REQUEST FOR A WAIVER OF AUTHORIZATION FOR THE RELEASE OF HEALTH INFORMATION

Date:	**Protocol #:**
Project Title:	
Principal Investigator:	

The Medical Sciences Campus Institutional Review Board (Federalwide Assurance Number 00005561) may waive or alter the requirement to obtain authorization from research subjects in order to use or disclose their protected health information (PHI*), provided that the investigator justifies, and the IRB agrees, that specific criteria have been met. Please explain how your research study meets the criteria by answering each of the following questions:

1. Explain why this research involves no more than minimal risk of loss of privacy to the subject. Include a detailed list of the PHI to be collected and a list of the sources(s) used/accessed for the PHI.

    a. Describe the plan for protecting the identifiers from improper use and disclosure and indicate where PHI will be stored and who will have access to the study's PHI. (IRB, Sponsor, FDA, DSMB)

    b. Describe the plan to destroy the identifiers at the earliest opportunity that is appropriate for the research study. Identifiers may only be maintained following completion of a study if there is a legitimate reason for maintaining the data (e.g required by law, etc.).

c. Provide written assurances that the identifiable health information will not be re-used or disclosed to any other person or entity, except as required by law, for authorized oversight of the project or for other permitted research purposes.

2. Explain how the research could not be practicably conducted without waiver of authorization or an alteration to the authorization form.

3. Explain how the research could not be practicably conducted without access to and use of the individually identifiable health information.

The information listed in the waiver application is accurate and all research staff** will comply with the HIPAA regulations and the waiver criteria. All research staff have completed HIPAA training.

I assure that the information I obtain as part of this research (including protected health information) will not be reused or disclosed to any other person or entity other than those listed 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 from the UPR-MSC IRB.

Principal Investigator Signature: _____

Name typed/printed: _____

Date: _____

*PHI: individually identifiable health information transmitted or maintained in any form (electronic means, on paper, or through oral communication) that relates to the past, present or future physical or mental health or conditions of an individual.
Note: Research staff is defined as **ALL study personnel (including PI) that is involved in the research.
***HIPAA Regulations allow IRBs to waive use of authorization form if all of the criteria listed above are met.