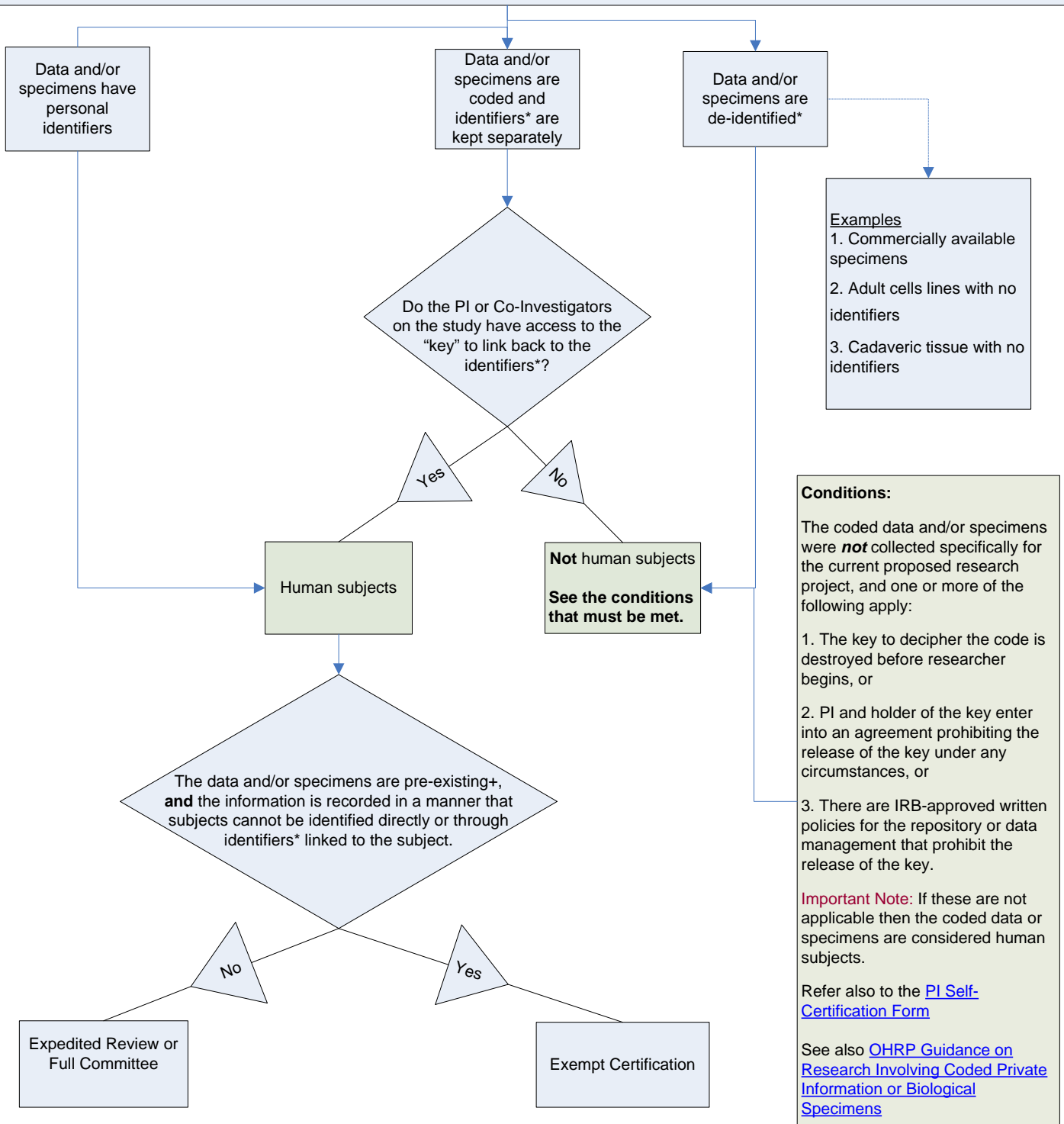


Determining Whether Human Subjects are Involved in Research When Obtaining[§] Private Information and/or Human Biological Specimens – 4/23/09

CAUTION: This diagram does not apply to 1) prospective collection of human tissue that involves human subject contact, 2) FDA-regulated research, and 3) research involving prisoners. All of these must be reviewed either 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 \(PHI\)](#). **IMPORTANT EXCEPTION:** 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. See page 2 of the Self Certification for Determining Whether Human Subjects Are Involved in Research for additional information about identifiers.

+ **Pre-existing** - means 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.