

## **Applying for Certificate of Exemption**

### How to Complete Form HS7

Form HS-7 is for research activities that qualify for a Certificate of Exemption. Does your research qualify for a Certificate of Exemption? Check if it falls in one of the six categories. If your research does not qualify for an exemption, then you must complete form HS1, the form for expedited or full review.

There are six categories for a **Certificate of Exemption**.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special educational instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management techniques. Educational research proposals are exempt providing all of the following are met:
  - a. All of the research is conducted in a commonly accepted educational setting (e.g., a private or public school).
  - b. The research involves normal educational practices (e.g., comparison of instructional techniques).
  - c. The study procedures do not entail a significant deviation in time or effort from those educational practices already existent in the study site.
  - d. The study procedures do not involve an increase in the level of risk or discomfort beyond normal, routine educational practices.
  - e. The study procedures do not involve sensitive topics, such as sexual behavior or individual subjects. A sensitive survey is one which deals with socially questionable or highly personal issues or alcohol and/or drug abuse.
  - f. Provisions are made to ensure the existence of a non-coercive environment for all students, including those who choose not to participate.
  - g. The school or other agency grants written approval for the research to be conducted.

Educational tests that are exempt from HSC review are tests of knowledge, mastery, or skills.

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 indirectly, through identifiers linked to the subjects; and (b) 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. **The HSC is required to review copies of the informed consent form and proposed questionnaire or survey instrument(s) prior to approval and implementation.**

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) (b) of this section, 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 be maintained throughout the research and thereafter. **Copies of the informed consent form and questionnaire or survey instrument(s) to be used must be forwarded to the HSC for review.**
4. Research involving the collection 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. **The source of the data, documents, records, pathological specimens or diagnostic specimens must be provided to the HSC, along with the name of the custodian of the data, documents, records or specimens.**
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: (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.
6. Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed; (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency or the Food Safety and Inspection Services of the U.S. Department of Agriculture.

Subject Population and number of subjects must be defined if you claim exemption category 1, 2, 3, 5, or 6. The P.I. must describe who will be studied (e.g. Students enrolled in Psych 101, or Library users) how the subjects will be selected, and if vulnerable populations are used. Vulnerable subjects are defined by federal law, as subjects who are under 18 years old, over 65 years old, economically or educationally disadvantaged, have cognitive disabilities, are terminally ill, are emergency room patients, pregnant women, non-English speakers, and prisoners. Other groups may be vulnerable; see the ISU Investigator's Manual for the Protection of Human Subjects for full details. The P.I must also say how many subjects will be used. If the number is not known a good estimate is sufficient.

All exemption categories must describe the purpose of the research and the procedures that will be employed. Define (a) questions(s) you trying to answer; (b) what will happen to the subjects who participate in your research; (c) methods to be used to analyze your data.

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Question #2:

If claiming **Exemption Category #4** (Use of Existing Data) answer question 2; if the answer is “yes”, continue with questions #3 through #11. Sometimes a category #4 exemption is not claimed when using existing data sets, but questions 2 through 11 will still have to be answered. The primary qualification for category #4 is that data must have been collected before the HS-7 form is submitted.

Question #3:

A brief description of content and structure of the data set(s) used (documents or biological specimens) is needed.

Question #4:

Explain who and how the data was gathered. a) If an ISU researcher was involved in the collection of these data, documents, or specimens, then exemption category #4 may NOT be used. b) If the collection was made as part of an agreement between an ISU researcher and an agency, the resulting data or samples are NOT considered existing data and category #4 may not be used. Question #5: The owner or steward of the data, documents or specimens used must be listed (e.g., government agency, historical society, hospital, etc.)

Question #6:

Only data collected for research can be considered for a category #4 Exemption.

Data collected routinely for agencies such as ongoing quality control is NOT data gathered for research. If the data, documents, or specimens were gathered for research, enclose the IRB (Institutional Review Board) approval document and original IRB protocol number when possible.

Question #7:

Data, documents, or specimens whose access is restricted to select groups are not considered publicly available.

Question #8:

Answer “Direct Identifier” is the date includes any of the following items:

- Names
- Geographical info
- Elements of dates (except year)
- Ages over 89 years
- Telephone and FAX numbers

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- Email addresses
- Social Security #
- Medical record or prescription #
- Account number
- Health plan beneficiary number
- Certificate or license number
- Serial or license plate numbers
- Web URLs
- Device identifiers
- IP address numbers
- Full face or comparable photos
- Any other unique identifying numbers

Answer “Indirect Identifier” if the data has an assigned number or code, but does not have any of the other items listed above.

Answer “No Identifier” if either PI or source providing the data could connect the information to identifiable individuals.

Question #9:

If the answer to question #8 was “Direct Identifier” or “Indirect Identifier” and all identifiers listed above will be removed, answer “yes”.

If identifiers are indirect or are not removed, the research does not qualify for a Certificate of Exemption. Complete HS-1.

Question #10: If a record of any identifier is used the research does not qualify for a Certificate of Exemption. Complete HS-1.

Question #11: If new data (documents or samples) will be added to the existing set after research is begun, the research does not qualify for a Certificate of Exemption. Complete HS-1.

**Questions #12 through #16 are to be completed if you are not claiming exemption Category #4.**

General guidelines for submitting proposals:

- Number all pages
- Submit signed original to
  - Human Subjects Committee, Mail Stop 8130, or submit to Office of Research Fine Arts Building Room 205
  - Double-sided to conserve paper and space is acceptable
- The PI must sign the Investigator’s Assurance page and the Faculty Sponsor (if applicable) must sign the Faculty Sponsor’s Assurance page.