DO NOT USE THIS DIAGRAM FOR 1) the initial collection of identifiable tissue for research purposes and 2) human stem cell research. The first activity involves human subjects research and must receive full committee or expedited review by the IRB. Research involving human stem cells requires review by the GESCR Committee and may require IRB review.

The researcher receives data and/or specimens that have identifiers

The researcher receives data and/or specimens that are coded and identifiers* are kept separately

The researcher receives data and/or specimens that are de-identified*

Is the provider of the data and/or specimens giving the UCSF Investigators access to study identifiers or the "key" to link back to the identifiers?*

Yes

No

Human subjects

Not human subjects

See the two conditions that must be met.

The data and/or specimens are pre-existing* and the PI has access to identifiable information, but the PI records the information in a manner that subjects cannot be identified directly or through identifiers* linked to the subject.

No

Yes

Expedited Review or Full Committee

Exempt Certification

Conditions:
1. The research is not regulated by the FDA.
2. One or more of the following apply:
   - The key to decipher the code is destroyed before the researcher begins, OR
   - The PI and holder of the key enter into an agreement prohibiting the release of the key under any circumstances, OR
   - There are IRB-approved written policies for the repository or data management that prohibit the release of the key, OR
   - There are other legal requirements prohibiting the release of the key under any circumstances.

Example: The UCSF PI is analyzing coded data collected from a study being done at UCLA. The UCSF PI and the UCLA PI have entered into an agreement that prohibits the UCSF PI from receiving the key to the code.

For documentation, complete the PI Self-Certification Form for Sponsors.

Important Note: If the conditions above are not met, the coded data or specimens are considered human subjects and the research requires IRB approval.

Definitions:
§ Obtaining - is defined as receiving or accessing data or biological specimens.

* Identifiers – Any of the 18 Protected Health Identifiers and other type of personal identifiers. IMPORTANT NOTE: The data or biological specimens may include a limited set of data including all elements of dates and geographical codes (zip codes) as long as the individuals identity cannot be ascertained.

+ Pre-existing - means existing before the research is proposed to the IRB. All data/specimens must be collected (i.e., on the shelf) prior to the research for a purpose other than the proposed research. It includes data or specimens collected during research and/or non-research activities.

http://www.research.ucsf.edu/chr/Guide/HSDecisTree.pdf