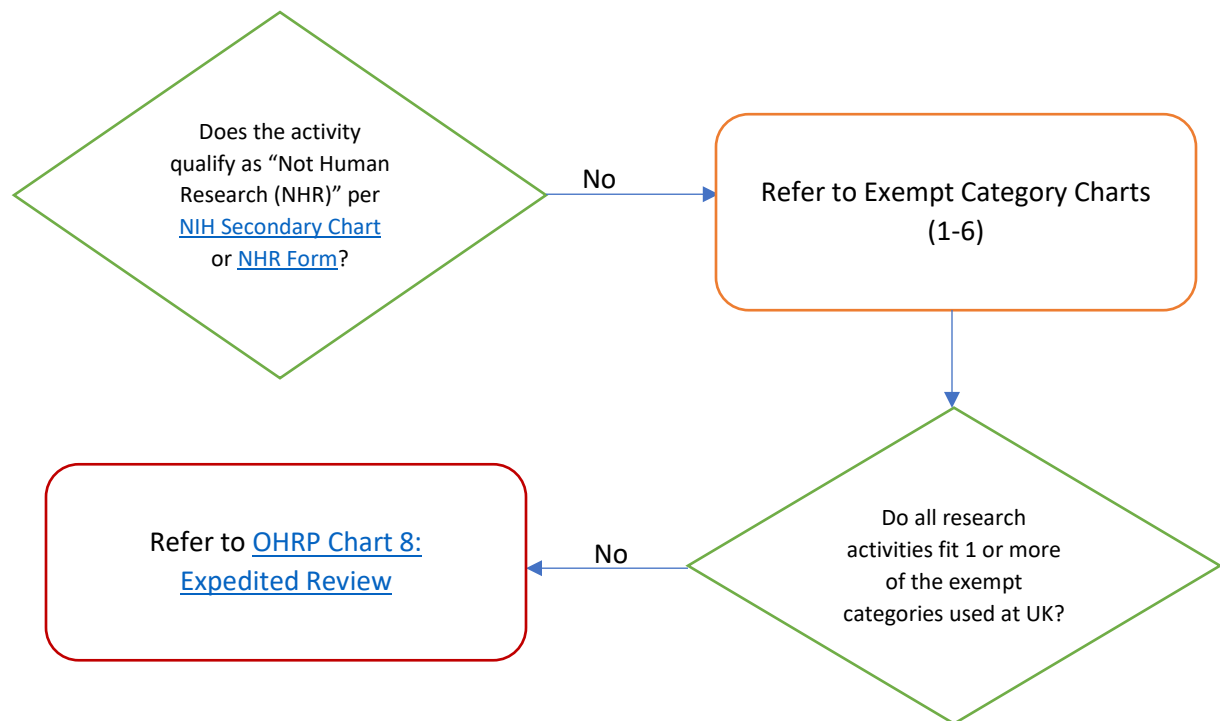


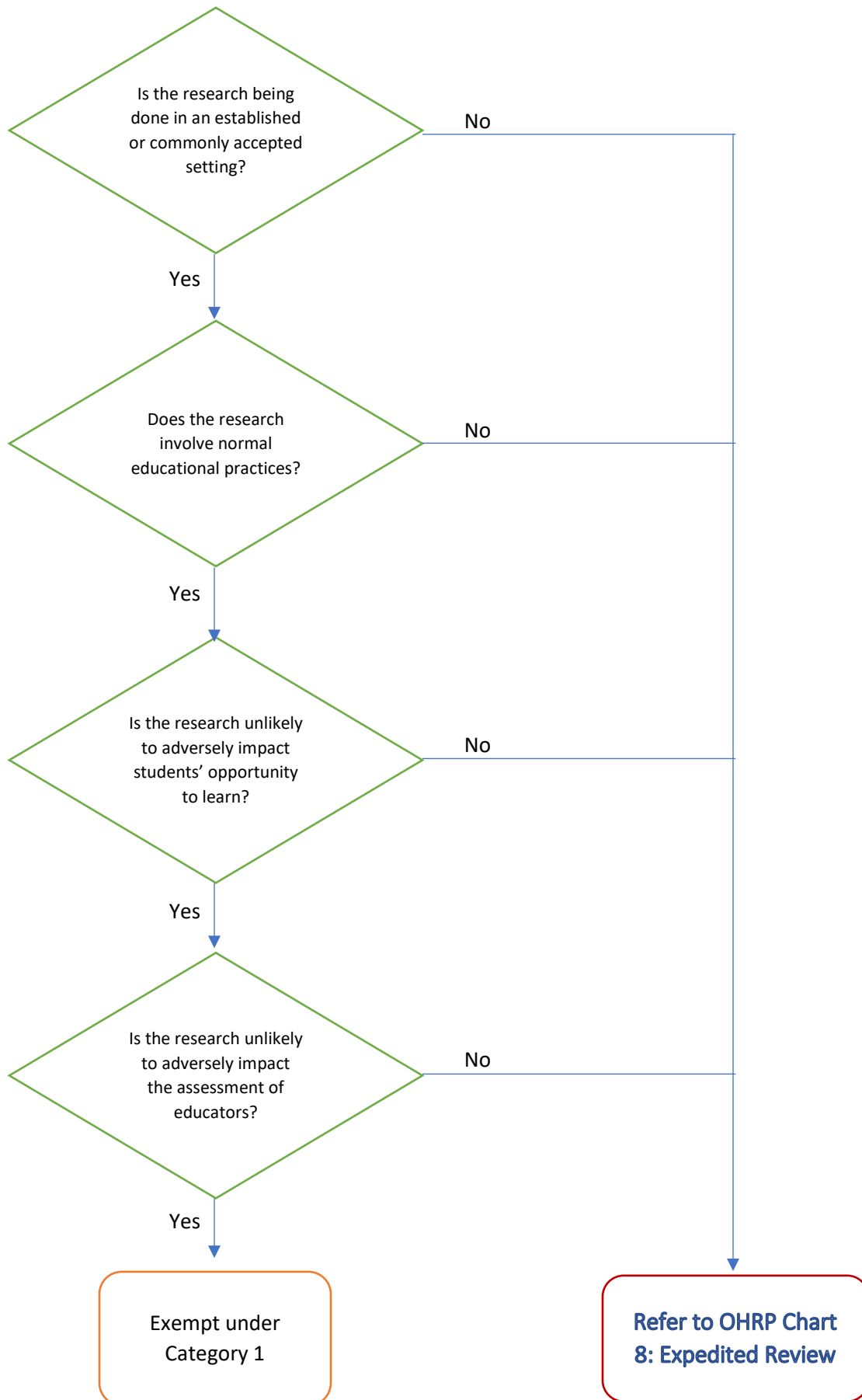
University of Kentucky Office of Research Integrity (ORI) Exemption Decision Charts

1. Some activities that do not meet the regulatory definitions of research and/or human subjects may not require IRB review. See [ORI Guidance](#) and/or submit a [Not Human Research \(NHR\) determination form](#) for an official ruling on whether an activity is human subject research requiring IRB review.
2. Researchers may not make a self-determination that their research qualifies for Exempt review. See the following Exempt Category Charts, refer to the ORI [Exempt Tool](#), and/or contact the [UK Office of Research Integrity \(ORI\)](#).
3. In order for the research to be eligible for exemption, the only involvement of human participants in the research must fall into one or more of the exemption categories.



