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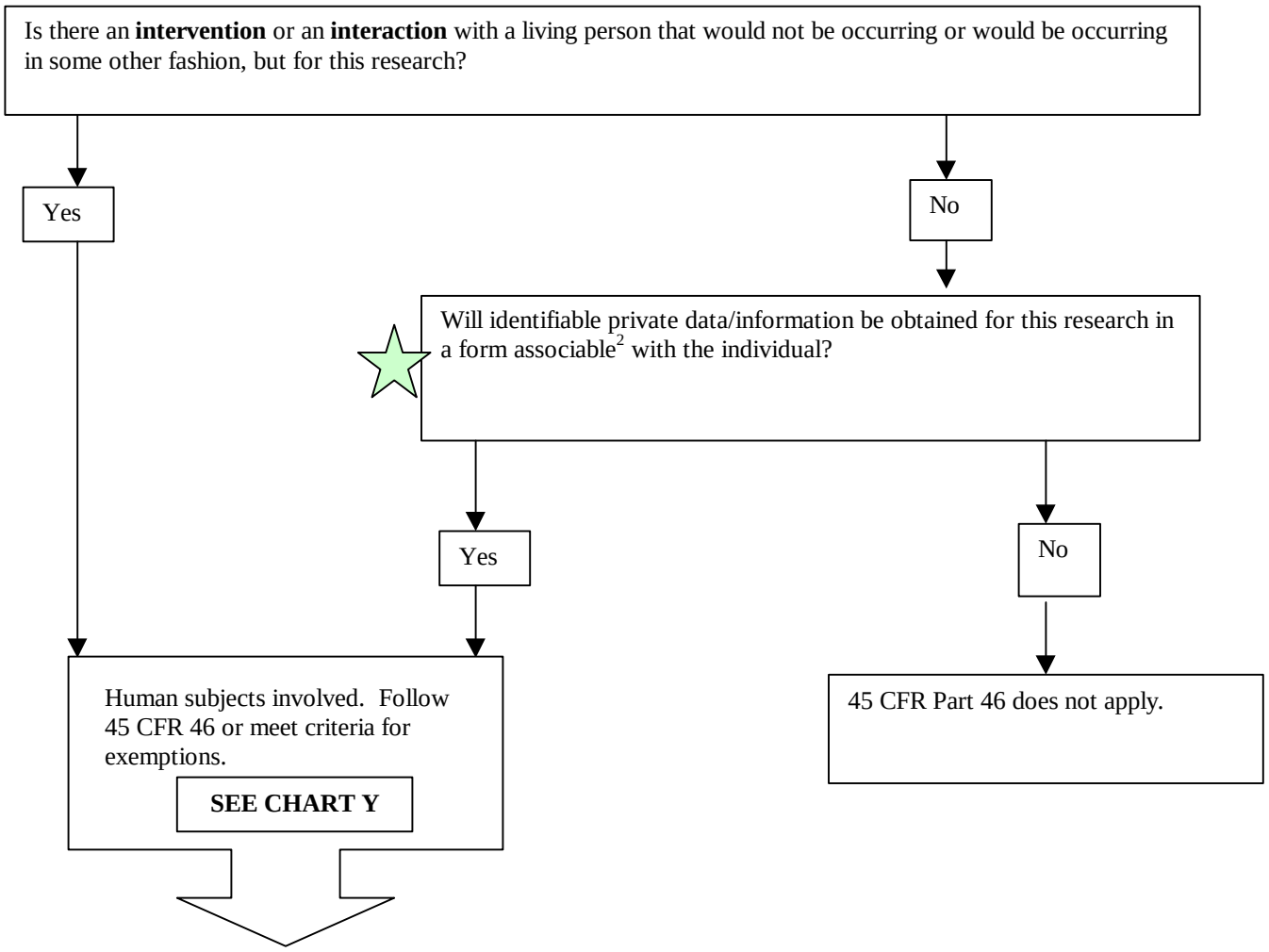
Chart 2: **Human Subject, Defined**[1]

Is the definition of "human subject" at Section 46.102 (f) met in this research activity?



☆ NBAC's guidance may be useful in interpreting this question.

1 Office for Protection from Research Risks, April, 1996.
2 That is, the identity of the subject is or may readily be ascertained or associated with the information.

