**IRB WAIVER OF HIPAA AUTHORIZATION**

Principal Investigator Name:

Study Title:

Protocol Number:

The HIPAA Privacy Standard at 45 CFR 164.512(i) requires that certain criteria be met in order to grant a waiver of individual authorization for research uses of Protected Health Information In addition to these criteria, the federal Common Rule (45 CFR 46 section 116(d)) stipulates that “whenever appropriate, the subjects will be provided with additional pertinent information after participation.”

# Please specify the purpose for which you are requesting the waiver:

(*Please respond to every question on this application)*

1. Does the use or disclosure of PHI involve no more than minimal risk to the privacy of the individual, based on at least the presence of the following:
	1. An adequate plan to protect the identifiers from improper use and disclosure.
	2. An adequate plan to destroy identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or as otherwise required by law.
	3. Adequate written assurances that the protected health information will not be reused or disclosed to another person or entity, except as required by law, for authorized oversight of the research study, or other research for which the use or disclosure of PHI would be permitted.

 **Yes** **No**

1. Describe in detail, 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 your data security methods. The use of encryption software is required if identifiers are going to be stored.

1. Describe the plan to *destroy* the identifiers at the earliest opportunity or provide justification for retaining the identifiers.

1. Will granting a waiver adversely affect the privacy rights of the individual?

**Yes** **No**

Please explain your answer:

1. Could the research be practicably done without the waiver?

**Yes** **No**

If “no” justify below:

1. Could the research practicably be done without access to, use or disclosure of the PHI identified below?

**Yes** **No**

 Fully identify the PHI that will be used under this waiver request: (E.g. Full or partial Medical Records, including laboratory reports, progress notes for certain dates, etc.)

1. Are the privacy risks to individuals whose PHI will be used or disclosed reasonable in relation to the anticipated benefit, if any, to the research? *(Please describe your risk/benefit analysis relating to the waiver request below.)*

**Yes** **No**

Please explain your answer:

9. Will the Principal Investigator be the **only** member of the research team who will **access**, **use** or **disclose** PHI?

**Yes** **No**

If no, please name all of the individuals who will have access to PHI during the research study, including students. As PI, you must ensure that these individuals have current Human Subjects Training & HIPAA Training. These individuals must also be listed as part of key personnel in the project roster of your IRB application.

Name, Job Description/Role

*By signing this form, I attest that the protected health information will not be reused or disclosed to another person or entity, except as required by law, for authorized oversight of the research study, or other research for which the use or disclosure of PHI would be permitted. If all of these criteria are met, the IRB may grant a Waiver of Authorization. The IRB’s action will be documented and communicated to the Principal Investigator.*

**INVESTIGATOR AGREEMENT:**

As Principal Investigator of this study, I assure the Office of Research Compliance & Integrity 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 substantive modifications to the proposal, 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 and will comply with all IRB 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 UCM policies governing human subject research.

**Signature of Principal Investigator: Date:**

**FACULTY ADVISOR AGREEMENT:**

**Student Research** (i.e., research performed by medical students, graduate students, residents, or fellows) requires the approval of your Faculty Advisor. As an Advisor to the Student Investigator, I assume responsibility for ensuring that the Student complies with all applicable federal and state laws and regulations as well as UCM policies governing human subject research.

**Signature of Faculty Advisor: Date:**