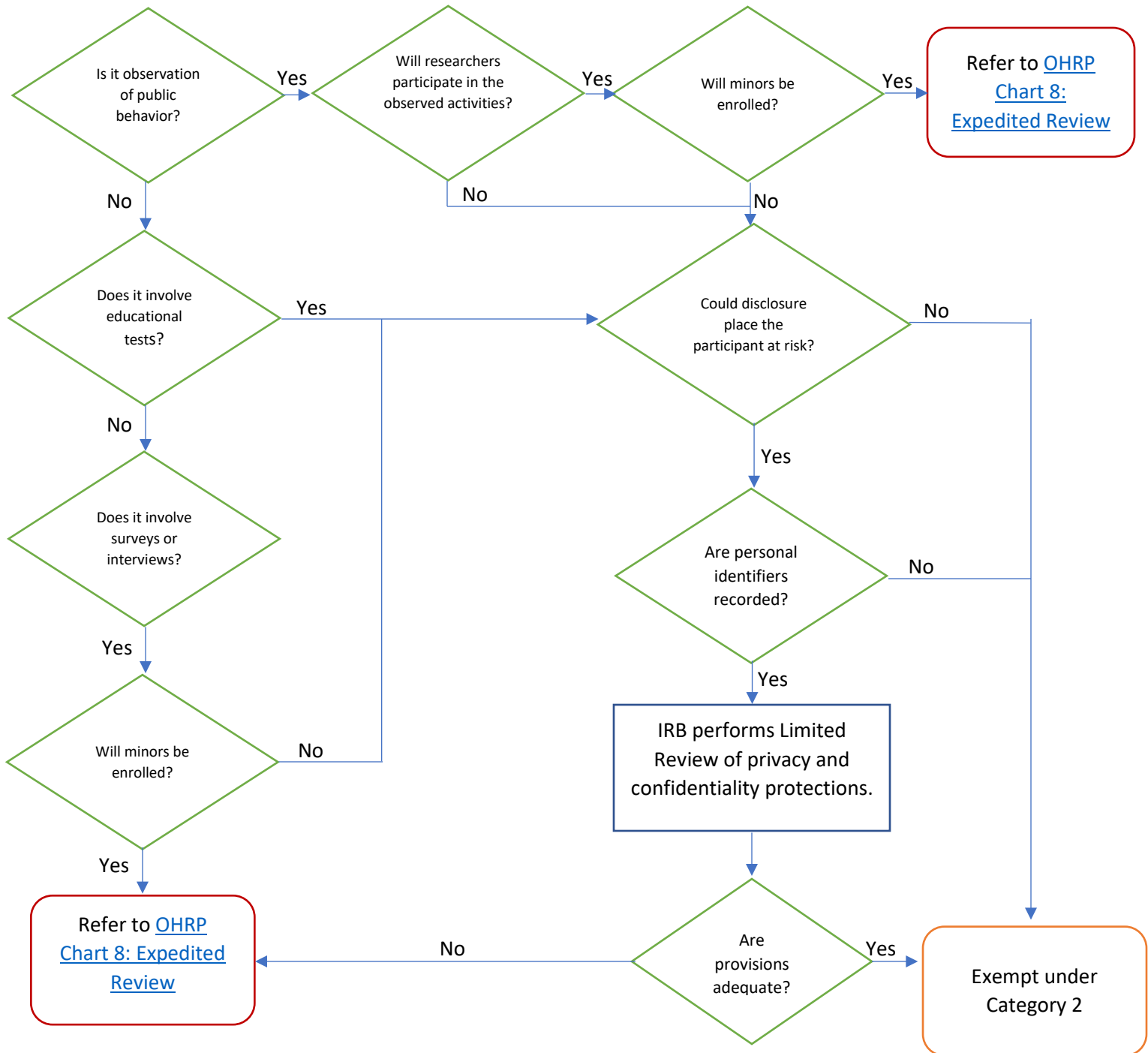
- Subpart B: Studies Involving Pregnant Women, Fetuses & Neonates are Eligible for Exempt Under All 8 Categories
- Subpart C: Exemptions Do Not Apply to Research Involving Prisoners Except "for Research Aimed at Involving a Broader Subject Population that Only Incidentally Includes Prisoners"
- Subpart D: Children are allowed in categories 1,4,5,6,7, & 8; Limitations & Exclusion of Children in Category 2 & 3

