Exemption Decision Charts For General Guidance

Is Your Human Participant Research Eligible for Exemption?

START: You are conducting human participant research

Participant population includes prisoners?

No

Prisoners your study population?

Yes -> Not eligible for exemption

No, but some prisoners might get included

Collecting data or biomaterials for research via interaction or intervention?

No -> Go to Category 1

Yes -> Go to Category 4

ONLY using identifiable data or biospecimens from living individuals for secondary research?

No

Storing, maintaining or using previously collected identifiable data or biospecimens for research?

No -> Possibly not human subjects research. Contact irbhp@cornell.edu

Yes -> Go to Categories 7 & 8

Yes -> Go to Category 4

NOTE:
1. Researchers may not make a self-determination of exemption from IRB review. All research with human subjects must be reviewed by the Cornell IRB office and either granted an Exemption or Approval before study procedures may begin.
2. 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.
3. Definitions and other resources are on the IRB website www.irb.cornell.edu
Educational practices: Does Exemption 1 apply? [45 CFR 46.104(d)(1)]

- Research involves collecting data or biomaterials
- Research conducted in normal educational settings?
  - Yes
  - Research examines normal education practices?
    - Yes
    - Participant population includes prisoners?
      - Yes
      - Are prisoners the study population?
        - Yes
        - No, but prisoners may get included
        - No
        - Research could adversely affect student learning?
          - Yes
          - Exempt under Category 1
          - No
        - Research could adversely affect assessment of instructors?
          - Yes
          - Exempt under Category 1
          - No
    - No
    - Research could adversely affect assessment of instructors?
      - Yes
      - Exempt under Category 1
      - No
- No
- Not exempt under Category 1. Could be Exempt under 2, 3, 5 or 6
Exemption Decision Charts For General Guidance

Surveys, tests, observations: Does Exemption 2 apply? [45 CFR 46.104(d)(2)]

Research involves collecting data (or biomaterials) but not Exempt under Category 1

Prisoners are not the intended population for the research

Observation of public behavior?

Yes

Researchers participate in the observed activities?

Yes

Minors enrolled in the study?

Yes

Not exempt under Category 2. Apply for regular IRB review

No

No

Involves educational Tests?

No

Involves survey or interview procedures?

Yes

Minors enrolled in the study?

Yes

Not exempt under Category 2. Apply for regular IRB review

No

No

Record personal identifiers?

Yes

Could disclosure reasonably place participants at risk?

Yes

Limited IRB review for adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

Yes

No

No

No

No

No

Are provisions adequate?

Yes

Exempt under Category 2

No
Exemption Decision Charts For General Guidance

Benign Interventions: Does Exemption 3 apply? [45 CFR 46.104(d)(2)]

- Collecting information, but research is not eligible for Category 1 or 2 exemption
- Study population includes prisoners?
  - Yes
    - Personal identifiers recorded?
      - Yes
        - IRB conducts a limited review to ensure there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data
      - No
        - Could disclosure of participants' responses reasonably place them at risk?
          - Yes
            - Exempt under Category 3
          - No
            - Are provisions adequate?
              - Yes
                - Exempt under Category 3
              - No

- No
  - Minors enrolled in the study?
    - Yes
      - Involves behavioral interventions?
        - Yes
          - Are the interventions benign?
            - Yes
              - Participants agree to the intervention in advance?
                - Yes
                  - Full purpose of the study disclosed at consent?
                    - Yes
                      - Exempt under Category 3
                    - No
                      - Not exempt under Category 3. Apply for regular IRB review
                - No
                  - Participants informed that they will be unaware of or misled regarding research purpose?
                    - Yes
                      - Not exempt under Category 3. Apply for regular IRB review
                    - No
    - No
      - Personal identifiers recorded?
        - Yes
          - Could disclosure of participants' responses reasonably place them at risk?
            - Yes
              - Exempt under Category 3
            - No
              - Are provisions adequate?
                - Yes
                  - Exempt under Category 3
                - No
                  - Not exempt under Category 3. Apply for regular IRB review
          - Not exempt under Category 3. Apply for regular IRB review
      - No
        - Not exempt under Category 3. Apply for regular IRB review

- No, but may be included
  - Not exempt under Category 3. Apply for regular IRB review

Cornell University Institutional Review Board
Secondary Research: Does Exemption 4 apply? [45 CFR 46.104(d)(4)]

Using IDENTIFIABLE, PRIVATE data or biospecimens for secondary research,*

Yes
   Data/ biospecimens originally collected for a different primary purpose?
   No
   Not Exempt under Category 4. Apply for regular IRB review

   Yes
   Data/ biospecimens covered by HIPAA?

   Yes
   Special concerns apply – contact the IRB at irbhp@cornell.edu

   No
   Data/biospecimens publicly available?

   Yes
   Exempt Under Category 4

   No
   Information recorded such that subject identity not readily ascertained?

   Yes
   Participants re-identified or contacted?

   Yes
   Research for or on behalf of a federal department/agency?

   Yes
   Information generated/obtained by the government for non-research purposes?

   Yes
   Exempt Under Category 4

   No
   Special concerns apply – contact the IRB at irbhp@cornell.edu

   No
   Information maintained in compliance with federal privacy laws?

   Yes
   Exempt Under Category 4

   No

*Use of de-identified data/biospecimens for research is not regulated by the IRB. No application to the Cornell IRB needed.
Public Health or Service Research: Does Exemption 5 apply? [45 CFR 46.104(d)(5)]

Collection of information, but not eligible for exemption under Categories 1, 2, or 3

Research conducted or supported by a federal agency?

Yes

Study, evaluate, improve, examine public benefit or service programs?

Yes

Has the project been published on a publicly available website?

No

Does the protocol include a plan and timeline?

No

Exempt under Category 5

Yes

No

Not exempt under Category 5. Could be Exempt under 1, 2 or 3 or 6
Food and Taste Evaluation: Does Exemption 6 apply? [45 CFR 46.104(d)(6)]

- Collecting data/biospecimens for research

  - Taste or food quality evaluation?
    - Yes
      - Wholesome foods without additives consumed?
        - Yes
          - Level of additives consumed considered safe by the FDA, EPA or USDA?
            - Yes
              - Exempt under Category 6
            - No
        - No
    - No
  - No
  - Not exempt under Category 6. Could be Exempt under 2 or 3 or 5
NOTE: These Exemption provisions carry significant requirements for documenting or waiving Broad Consent and for ensuring privacy of subjects and confidentiality of data. The Cornell IRB recommends that projects involving secondary use of identifiable private data or biospecimens that cannot be exempted under Category 4, are reviewed by the Cornell IRB via the non-exempt review process and granted IRB approval. Contact the IRB with questions irbhp@cornell.edu.