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| **Instructions** |
| * Complete this template if your project involves Protected Health Information. For the definition of Protected Health Information, please visit the HRPP website: <http://hrpp.msu.edu/help/definitions.html>
* CLICK™ IRB
	+ Include template with New Study Submission.
	+ Upload completed template to the MSU Additional Information SmartForm page, Supporting Documents.
* See HRPP Manual 7-6, Health Insurance Portability and Accountability Act Compliance in Human Research for more information.
 |
| Complete Questions 1 – 3. |
| 1 | Study title.       |
| 2A | Select all covered entity(ies) where PHI will be obtained.  |
| [ ]   | MSU Health Care, Inc. |
| [ ]  | MSU (e.g. Olin) |
| If any of the below covered entities are selected (not MSU Health Care, not MSU), complete 2B and 2C. |
| [ ]  | Genesys Health System |
| [ ]  | Henry Ford Allegiance Health |
| [ ]  | Hurley Medical Center |
| [ ]  | McLaren Health Care |
| [ ]  | Memorial Healthcare |
| [ ]  | Mercy Health Saint Mary’s |
| [ ]  | Michigan Department of Health and Human Services |
| [ ]  | Michigan Public Health Institute |
| [ ]  | MidMichigan Health |
| [ ]  | Munson Medical Center |
| [ ]  | Pine Rest Christian Mental Health Services |
| [ ]  | Providence-Providence Park Hospital |
| [ ]  | Sparrow Health Systems |
| [ ]  | Spectrum Health System |
| [ ]  | UP Health System Research - Marquette |
| [ ]  | Van Andel Research Institute |
| [ ]  | Other(s) | List:       |
| 2B | Do any of these sites (not MSU Health Care, not MSU) have their own IRB/Privacy Board? | [ ]  No [ ]  Yes |
| 2C | Have you or will you submit this project to any non-MSU IRB/Privacy Board? | [ ]  No [ ]  Yes |
| *If you answered yes to 2C, complete 2C1.*  |
| 2C1 | List the contact information for the Privacy Officer(s) for these sites (not MSU Health Care, not MSU).       |
| 3 | A covered entity may use or disclose PHI for research provided the activity meets HIPAA requirements. Identify the method(s) you are requesting to use or disclosure of PHI for your project: |
| [ ]  3A. Research Use or Disclosure with Individual Authorization  |
| [ ]  3B. Board approval of an alteration of the use or disclosure with individual authorization |
| [ ]  3C. Board approval of a waiver of authorization |
| [ ]  3D. Limited data sets with a data use agreement |
| [ ]  3E. Reviews preparatory to research |
| [ ]  3F. Research in decedents information |
| [ ]  3G. De-identification |
| * *If you selected 3A, complete 3A*
* *If you selected 3B, complete 3B AND 3C*
* *If you selected 3C, complete 3C*
* *If you selected 3D, complete 3D*
 |
| 3A | Research Use or Disclosure with Individual Authorization. * *Use the MSU Health Care template authorization form when MSU Health Care is the covered entity. Find the template at -* <http://hrpp.msu.edu/templates/index.html>
* *There may be limited circumstances when MSU is the covered entity (e.g. Olin Clinic). Use the MSU template authorization form when MSU is the covered entity. Please contact the HRPP Compliance office with questions. Find the template at:* <http://hrpp.msu.edu/templates/index.html>
* *Submit a copy of the authorization form(s)*
 |
| 3A1 | Please explain the process you will use to ensure the subject's permission is obtained prior to accessing protected health information (e.g. medical records) for research purposes. It is the responsibility of the covered entity to keep the authorization forms for 6 years after the expiration date.       |
| 3A2 | Describe the process you will use to present the signed authorization to the covered entity prior to accessing PHI. Note: It is the University's best practice that the PI also keeps a copy of the signed authorization.       |
| 3B | Board approval of an alteration of the use or disclosure with individual authorization* CLICK IRB: Upload a copy of the authorization form(s) to the MSU Additional Information SmartForm page, Supporting Documents.
 |
| 3B1 | What element(s) of the authorization are you requesting an alteration to and why?       |
| 3C | Board approval of a waiver of authorization (and Board approval of an alteration of the use or disclosure with individual authorization) |
| 3C1 | Is MSU or MSU Health Care, Inc., the covered entity?  | [ ]  No [ ]  Yes  |
| *If you answered yes to 3C1, complete 3C2, 3C3, 3C4, 3C5, 3C6, 3C7, 3C8, 3C9, and 3C10.* |
| 3C2 | Description of the protected health information that is needed:       |
| 3C3 | Explain why the use or disclosure of PHI involves no more than minimal risk to the privacy of individuals.       |
| 3C4 | Explanation of why the research could not practicably be conducted without access to and use of the protected health information.       |
| 3C5 | Explanation of why the research could not be practicably conducted without the waiver or alteration.       |
| 3C6 | Description of an adequate plan to protect the identifiers from improper use or disclosure.       |
| 3C7 | Select and complete either 3C7A or 3C7B.  |
| [ ]  3C7A: A Description of an adequate plan to destroy the individual identifiers at the earliest opportunity consistent with conduct of the research.       |
| [ ]  3C7B: Provide an explanation of a health or research justification for retaining the identifiers or reasons why they will be retained.       |
| 3C8 | Provide adequate assurance that the protected health information will not be reused or disclosed to any other person or entity, except as required by law.       |
| 3C9 | For authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted, include a description of all planned uses and disclosures.       |
| 3C10 | The HIPAA waiver is designed primarily for retrospective review of medical records. Describe for what period of time the records will be accessed (i.e. patients admitted to ICU between 2/08 and 7/09).       |
| 3D | A limited data set must have all of the identifiers listed below removed from the data. It is the responsibility of the researcher(s) and the party releasing the PHI to have in place and maintain a copy of the data use agreement which meets HIPAA requirements.A limited data set is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual: * Names;
* Postal address information, other than town or city, State, and zip code;
* Telephone numbers;
* Fax numbers;
* Electronic mail addresses;
* Social security numbers;
* Medical record numbers;
* Health plan beneficiary numbers;
* Account numbers;
* Certificate/license numbers;
* Vehicle identifiers and serial numbers, including license plate numbers;
* Device identifiers and serial numbers;
* Web Universal Resource Locators (URLs);
* Internet Protocol (IP) address numbers;
* Biometric identifiers, including finger and voice prints; and
* Full face photographic images and any comparable images.

For MSU Health Care clinics, contact MSU Health Care to complete and obtain a data use agreement.  |