Exempt Category 1: Commonly Accepted Education Setting and Practices



ORI Exemption Decision Charts

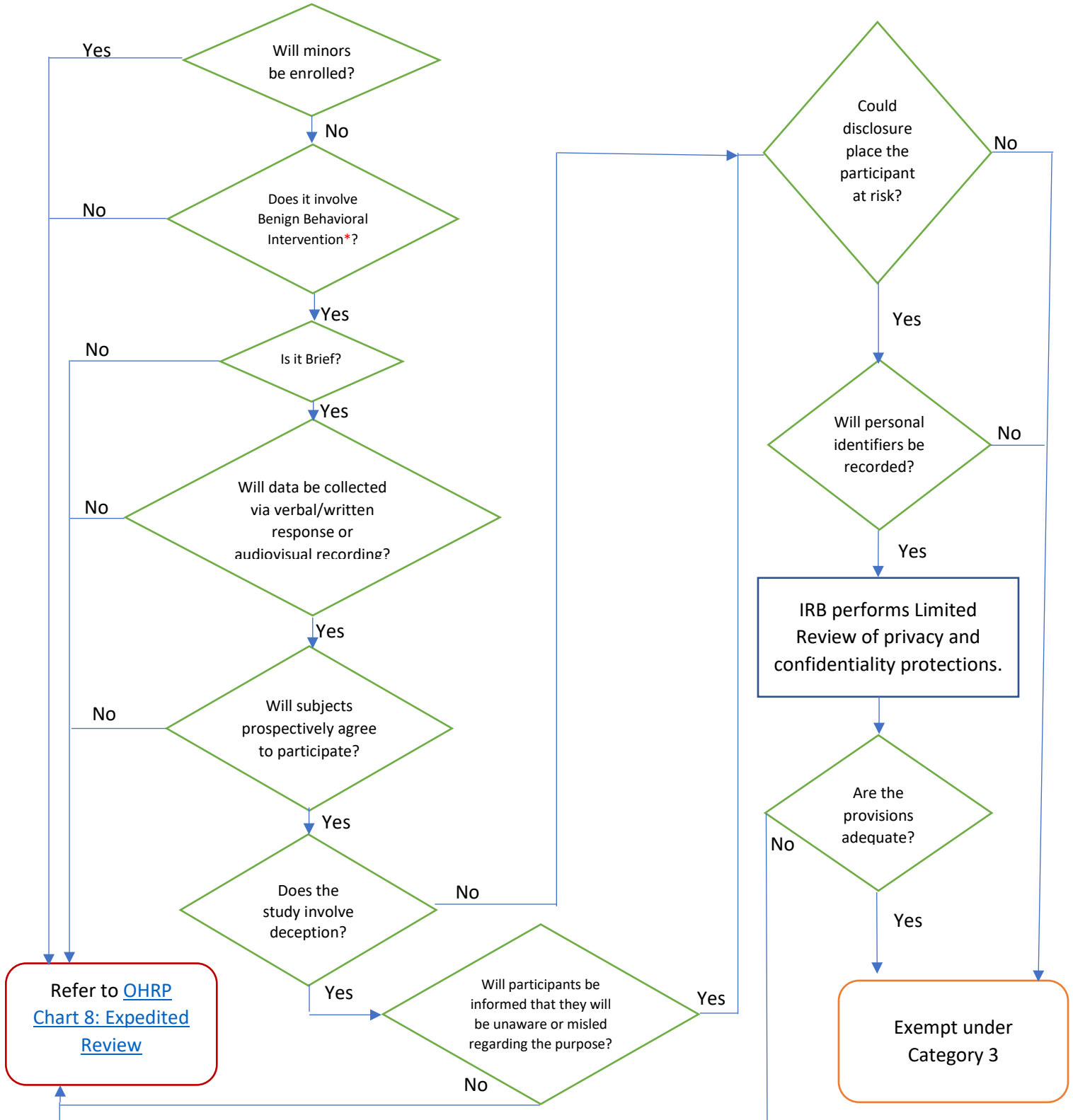
Exempt Category 2: Surveys, tests, interviews, observations.



ORI Exemption Decision Charts

1. ***Benign Behavioral Interventions** are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.
2. This exemption allows for the intervention to be distinct from the data collection method.

