Tip Sheet

Human Research Protection Program Office (HRPPO)

FAQs:

Q: Does Exempt = No IRB Review?

A: Not exactly. Exempt determination indicates regulations for IRB approval and oversight do not apply. Exempt determinations should only be made by the IRB or HRPPO staff.

Q: Is Informed Consent Required?

A: Information about the study should be provided whenever there will be interactions with subjects.

Q: How long is my approval?

A: Exempt studies will expire within 5 years unless you request an extension.

Q: What Approvals are Required?

A: Before you begin your research, you **MUST** receive the following:

- ✓ **Exempt Determination** via eIRB (IRB/HRPPO review)
- ✓ **Site Approval** via Velos (Parkland, Children's, TSRH, THR, etc.)

Regulatory Reference:
45 CFR 46.101(b)

For Further Information Contact:
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Exempt Review of Human Subjects' Research

Exempt Research Review Requirements:

- ✓ Exempt Determination (submission to eIRB) by UTSW HRPP Office
- ✓ Site Approval (Parkland, Children's etc.) ***BEFORE*** beginning research

Criteria

- ✓ The research must be minimal risk;
- ✓ The selection of subjects is equitable (e.g., doesn't unnecessarily target one or more vulnerable groups);
- ✓ Research activities MUST fall entirely within one or more of the six categories for exemption;
- ✓ Adequate provisions exist to maintain the confidentiality of data;
- ✓ The research CANNOT involve prisoners;
- ✓ The research CANNOT be FDA regulated.

Ethical Requirements

Exempt research studies are reviewed in the same ethical manner and with the same respect for the privacy and confidentiality of research subjects as approved under full board or expedited procedures. If there are interactions with participants, there should be a consent process that will disclose such information to subjects including:

1. A description of the activity including a statement that it is research
2. A description of the procedures
3. That participation is voluntary
4. Name and contact information for the Researcher

Important:

- ✓ Studies involving deception should not be reviewed and approved under one of the exemption categories.
- ✓ Researchers DO NOT have the authority to make an independent Exemption determination - this is the responsibility of the HRPP/IRB.
- ✓ Studies CANNOT be initiated prior to receiving an Exempt Determination AND Site approval for the proposed research.
- ✓ Each project requires a separate review and approval for exemption.
- ✓ Studies not meeting the criteria for exemption may be sent for expedited or full board review.
- ✓ All exemptions, except exemption category 2, are applicable to children. Under exemption category 2, educational testing is allowable with children, HOWEVER research involving survey/interview procedures or observations of public behavior is NOT applicable to children. The only exception is research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

Exempt Review Categories:

(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.

Important Notes:

Commonly accepted educational settings include but are not limited to K-12 schools, college classrooms, preschools, vocational schools, alternative education programs, and other sites where educational activities regularly occur.

Normal educational practices include established teaching methods, curriculum content and other commonly accepted classroom management techniques.

*If a study qualifies under Category 1 Exemption, DO NOT apply additional exempt categories below.

Example: A study evaluating the effectiveness of two commonly accepted instructional techniques (lecture versus hands-on training). For the study, the researchers will observe the classroom instruction and collect test scores. In addition, the researchers may collect pre and post-test surveys to test the change in knowledge.

(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 subjects' financial standing, employability, or reputation.

Important Notes:

Public behavior refers to behavior taking place in a publicly accessible location in which the subject does not have an expectation of privacy (e.g., a public plaza or park, a street, a building lobby, a government building).

If research data may pose risk if released - the data collected in the research must not include any identifiers (must be anonymous). Researchers may not assign a code to each case to link to the identity of subjects.

Note: Research involving surveys or interviews with children or observation of public behavior when investigators interact with the children does not qualify for exemption.

Example: A study evaluating medical literacy of patients. The research will employ anonymous surveys and only collect non-identifiable demographic information (i.e., education, age, gender, ethnicity, etc.).

Exempt Review Categories (Continued):

(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 (b)(2) of this section, 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.

Important Notes:

Part (a) includes the research procedures previously described in Category 2, but holds public servants (e.g., public officials and candidates for public office) to a different privacy standard by not requiring that the data be collected anonymously, and is not concerned with any risks that may result from disclosure of the data. This category does not apply to public employees such as managers and staff in public agencies/offices.

Part (b) of this category applies only to research on specific programs conducted or supported by the Department of Justice or the National Center for Education Statistics. These agencies have specific programs that create databases which are protected by law from being accessed by anyone other than those agencies. The data collected for these programs is immune from legal process and cannot be revealed or furnished for any purpose other than that for which it was collected.

Example: A study that involves interviewing local elected officials (i.e., judges, mayors, etc.) about their opinions on marriage equality.

(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.

Important Notes:

These studies are one-and-done studies. This means you will only have **one opportunity** to review the data. You may not record identifiers or assign codes allowing you to re-review records/data.

Existing means on the shelf or in the record when you submit to the IRB. It **does not** include data or specimens that have not been collected, but will be collected for clinical purposes.

Data must be recorded in an anonymous manner: While data may be identifiable at the source, the data collected in the research must not include **any** identifiers (must be anonymous). Researchers **may not** assign a code to each case to link to the identity of subjects.

Data collection tools are generally required to confirm the data collected will not include codes or other identifiable information.

HIPAA Waiver required (medical information) – if your source involves medical records (or specimens from pathology), you must receive a HIPAA waiver to allow research access to the identifiable health information. This waiver **will not** allow you to record identifiable health information, only to view it at the source.

Example: A study involves will evaluate the treatment responses to a certain class of drugs for patients over the past 10 years. The research will include the review of medical record data that is in the medical records today. The data recorded will be limited to non-identifiable information such as age, gender, ethnicity, diagnosis and treatment outcome. The research team will keep a separate list of eligible subjects and cross them off the list once each record is reviewed. A CODE WILL NOT BE ASSIGNED. Once data is collected, there is no way the researcher or anyone else will be able to re-identify the original patient from the data collected.

Exempt Review Categories (Continued):

(5) Research and demonstration projects which are conducted by or subject to the approval of 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.

> **Important Notes:**
> These studies are very rare. If you think your study qualifies, you must obtain concurrence from the Funding Agency before the Exempt determination will be granted

(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 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.

> **Important Notes:**
> These taste and food quality studies are very rare. If you think your study qualified, you much confirm it meets the requirements above.