

# U-M Health Statewide Network of Care HIPAA Letter of Understanding Template Language

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## I. Introduction

This Companion Piece provides template language for the U-M Health Statewide Network of Care sites. This is to be used when the site is not engaged in the research activities but U-M Faculty/Staff are accessing PHI at the site for the purpose of research. This access to PHI requires a review/determination. If the Network of Care site chooses to rely on U-M IRB's HIPAA determination, the following template language can be used to draft a study-specific HIPAA letter of understanding.

## II. Template Language for HIPAA Letter of Understanding

- **Example #1:** Addresses just the reliance on U-M IRB for review and approval of the waiver if HIPAA authorization. This is used when:
  - the site has already provided the engagement determination and still needs to address the HIPAA letter of understanding, or
  - the site would like the HIPAA letter of understanding to remain a separate document.
- **Example #2:** Addresses both the engagement determination and the site's reliance on U-M IRB for the review and approval of the waiver of HIPAA authorization.

### A. Example #1

**Date:** <Insert Date>

**To:** UM Institutional Review Board for Human Subject Research-Medical School (IRBMED)

This is to confirm that we are willing to collaborate with University of Michigan (UM) researchers on a research project entitled **XXX** study conducted by UM principal investigator **XXX**.

We are aware that the procedures used in this project involve the use and/or disclosure of protected health information (PHI) for research purposes without authorization from the patients at this institution.

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| File Name: CSP_CP.301.UM Network of Care HIPAA LOU Template Language.2025.Apr.03 | Target Audience: Research Community |
| Author/Responsible Unit: Coordinated Services and Practices (CSP) unit           | Date Released: 04/03/2025           |
| Date Modified: N/A                                                               |                                     |

We understand the UM IRB has approved a waiver of authorization per 45 CFR 164.512, Uses and disclosures for which an authorization or opportunity to agree or object is not required, specifically 45 CFR 164.512(i), Uses and disclosures for research purposes. This letter confirms that we will rely on this waiver of authorization for the project named above.

We are also aware that we must provide to our patients, upon request, an accounting of disclosures of their PHI under a waiver of authorization per 45 CFR 164.528, Accounting of disclosures of protected health information.

This letter does not speak to whether our location is engaged in research as outlined in the OHRP Engagement of Institutions in Human Subjects Research Guidance and that determination will be made in another communication with the University of Michigan.

## **B. Example #2**

**Date:** <Insert Date>

**To:** UM Institutional Review Board for Human Subject Research-Medical School (IRBMED)

This is to confirm that we are willing to collaborate with University of Michigan (U-M) researchers on a research project entitled **XXX** conducted by UM principal investigator **XXX**.

**[Insert PI's Name]** would like to **[describe what is being collected]** according to the IRBMED approved application HUMXXX. It was determined by the **[site name]** IRB that **[site name]** is not engaged in this project. Given that the procedures used in this project involve the use and/or disclosure of protected health information (PHI) for *research* purposes, the HIPAA Privacy Rule still applies. Under HIPAA Privacy Rule, a covered entity may use or disclose PHI without authorization if an IRB (or Privacy Board) has approved a waiver of authorization. There are specific regulatory requirements that govern when an IRB/Privacy Board may approve such a waiver. A covered entity may accept documentation of the waiver of authorization from another IRB/Privacy Board to facilitate use/disclosure of PHI.

We understand the UM IRB has approved a waiver of authorization per 45 CFR 164.512, *Uses and disclosures for which an authorization or opportunity to agree or object is not required*, specifically 45 CFR 164.512(i), *Uses and disclosures for research purposes*. This letter confirms that we will rely on this waiver of authorization for the project named above.

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