**EXEMPT HUMAN SUBJECTS RESEARCH APPLICATION**

**INSTRUCTIONS:** Complete each section. If a section doesn’t apply to your proposed research, enter “N/A” (do not delete the section or the question from the template). Refer to Investigator Guidance – Exempt Research if you have questions about the exempt categories.

Submit a copy of the completed application to the North Memorial Health Research Office at Research.Office@northmemorial.com for review. If you will be interacting with participants, your submission must include an information sheet or a verbal script that includes the following elements: a statement that the activity involves research, a statement regarding the study purpose, a description of any study procedures, a statement that participation is voluntary and will not affect their health care or relationships with providers, name and contact information for the PI, and describe provisions to maintain privacy interests of participants and confidentiality of the data. Attach any study documents (e.g. questionnaires, surveys, focus group guides) in your email. The Research Office will conduct a review and determine whether the research is eligible for an exempt determination.

**SECTION I – STUDY PERSONNEL AND BASIC STUDY INFORMATION**

**Section A: Study Title**

Click or tap here to enter text.

**Section B: North Memorial Health Investigator Information**

|  |  |
| --- | --- |
| Name of North Memorial Health Principal Investigator | Click or tap here to enter text. |
| Email address of North Memorial Health PI  | Click or tap here to enter text. |
| Phone number of North Memorial Health PI  | Click or tap here to enter text. |
| List any additional NMH contact persons, including their name and contact information  | Click or tap here to enter text. |

**Section C: North Memorial Health Study Team Information**

List all North Memorial Health employees who will be engaged in this research. It is the NMH PI’s responsibility to ensure that each study team member has current human subjects protections training and has completed a COI disclosure.

|  |  |  |  |
| --- | --- | --- | --- |
| **Study team member name** | **Role in the research** | **Current human subjects training? Y/N** | **Conflict of interest related to this research? Y/N** |
| Click or tap here to enter text. | Click or tap here to enter text. |  |  |
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| Click or tap here to enter text. | Click or tap here to enter text. |  |  |

Select all research activities in which North Memorial Health employees will be engaged:

[ ]  Subject recruitment

[ ]   Consenting and conducting study-related procedures

[ ]   Analysis of identifiable data/specimens only

[ ]   Other: *Click or tap here to enter text.*

**Section D: Funding Information**

[ ]  This research is funded. If so, please indicate the funding type (federal, industry, non-profit) **and** sponsor’s name in the text box below.

|  |
| --- |
|  |

[ ]  This research is not funded.

**Section E: Performance Sites**

A performance site is a location where the research will be conducted, where data will be gathered from subjects or records, where participants will be recruited for the research, and/or where participants will provide consent to participate in the research.

Please indicate all performance sites where research activities will be performed:

[ ]  North Memorial Health Hospital or Hospital-based Clinics

[ ]  Maple Grove Hospital

[ ]  Blaze Health d/b/a North Memorial Clinics

[ ]  Non-North Memorial Health facilities, as listed: Click or tap here to enter text.

**SECTION II – STUDY OVERVIEW**

**Section A: Study Summary**

**Purpose of the research:** *Provide a brief explanation of the purpose of the proposed research. Include a concise statement of your research questions or hypotheses.*

Click or tap here to enter text.

**Background:** *Provide the scientific or scholarly background for, rationale for, and significance of the research based on the current literature and explain how this study will add to existing knowledge.* *If applicable, include citations and a list of references.*

Click or tap here to enter text.

**Research summary:** *Provide a brief overview outlining how you will achieve the study objectives and answer your research questions. Include a description of your study design, data collection methods, and data analysis plan.*

Click or tap here to enter text.

**Section B: Study Population**

**Type of subjects:** *Describe the participant pool or community from which you will recruit and enroll participants. If you will only be accessing secondary (existing) data, describe whether you are targeting a specific population (e.g., prisoners, children) and the source and type of data you will be accessing and using.*

Click or tap here to enter text.

**Number of subjects:** *State the expected number of participants to be enrolled locally. Account for screen fails, withdrawals and drops, if applicable.*

Click or tap here to enter text.

**Inclusion and exclusion criteria:** *Describe the criteria that define who will be included in your study (including age range, gender, etc.). Also describe the criteria that define who will be excluded from your study.*

Click or tap here to enter text.

**Vulnerable populations:** *Indicate any vulnerable populations that may be targeted for inclusion in the research.*

 [ ]  Minors (individuals under the age of 18)

 [ ]  Pregnant women

 [ ]  Decisionally impaired individuals

 [ ]  Economically or educationally disadvantaged individuals

 [ ]  Prisoners (only check this box if you are *targeting* prisoners as potential participants; if prisoners may be incidentally included in your population (e.g., if you are conducting a retrospective chart review and the cohort may incidentally include prisoners) do not check this box)

 [ ]  North Memorial Health, Maple Grove, or Blaze Health employees

**Section C: Study Procedures**

**Recruitment:** *Describe how, where, and when prospective participants will be identified and approached for study participation. If you will only be accessing data, describe how you have access to such data and what type of permission you have to access private data (e.g., clinician with privileges and access to the NMH EMR).*

Click or tap here to enter text.

