Title:	Exempt Studies		
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1 Purpose

All research using human subjects must be approved by the University of North Carolina at Chapel Hill (UNC-Chapel Hill). However, certain categories of human subject research are exempt from IRB approval. Exempt research is subject to review for determination of exemption status. At the UNC-Chapel Hill exemptions are reviewed IRB Staff, and granted by an IRB Chair or designee.

Individuals involved in making the determination of an IRB exempt status of a proposed research project cannot be involved in the proposed research. Reviewers must not have any apparent conflict of interest. Identification of individuals designated to conduct exempt determinations will be made in writing.

Exempt research fulfills the organization's ethical standards, such as:

- The research holds out no more than minimal risk to subjects.
- Selection of subjects is equitable.
- If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data.
- There are adequate provisions to maintain the privacy interests of subjects.

2 Procedure

2.1 Exemption Determinations

Exemptions are determined or granted, rather than approved. Exempt studies are exempt from the Common Rule [45 CFR 46] (i.e., FWA, IRB approval and full research consent are not required). They do require a determination/confirmation of exemption status. Although exempt research is not covered by the federal regulations, this research is not exempt from ethical considerations, such as honoring the principles described in the Belmont Report. The individual/s making the determination of exemption will determine whether to require additional protections for subjects in keeping with ethical principles (e.g., requiring disclosure/consent, etc.).

Records of exemption actions will be maintained in accordance with SOP 1001.

Changes to an exempted study may render it no longer exempt. Decision charts published by OHRP may assist the IRB in determining level of IRB review needed: http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm

2.2 Limitations on Exemptions

The following limitations on exemptions apply to research conducted or supported by HHS:

Children: The exemption for research involving survey or interview procedures or observations of public behavior (#2) does NOT apply to research in children, except for research involving observations of public behavior when the investigator does not participate in the activities being observed.

Prisoners: Exemptions do NOT apply. IRB review is required.

2.3 Categories of Exempt Research

With the above-referenced limitations, research activities not regulated by the FDA (see Section 2.4 for FDA Exemptions) in which the only involvement of human subjects are determined to be in one or more of the following categories are exempt from IRB approval:

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 subject's financial standing, employability, or reputation.

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.

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 as provided under the Older Americans Act).

The research demonstration project must be conducted pursuant to specific federal statutory authority, there must be no statutory requirements of IRB review, the research must not involve significant physical invasions or intrusions upon the privacy of subjects, and the exemption must be invoked only with authorization or concurrence by the federal funding agency.

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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

2.4 Procedures for Exemption Determination

In order to obtain an exemption determination, investigators must submit:

1. Completed *Request Exemption* section of IRBIS application;
2. All recruitment materials (e.g., letter of invitation, recruitment script, flyer);
3. Consent form/disclosure/information sheet (when appropriate);
4. All surveys, questionnaires, instruments, etc.;

5. Confirmation that permission will be obtained from each non-UNC-Chapel Hill site of performance;
6. If sponsored/funded, one copy of the grant application(s) and/or contract; and
7. Verification of current human research protection training for all members of the research team, including the faculty advisor.

The IRB Analyst or IRB reviewer reviews all requests for exemptions and determines whether the request meets the criteria for exempt research.

To document the reviewer's determination of the request for exempt research, the reviewer completes the Exemption Determination Form. The reviewer verifies on the form whether the submission meets the definition of human subject research. If the request meets the definition of human subject research, the reviewer then determines whether or not the research is eligible for exemption. Although exempt research is not covered by the federal regulations, this research is not exempt from the ethical guidelines of the Belmont Report.

The individual making the determination of exemption will determine whether to require additional protections for subjects in keeping with the guidelines of the Belmont Report.

If there are interactions with participants, the reviewer should determine whether there should be a consent process that will disclose such information as:

- That the activity involves research.
- A description of the procedures.
- That participation is voluntary.
- Name and contact information for the researcher

The reviewer indicates whether the request for exemption was approved or denied, and if approved, the rationale for the determination and category/s under which it was permitted.

The exempt application, review form, and determination letter are recorded and maintained in the same manner and for the same length of time as other IRB review documentation.

Once exemption review is completed, IRB staff will send written notification of the results of the review to the investigator.

Exempt determinations do not have a termination date. After a determination is made, the reviewer will file the study in the archives. Investigators must report any proposed modification to the research during the course of the exempt study if the modification could impact the exemption determination. Investigators should notify the IRB office when an exempt research project is complete so that the organization can maintain an accurate database of active research.