De-identified health information does not typically require Michigan State University Institutional Review Board (IRB) review because a “human subject” is defined, in part, a living individual about whom an investigator obtains “private identifiable information” (HHS) and as an “individual who is or becomes a participant in research” (FDA). See HRPP Manual Section 4-3, Determination of Human Subject. However, the researcher is responsible for complying with HRPP Manual Section 4-3, and contacting the MSU IRB if there is any question about whether the activity involves human subjects and requires MSU IRB review.

The covered entity and the individual accessing the health information are responsible for complying with the requirements under HIPAA for de-identification.

If de-identification of the protected health information is proposed through an application to the MSU IRB or request for a not human subject research determination, a Human Research Liaison will be assigned. If the request involves a clinic that is part of the MSU covered entity, the HRL will notify the MSU Health Team and copy the Principal Investigator (PI). If the request does not involve a MSU covered entity, the HRL will notify the PI that they must contact the covered entity(ies) for requirements.

De-identification Of Protected Health Information
The uses and disclosures of de-identified protected health information are described at 45 CFR 164.502, beginning at subpart (d):

(d)(2) Uses and disclosures of de-identified information. Health information that meets the standard and implementation specifications for de-identification under § 164.514(a) and (b) is considered not to be individually identifiable health information, i.e., de-identified. The requirements of this subpart do not apply to information that has been de-identified in accordance with the applicable requirements of § 164.514, provided that:

i) Disclosure of a code or other means of record identification designed to enable coded or otherwise de-identified information to be re-identified constitutes disclosure of protected health information; and

(ii) If de-identified information is re-identified, a covered entity may use or disclose such re-identified information only as permitted or required by this subpart.
The requirements for de-identified information under HIPAA are found at 45 CFR 164.514:

(a) **Standard: De-identification of protected health information.** Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information.

(b) **Implementation specifications: Requirements for de-identification of protected health information.** A covered entity may determine that health information is not individually identifiable health information only if:

1. A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:
   
   (i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and
   
   (ii) Documents the methods and results of the analysis that justify such determination; or

2. (i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

   A) Names;
   
   B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
   
   C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
   
   D) Telephone numbers;
   
   E) Fax numbers;
   
   F) Electronic mail addresses;
   
   G) Social security numbers;
   
   H) Medical record numbers;
   
   I) Health plan beneficiary numbers;
   
   J) Account numbers;
   
   K) Certificate/license numbers;
   
   L) Vehicle identifiers and serial numbers, including license plate numbers;
   
   M) Device identifiers and serial numbers;
   
   N) Web Universal Resource Locators (URLs);
   
   O) Internet Protocol (IP) address numbers;
   
   P) Biometric identifiers, including finger and voice prints;
   
   Q) Full face photographic images and any comparable images; and
   
   R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section; and

   (ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

(c) **Implementation specifications: Re-identification.** A covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the covered entity, provided that:
(1) \textit{Derivation}. The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and

(2) \textit{Security}. The covered entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.

(d) (1) \textit{Standard: Minimum necessary requirements}. In order to comply with § 164.502(b) and this section, a covered entity must meet the requirements of paragraphs (d)(2) through (d)(5) of this section with respect to a request for, or the use and disclosure of, protected health information.