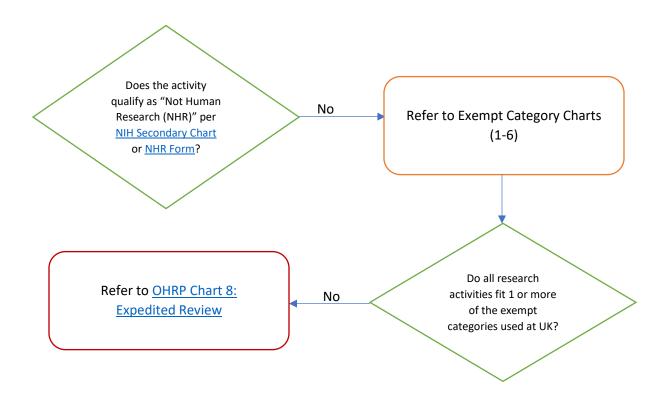
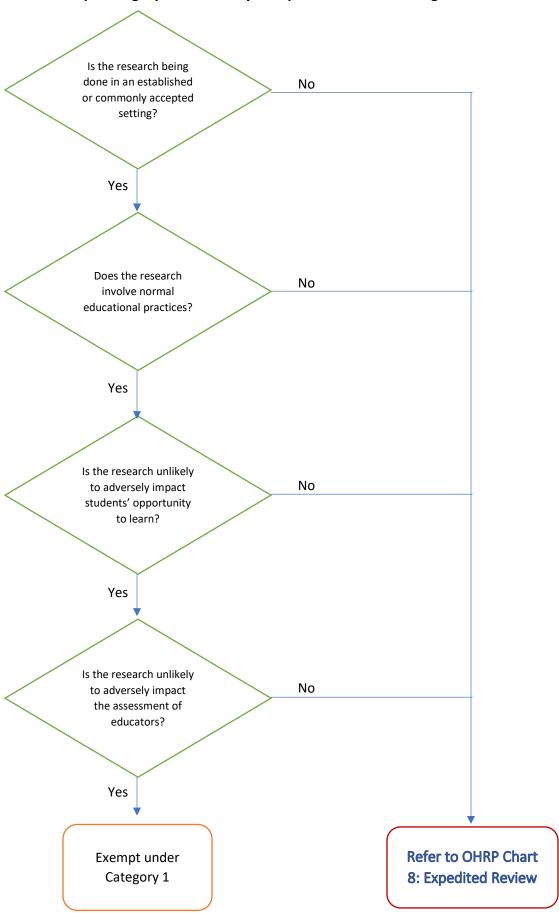
#### University of Kentucky Office of Research Integrity (ORI) Exemption Decision Charts

- 1. Some activities that do not meet the regulatory definitions of research and/or human subjects may not require IRB review. See <u>ORI Guidance</u> and/or submit a <u>Not Human Research (NHR) determination form</u> 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.