*Select the recruitment methods you will employ in the table below. For each recruitment method: 1) provide a copy of the corresponding recruitment material for review when you submit this application, and 2) if applicable, specify where the material will be posted (e.g., for social media ads, specify which social media platforms you will post advertisements on).*

|  |  |
| --- | --- |
| [ ] Email | [ ] Online/Social Media Advertisement |
| [ ] Flyer | [ ] Record Review |
| [ ] Letter | [ ] Other (describe) |
| [ ] Printed Advertisement |

**Process to obtain participants’ voluntary agreement:** *If you will be interacting with participants (e.g., to conduct surveys or focus groups), describe the process you will use to inform participants about the research and obtain their agreement to participate. Include a description of where the consent process will take place, how you will ensure that participants have adequate time to consider participating, and steps that will be taken to minimize the possibility of coercion or undue influence. Attach a copy of the information sheet or verbal script you will use to obtain participants’ agreement.*

Click or tap here to enter text.

**Study procedures:** *Provide a summary of the research that includes: the research methods and procedures, the frequency and duration of research procedures, the type of data to be collected, and the method of data collection. If you will be accessing or collecting existing data, describe: the data that will be collected (e.g., demographic data, Protected Health Information, etc.), the source or location of the data (e.g., medical records, publicly available dataset), and attach a copy of your data capture sheet when you submit this application.*

Click or tap here to enter text.

**Data and specimen storage for future research:** *If data or specimens will be banked/stored for future use, describe where the data/specimens will be stored, for how long they will be stored, how they will be labelled (e.g., coded with a link to a key, de-identified), how they may be accessed and who will have access. List the data to be stored or associated with each specimen (e.g., de-identified data only, a Limited Data Set). Describe the process you will use to release data or specimens, including the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.*

Click or tap here to enter text.

**Risks to subjects:** *List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to their participation in the research. Consider physical, psychological, social, legal, and economic risks as well as risks to privacy/confidentiality.*

Click or tap here to enter text.

**Provisions to protect privacy:** *Describe the measures you will take to protect subjects’ privacy interests. Note that the “privacy interests” refers to a person’s desire to place limits on with whom they interact or to whom they provide personal information.*

Click or tap here to enter text.

**Provisions to protect confidentiality:** *Describe the measures you will take to secure the data collected from or about participants. Specifically, state where the data will be stored and steps you will take to secure the data (e.g., password protection, encryption, physical controls, separation of identifiers from other data, etc.). If you plan to share data with anyone outside the NMH study team, describe with whom you will share data and specifically what data will be shared (e.g., a de-identified dataset, a coded dataset, a Limited Data set).*

Click or tap here to enter text.

**Waivers and alterations of HIPAA authorization:** *If you will review, access, collect, or obtain Protected Health Information (PHI) during recruitment or in conducting study procedures, select all that apply:*

|  |  |
| --- | --- |
| [ ] Obtaining Signed Authorization | [ ] Waiver of HIPAA Authorization for Recruitment/Screening Purposes Only |
| [ ] Obtaining Online or Verbal Authorization (Alteration of HIPAA Authorization) | [ ] Waiver of HIPAA Authorization for Entire Study |
| [ ] Data Use Agreement | [ ] Business Associate Agreement |

*Describe the PHI you will review, access, collect, or obtain and check all identifiers you will access, review, collect, or store in the table below.*

Click or tap here to enter text.

|  |  |
| --- | --- |
| [ ] Name  | [ ] Medical record number |
| [ ] Address (all geographic subdivisions smaller than a state, including street address, city, county, and zip code) | [ ] Health plan beneficiary number |
| [ ] Dates (all elements of dates relating to an individual, including birth date, admission date, discharge date, date of death, date of labs/procedures, and exact age if over 89) | [ ] Account number |
| [ ] Telephone numbers, fax numbers | [ ] Certificate or license number |
| [ ] Email address | [ ] Vehicle identifiers and serial numbers, including license plate number |
| [ ] Social security number | [ ] Device identifiers and serial numbers |
| [ ] Web URL | [ ] Internet protocol (IP) address |
| [ ] Finger or voice print | [ ] Photographic image (*not* limited to images of the face) |
| [ ] Any other characteristic that could uniquely identify an individual: Click or tap here to enter text. |

*If you are requesting a waiver or alteration of authorization, answer the following:*

1. *Describe your plan to protect identifiers from improper use and disclosure.*

Click or tap here to enter text.

1. *Describe your plan to destroy identifiers at the earliest opportunity consistent with the conduct of the research.*

Click or tap here to enter text.

1. *Provide written assurance that the PHI will not be reused or disclosed to any other person or entity, except as required by law for authorized oversight of the research, or for other research which use/disclosure of PHI would be permitted by HIPAA privacy regulations.*

Click or tap here to enter text.

1. *Why it is not practicable to obtain signed HIPAA authorization from subjects before using/disclosing their PHI for research purposes.*

Click or tap here to enter text.

1. *Why the research cannot be conducted without access to and use of subjects’ PHI.* Click or tap here to enter text.

**Costs, Reimbursement, and Compensation:**

1. *Costs and Reimbursement: Describe any costs subjects will incur due to their participation in the research (e.g., travel costs, parking fees, mobile device fees). Indicate whether these costs will be reimbursed and if so, how.*

Click or tap here to enter text.

1. *Compensation: If you will provide compensation to subjects, indicate the amount and timing of payments as well as the type of compensation (e.g., cash, gift card, check).* Click or tap here to enter text.