

Cornell University
Office of Research Integrity and Assurance
Human Research Participant Protection Program

SOP 2: REQUIREMENTS FOR SUBMISSION OF RESEARCH PROTOCOLS FOR A
DETERMINATION BY ORIA OF EXEMPTION FROM IRB REVIEW

1. Subject of Policy & Procedure

If a Protocol Principal Investigator (Protocol PI) or ORIA determines that a project/activity constitutes human participant research and, thus, requires IRB review and approval or the project/activity needs an ORIA determination of exemption from IRB review, the Protocol PI must complete and submit to ORIA the research protocol and all support documents required for IRB review, in accordance with the following Policy and Procedure. While the Protocol Principal Investigator may determine that a research activity does or does not constitute human participant research by using the Decision Tree entitled “Is your activity covered under the Human Research Protection Program?,” s/he *may not* self-determine that his or her own protocol meets the requirements to be eligible for exemption from IRB review.

2. Scope of Policy & Procedure

This Policy & Procedure applies to all on-going and future human participant research projects conducted by Cornell faculty, students, and staff or by anyone conducting a research activity on property maintained by Cornell.

3. Terms and Definitions

Employees (faculty and staff) and students should consult the IRB Glossary at <http://www.irb.cornell.edu/glossary/>.

4. See Also

Affected researchers and employees should also consult: (1) Cornell University Federal Wide Assurance Registration, available at <http://www.irb.cornell.edu/regulations/fwa.htm>, and (2) Exemption Form, available at <http://www.irb.cornell.edu/forms/>.

5. Regulations and Guidance Applicable to Completion of Submission of Research Protocols for IRB Review

5.1. Federal Regulations

5.1.1. In accordance with its FWA, it is Cornell’s policy to apply federal laws and regulations to all human participant research, regardless of source of funding, that is conducted by Cornell faculty, students, and staff or by anyone on property maintained by Cornell. *See* Attachment 2:B.

5.1.2. Eligibility of certain research protocols to be exempt from IRB review: 45 CFR 46.101(b).

6. Categories of Research Protocols Eligible for Exemption from IRB Review

6.1. ORIA **may** grant exempt status **only** to the following categories of research activities:

- 6.1.1. Research that is conducted in settings that are established or commonly accepted as educational and involves normal educational practices, such as: (1) regular and special education instructional strategies, or (2) effectiveness or comparison of instructional techniques, curricula, or classroom management methods.
- 6.1.2. Research that involves (1) the use of educational tests (cognitive, diagnostic, aptitude, achievement); (2) survey procedures; (3) interviewer procedures; or (4) observation of public behavior of non-minors, *unless* (a) information is recorded in a manner that individuals can be identified (directly or through identifiers linked to the individual) AND (b) disclosure of the information could reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.
- 6.1.3. Research that involves (1) the use of educational tests (cognitive, diagnostic, aptitude, achievement); (2) survey procedures; (3) interviewer procedures; or (4) observation of public behavior, that is not eligible for the above exemption, *if*: (a) the human participants are elected or appointed public officials or candidates for public office; or (b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- 6.1.4. Research that involves the collection or study of data, documents, records, pathological specimens, or diagnostic specimens that are (1) pre-existing (*i.e.* in existence before the start of the research project) *and* (2) publicly available or the information was recorded in a manner that does not allow the participants to be identified directly or through identifiers linked to them.
- 6.1.5. Research and demonstration projects that are (1) conducted by or subject to the approval of federal department or agency heads, *and* (2) are designed to study, evaluate, or otherwise examine (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.
- 6.1.6. Taste and food quality evaluation and consumer acceptance studies, if: (1) wholesome foods without additives are consumed; or (2) food is consumed that contains a food ingredient at or below the level (or 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.

6.2. ORIA will **not** grant exempt status to a research activity that meets any one of the following four conditions:

6.2.1. Protocols involving Children *and*

- (a) a survey or interview is being utilized, *or*

(b) public behavior is being observed and the Protocol PI, co investigators, or key personnel interacts with the participants or in any way manipulates the setting/situation;

6.2.2. Protocols involving Prisoners;

6.2.3. Protocols involving records where information is collected in a manner that allows human participants to be identified directly or through identifiers, such as the following:

(a) Names;

(b) All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, *except for* the initial three digits of a zip code, *if* according to the current publicly available data from the Bureau of the Census: (a) the geographic unit formed by combining all zip codes with the same initial digit contains more than 20,000 people; and (2) the initial three digits of the zip code for all such geographic units containing fewer than 20,000 of fewer people is changed to 000.

