eRESEARCH | REGULATORY MANAGEMENT SAND

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25-1. Protected Health Information/HIPAA

Completion of this section is required based on the responses to questions 4-1.1, 5-1.3, 7.3, or 7-3.2 and question 25.1.

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25-1.1* Identify the PHI to be used.

Select all that apply:

- [x] Hospital/doctor's office records, including test results and dental records
- [ ] Mental health care records (except psychotherapy notes not kept with medical records)
- [ ] Psychotherapy notes (e.g., process notes) maintained separately from the regular medical record
- [ ] Alcohol/substance abuse treatment records
- [ ] AIDS/HIV, STD, or other serious communicable disease records (including testing, diagnosis, treatment, and outcomes records)
- [ ] Genetic counseling/genetic testing records
- [ ] Health plan/health insurance records
- [x] Any records relating to condition, the treatment received, and response to the treatment
- [ ] Billing information
- [x] Demographic information
- [x] Personal identifiers
- [ ] Other

If other, please specify:

Several IRBMED Informed Consent templates include HIPAA authorization (e.g. section 9 in the Standard Informed Consent template). Checkbox answers in 25-1.1 **must** match what is listed in the Informed consent under "Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:"

25-1.2* Explain why the PHI listed above is the minimum necessary to conduct the study.

Answer as appropriate.

Provide explicit justification for the need for any particularly sensitive categories of information, such as STD status or genetic counseling records.

For example, explain why the study could not reasonably and effectively be conducted without the PHI.

25-1.3* Will HIPAA authorization for access to the PHI be obtained for all or some subjects?

Select one:

- ○ **Yes, always** - HIPAA authorization was/will be obtained from all subjects
- ○ **Yes, sometimes** - HIPAA authorization will not be obtained from some subjects or from some candidates for recruitment before their records are reviewed for eligibility determination or to obtain contact information
- ● **No** - HIPAA authorization will not be obtained from any subjects

Clear

This answer often pairs with "pre-existing consent covers this activity" in 10.3.

To be valid, HIPAA authorization for research must be obtained **in writing** and must be **project-specific**. Standard UMHS clinical

Full waiver of Authorization is common for secondary use-only studies.

25-1.3.2* **If HIPAA authorization for access to the PHI will NOT be obtained from some or all subjects/candidates for recruitment, indicate what alternative(s) will be used:**

Select all that apply:

- [x] Request for full or partial waiver of HIPAA authorization to be approved by U-M IRB or Privacy Board
- [ ] Non-UM IRB or Privacy Board has approved/will approve full or partial waiver of HIPAA authorization (this option is rare, but may be appropriate when U-M receives external PHI, or when U-M "cedes" oversight to an external IRB)
- [ ] Review of data preparatory to research. Note: this exception is not necessary if a full or partial waiver of authorization is granted.
- [ ] Limited data set(s)
- [ ] Deidentified data sets (data will be completely deidentified before use for research purposes).

records) should answer 25-1.3 "**Yes, sometimes**."

A study requesting a **FULL** waiver of consent in eResearch section **10-3** (no interaction with subjects or consent process at any point) should answer **25-1.3** "**No**."

See U-MIC presentations

- Protected Health Information (PHI)
- The HIPAA Privacy Rule: Requirements and Waivers

Additional Help

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