

CUNY HRPP Procedures: Human Subjects Research Exempt from IRB Review

1. Applicability

These procedures apply to CUNY research involving human subjects that meets the criteria for exemption from IRB review, as outlined in the federal regulations at [45 CFR 46.101\(b\)](#).

2. Determination of Exemption

The HRPP Coordinator, not the Principal Investigator (PI), determines whether a research study meets the criteria for exemption from IRB review. Please refer to Section 7 below for submission and review procedures. Researchers may not initiate exempt research until and unless they have received a determination of exemption from the local HRPP Office.

3. Exemption Criteria

Research that falls within one of the following categories may qualify for exemption from IRB review:

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. [NOTE: See Section 4.1 for limitations on this exemption category for research involving children.]
- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2), if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such

a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. [NOTE: In order to be eligible for this exemption, all of the materials have to exist at the time the research is proposed.]

- (5) Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

- (6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed; or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

4. Limitations on Exemptions

- 4.1. **Children.** Under exemption #2, research involving survey or interview procedures or observations of public behavior with children does not qualify for exemption, except for research involving observations of public behavior when the investigator does not participate in the activities being observed. The other five exemptions apply to research involving children as human subjects in the same way that they apply to research involving adults.

- 4.2. **Prisoners.** Research involving prisoners does not qualify for exemption.

- 4.3. **FDA.** Exemption Criteria Category 6 (Taste and food quality evaluation as described in section 3 above) is the only allowable category that is exempt from the requirements of FDA regulations for IRB review. For research that falls within FDA's oversight, if category 6 does not apply, the study cannot be considered as exempt from IRB review.

- 4.4. **Belmont Report Applies.** Although exempt research does not require IRB review, this research is not exempt from the ethical guidelines of the Belmont Report. The individual 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

5. **Validity of the Determination of Exemption**

Determinations of exemptions are valid until the expiration date noted on the *Exempt Determination Letter*, up to a maximum of three years from the decision date. Investigators wishing to continue exempt research beyond the period specified on the determination of exemption must submit a *Request for Extension of Exemption Determination*.

6. **Amendments to Exempt Research**

6.1. Investigators shall not implement any changes to the exempt protocol without prior review and new determination of exemption from the local HRPP Office, even if the changes are planned for the period for which approval has already been given.

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

6.3. 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.

7. **Process for Submission and Determination of Exempt status**

7.1. Researchers shall submit a *Request for Exemption* in IRB Net. Detailed instructions for registering and submitting in IRB Net are available in the *Researcher Manual for Using IRB Net* available at <http://www.cuny.edu/research/compliance/human-subjects-research-1.html>

7.2. The HRPP Coordinator of the PI's primary campus reviews the submission for completion and determines whether the research qualifies for exemption from IRB review.

7.3. The HRPP Office issues an *Exempt Determination Letter* to the PI, which conveys whether the research qualifies for exemption from IRB review.

7.4. If the research does not qualify for exemption from IRB review, the PI must re-submit the research using the Initial Application Submission form.

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
3. US Food and Drug Administration, [*Comparison of FDA and HHS Human Subject Protection Regulations*](#)
4. Office for Human Research Protections, [*Research with Children - FAQs*](#)