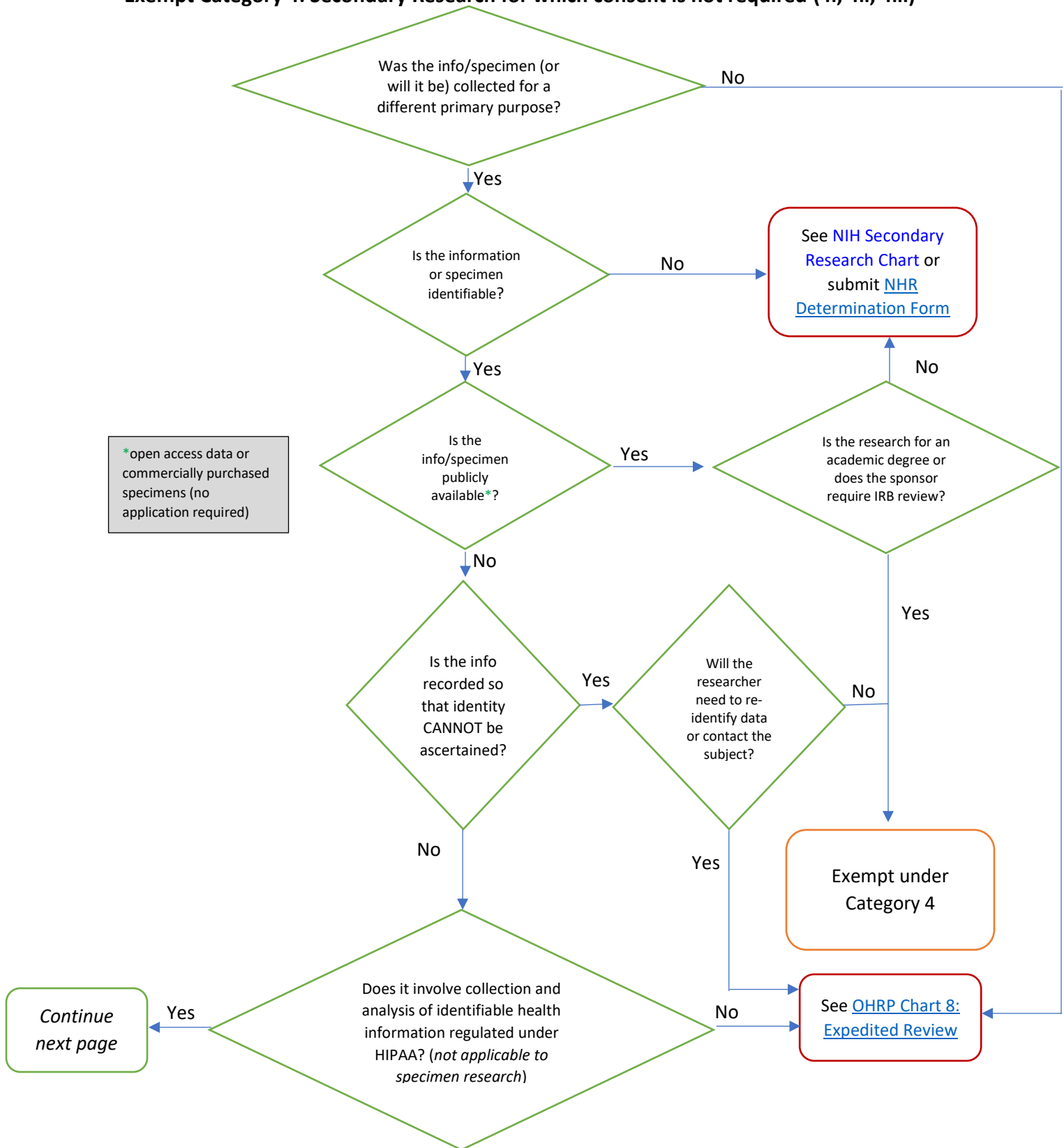
Exempt Category 3: Benign Behavioral Intervention (BBI)

