Who needs to be certified in human subjects protection training?

All KUMC research personnel, KUMC staff and affiliated staff whose role in the study involves human subjects research must pass and maintain current training in human subjects protection. The following activities are considered to involve human subjects research:

- Intervening/interacting directly with study participants to perform research activities
- Access to research data that contains any elements of protected health information as defined by HIPAA.
  - PHI elements are listed below.
  - Please note that access to identifiable data includes access to linking lists and key codes by which research subjects can be identified.

The requirement to maintain current training also applies to collaborators from other institutions who are working on KUMC projects. KUMC uses CITI (Collaborative Institutional Training Initiative, housed at the University of Miami) for the Human Subjects Protection Training and some training required by other compliance areas. Investigators who are transferring to KUMC from another institution may email their current certification to humansubjects@kumc.edu if they have already completed the appropriate CITI Basic Course through a previous institution.

Who needs to take a CITI Course for Biomedical or Social-Behavioral Researchers?

1. Personnel who have never been certified in human subjects protection
2. Personnel whose certification was completed more than 3 years ago
3. Persons affiliated with research at KUMC, but not employed or enrolled at KUMC, whose activities qualify as human subjects research, described above.

*The KUMC IRB website posts instructions on which courses are required and how to access refresher modules*

What is protected health information?

If any of the following demographic characteristics are paired with information about past, present, or future physical or mental health, or information about the payment of health care, the resulting information is **Protected Health Information** under HIPAA.

- Names
- 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:
The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

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;

- 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;
- Full face photographic images and any comparable images; and
- Any other unique identifying number, characteristic, or code

To qualify as de-identified data, each of the elements listed above must be removed.

Note: a de-identified data set may include a tracking code or other numbering system, provided that:

a. the tracking code is not related to information about the individual
b. the re-identification algorithm is not disclosed to the data recipient