|  |  |
| --- | --- |
| **Medical Record Chart Review**Version 1.0Updated September 2013This application form is based on the University of Minnesota IRB's *Medical Record Chart Review* and has been adapted with their permission. | IRB Use Only |
| Date received: \_\_\_\_\_\_\_\_\_\_\_Project Number: \_\_\_\_\_\_\_\_\_IRB Review Date: \_\_\_\_\_\_\_\_[ ] Approved as submitted[ ] Approved with minor suggestions for changes[ ] Approved with stipulations[ ] Deferred[ ] Not approved |

* 1. Project Title (Project title must match grant title. If different, also provide grant title):

|  |
| --- |
|       |

* 1. Principal Investigator (PI)

|  |  |
| --- | --- |
| Name (Last name, First name MI): | Highest Earned Degree:      |
| Mailing Address:       | Phone Number:       |
| University Department (if applicable):       | Email:      |
| Occupational Position: [ ] Faculty [ ] Staff [ ] Student [ ] Other:       |
| Indicate the training and education completed in the protection of human subjects or human subjects records. Training is required for all research. |
| Human Subjects Training (one of these must be checked)[ ]  CITI training https://www.citiprogram.org/[ ]  Other (attach documentation):       | HIPAA Training (Required if Data Contains PHI)[ ]  HIPAA  |
| **As Principal Investigator of this study, I assure the IRB that the following statements are true:**The information provided in this form is correct. I will seek and obtain prior written approval from the IRB for any substantive modifications in the proposal, including changes in procedures, co-investigators, funding agencies, etc. I will promptly report any unexpected or otherwise significant adverse events or unanticipated problems or incidents that may occur in the course of this study. I will report in writing any significant new findings which develop during the course of this study which may affect the risks and benefits to participation. I will not begin my research until I have received written notification of final IRB approval. I will comply with all IRB requests to report on the status of the study. I will maintain records of this research according to IRB guidelines. If applicable, the grant that I have submitted to my funding agency which is submitted with this IRB submission accurately and completely reflects what is contained in this application. If these conditions are not met, I understand that approval of this research could be suspended or terminated. |
|  |
| Date |

**1.3 Are there additional Co-investigators and Staff?**

[ ]  **Yes.** *Include* ***Additional Co-investigators*** *form*

[ ]  No.

1.4 Is the PI of this research a student or resident?

[ ]  Yes.

[ ]  No. Continue to 2.

|  |
| --- |
| As Academic Advisor to the Student Investigator, I assume responsibility for ensuring that the student or resident complies with Northwestern Health Sciences University policies and federal regulations regarding the use of human subjects in research |
| Advisor’s Name (Last name, First name MI):      | University Department:       |
| Mailing Address:       | Phone Number:      |
| Email:       |

2. Funding

2.1 Is this research funded by an internal or external agency?

[ ]  Yes. *Include Appendix A*

[ ]  No.

If no, explain how costs of research will be covered:

|  |
| --- |
|       |

3. Institutional Oversight

3.1 Will this research be utilizing Northwestern Health Sciences University resources or medical records?

[ ]  Yes.

[ ]  No.

3.2 Is this research proposal being reviewed by any other institution or peer review committee?

[ ]  Yes. It is the responsibility of the PI to secure the appropriate approval from these committees and document that approval to the IRB. Attach a copy of documentation of approval, if received, and indicate committees below.

[ ]  No.

If yes, then please list which committees will review this proposal:

|  |
| --- |
|       |

*4. Conflict of Interest*

Federal Guidelines emphasize the importance of assuring there are no conflicts of interest in research projects that could affect the welfare of human subjects. Reporting of financial interests is required from all individuals responsible for the design, conduct, or reporting of the research. If this study involves or presents a potential conflict of interest, additional information will need to be provided to the IRB. Examples of conflicts of interest may include, but are not limited to:

* A researcher participating in research on a technology, process, or product owned by a business in which the researcher or family member holds a significant financial interest or a business interest
* A researcher participating in research on a technology, process or product developed by that researcher or family member
* A researcher or family member assuming an executive position in a business engaged in commercial or research activities related to the researcher’s University responsibilities
* A researcher or family member serving on the Board of Directors of a business from which that member receives University sponsored research support
* A researcher receiving consulting income from a business that funds his or her research
* A researcher receiving consulting income from a business that could benefit from the results of research sponsored by a federal agency (i.e., NIH)

**“Family Member”** means the covered individual’s spouse or domestic partner, dependent children, and any other family member whom the covered individual reasonably knows may benefit personally from actions taken by the covered individual on behalf of the University.

**“Business Interest”** means holding any executive position in, or membership on a board of a business entity, whether or not such activities are compensated.

**4.1 Do any of the investigators or personnel listed on this research project have a business interest or a financial interest of $10,000 or more ($5,000 or more if research is funded by a Public Health Service (PHS) agency or researcher is involved in clinical health care) associated with this study when aggregated for themselves and their family members?**

[ ]  No.

[ ]  Yes.

 **If yes**, identify the individual(s) and complete section 4.3:

|  |
| --- |
|       |

**4.2 Do any of the investigators or personnel (when aggregated for themselves and their family members) listed on this research have:**

**Ownership interests less than $10,000 ($5,000 if research is funded by PHS or researcher is involved in clinical health care) when the value of interest could be affected by the outcome of the research?**

[ ]  No. [ ]  Yes.

