

CUNY HRPP Policy: Human Subjects Research Exempt from IRB Review

1. Purpose

The purpose of this policy is to establish the requirements for human subject research that may qualify for exemption from IRB review.

2. Determination of Exemption

At CUNY, the HRPP staff determine whether a research study meets the criteria for exemption from IRB review. CUNY researchers may not initiate exempt research until and unless they have received a documented determination of exemption from the CUNY HRPP.

3. Exemption Criteria

Research activities that meet the criteria defined in 45 CFR 46.104 may qualify for exemption from IRB review.

3.1. The exemption criteria apply to all human subject research at CUNY regardless of funding.

3.2. For exemption category at 45 CFR 46.104(d)(2):

- *Survey* refers to information collected about individuals (not businesses or organizations) through questionnaires or similar procedures.
- Research cannot include interventions. Examples of interventions that would disqualify the research from this exemption category include:
 - Randomly assigning students to take educational tests in a quiet room vs. moderate level of noise; or to consume snack or not before taking a test
 - Research that aims to see if respondents answer questions differently depending on gender of interviewer
 - Observational research that introduces an intervention such as offering a lot wallet to see if someone accepts it.

3.3. For exemption categories at 45 CFR 46.104(d)(4), 45 CFR 46.104(d)(7), and 45 CFR 46.104(d)(8):

- *Secondary research* refers to re-using identifiable private information and identifiable biospecimens that are collected for some other primary or initial activity.
- This exemption does not cover any primary collections of either information or biospecimens.

3.4. **Belmont Principles Apply**

Although exempt research does not require IRB review, this research is not exempt from the ethical guidelines delineated in the [Belmont Report](#). The HRPP staff making the determination of exemption has the authority to require additional protections for subjects in keeping with the guidelines of the Belmont Report, even though the research falls within an exempt category.

4. **Exempt Categories Requiring Limited IRB Review**

CUNY UI-IRBs have the authority to approve, require modifications in, or disapprove exempt research for which limited IRB review is a condition of exemption.

5. **Amendments to Exempt Research**

5.1. Investigators shall not implement any changes to the exempt protocol without prior review and new determination of exemption from the CUNY HRPP.

5.2. If the HRPP Office determines that, with the proposed changes, the research continues to meet the criteria for exemption from IRB review, the HRPP shall issue an *Exemption Determination Letter* for the amendment.

5.3. If the HRPP Office determines that the research no longer meets the criteria for exemption from IRB review, the submission shall be forwarded to the IRB for expedited or convened IRB review, as appropriate.

References

1. [Code of Federal Regulations, Title 45 – Public Welfare DHHS, Part 46 – Protection of Human Subjects](#)
2. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, [The Belmont Report](#), April 18, 1979