BINGHAMTON UNIVERSITY
STATE UNIVERSITY OF NEW YORK

Binghamton University
APPLICATION FOR WAIVER OF HIPAA AUTHORIZATION

Principal Investigator:

Title of Study:

☐ **TOTAL WAIVER**

When you request a total Waiver of the HIPAA Authorization, you are requesting permission to access, use or disclose a research subject's PHI for your research study without seeking the subject specific authorization for that use or disclosure.

☐ **PARTIAL WAIVER**

When a partial waiver is requested, you may request that certain required elements of the HIPAA authorization be altered or that the HIPAA authorization be waived for a portion of the study (i.e., such as accessing medical records only to determine eligibility before consent/authorization has been obtained).

Researchers requesting either a partial or total waiver of HIPAA Authorization must demonstrate that their research meets all of the following criteria listed below. Please verify the status of your study by checking YES or NO to the criteria below as applicable:

YES	NO	CRITERIA
☐	☐	The use or disclosure involves no more than minimal risk to the privacy of individuals based on at least the presence of: a. An adequate plan to protect PHI identifiers from improper use and disclosure in included in the research protocol; *b.* An adequate plan to destroy PHI identifiers at the earliest opportunity or justification for retaining identifiers, is included in the research protocol (i.e., health justification, research justification, requirement of the law); and
☐	☐	The privacy risks are reasonable relative to the anticipated benefits of the research.
☐	☐	The project proposal includes adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule;
☐	☐	The research could not practicably be conducted without the waiver or alteration; and,

☐	☐	The research could not practicably be conducted without access to and use of the PHI.
☐	☐	Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Please specify what you are requesting the waiver (total or partial) for:

Describe the plan to protect the identifiers (names, addresses, telephone numbers, social security numbers, medical record numbers, photos, and other identifying information etc.) from improper use and disclosure:

Describe the plan to destroy the identifiers at the earliest opportunity, or provide justification for retaining the identifiers:

Describe why the research could not be practicably be done without the waiver:

Please identify the PHI that will be used under this waiver request:

Describe why the research practicably be done without access to, use or disclosure of the PHI identified above:

The HIPAA regulation requires reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure or request. Please note that researchers are also accountable for any PHI released under a waiver. Explain why PHI obtained for this study is/are the minimum information needed to meet the research objectives:

Who will have access to the PHI? (Note: researchers must list all of the entities that are able access to the study's PHI (i.e.: sponsors, FDA, data safety monitoring boards, IT, and any others given authority by law)?

Principal Investigator Statement

As Principal Investigator of the above named study, I assure the IRB that the following statements are true:

- The information that is provided in this form is true and accurate. I will seek and obtain prior written approval from the IRB for any modifications to the study protocol, including, but not limited to, changes in procedures and co-investigators.
- I will report in writing any significant new findings that develop during the course of this study that may affect the risks and benefits to the individuals whose PHI is being obtained.
- I will not begin my research, including subject identification or recruitment, until I have received written notification of IRB approval. I will comply with all IR requests to report on the status of the study.
- I will not reuse or disclose any PHI to any other person or entity, except as required by law, for the authorized oversight of research or for other permitted research.
- I will conduct the research in compliance with all applicable federal and state laws and regulations and Binghamton University's policies governing human subject research.

Principal Investigator Signature **Date**