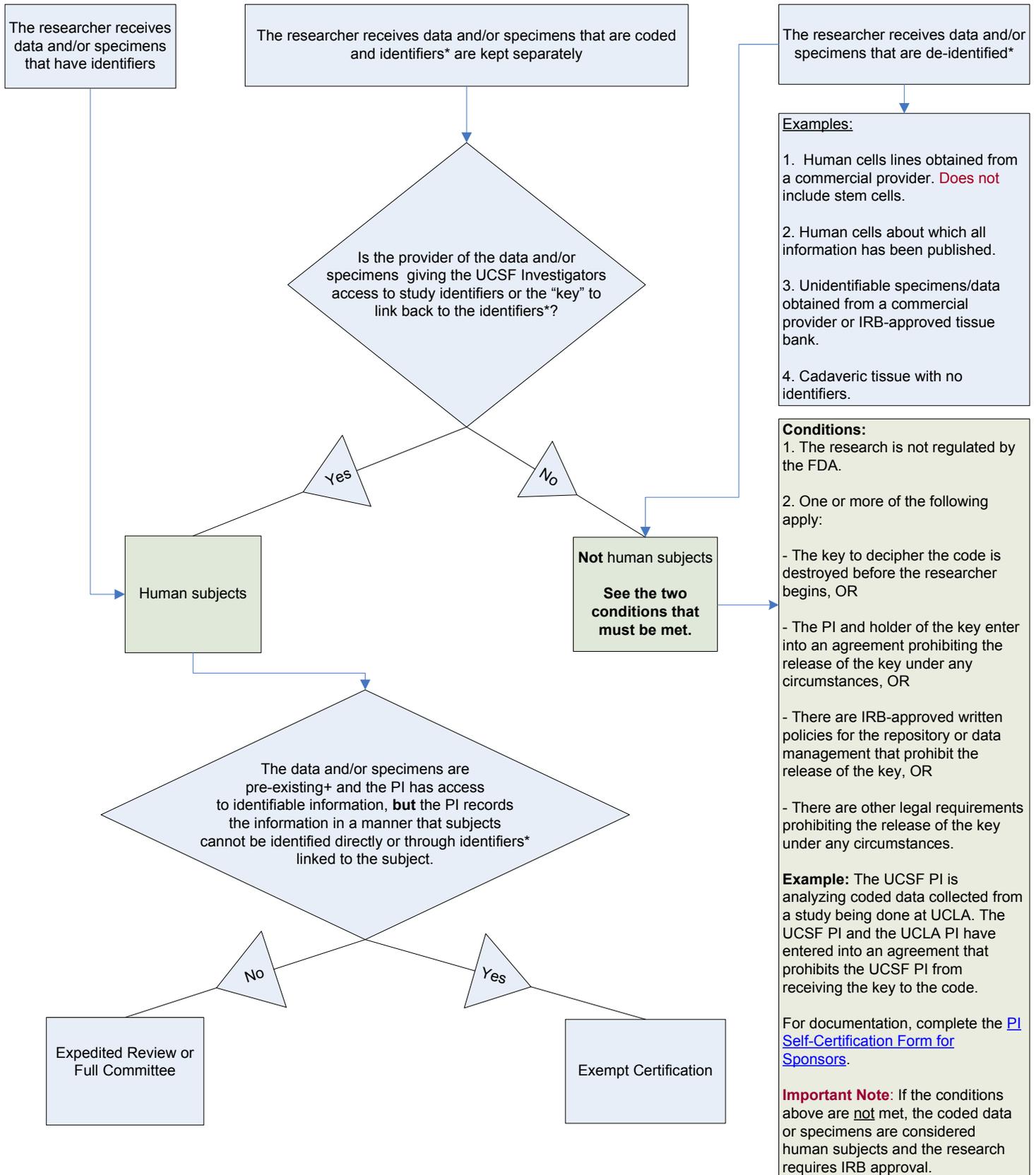


Determining Whether Human Subjects are Involved in Research When Obtaining[§] Private Information (data) and/or Biological Specimens – January 2011

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.



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.