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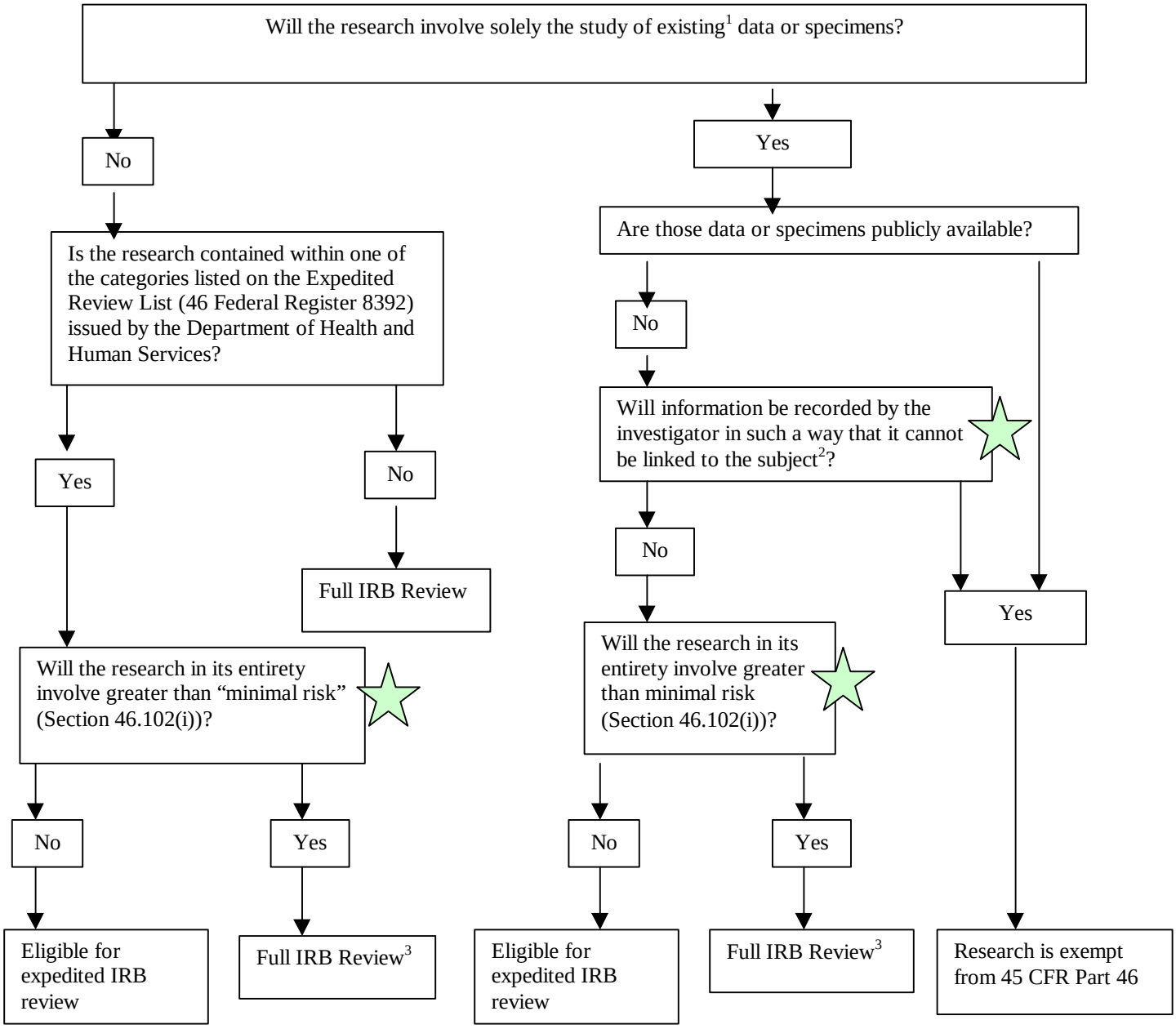
Chart 3: **IRB Review for Research with Human Biological Materials**
Guidelines for applying the exemption stated at 45 CFR 46.101(b)(4), and criteria for expedited review at §46.110.



☆ NBAC's guidance may be useful in interpreting this question.

