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

2020: UK ORI Exempt Decision Charts are based solely on current interpretation of the revised Common Rule regulation (absent federal guidance or review). Select charts adapted with permission from Cornell University IRB. Contact belinda.smith@uky.edu with questions.
Exempt Category 1: Commonly Accepted Education Setting and Practices

Is the research being done in an established or commonly accepted setting? No → Yes

Does the research involve normal educational practices? No → Yes

Is the research unlikely to adversely impact students' opportunity to learn? No → Yes

Is the research unlikely to adversely impact the assessment of educators? No → Exempt under Category 1

Refer to OHRP Chart 8: Expedited Review
Exempt Category 2: Surveys, tests, interviews, observations.

- Is it observation of public behavior? Yes → Refer to OHRP Chart 8: Expedited Review
  No →

- Does it involve educational tests? Yes → Refer to OHRP Chart 8: Expedited Review
  No →

- Does it involve surveys or interviews? Yes → IRB performs Limited Review of privacy and confidentiality protections.
  No →

- Will researchers participate in the observed activities? Yes → Will minors be enrolled? Yes → Refer to OHRP Chart 8: Expedited Review
  No →

- Could disclosure place the participant at risk? Yes → Are personal identifiers recorded? Yes → Exempt under Category 2
  No →

- Are provisions adequate? Yes → Exempt under Category 2
  No →
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)**
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)

- Was the info/specimen (or will it be) collected for a different primary purpose?
  - Yes
    - Is the information or specimen identifiable?
      - Yes
        - Is the info/specimen publicly available*?
          - No
            - See NIH Secondary Research Chart or submit NHR Determination Form
          - Yes
            - Is the research for an academic degree or does the sponsor require IRB review?
              - No
                - See OHRP Chart 8: Expedited Review
              - Yes
                - Exempt under Category 4
        - No
          - Will the researcher need to re-identify data or contact the subject?
            - Yes
              - Exempt under Category 4
            - No
              - Doesn't involve collection and analysis of identifiable health information regulated under HIPAA? (not applicable to specimen research)
                - Yes
                  - See OHRP Chart 8: Expedited Review
                - No
                  - Continue next page

*open access data or commercially purchased specimens (no application required)
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)?

No

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

No

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

Yes

Exempt under Category 4

See OHRP Chart 8: Expedited Review
ORI Exemption Decision Charts

Exempt Category 5: Federal Agency Supported Research and Demonstration Projects

Is research conducted or supported by a federal agency?

- Yes
  - Does study, evaluate, improve, examine public benefit or service?
    - Yes
      - Has the project been published on a publicly available website?
        - Yes
          - Exempt under Category 5
        - No
    - No
  - No

Refer to OHRP Chart 8: Expedited Review
ORI Exemption Decision Charts

Exempt Category 6: Food and Taste Evaluation

- Does it involve taste or food quality evaluation?
  - No: Refer to OHRP Chart 8: Expedited Review
  - Yes:
    - Are foods consumed wholesome without additives?
      - No: Is level of additives consumed considered safe by FDA, EPA, or
        - Yes: Exempt under Category 6
      - Yes: Refer to OHRP Chart 8: Expedited Review