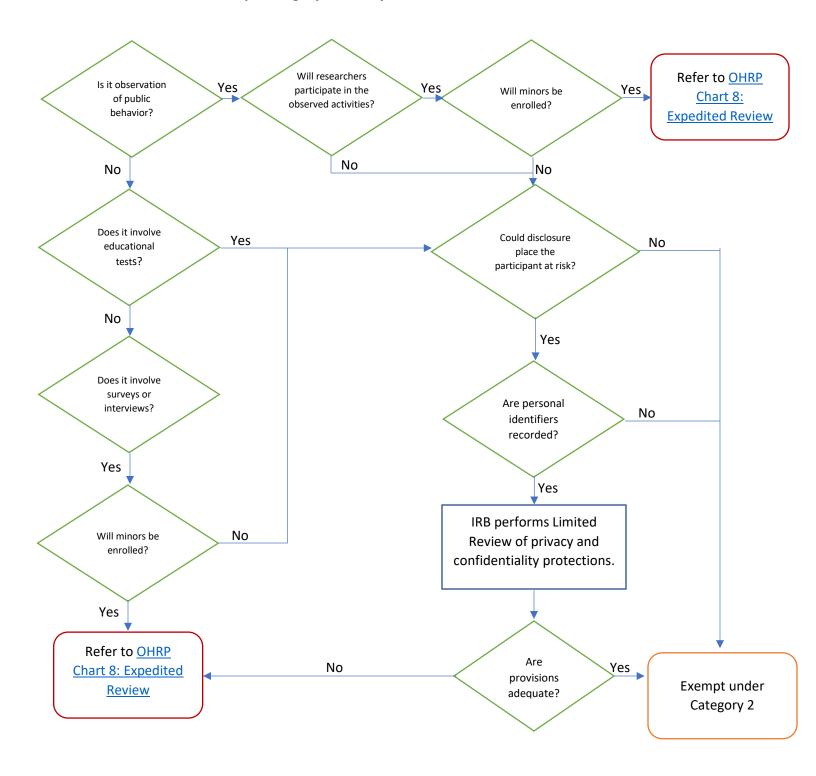


- Subpart B: Studies Involving Pregnant Women, Fetuses & Neonates are Eligible for Exempt Under All 8 Categories
- Subpart C: Exemptions Do Not Apply to Research Involving Prisoners Except "for Research Aimed at Involving a Broader Subject Population that Only Incidentally Includes Prisoners"
- Subpart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

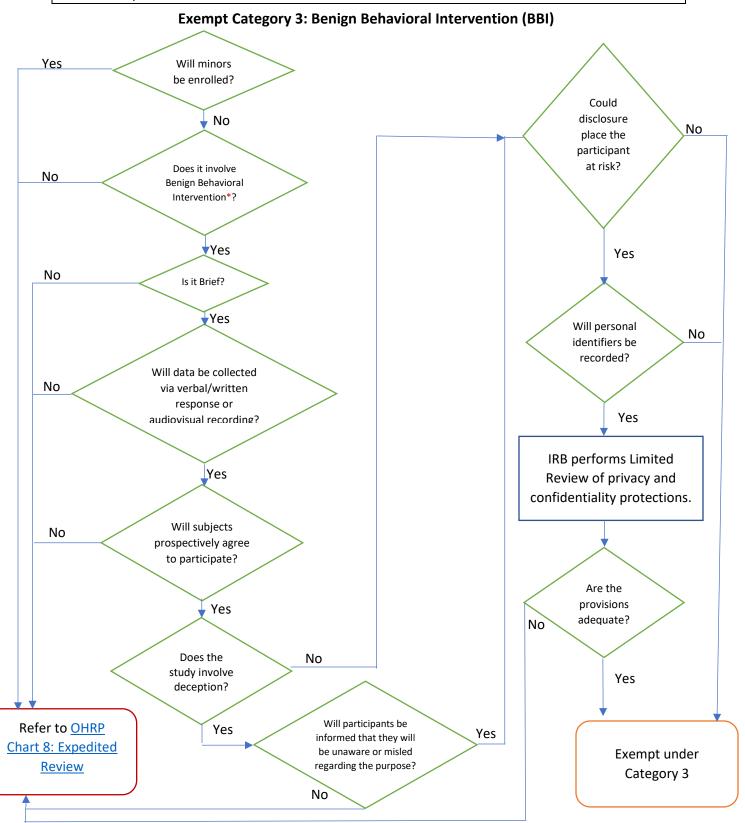
## **Exempt Category 1: Commonly Accepted Education Setting and Practices**



