WAYNE STATE UNIVERSITY

HIPAA Review Form

Principal Investigator		**IRB#**	
HIPAA Reviewer's Name:		**Date**	

HIPAA Documents Reviewer Recommendation & Comments

☐ **Accept**	☐ **Revisions Required**	☐ **Not Accepted**
HIPAA Reviewer's Signature_____		

eProtocol HIPAA Summary Form

Section	Yes	No	Comments
Are all the elements of PHI selected included for PHI that will be **USED** or **DISCLOSED**?	☐	☐	
1st box: Does the PHI that will be **USED** match the HIPAA Authorization?	☐	☐	
2nd box: Does the PHI that will be **DISCLOSED** match the HIPAA Authorization?	☐	☐	
Items (a) & (b): Will someone with a clinical relationship contact potential participants?	☐	☐	If No, has a justification been provided? ☐ Yes ☐ No
Item(i): Are the entities indicated for the HIPAA form that will receive PHI also listed for the HIPAA Authorization section: "Your study information may be **used** or **shared** with the following people or groups" section? This includes the study sponsor/funding source and other companies	☐	☐	
Waiver of HIPAA Authorization section: Is a Waiver of Authorization requested?	☐	☐	

HIPAA Authorization & Informed Consent Documents

Section	Yes	No	Comments
HIPAA Authorization: Has an option been provided regarding whether participants will have access to their medical records?	☐	☐	
HIPAA Information in Consent Documents or Additional Comments:			

Is a Waiver of HIPAA Authorization requested? ☐ **Yes,** go to next page ☐ **No,** STOP FORM IS COMPLETE

Waiver of HIPAA Authorization

Complete only if the Principal Investigator requests a Waiver of HIPAA Authorization

The research could not practicably be conducted without the waiver or alteration.	☐ True	☐ False
The research could not practicably be conducted without access to and use of the PHI.	☐ True	☐ False
There is an adequate plan to protect health information identifiers from improper use and disclosure.	☐ True	☐ False
There is an adequate plan to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so). ☐ True ☐ False ☐ There is adequate justification to keep identifiers.		
There are adequate written assurances that the PHI will not be reused or disclosed to (shared with) 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 the PHI would be permitted under the Privacy Rule.	☐ True	☐ False

Is a Waiver of HIPAA Authorization granted? ☐ **Yes** ☐ **No** ☐ **Other:**

Protocol-specific justification for a Waiver of HIPAA Authorization:
Notes:

A Waiver of Authorization is granted that allows for access to protected health information identified as being necessary for this study by the PI on the HIPAA Summary Form.

It has been determined that a Waiver of Authorization (for this study OR to screen for eligible potential participants in this study) satisfies the criteria of the Privacy Rule for the following reasons:
- The research could not be practicably conducted without the Waiver of Authorization
- The research could not be practicably conducted without access to and use of protected health information
- There is an adequate plan to protect identifiers from improper use or disclosure.
- There is an adequate plan to destroy identifiers at the earliest opportunity. Or There is adequate justification for the retention of identifiers.
- The PI provided a signature on the Waiver Agreement which serves as written assurance that 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 project, or for other research for which the use or disclosure of protected health information would be permitted under the Privacy Rule.