IRB Waiver Request Form (Preparatory Research-Non-covered Entity Workforce)
Form for Requests Submitted to NSU-IRB

Note: This form is to be used only for preparatory research. All waivers involved in actual research projects are required to be part of the normal application required by the IRB

Section 1: To be completed by researcher (attach extra pages as needed)

Name of Researcher: ____________________________________________________

Title of Research Project: ________________________________________________

Describe the specific Protected Health Information that is needed for the preparatory research.

____________________________________________________________________
____________________________________________________________________

Describe the reasons why the preparatory research could not practicably be done without the Protected Health Information listed above.

____________________________________________________________________
____________________________________________________________________
____________________________________________________________________

Describe the reasons why the preparatory research could not practicably be done without a waiver of authorization (i.e., describe reasons why it is not practicable to have patients sign an authorization form or to gain authorization in another manner).

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____________________________________________________________________
____________________________________________________________________
____________________________________________________________________

Describe why the information you need could not be attained through a de-identified data set.

____________________________________________________________________
____________________________________________________________________
Describe your plan to protect identifiable information from improper uses and disclosures. Include information on where the information will be stored and who will have access to the information.

______________________________________________________________________
______________________________________________________________________
______________________________________________________________________
______________________________________________________________________
______________________________________________________________________
______________________________________________________________________

Describe your plan to destroy identifiable information at the earliest opportunity consistent with conduct of your research protocol, including a description of when and how the information will be destroyed.

______________________________________________________________________
______________________________________________________________________
______________________________________________________________________
______________________________________________________________________
______________________________________________________________________
______________________________________________________________________

Explain why there is no other alternate way to do this other than the granting of a waiver. Please note that neither the inconvenience nor cost of a possible alternative is a valid reason for the granting of a waiver.

______________________________________________________________________
______________________________________________________________________
______________________________________________________________________
______________________________________________________________________
______________________________________________________________________
______________________________________________________________________

By my signature below, I attest that 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 for which the use or disclosure of Protected Health Information would be permitted by this subpart. I also agree that I will not contact any potential research subject without express IRB permission.

Signature of Researcher: _________________________________________________
Title: __________________________________________________________________
Relationship to NSU: _____________________________________________________
Address: __________________________________________________________________
Phone contact: __________________________ Fax: _________________________
E-mail contact: ___________________________________________________________
Section II: To be completed by the IRB

The waiver request was reviewed by Full IRB review on ______________.

The IRB has determined that the following criteria have been met (please check all that apply):

______ There is an adequate plan to protect the identifiable information from improper use and disclosure.

______ There is an adequate plan to destroy identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

______ The researcher’s signature above provides adequate written assurances that 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 for which the use or disclosure of protected health information would be permitted by this subpart.

______ The research could not practicably be conducted without the requested waiver of authorization.

______ The research could not practicably be conducted without access to and use of the protected health information and there is no alternative manner which does not require a waiver to conduct this research.

IRB Determination

The above criteria have been met and the request is APPROVED ___________
Some of the criteria have not been met and the request is DENIED __________

Signature of IRB Officer ______________________________

Date of IRB Action: ________________________________