

Guidelines for De-Identifying Human Tissue for Research in the Innovative Translational Research Shared Resource (ITR)

Background: The ITR works with clinical and laboratory investigators to understand patient phenotypes in the laboratory with the goal of translating the knowledge into improved patient therapies. Often, this type of research requires the use of human tissues.

Purpose: The purpose of these guidelines is to provide a framework for clinical and laboratory investigators to use to protect the privacy and confidentiality of patients who consent to and participate in research studies.

Guidelines: The study Principal Investigator (PI) is responsible for removing identifying information from the tissue, or vessel housing the tissue, before releasing the samples to the ITR. It is the responsibility of the study Principal Investigator (PI) to assign each sample a unique identifier and label the sample accordingly. If approved by the Institutional Review Board, the study PI can possess a “key” that links the unique identifier with the clinical information associated with that patient. In the event that the ITR Director is a study co-investigator and included in the IRB, the ITR Director may have access to this key and patient information. The ITR staff will not keep a record of the identifying information.

Individually identifiable health information is defined as any information collected from an individual (including demographics) that is created or received by a health care provider, health plan, employer, and/or health care clearinghouse that relates to the past, present or future physical or mental health or condition of an individual, or the provision of health care to an individual or the past, present or future payment for the provision of health care to an individual and identifies the individual and/or to which there is reasonable basis to believe that the information can be used to identify the individual (45 CFR 160.103).

These identifiers include:

1. Names
2. Any 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
3. All elements of dates (except year) for dates directly related to an individual (e.g., date of birth, admission)
4. Telephone numbers
5. Fax numbers
6. Electronic mail addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voiceprints
17. Full-face photographic images and any comparable images

If you have any questions please contact Kimberly Dahlman for more information at 936-6589 (office) or Kimberly.b.dahlman@vanderbilt.edu.