(c) All elements of dates (excluding year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death;

(d) All ages over 89 and all elements of dates (including year) indicative of such age, except that such dates and elements may be aggregated into a single category of age 90 or older;

(e) Phone numbers;

(f) Fax numbers;

(g) Electronic mail addresses;

(h) Medical record numbers;

(i) Health plan/beneficiary numbers;

(j) Account numbers (*e.g.*, credit card, bank);

(k) Certificate/license numbers;

(l) Vehicle identifiers and serial numbers, including license plate numbers;

(m) Device identifiers and serial numbers;

(n) Web Universal Resource Locators (URLs);

(o) Internet Protocol (IP) address numbers;

(p) Biometric identifiers, including finger and voice prints;

(q) Full face photographic images and any comparable images;

(r) Biological samples or genetic material (*e.g.*, human specimens, cells, cell lines, or data);

(s) Any other unique identifying number, characteristic, or code (*e.g.*, Global Positioning System (GPS) readings) (note that this does not mean the unique code assigned by the investigator to code the data);

There are also additional standards and criteria to protect a research participant from re-identification. Any code used to replace the identifiers in datasets cannot be derived from any information related to the individual and the master codes, nor can the method to derive the codes be disclosed. For example, the unique code cannot include the last four digits (in sequence) of a participant's social security number.

Additionally, the researcher must not have actual knowledge that the participant could be re-identified from the remaining identifiers in the individual health information used in the research study. In other words, even after removal of all of the above-listed identifiers, the information would still be deemed to allow the participant to be identified if it remained possible to identify him.

OR

6.2.4. Protocols that extract responses from human participants which, if disclosed outside the research, could reasonably place the participants at risk of criminal or civil liability or damage their financial standing, employability, or reputation.

7. Process for Submitting Research Protocol and Support Documents to ORIA for a Determination of Exemption from IRB Review

7.1. The Protocol PI **may not** self-determine that his or her own research protocol meets one of the categories for exemption from IRB review.

Therefore, if the Protocol PI, in consulting the IRB Review Decision Tree entitled "When does an activity/project not require IRB review?," or ORIA determines that the research activity constitutes human participant research (*see* SOP 1: Determining Whether a Research Activity Needs IRB Review or Exemption from IRB Review) the Protocol PI **must** submit to ORIA a complete research protocol and support documents of sufficient detail for IRB review and approval (research protocol application).

7.2. After being notified by ORIA that a research protocol is **not eligible** for exemption from IRB review, per 6.1 or 6.2 above, the Protocol PI should submit a research protocol application to ORIA for expedited or full committee review. *See* SOP 3: Initial and Continuing Review by the IRB: Requirements for Submission of Applications, Approval Criteria, and Expedited and Convened Committee Review Procedures.

7.3. If the Protocol PI and/or ORIA makes a preliminary assessment that the research activity meets one of the categories for exemption from IRB review, per 6.2 above, the Protocol PI

must complete and submit 1 copy of an Exemption Form and, if applicable, 1 copy of the following documents: a consent script; external funding research proposal; recruitment materials; and all other study instruments including, but not limited to blank interview forms, questionnaires/surveys, sample contact letters, advertisements, instructions to interviewers/Research Assistants, debriefing test, and focus group guides.

- 7.4. ORIA, upon receipt of the research protocol and support documents, will (1) verify that the research activity constitutes human participant research and clearly meets one of the categories for exemption from IRB review; and if so, (2) will verify the completeness of the materials or coordinate with the Protocol PI to achieve completion; and (3) enter selected information from the Exemption Form into the research protocol tracking database.

ORIA then will issue a formal notice of exemption covering the duration of the project to the Protocol PI. A copy of this notice and all submission documents will be archived by ORIA until five years after the termination of the research activity. In addition, the Protocol PI should maintain these documents for a period of five years after the research activity has concluded and all publication and/or reports have been accepted. *See SOP ___: Document Management.*

Protocols that are granted exempt status do not require continuing review unless there are changes to the protocol. For each change that is proposed or occurs during the execution of the research activity, the Protocol PI may need to consult with ORIA to determine if the change affects the eligibility of the research activity to continue to be exempt from IRB review and approval.

- 7.5. If ORIA determines that the research activity does not fall clearly within one of the exemption categories or ORIA has identified additional concerns, they will submit the research protocol application to the IRB for review and approval via the Expedited Review Process. *See SOP 3: Initial and Continuing Review by the IRB: Requirements for Submission of Applications, Approval Criteria, and Expedited and Convened Committee Review Procedures.*
- 7.6. All projects that have been exempted from IRB review will be reported to the IRB as a part of the minutes of the IRB.