Policy
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: III.C
Section: IRB Review Procedures
Review Responsibility: HRPP Policy and Procedure Committee
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Subject: IRB Review of Human Subjects Research – Exempt

Definitions:
1. **Children:** Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. According to Tennessee State law, the legal age for consent is 18 years of age.
2. **Minimal Risk:** The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Policy:
It is the policy of the HRPP that all human subjects research activities under its jurisdiction be reviewed to determine whether the research meets one or more of the exemption categories described in the federal regulations and complies with the Institution’s ethical standards.

I. Exempt Eligibility.
A. Research activities involving human subjects that are exempt from the requirement that they receive IRB full or expedited review are identified in 45 CFR 46.101(b)(1)-(6), 45 CFR 406.301(a), 45 CFR 46.401(b) and 21 CFR 6.104(d). The HRPP may not create new categories of this exempt research. Only the HRPP may determine which activities qualify for an exempt review. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt and must contact the HRPP concerning the status of proposed research or changes in ongoing research.
B. An Investigator may request a particular category of exemption, but the final determination of applicability will be made by the HRPP. A final determination for exemption may be made by a RCA, Level II or higher.
C. Research may be granted exempt status by the HRPP if all research activities involve procedures listed in one or more of the specific categories under 45 CFR 46.101(b). **NOTE:** These categories do not apply to research involving prisoners and categories 1-5 do not apply to FDA regulated research. They are:

1. **45 CFR 46.101(b)(1):** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
   a) Research on regular and special education instructional strategies; or
   b) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. **45 CFR 46.101(b)(2):** Research involving 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 subjects can be identified, directly or through identifiers linked to the subjects; and
   b) Any disclosure of the human subjects’ responses outside of 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.
c) If the research involves children as participants, the research must be limited to educational tests (cognitive, diagnostic, aptitude, achievement), and observation of public behavior when the investigator(s) do not participate in the activities being observed. Research that uses survey procedures, interview procedures, or observation of public behavior when the investigator(s) participate in the activities being observed cannot be granted an exemption.

3. **45 CFR 46.101(b)(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 45 CFR 46.101(b)(2) if:
   a) The human subjects are elected or appointed public officials or candidates for public office; or
   b) Federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. **45 CFR 46.101(b)(4):** Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or the information is recorded by the Investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
   a) To qualify for this exemption, data, documents, records, or specimens must have been collected before the research project begins.
      1) Example: Investigator A wishes to screen blood samples at a rural hospital for incidence of HIV infection. She does not want to draw specimens specifically for this purpose; rather she proposes to use specimens that were drawn for some other purpose but which remain in the hospital laboratory. If Investigator A proposes to use specimens that had been drawn prior to the initiation of her research and are, for some reason, "on the shelf," the protocol may qualify as exempt, assuming the other requirements are met (i.e., the sources are either publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects). If she proposes to use specimens that will be drawn after the start date of her project for reasons unrelated to her research, the protocol is not exempt, even though the specimens will be drawn regardless of her use of the excess blood. The protocol may, however, qualify for expedited review.
   b) Under this exemption, an investigator (with proper institutional authorization) may inspect private, identifiable records, but may only record information in a non-identifiable manner. The data must be permanently and completely de-linked at the time of extraction. A code may be used to organize data as it is collected. However, the code may not be a means of re-linking the data set to the original data source.
      1) Example: Investigator B wishes to examine court records of involuntary commitments to psychological institutions. If he uses court records that were on file before the initiation of his research, the protocol may qualify as exempt. If he proposes to use records filed after the initiation of the project, the protocol is not exempt, although it may qualify for expedited review.

5. **45 CFR 46.101(b)(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 benefit or service programs; this exemption is for Federally supported projects and is most appropriately invoked with authorization or concurrence by the funding agency. The following criteria must be
satisfied to invoke the exemption for research and demonstration projects examining "public benefit or service programs:"

(1) The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services under the Older Americans Act);

(2) The research or demonstration project must be conducted pursuant to specific Federal statutory authority;

(3) There must be no statutory requirements that the project be reviewed by an IRB; and

(4) The project must not involve significant physical invasions or intrusions upon the privacy of participants.

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.

e) This exemption is for projects conducted by or subject to approval of Federal agencies and requires authorization or concurrence by the funding agency.

6. **45 CFR 46.101(b)(6) and 21 CFR 56.104(d):** Taste and food quality evaluation and consumer acceptance studies;

   a) If wholesome foods without additives are consumed; or

   b) 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.

II. Amendments.

A. Certain changes may disqualify the research from exempt status; therefore, all changes in the research plan must be reported to the HRPP for review and approval, prior to implementation.

1. Proposed changes to an exempt study within the first year of approval must be submitted to the HRPP for review and approval prior to implementation.

2. Proposed changes to an exempt study occurring after the first year of HRPP approval must be submitted to the HRPP as a new “Request for Exemption.”

III. Research conducted under exempt review is subject to all applicable institutional and HRPP policies and procedures.

IV. Exempt research activities are subject to the same protections and ethical standards as outlined in the Belmont Report.

References:
45 CFR 46.101(b)
HRPP Policy III.I
OHRP Compliance Activities: Common Findings and Guidance, 7/10/2002