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

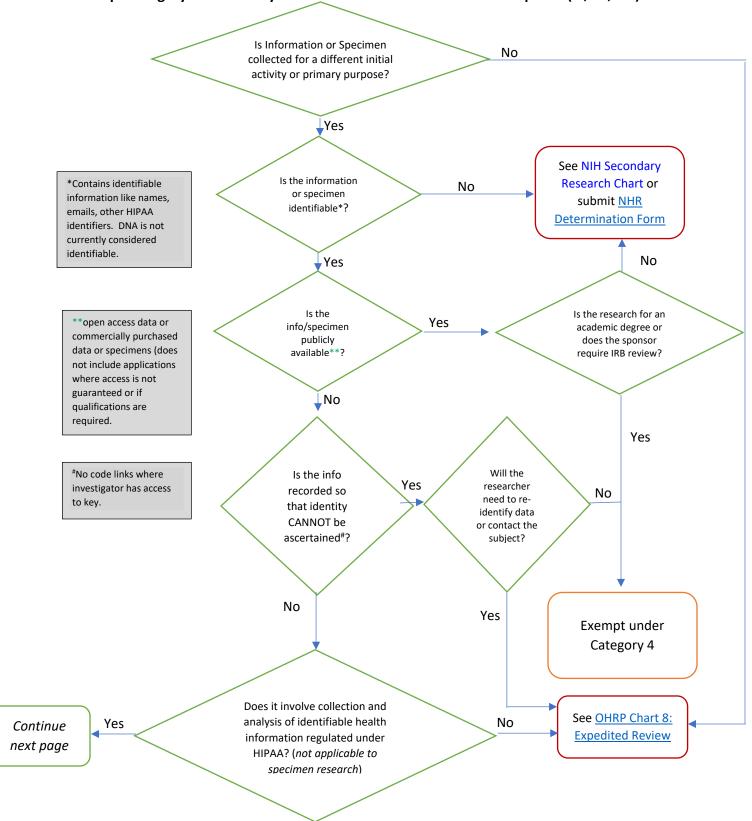


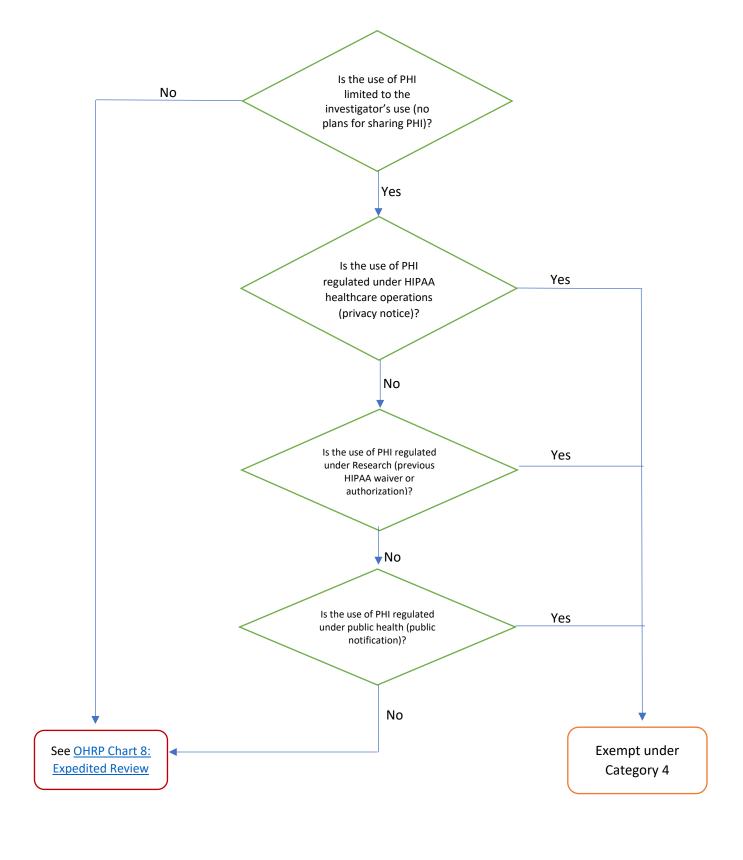
- \*Benign Behavioral Interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.
- 2. This exemption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



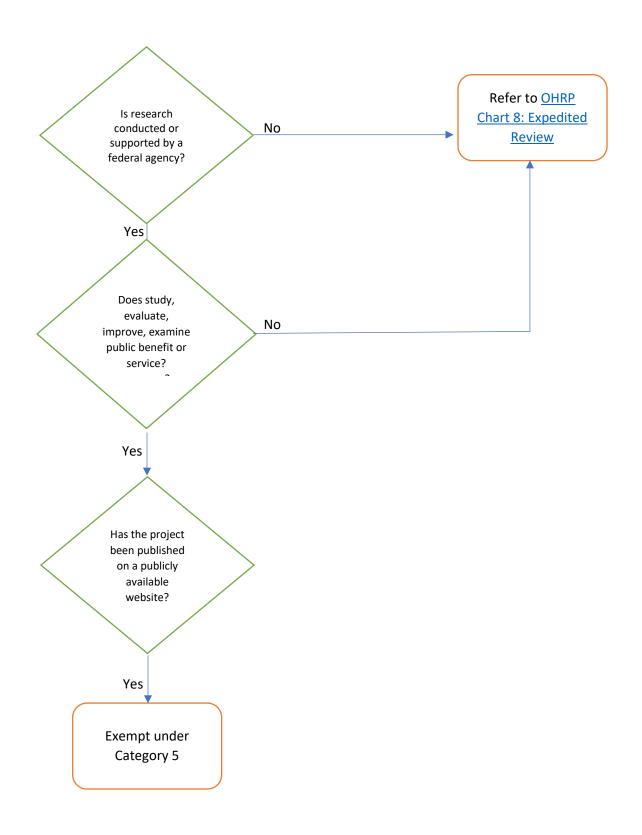
- Some activities may not meet the regulatory definitions of research and/or human subjects.
  See the <u>Guide for Determining When Protocols Involving Coded Private Information or Biological Specimens Meet the Federal Definition of "Human Research"</u>
  - Submit the <u>Not Human Research (NHR) determination form</u> 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)





# **Exempt Category 5: Federal Agency Supported Research and Demonstration Projects**



## **Exempt Category 6: Food and Taste Evaluation**

