (IAA) OR Independent Investigator Agreement (IIA) as applicable.

4. Other IRB review: Is other IRB/Research Ethics Board review required (e.g. from a collaborating institution, research site, tribal board, or national research ethics board, etc.)?

 [ ]  Yes - name of IRB and status of the application:

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![MCSY00871_0000[1]]() Attach a complete copy of the protocol reviewed and the IRB/REC’s determination.

 [ ]  No.

***NOTE****: If permission letter(s) or approval(s) from sites or collaborator(s) are not immediately available, the IRB may approve the protocol provided that:*

*1) all other requirements are met, and*

*2) the documentation from the site(s) are forwarded to the IRB prior to initiating research that site.*

1. **PERSONNEL**

*List all NDSU students, faculty or staff who will assist in the project (recruiting participants, obtaining informed consent, intervening or interacting with participants to obtain information/data, and/or handling identifiable information for research purposes). May provide as a separate attachment.*

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| Name, Dept. | Email Address | Duties | Training Date |
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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*](https://www.ndsu.edu/research/integrity_compliance/irb/training/) *for information and a link to the* [*CITI online training*](file:///C%3A%5CUsers%5Ckristy.shirley%5CDesktop%5CSOPS%20for%20January%202018%5Ccitiprogram.org)*.*
* ***The PI is responsible to ensure that any non-NDSU research team member is trained in the protection of human subjects; however, the IRB does not require submission of the documentation of training.***

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**SUBMISSION INSTRUCTIONS:**

The Principal Investigator must submit via official NDSU Email with all applicable supplemental materials (e.g., recruitment notices, oral script/information sheet or consent document, questionnaires, etc.) and carbon copy the co-investigator(s) and the department chair.