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

Does the activity qualify as “Not Human Research (NHR)” per NIH Secondary Chart or NHR Form?

No

Refer to Exempt Category Charts (1-6)

No

Do all research activities fit 1 or more of the exempt categories used at UK?

Refer to OHRP Chart 8: Expedited Review
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

Yes

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: Will researchers participate in the observed activities? 
    - Yes: Will minors be enrolled? 
      - Yes: Refer to OHRP Chart 8: Expedited Review 
      - No: Exempt under Category 2 
    - No: Does it involve educational tests? 
      - Yes: Could disclosure place the participant at risk? 
        - Yes: Are personal identifiers recorded? 
          - No: Exempt under Category 2 
        - No: Does it involve surveys or interviews? 
          - Yes: Will minors be enrolled? 
            - Yes: Refer to OHRP Chart 8: Expedited Review 
            - No: Exempt under Category 2 
          - No: Does it involve surveys or interviews? 
            - Yes: Will minors be enrolled? 
              - Yes: Refer to OHRP Chart 8: Expedited Review 
              - No: Exempt under Category 2 
            - No: Does it involve surveys or interviews? 
              - Yes: Will minors be enrolled? 
                - Yes: Refer to OHRP Chart 8: Expedited Review 
                - No: Exempt under Category 2 
              - No: Exempt under Category 2
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)

Will minors be enrolled?

No

Could disclosure place the participant at risk?

Yes

Will personal identifiers be recorded?

No

IRB performs Limited Review of privacy and confidentiality protections.

Are the provisions adequate?

No

Does the study involve deception?

No

Will participants be informed that they will be unaware or misled regarding the purpose?

No

Exempt under Category 3

Refer to OHRP Chart 8: Expedited Review
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

- Was the info/specimen (or will it be) collected for a different primary purpose?
  - Yes
    - Is the information or specimen identifiable?
      - No
        - Will the researcher need to re-identify data or contact the subject?
          - Yes
            - Exempt under Category 4
          - No
            - See OHRP Chart 8: Expedited Review
        - Yes
          - Is the research for an academic degree or does the sponsor require IRB review?
            - No
              - See NIH Secondary Research Chart or submit NHR Determination Form
            - Yes
              - Is the information or specimen publicly available?*
                - Yes
                  - Does it involve use of Protected Health Information (PHI) regulated by HIPAA or a federal agency research?
                    - No
                      - See OHRP Chart 8: Expedited Review
                    - Yes
                      - Exempt under Category 4
                - No
                  - See OHRP Chart 8: Expedited Review
  - No
    - Is the info/specimen publicly available?*
      - Yes
        - Does it involve use of Protected Health Information (PHI) regulated by HIPAA or a federal agency research?
          - No
            - See OHRP Chart 8: Expedited Review
          - Yes
            - Exempt under Category 4
        - No
          - See OHRP Chart 8: Expedited Review

*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)?

Yes

See OHRP Chart 8: Expedited Review

No

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

Yes

Exempt under Category 4

No

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

Yes

No

Is the research being done by/on behalf of federal government?

Yes

Will the information be maintained in compliance with federal privacy laws?

Yes

No

See OHRP Chart 8: Expedited Review
Exempt Category 5: Federal Agency Supported Research and Demonstration Projects

1. Is research conducted or supported by a federal agency?
   - Yes
   - No
     - Refer to OHRP Chart 8: Expedited Review

2. Does study, evaluate, improve, examine public benefit or service?
   - Yes
   - No

3. Has the project been published on a publicly available website?
   - Yes
   - No

Exempt under Category 5
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?

Yes

Exempt under Category 6

No

Is level of additives consumed considered safe by FDA, EPA, or

Yes

No