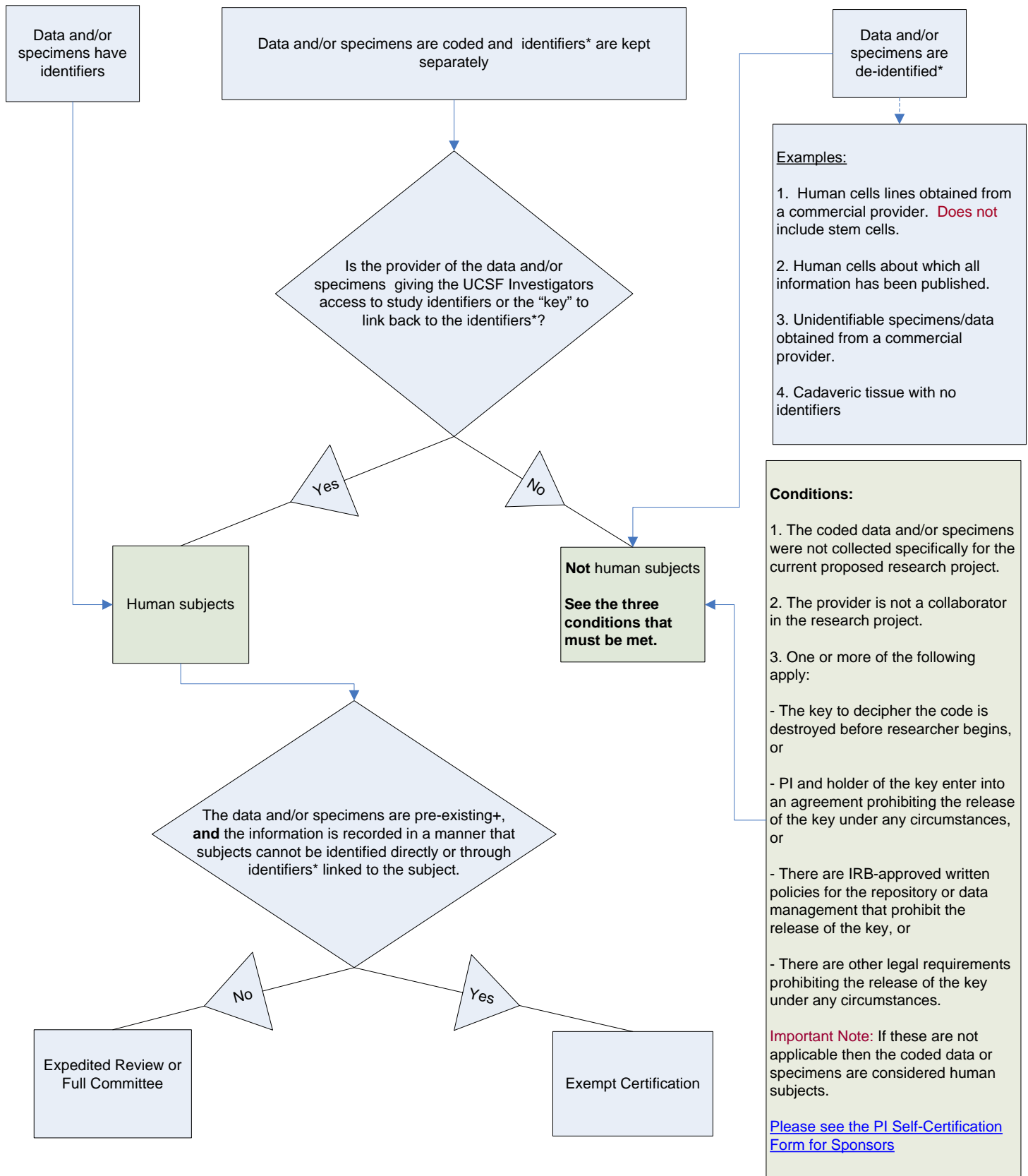


Determining Whether Human Subjects are Involved in Research When Obtaining[§]
Private Information (data) and/or Biological Specimens – July 11, 2009

CAUTION: This diagram does not apply to 1) initial collection of tissue, 2) [human stem cell research](#), 3) FDA regulated research, and 4) research involving prisoners. All of these must be reviewed by Full Committee or Expedited 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.