**Ownership interests exceeding 5% interest in any one single entity (or any equity interest in a non-publicly traded entity if research is funded by PHS or researcher is involved in clinical health care)?**

[ ]  No. [ ]  Yes.

**Compensation less than $10,000 ($5,000 if research is funded by PHS or researcher is involved in clinical health care) when the value of the compensation could be affected by the outcome of the research?**

[ ]  No. [ ]  Yes.

**If yes**, identify the individual(s) and complete section 4.3:

|  |
| --- |
|       |

**4.3 Has the business or financial interest been reported?**

[ ]  N/A (No business or financial interest indicated in 4.1 or 4.2)

[ ]  No.

[ ]  Yes.

**If yes, have you been informed that a Conflict of Interest Review Committee is reviewing the information you reported? [ ]**  No.

**[ ]** Yes.

**The IRB will verify that a management plan is in place with the Conflict of Interest (COI) Program.** **If the COI Program does not have an approved management plan in place for this research, they will contact the individual(s) listed in question 4.1 for additional information.**

**Final IRB approval cannot be granted until all potential conflict matters are settled. The IRB receives a recommendation from the Conflict of Interest Review Committee regarding disclosure to subjects and management of any identified conflict. The convened IRB determines what disclosure language should be in the consent form.**

5. Use of Protected Health Information (PHI): HIPAA Requirements

**5.1 As part of this study, do you:**

1. **Collect protected health information (PHI)\* from subjects in the course of providing treatment/experimental care; or**
2. **Have access to PHI\* in the subjects’ records?**

 Please read the definition of PHI below before answering.

\*PHI is defined under HIPAA as health information transmitted or maintained in any form or medium that:

1. identifies or could be used to identify an individual;
2. is created or received by a healthcare provider, health plan, employer or healthcare clearinghouse; and
3. relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of healthcare to an individual.

The following records ARE EXEMPTED from the definition of PHI even though they may contain health-related information: student records maintained by an educational institution and employment records maintained by an employer related to employment status. If your study uses these kinds of records, it is **not** subject to HIPAA; however, existing IRB rules on informed consent and confidentiality still apply.

**Health-related information is considered PHI if any of the following are true:**

1. the researcher obtains it directly from a provider, health plan, health clearinghouse, or employer (other than records relating solely to employment status);
2. the records were created by any of the entities in "1" and the researcher obtains the records from an intermediate source which is NOT a school record or an employer record related solely to employment status; OR
3. the researcher obtains it directly from the study subject in the course of providing treatment to the subject.

**Health-related information is not considered PHI if the researcher obtains it from:**

1. student records maintained by a school;
2. employee records maintained by an employer related to employment status; OR
3. the research subject directly, if the research does NOT involve treatment.

[ ]  **Yes.** **If yes to a or b above, complete *Appendix H* to show how you will satisfy HIPAA requirements for authorization to use PHI in research.**

[ ]  No.

6. Summary of Activities

***Use lay language, do not cut and paste from or refer to grant or abstract.***

6.1 Briefly state your research question.

|  |
| --- |
|       |

6.2 Describe the source of the medical records for chart review.
*In addition, inform the IRB if you will use medical records that are OLDER than January 1, 1997 or if you will use medical records dated AFTER January 1, 1997 that contain documentation of patients decisions about research.*

|  |
| --- |
|       |

6.3 Number of medical records to be used:

|  |
| --- |
|       |

6.4 Do you have permissible access to the medical records (i.e., through a job, internship, etc.)?

 [ ]  Yes. Describe how you have permissible access to the medical records.

|  |
| --- |
|       |

[ ]  No. Continue to question 6.4a.

**6.4a Will the records you receive be stripped of all identifiers that would make it possible for you to identify a subject?**

[ ]  Yes.

[ ]  No.

6.5 Will you have access to, or create a link, which would make it possible to identify subjects?

[ ]  I will not have access to, or create a link.

[ ]  I will have access to a link.

6.6 Describe the identifying information you will record:

|  |
| --- |
|       |

7. Exempt or Expedited Review Eligibility

Medical Record Chart Reviews can be reviewed either as Exempt Category 4 or Expedited Review Category 5 based on how the data is recorded and/or stored.

7.1 What is the level of risk to subjects in this research study?

[ ]  No risk, not keeping private, identifiable data from the Medical Records, Exempt Category 4: “…if the information is

 recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.”

 (45CFR46.101(b)(4))

[ ]  Not greater than minimal risk, keeping data linked to identifiers Expedited Review Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected, solely for non-research purposes (such as medical treatment or diagnosis.) (45CFR46.110)

8. Confidentiality

8.1 Describe the mechanism you will use to confirm that the patient has agreed to release their protected health information (PHI) contained in their medical record for research purposes; for example, the patient has documented consent to external research on their treatment, intake, or hospital admitting form. (MN Statute 144.335, Subd. 3; Access to Medical Records for Research):

|  |
| --- |
|       |

8.2 Describe provisions taken to maintain confidentiality of data:

|  |
| --- |
|       |

8.3 Describe the security plan for data including how and where stored and duration of storage (i.e., password protection, encrypted data, etc.). Files maintained on off-site electronic media must be encrypted:

|  |
| --- |
|       |

8.4 Will identifiable data be made available to anyone other than the PI?

[ ]  Yes.

**[ ]** No.

If yes, explain who and why they will have access to the identifiable data:

|  |
| --- |
|       |

*You have reached the end of this form. Please make sure that you have responded to every question on this application (even if your response is “not applicable”).*