UNG UNIVERSITY of NORTH GEORGIA™

Institutional Review Board (IRB)

IRB Guidelines 1.1

Exempt Research Applications

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Overview

All research projects – including those considered "exempt" – require IRB oversight at the University of North Georgia and must meet the ethical intent of the Belmont Report and Common Rule, including obtaining informed consent for research participation. In order to qualify for exempt status, research must fall within one or more of the six categories of exemption (see Code of Federal Regulations, §46.101), cannot place subjects at greater than minimal risk, and cannot involve participation of vulnerable populations (defined below).

Specific Exempt Research Policy

The IRB of the University of North Georgia uses DHSS policies 45 CFR 46.101, 45 CFR 46.116(d) and 45 CFR 46.117(c) to determine whether a research project qualifies for exempt status and under what conditions informed consent can be altered or waved (also see DHHS guidelines).

1. Exempt Research Submission Requirements

Based on the recommendations I(c)4 of the Secretary's Advisory Committee on Human Research Protections (SACHRP), researchers may not self-exempt their human participant research projects. The determination as to whether a project is exempt or not is an administrative review process handled by the IRB chair and/or IRB committee. In practical terms this means that each research team that seeks exempt status needs submit a regular IRB application (use IRB Form 1.1) along with other study-related materials (e.g., consent/assent forms [see IRB Form 3.1], surveys, questionnaires, interview scripts/outlines, recruitment flyers etc.) to the IRB (refer to the IRB application process).

2. Exempt Research Categories (see Code of Federal Regulations, §46.101**;** phrasing borrowed from Georgia Southern: http://research.georgiasouthern.edu/researchintegrity/276-2/)

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices.
2. Research involving only the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
    a. Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to them.
    b. Any disclosure of the human participant's responses outside the research could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability or reputation.
    c. Survey or interview 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 category two (B2) of this section, if:
    a. The participants are elected or appointed public officials or candidates for public office.
    b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information 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 researcher in such a manner that participants cannot be identified, directly or through identifiers linked to them.
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: (a) public health benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs; (d) 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.

3. Vulnerable Populations

Exemptions do not apply to research involving prisoners, fetuses, pregnant women, or newborns. Exempt status may also be affected granted if FERPA requirements apply (see UNG IRB Guidelines 1.2).

Further, the exemption Category 2 above does not apply to children, except in research involving observations of public behavior when the researcher(s) do not participate in the activities being observed. Interviews, surveys, and interactive observations are not exempt, while educational tests and non-interactive observations are exempt.

4. Monitoring and Approval Period

If exempt status is granted, the research activity – unlike applications with expedited and/or full status – are not monitored by the IRB and do receive an expiration date. Exempt status does not, however, lessen the research team's responsibility to adhere to all ethical requirements as outlined by federal, state and professional codes of conduct. Also note, that any proposed change to the "approved" research design/protocol will require a new IRB review to establish whether the research remains exempt from IRB review/approval [use IRB Form 1.4]

If you need this document in another format, please email irbchair@ung.edu or call 706-867-2969.