Migrant Clinicians Network

HIPAA COMPLIANCE APPLICATION

PROJECT TITLE:

PRINCIPAL INVESTIGATOR Name (Last, First):

Please complete this form if you intend to use/disclose protected health information (PHI) in your research.

An investigator may access PHI using one or more of the following methods. Unless otherwise noted, you should complete this entire form as applicable.

A. Please check the appropriate box(es) for your specific research.

1. ☐ De-identified Information: De-identified Information is health information that cannot be linked to an individual. Research which involves the use of "de-identified" PHI is exempt from HIPAA requirements. The HIPAA Privacy Rule regulations [45 CFR 164.514(b)] lists 18 specific identifiers that must be removed from the health information before the researcher obtains the information for it to be considered not identifiable. The list includes: Name/initials; Street address, city, county, precinct, zip code and equivalent geocodes; All elements of dates (except year) directly related to an individual (date of birth, admission date, discharge date, date of death); Elements of date, including year, for persons 90 or older; Telephone number; Fax number; Electronic mail address; Social Security Number; Medical record numbers; Health plan identification numbers; Account numbers Certificate/license numbers; Vehicle identifiers and serial numbers, including license plate numbers; Device identifiers and serial numbers; Web addresses (URLs); Internet IP addresses; Biometric identifiers, including finger and voice prints; Full face photographic images and any comparable images; Any other unique identifying number, characteristic or code.

   If the research does not include access to any of the above identifiers, sign the certification at the bottom of the page. The HIPAA privacy regulations do not apply and you are not required to complete the rest of the application.

(Sign and Date this section only if the research involves De-Identified Information)

I certify the PHI received or reviewed by research personnel for the research referenced above does not include any of the identifiers listed above.

_____ _____

Principal Investigator Signature Date

2. ☐ Limited Data Set: 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 date 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 the recipient.

3. ☐ Patient Authorization: A patient authorization is a document, signed by the subject that gives the researcher permission to use/disclose PHI collected during the research study for defined purposes. An Authorization Form needs to be prepared in addition to the Informed Consent Document. The authorization information may also be addressed in the consent form. Please prepare the Authorization Form and submit it with your IRB application.

4. ☐ Waiver/Alteration: A waiver/alteration is a request to forgo the authorization requirement based on the fact that the use and/or disclosure of PHI involves minimal risk to the subject's privacy and the research cannot be practically done without this waiver/alteration and access to/use of PHI. Refer to Section H to see if you may qualify for a waiver/alteration. Please designate if a waiver is being sought for initial recruitment purposes or for the entire research protocol.

   Once a waiver of Authorization is granted, contact your source of PHI (i.e. Health Information Management) to ensure that you follow the accounting procedures established as required by the Privacy Rule. Per the Privacy Rule, the covered entity must receive documentation of the waiver/alteration before PHI can be used or disclosed for the research.

The categories listed below are additional opportunities allowed under the HIPAA Privacy Rule to view/record PHI without prior individual authorization.

5. ☐ Reviews Preparatory to Research: 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.

6. ☐ Research on Decedent's Information: Decedent research is when PHI is collected from deceased (prior to the study) patients/subject's records.

B. Provide a description of the Protected Health Information (PHI) to be used or disclosed for your research:

C. Source and Data Collection

1. Indicate your sources of health information:

☐	Data containing no health information*****	☐	Hospital/medical records (in and out patient)
☐	Physician/clinic records	☐	Psychotherapy Notes
☐	Lab, pathology and/or radiology results	☐	Data previously collected for research purposes
☐	Biological samples	☐	Billing records
☐	Interviews/Questionnaires	☐	Other (describe below)

If the research does not include PHI, the HIPAA Privacy Rule regulations do not apply to this research study and you do not need to finish this form. Please be sure to note on your initial review protocol application that the research does not include PHI.

2. Indicate how the research team will access and/or receive health information:

☐ With limited identifiers: ZIP codes, geocodes, dates of birth, or other dates only.

The study qualifies as a Limited Data Set *and requires a* Data Use Agreement*.*

☐ With a code that can be linked to the identity of the subject.*

The research includes PHI because the research team will have health information with identifiers.

☐ With unrestricted identifiers. *

**Requires Consent and Authorization from the subject or a Waiver of Consent and Waiver of Authorization from the IRB.*

3. Indicate how the research team will record health information:

☐ Without any direct or indirect identifiers – as a de-identified data set

☐ With limited identifiers: ZIP codes, geocodes, dates of birth, or other dates only.

☐ With a code that can be linked to the identity of the subject.

