Exempt Categories, Examples & Tips

References:

- OHRP Exempt Regulations Decision Charts
- Glossary of Terms
- IRB Website

Exempt Category 1: Educational Setting

Research may be exempt if it is conducted in an established or commonly accepted educational setting and involves normal educational practices such as:

- research on regular and special education instructional strategies or
- research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods

Examples under category 1:

- Evaluating the use of accepted or revised standardized tests
- Evaluating the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods
- Study of a new reading technique on delayed readers in 4th grade.

What to submit with application:

1. An approval letter from an institutional representative or principal of the school in which you intend to do research.
2. Recruitment scripts, child assent, parental consent forms (waiver of consent is not recommended for exempt category 1), any surveys or interview guides (where applicable)

Exempt Category 2: Public behavior or anonymous questionnaires

Research involving the use of:

- educational tests (cognitive, diagnostic, aptitude, achievement),
- survey procedures,
- interview procedures, or
- observation of public behavior may be exempt,

unless the 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.
NOTE: This exemption does not apply to research with children except for research involving observation of public behavior where the investigator(s) do not participate in the activities being observed.

NOTE: This exemption does not apply if it involves human subjects who are elected or appointed public officials or candidates for public office or, Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Examples under Category 2:

- An anonymous survey of college students on their use of the Internet
- Interviewing business managers about a management style or business growth
- Observing, from a distance, adult and child interactions at a baseball game
- Interviews with Native Americans on their college experience

What to submit with application:
1. Surveys, consent forms, recruitment scripts and interview guides (where applicable)
2. Provide scripts for any and all forms of initial contact with participants including but not limited to, advertisement, e-mail, phone or letter introduction.

Exempt Category 3: Public Officials

Research involving the following:
- Educational tests (cognitive, diagnostic, aptitude, achievement)
- Survey procedures
- Interview procedures
- Observation of public behavior

NOTE: Research under this category applies when research activities involve the following:

1. human subjects who are elected or appointed public officials or candidates for public office; or
2. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Examples under category 3:

- Interviewing public officials about a local or global issue
- Comparing personality assessments scores of appointed judges in the state of NJ.

What to submit with application:
1. If you intend to conduct interviews with public figures, it is recommended that you develop and submit an introduction letter that includes basic consent information regarding subject matter, data confidentiality, study procedures, etc.

2. Surveys, consent forms, recruitment scripts and interview guides (where applicable)

3. Provide scripts for any and all forms of initial contact with participants including but not limited to, advertisement, e-mail, phone or letter.

**Exempt Category 4: Existing Data: Records Review, Pathological Specimens**

- Research involving the collection or study of **existing** data, documents, records, pathological specimens, or diagnostic specimens may be exempt if they are being:
  - obtained from publicly available sources **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:** To qualify for Exemption 4, data, documents, records or specimens must **already exist** at the time the research is proposed.

**Examples under category 4:**

- Analyzing de-identified data or tissue samples
- Analyzing census data about aging or housing
- Collecting de-identified data from patient charts that underwent knee replacement from 1995 to 2005

**Data Analysis:**

- A researcher proposes to conduct a retrospective chart review to review existing data that is part of a medical record. The researcher will not record any individually identifiable data when recording information about subjects. As long as the researcher has permission consistent with HIPAA, the research could be exempt.

**Analyzing de-identified records:**

- A researcher proposes to conduct a review of criminal files for violent offenders. The data being used exists at the time of the research. The researcher will not record any individually identifiable data when recording information about subjects.

**Analyzing de-identified tissue samples or data set:**

- A researcher proposes to study existing biological specimens leftover from a previous study that are “in a freezer” in a laboratory. The researcher will remove the individual identifiers on the label prior to
beginning the research so that information will be recorded without any links (direct or indirect) to the subjects.

**What to submit with application:**

1. Complete all required HIPAA documentation and initial and date form(s) if applicable.
2. Consent forms are not required.
3. Instruments from the original study are not required for submissions.
4. The original study must have IRB approval.

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**Exempt Category 5: Public Service Programs**

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:

- Public benefit or service programs.
- Procedures for obtaining benefits or services under those programs.
- Possible changes in or alternatives to those programs or procedures.
- Possible changes in methods or levels of payment for benefits or services under those programs.

**NOTE:** To qualify for Exemption 5 for Public Benefit Projects, which is for projects conducted by or subject to approval of federal agencies, the following criteria must be satisfied:

- 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 or demonstration project must be conducted pursuant to specific federal statutory authority
- There must be no statutory requirement that the project be reviewed by an IRB
- The project must not involve significant physical invasions or intrusions upon the privacy of participants
- Authorization or concurrence by funding agency

**Examples under category 5:**

- A researcher is sponsored by the Department of Health and Human Services wants to conduct a study analyzing the effectiveness of various government sponsored programs in decreasing obesity in the United States.
- A researcher sponsored by the Department of Agriculture- Food and Nutrition Service wants to compare the current use of the Supplemental Nutrition Assistance Program (i.e., food stamps) by Americans compared to twenty years ago.
What to submit with application:
1. Surveys, consent forms, recruitment scripts and interview guides (where applicable)
2. Provide scripts for any and all forms of initial contact with participants including but not limited to, advertisement, e-mail, phone or letter.

Exempt Category 6: Taste Tests

Taste and food quality evaluation and consumer acceptance studies if:

- Wholesome foods without additives are consumed; or
- 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.

**NOTE 1:** This category may be applied to research involving children; however, written parental consent to include children in taste testing studies will be required.

**NOTE 2:** While not explicitly prohibited in the regulations, inclusion of children in Food Quality and Consumer Acceptance Studies may pose greater than minimal risk to participants and may require IRB review.

Examples under category 6:
- Taste testing whole grain food products
- Comparing taste or smell of molasses, cheese or milk
- Tasting of several ice cream flavors to determine which texture is more pleasing.

What to include in application:

1. Please include specific descriptions of the foods (expected flavor differences, texture, etc.) as this may assist in the review of the proposed research activity.

Please send general inquiries to irb@princeton.edu, or contact us at (609)258-0865 Compliance Administrator for further assistance.