UMass Memorial Medical Center

HIPAA IRB WAIVER OF AUTHORIZATION[[1]](#endnote-1)\*\*\*

Principal Investigator:

IRB Study ID #: H

Protocol Title:

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1. Indicate if you are requesting a waiver of authorization to review electronic/paper medical records just to find potential subjects or to conduct the entire study.
2. The HIPAA regulation requires reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request. List the PHI to be collected and its source(s).
3. Explain why the research could not practicably be conducted without this PHI.
4. Describe the plan to protect identifiers from improper use or disclosure. Be sure to indicate where PHI will be stored, who will have access (researchers must list all of the entities that might have access to the study’s PHI such as IRB, sponsors, FDA, data safety monitoring boards, and any others given authority by law), and the procedure used to destroy them. (Note that identifiers must be destroyed at the earliest opportunity, unless there is a justification for retaining the identifiers or retention is required by law.)
5. Explain why the research could not practicably be conducted if you had to obtain permission from the individuals to access their PHI for research purposes.

By submitting this form, the PI attests the following:

1. The information listed in the waiver application is accurate and all research staff[[2]](#endnote-2)\*\* will comply with the HIPAA regulations and the waiver criteria.
2. Protected health information for which a Waiver of Authorization has been requested will not be reused or disclosed to any person or entity other than those listed in this application, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB.

*REMINDER:* The PI is ultimately responsible for completing the required accounting of research disclosures for any PHI released under a waiver. The relevant forms are available on the IRB website and additional information regarding these obligations is available by contacting the Office of Clinical Research, UMass Center for Clinical & Translational Science (UMCCTS), or the UMass Memorial Medical Center Privacy Officer.

1. [↑](#endnote-ref-1)
2. \*\*Note: Research staff is defined as ALL study personnel (including PI) that is involved in the research.

   \*\*\*HIPAA Regulations allow IRBs to waive the use of authorization forms if all of the criteria listed above are met. [↑](#endnote-ref-2)