☐ With unrestricted identifiers

D. <u>Summary</u>: *Briefly summarize the collection, use and sharing of PHI for this research study*.

E. <u>Recruitment</u>: *Please mark all that apply:*

☐ 1. PI/collaborators will recruit his/her/their own patients.

☐ 2. PI will send an IRB approved letter to colleagues asking for referrals of eligible patients. The treating physician will make initial patient contact. If the patient is interested, the patient will contact the PI.

☐ 3. PI will send an IRB approved letter to colleagues asking the physician to send out IRB approved general "Dear Patient" letters describing the research study. *The PI may draft the letter with the treating physicians' signature, but may not have access to the patient names or addresses for mailing. If the PI wants the letters to be personalized (Dear Mr. Doe), the personal information would have to be entered by the treating physician.*

☐ 4. Advertisements/media. A*ll recruitment materials must have IRB approval.*

☐ 5. The PI requests an initial Waiver of Authorization for the purpose of identifying subjects for recruitment purposes including (with permission of the patient) the treating physician will invite the PI/research team to talk with the patient about enrollment. Be sure and complete section H.

☐ 6. Other , please specify:

F. PHI Sharing:

1. Indicate who may **receive** PHI during the course of the research study.

☐ Statistician	☐ Consultants
☐ Colleagues (s) / Collaborators	☐ Data, Tissue, Specimen Registry(s)
☐ Other Research Laboratory (s)	☐ Sponsor / Funding Agency
☐ Study Data Coordinating Center	☐ Publication (s)
☐ Other. p*lease specify*:	

2. Indicate how the data will be shared or disclosed.

☐ Without any identifiers. ☐ With a linked code*.

☐ With identifiers*. ☐ As a Limited Data Set*.

* *In this format, Authorization must specifically note who data will be shared or disclosed to.*

G. Data Security: Describe how the data will be secured. *Please mark all that apply*.

1. Electronic data:

☐ secure network ☐ password access ☐ coded, with a master list secured and kept separately

☐ other (specify):

2. Hardcopy data:

☐ locked suite ☐ locked office ☐ locked file cabinet

☐ data coded by PI or research team with a master list secured and kept separately.

☐ data de-identified by PI or research team

☐ other: *(specify)*

H. Waiver/Alteration of Authorization [Complete this section to request a waiver of authorization for the entire research protocol, for recruitment purposes, or to request an alteration of authorization process such as no signed documentation].

1. Describe the protected health information (PHI) for which use, access, or disclosure is necessary. Include a detailed list of the PHI and also a list of the sources.

2. Criteria for Waiver/Alteration of Authorization:

   A. Explain how the use and disclosure of the information presents no more than minimal risk to the privacy of the individual.

   B. Describe the plan to protect the identifiers from improper use and disclosure (i.e., where will the identifiers will be stored and who will have access).

   C. Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. If there is a health or research justification for retaining identifiers or if such retention is required by law, please provide this information as well.

D. Explain why the research could not be practicably conducted without the alteration or waiver.

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

F. The Privacy Rule requires that when a waiver is granted that only the minimum necessary health information be used/disclosed. Therefore, provide justification that the PHI being requested is the minimum necessary information reasonably necessary to accomplish objectives of the proposed research.

STOP Continue to Section I

The MCN Institutional Review Board determined that this waiver request satisfies all of the requirements of the HIPAA Privacy Rule in 45 CFR 164.512(i)(2)).

☐ The proposed research activity will present no more than minimal risk to the privacy of the human subjects.
☐ There is an adequate plan to protect the patient identifiers from improper use and disclosure.
☐ There is an adequate plan to destroy the patient identifiers at the earliest opportunity and/or by the end of the research study, or there is a health, research or legal justification for retaining the patient identifiers.
☐ There are adequate assurances that the requested information will not be reused or disclosed to any other person ore entity, except as required by law, for authorized oversight of this research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule.
☐ The research could not be practicably conducted without the Waiver for Patient Authorization to access and use the requested PHI.
☐ The approval process was conducted by normal review procedures.

_____ _____
Signature of IRB Chair or Member Date

I. HIPAA Privacy Rule Assurance

The information listed in the application is accurate and all research staff (investigators, key research personnel) that are involved in the research will comply with the HIPAA regulations. Further, I assure that all research staff will have completed the UND IRB research training requirement prior to research participation.

I assure that the information obtained as part of this research (including protected health information) will not be reused or disclosed to any other person or entity other than those identified on this form, except as required by law. If at any time I want to reuse this information for other purposes or disclose the information to other individuals or entities I will seek approval by the MCN IRB.

_____ _____
Principal Investigator Signature Date