

## PROTOCOL APPLICATION

### Activity Determination Form (Non-Human/Non-Research)

There are limits on what the CWRU IRB can evaluate. If the IRB determines it is not under their purview, you will be contacted by the IRB Office to discuss the available options. If you have any questions, please contact the IRB before submitting a protocol.

1. All activities that have the potential to involve humans, living or deceased, or specimens/data obtained from humans must receive a determination from the CWRU IRB regarding the nature of the activity and the type of review required. Any investigator who believes an activity does not constitute "*human subject research*" as defined by the Department of Health and Human Service (DHHS) regulations 45 CFR 46 must fill out this form.
2. Type of Determination Request (select at least one - Category A, B and/or C)  
Select from the following categories to determine the applicability of DHHS requirements.
3. A. DHHS - Not Research
  - 45 CFR 46.102 (d): Activity is not considered "Research" because (all of the following must be true)
    - The activity is not a systematic investigation, including research development, testing and evaluation
    - The activity is not designed to develop or contribute to generalizable knowledge
4. B. DHHS - Not Human Subjects
  - 45 CFR 46.102 (f): Activity does not involve "Human Subjects" because (select which is true):
    - The activity does not involve information obtained about living individuals
  - OR**
  - The activity involves information obtained about living individuals BUT (both of the following must be true)
    - The activity does not involve direct or indirect contact through **one or more** of the following: physical procedures performed on individuals, manipulation of an individual or an individual's environment, communication with an individual or interpersonal contact with an individual **AND**;
    - The information obtained from the activity cannot be linked, or associated to a particular individual **AND** the identity of the person may not be ascertained by the investigator
5. Use of Protected Health Information (PHI) / Research HIPAA  
Select one:

*All projects must indicate PHI use below. Elaborate on how the activity qualifies in the summary section below:*

- The activity is exempt from research HIPAA requirements as no PHI is used or collected
    - Information collected must have all 18 elements (as defined by the **HIPAA Privacy Rule**) removed so that an individual or the individual's relatives may not be identified
  - The activity is considered "Preparatory to Research" under the Privacy Rule (discuss each of the following in the summary)
    - the use or disclosure is requested solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research;
    - the PHI will not be removed from the covered entity in the course of review, and
    - the PHI for which use or access is requested is necessary for the research
  - The activity involves use or disclose PHI of the deceased for research (discuss each of the following in the summary):
    - the use and disclosure is sought solely for research on the PHI of decedents
    - the PHI for which use or disclosure is sought is necessary for the research purposes
    - documentation of the death of the individuals whose PHI is sought by the researchers must be provided upon request of the covered entity
  - The activity utilizes a "Limited Data Set" NOTE: Prior to a limited data set being used or disclosed outside of the covered entity, the investigator (recipient) must enter into a Data Use Agreement with the covered entity (see 45 CFR 164.514(e)).
  - A waiver for use and/or disclosure of PHI is requested
  - HIPAA Authorization will be obtained
6. Describe the proposed activity, the specific objectives, the type of information to be used, the methods in which the data or specimens will be collected and stored and how confidentiality will be maintained.

Discuss the use and disclosure of Protected Health Information (PHI) under the HIPAA Privacy Rule.

Describe the tissue or cell lines