EXEMPT RESEARCH

Introduction

"Many educational, behavioral, and social science studies present little or no risk to the participants. Likewise, research involving existing data, medical records, and pathologic specimens usually has little, if any, associated risk, particularly if subject identifiers are removed from the data or specimens. Thus, although the rights and welfare of subjects in those studies still require protection, there is usually no need for a detailed institutional review board (IRB) review, the equivalent of the kind performed at a convened meeting of the IRB. Accordingly, certain research activities are exempt from compliance with Department of Health and Human Services (DHHS) regulations for the protection of human subjects."

Bankert, E.A. and Amdur, R.J. Institutional Review Board Management and Function, Second Edition (2006). Jones and Bartlett Publishers, Inc.

What Does "Exempt" Mean?

Exempt studies are minimal risk and fit within a set of established exemption categories. Studies that qualify for exemption are only required to adhere to certain federal regulations and must also follow state laws and University policies applicable to research. Studies that qualify for exemption must adhere to principles of sound research design and ethics. Participant rights and welfare must also be protected in a manner appropriate for research that poses minimal risk.

Exemption determinations are made by the IRB and may not be made by the individual investigator. IRB review of exempt studies ensures that these standards and requirements are met prior to initiation of the research (see the IRB Responsibilities Related to Exempt Research section).

Studies that receive an exemption do not expire and are not required to obtain continuing review from the IRB; thus, continuing review applications are not required. However, the IRB must review any substantive changes to the study, via an amendment application, to ensure the study still qualifies for exempt status in light of the changes. Substantive changes include, but are not limited to the following:

- Changes that increase the risk to participants or change the risk:benefit ratio of the study
- Changes that affect a participant's willingness to participate in the study
- Changes to study procedures or study components that are not covered by the Exemption Category determined for this study (listed below)
- Changes to the study sponsor
- Changes to the targeted participant population
- Changes to the stamped consent document(s)

Investigators should contact the IRB Office if there are questions about whether an amendment consists

of substantive changes.

Exempt studies must adhere to the University of Utah IRB reporting requirements for unanticipated problems and deviations. Exempt studies must be closed with the IRB once the research activities are complete.

Research Regulated by the Department of Health and Human Services (DHHS)

The Department of Health and Human Services has identified certain categories of research involving human subjects that qualify for exemption from certain federal regulations applicable to research. At the University of Utah, the IRB makes federal exemption determinations according to 45 CFR 46.101.

Research Regulated by the Food and Drug Administration (FDA)

The Food and Drug Administration does not have categories of research that qualify for exempt status like those listed by DHHS. The FDA does not exempt any research under its jurisdiction from IRB review except in extremely limited circumstances (e.g. emergency use, taste and food quality studies, etc.).

Research that is Not Federally Funded or Regulated

The University of Utah has elected to apply its Federal-wide Assurance to research sponsored by federal agencies that require adherence to 45 CFR 46. In the case of non-federally funded or regulated human research, the University of Utah IRB has created additional exemption categories. Research that is determined by the IRB to meet a non-federal exemption category must follow all stipulations for the category and the PI must adhere to all responsibilities described in this document.

Obtaining Informed Consent in Exempt Research

Informed consent is a practice that helps to ensure that the rights and welfare of participants are protected. The IRB requires that informed consent from participants be obtained when it is reasonable and practicable to do so. Justification for waiving the informed consent process must be provided in the submission to the IRB.

The informed consent process may or may not include a consent document. The IRB requires that the consent process disclose at least the following information to potential participants:

- That the activity involves research
- A description of the procedures
- That participating is voluntary
- Name and contact information for the investigator

Other information may be provided to the potential participants as appropriate in order for participants to make an informed decision.

Consent documents processed for exempted research are marked with an IRB approval stamp in the footer; however, because the project does not expire or require continuing review, no expiration date will appear with the stamp. The document is considered “approved” until another approved document

supersedes it, or until the project is closed. Investigators should only use the most recent version of the document with the IRB approval stamp in the footer.

IRB Responsibilities Related to Exempt Research

The IRB ensures valid claims of exemption by reviewing the proposed research via an IRB application. A designated IRB member determines that the study is exempt from further IRB review and from applicable federal regulations governing human research, under 45 CFR 46.101(b) or according to University of Utah IRB policy. All research involving human subjects must be approved or exempted by the IRB before the research is conducted.

The IRB determines that the study is in compliance with applicable laws and regulations, including the HIPAA Privacy Rule, state law, and institutional policy.

The IRB determines that the study conforms to the principles of sound research ethics, in accordance with principles of the Belmont Report, as follows:

a. The research holds out no more than minimal risk to participants
b. The selection of subjects is equitable
c. If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data
d. If there are interactions with participants, there is a consent process that will disclose such information as:
    - That the activity involves research
    - A description of the procedures
    - That participating is voluntary
    - Name and contact information for the investigator
e. There are adequate provisions to maintain the privacy interest of participants
f. The research is conducted in an ethical manner which does not adversely affect the rights and welfare of the participants

The IRB maintains orderly accounting for such activities via the ERICA online system.