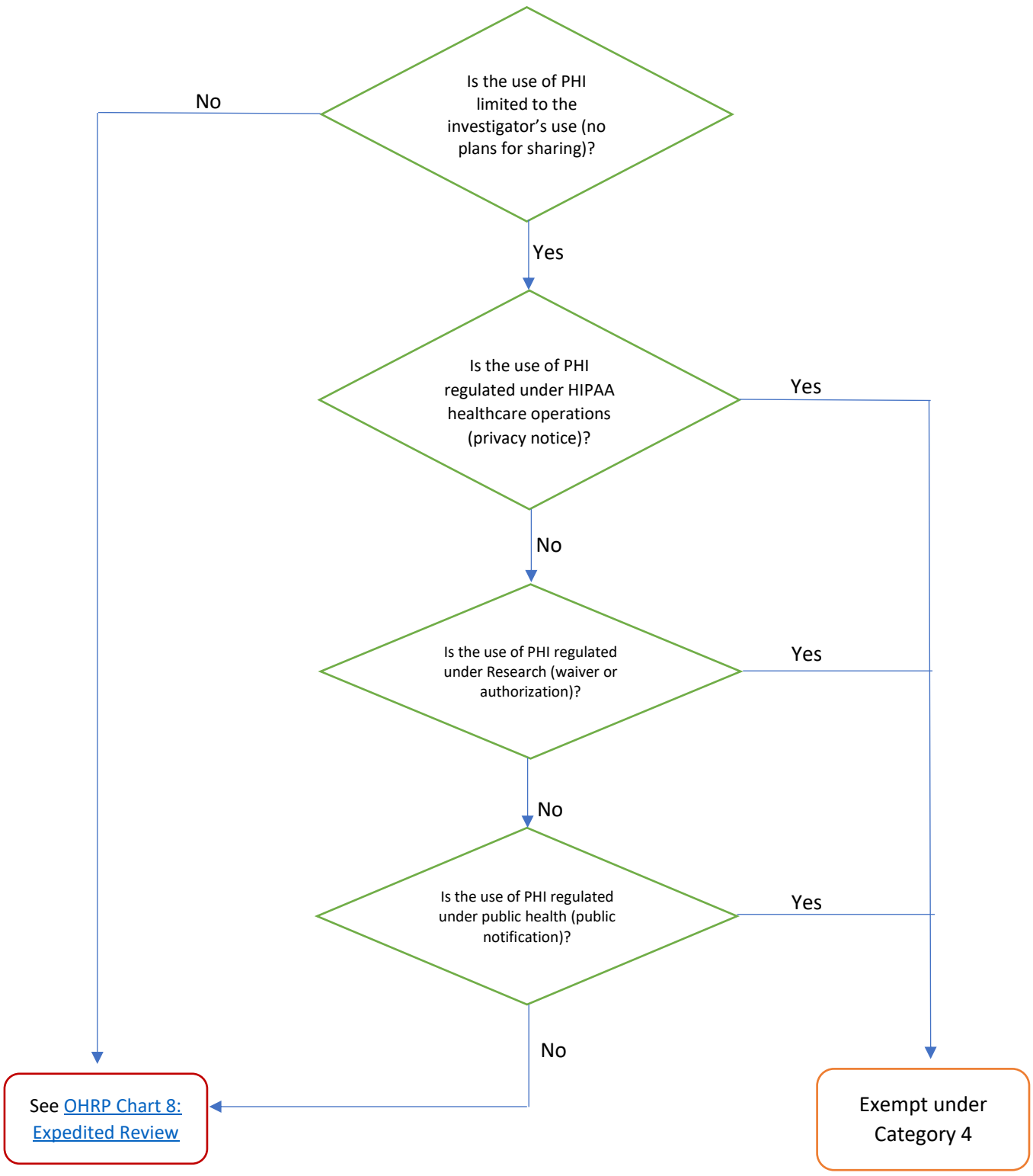


ORI Exemption Decision Charts

1. Some activities may not meet the regulatory definitions of research and/or human subjects. See the [Guide for Determining When Protocols Involving Coded Private Information or Biological Specimens Meet the Federal Definition of "Human Research"](#). Submit the [Not Human Research \(NHR\) determination form](#) for an official ruling on whether your activity is human subject research requiring IRB review.
2. Secondary Research - this exemption is referring to re-using identifiable information and identifiable biospecimens that are collected for some other "primary" or "initial" activity.

Exempt Category 4: Secondary Research for which consent is not required (4i, 4ii, 4iii)





No

Is the use of PHI limited to the investigator's use (no plans for sharing)?

Yes

Is the use of PHI regulated under HIPAA healthcare operations (privacy notice)?

Yes

No

Is the use of PHI regulated under Research (waiver or authorization)?

Yes

No

Is the use of PHI regulated under public health (public notification)?

