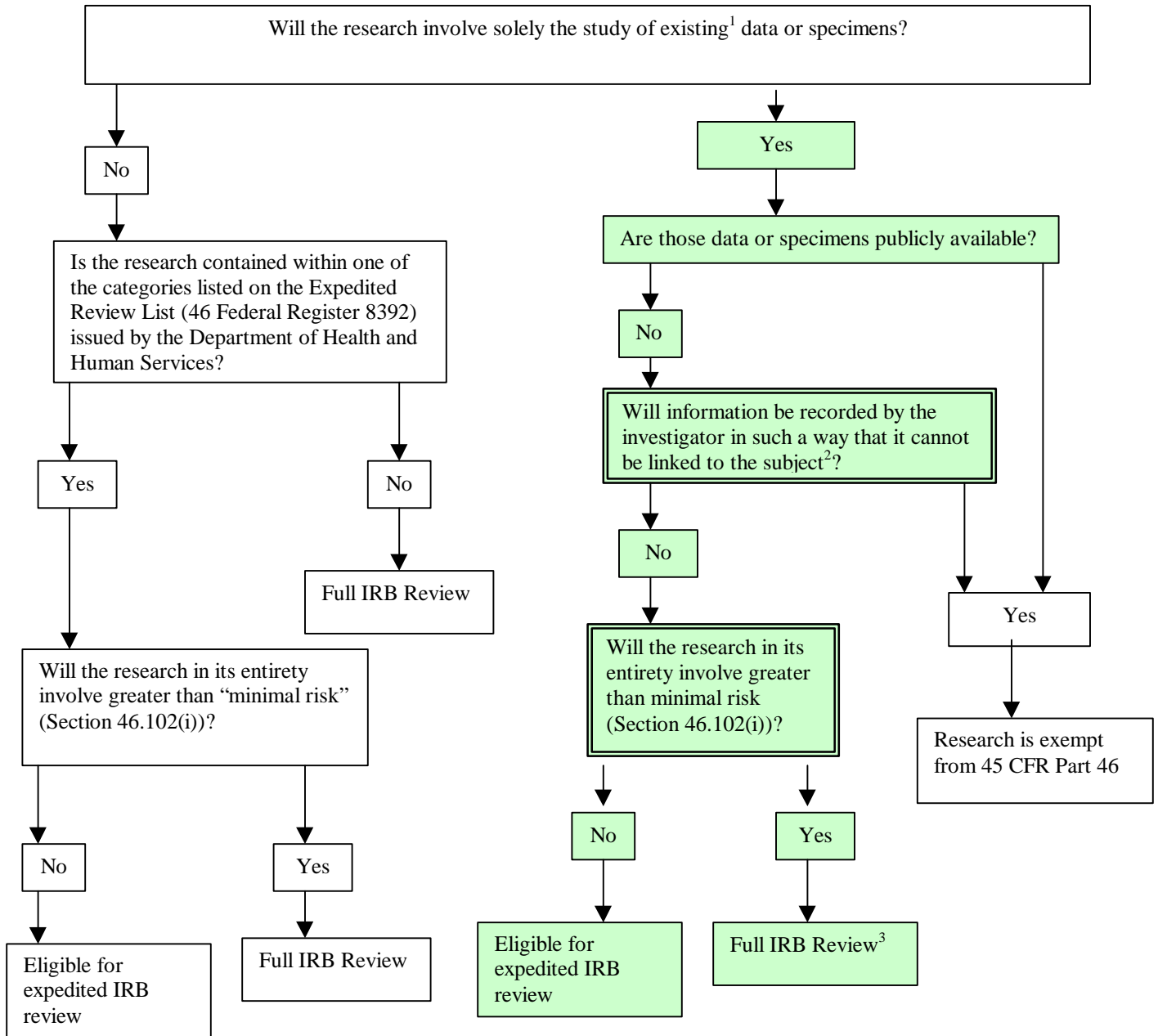


Table x: IRB Review for Research with Human Biological Materials
 Guidelines for applying human subjects regulations at 45 CFR Part 46



- Application of the regulations to a sample protocol involving the use of **existing coded samples**.
- Question which may benefit from interpretive guidance.

¹ “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 in research and nonresearch activities.

² This question is relevant to determine both (1) Is the definition of “human subject” at Section 46.102 (f) met in this research activity?, and (2) Is the research exempt in accordance with Section 46.101 (b)(4)?

³ The research is eligible for expedited IRB review if the subject of review involves exclusively minor changes in previously approved research during the period (of one year or less) for which approval is authorized.