[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] Research is also 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.

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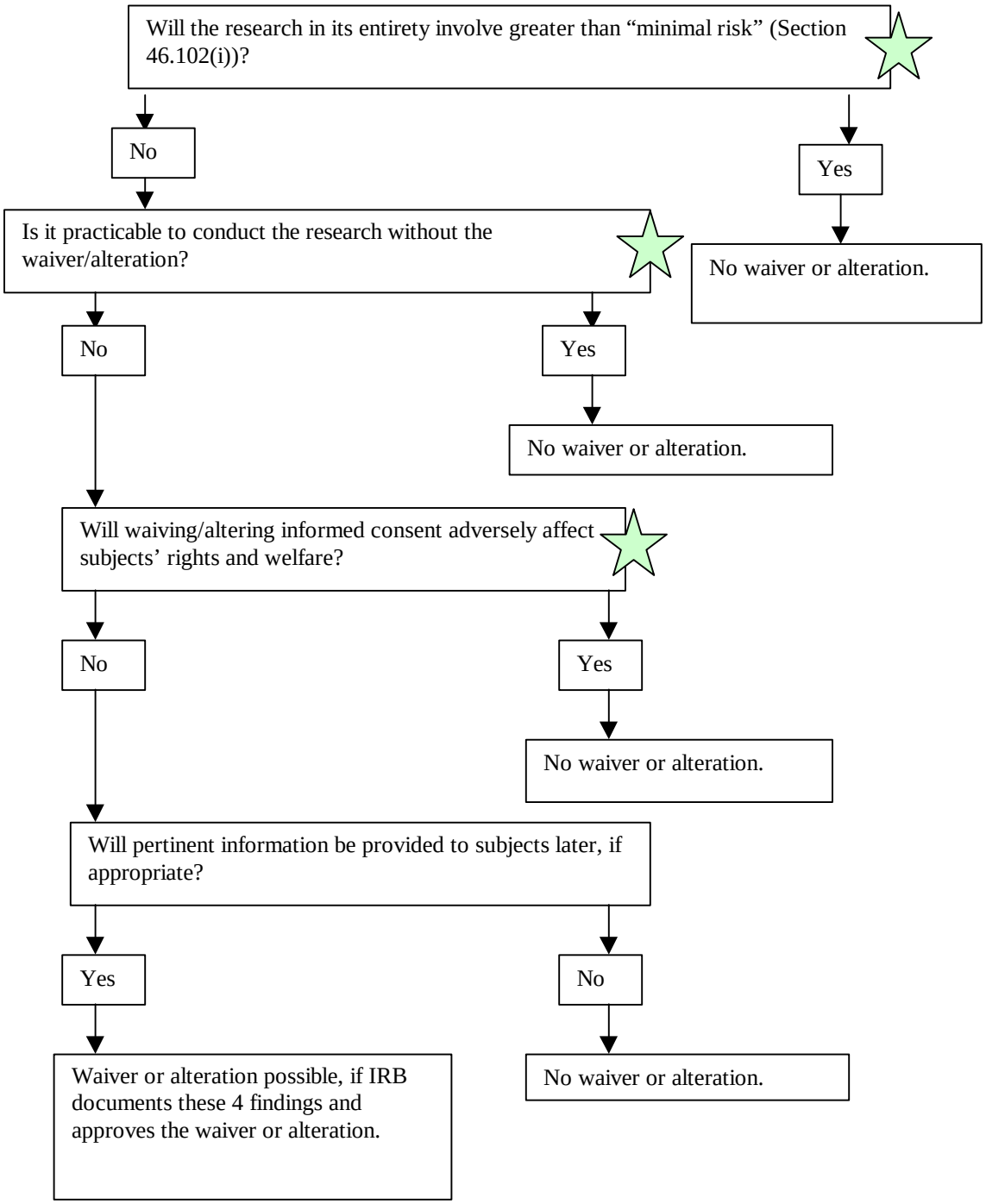
Chart 4: **Informed Consent Requirements for Research with Human Biological Materials**[1]

Can the Institutional Review Board employ §46.116(d) to waive informed consent or alter informed consent elements?



☆ NBAC's guidance may be useful in interpreting this question.

[1] Office for Protection from Research Risks, April, 1996.