Investigator Responsibilities Related to Exempt Research

1. The investigator submits proposed research to the IRB for review using the ERICA online system when exemption eligibility is expected. The investigator only begins research activities after documentation of IRB approval or exemption is received.
2. The investigator ensures that the study is conducted in compliance with applicable laws and regulations, including the HIPAA Privacy Rule, state law, and institutional policy.
3. The investigator ensures that the study conforms to the principles of sound research ethics, in accordance with principles of the Belmont Report, including but not limited to:
    a. Ensuring the research presents no more than minimal risk to participants
    b. Selecting subjects equitably

c. If there is recording of identifiable information, maintaining the confidentiality of the data
d. If there are interactions with participants, conducting a consent process that will disclose such information as:
    - That the activity involves research
    - A description of the procedures
    - That participating is voluntary
    - Name and contact information for the investigator
e. Maintaining the privacy interest of participants
f. Conducting the research in an ethical manner which does not adversely affect the rights and welfare of the participants

4. The investigator conducts the research in compliance with the protocol as submitted to and exempted by the IRB.
5. The investigator obtains approval for all changes to the protocol prior to implementing the changes.
6. The investigator adheres to IRB policy for reporting unanticipated problems and deviations.
7. The investigator adheres to all other the terms outlined in the Investigator's Statement of Assurance.

References & Links

- **45 CFR 46.101(b) Categories of Exempt Human Subject Research:** http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101(b). Accessed January 31, 2012.
- Bankert, E.A. and Amdur, R.J. **Institutional Review Board Management and Function, Second Edition** (2006). Jones and Bartlett Publishers, Inc.
- **SOP 401b Research Activities Exempt from IRB Review:** http://irb.utah.edu/guidelines/irb-sops.php.
- **Office for Human Research Protections (OHRP) Exempt Research Determination – FAQs:** http://answers.hhs.gov/ohrp/categories/1564. Accessed January 31, 2012.
- **National Institutes of Health (NIH) FAQ – Human Subjects Research – Human Specimens, Cell Lines or Data:** http://grants.nih.gov/grants/policy/hs/faqs_specimens.htm. Accessed January 31, 2012.
- **OHRP Guidance on Research Involving Coded Private Information or Biological Specimens:** http://www.hhs.gov/ohrp/policy/cdebiol.html. Accessed January 31, 2012.
- **ORPP Guidance on 45 CFR 46.101(b)(5), Exemption for Research and Demonstration Projects on Public Benefit and Service Programs**: http://www.hhs.gov/ohrp/policy/exmpt-pb.html. Accessed September 6, 2013.

EXEMPT CATEGORIES OF RESEARCH

Federal Exemption Categories (1-6)

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.

    AND

    c. Research is not subject to FDA regulations.
    d. Research does not involve prisoners as participants.
    e. Research does meet the University's ethical standards governing the conduct of the research.

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 subjects can be identified, directly or through identifiers linked to the subjects and 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.
    b. Research involves children, with the exception of research involving observations of public behavior when the investigator(s) do not participate in the activities being observed. (45 CFR 46.101(b))
    c. Research is subject to FDA regulations.
    d. Research involves prisoners as participants.
    e. Research fails to meet the University's ethical standards governing the conduct of the research.

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:**
    a. The human subjects 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.
    c. Research is not subject to FDA regulations.
    d. Research does not involve prisoners as participants.
    e. Research meets the University's ethical standards governing the conduct of the research.

4. **Research involving the collection or study of existing data, documents, record, pathological specimens or diagnostic specimens,** if these sources are publicly available or the information is recorded by the investigator in such a manner that the subjects *cannot be identified directly or through identifiers linked to the subjects*.

   AND:

   a. Research is not subject to FDA regulations.
   b. Research does not involve prisoners as participants.
   c. Research meets the University's ethical standards governing the conduct of the research.

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 examined:**

   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.

   AND[1]:

   e. Research or demonstration project must be conducted pursuant to specific federal statutory authority.
   f. There must be no statutory requirement that the research or demonstration project be reviewed by an Institutional Review Board.
   g. The research or demonstration project must not involve significant physical invasions or intrusions upon the privacy of participants.
   h. The research or demonstration project must have authorization or concurrence from the funding agency before invoking this exemption.
   i. The program under study will 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).

   [1]*The requirements e-i are derived from the OPRR Guidance on 45 CFR 46.101(b)(5), Exemption for Research and Demonstration Projects on Public Benefit and Service Programs.*

6. **Taste and food quality evaluation and consumer acceptance studies, if:**

   a. 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.

Non-Federal Exemption Categories (7-11)

For the following non-Federal exemption categories (7-11), the research must meet the following criteria in addition to all specification of the exemption category:

a) Research is not subject to FDA regulations;
b) Research is not federally funded;
c) Research is not contractually or otherwise subject to federal research requirements, including but not limited to research conducted under the Department of Veterans Affairs or under an NIH Certificate of Confidentiality;
d) Research does not involve prisoners as participants;
e) Research meets the University's ethical standards governing the conduct of the research, including appropriate provisions for the protection of privacy and confidentiality when identifiable and coded information are used.

7. **Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, where this information is personally identifiable or coded.**

8. **Research involving the collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:**
    a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml [37 Tbsp] in an 8 week period and collection may not occur more frequently than 2 times per week; OR
    b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml [3.4 Tbsp] or 3 ml per kg [0.28 tsp per lb] in an 8 week period and collection may not occur more frequently than 2 times per week.

9. **Prospective collection of biological specimens for research purposes by noninvasive means.**

10. **Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not eligible for exempt review under this category.)**

11. **Research on individual or group characteristics or behavior (including, but not limited to, research or perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, collection of recordings (voice, video, digital, or image), program evaluation, human factors evaluation, or quality assurance methodologies, unless:**
    a. Information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects and 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.