Yes

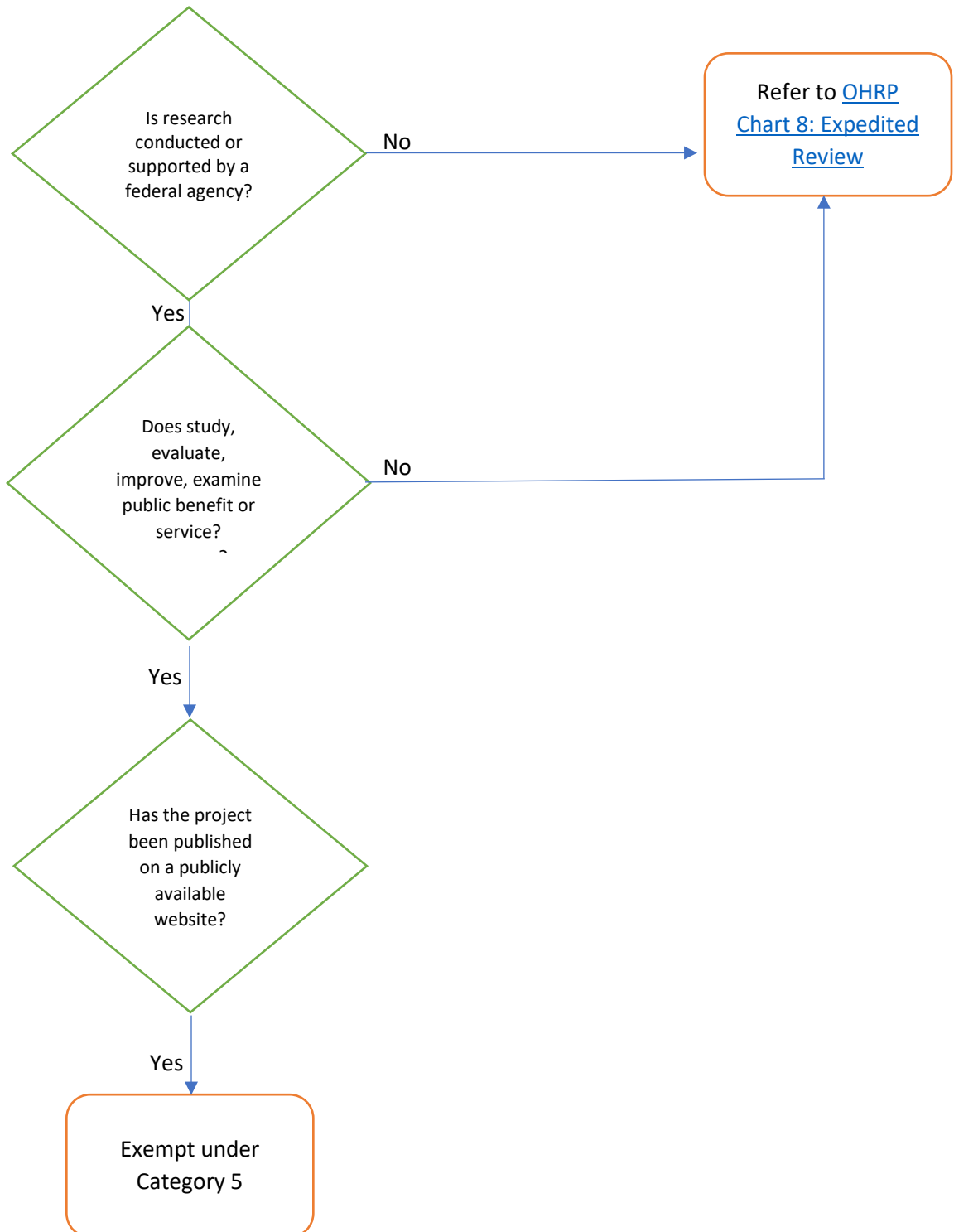
No

See [OHRP Chart 8: Expedited Review](#)

Exempt under Category 4

ORI Exemption Decision Charts

Exempt Category 5: Federal Agency Supported Research and Demonstration Projects



ORI Exemption Decision Charts

Exempt Category 6: Food and Taste Evaluation

