

Idaho State University
Human Subjects Committee

Instructions for Completing HS-1 Application for Involving Humans in Research for Expedited and Full Board Reviews

General Guidelines:

- ❖ Download the HS-1 form. The Headings are in boldface.
- ❖ Submit 1 copy for expedited review; 11 copies for full review.
- ❖ There are special instructions for Renewal Applications and a separate renewal form.
- ❖ Use “NA” for questions not applicable to your research.
- ❖ Attaching sections of a thesis, dissertation, or grant is not an acceptable substitute to filling out the form.
- ❖ Provide sufficient information for effective review by all members of the HSC, including the non-University member(s). Define all abbreviations and terms not part of common language and use simple words and sentence structure as much as possible.
- ❖ **Number each page of your protocol**, double-sided copying is recommended.
- ❖ **Sign** the Investigator’s Assurance page and Faculty Advisor’s Assurance (if necessary) before submitting.

RENEWAL APPLICATION: HSC approval is for no more than one year at a time for expedited reviews and research requiring full board review. Projects must be renewed after one year. If renewing a proposal, use the renewal form.

PROTOCOL INFORMATION

1. **Purpose of the Study:** Provide a clear, simple, BRIEF statement of what you want to learn from this study.
2. **Lay Language Summary:**
3. **Summarize current state of research with references(for full board review only):** State the background of the study. Include a critical evaluation of the existing knowledge, and specifically identify the information gaps which this project is intended to fill. Describe previous work in animal and/or human studies that provides a basis for the proposed research and that support the expectation of obtaining useful results without undue risk to human subjects.
4. **Number of Subjects:** What is the anticipated number of subjects to be enrolled at ISU (or an off-campus site), and in the case of multi-center research, the total number of subjects for the entire project? How did you arrive at the number of subjects to be enrolled?
5. **Inclusion/Exclusion Criteria:**
 - a) What are the subject inclusion criteria?
 - b) What are the subject exclusion criteria?

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c) How will eligibility be determined and by whom?

Note: Equitable inclusion of both men and women of all ages, and individuals from diverse racial/ethnic groups, is important to assure that they receive an equal share of the benefits of the research and that they do not bear a disproportionate share of its burdens. Participation of adult subjects of both genders and diverse racial/ethnic backgrounds should not be restricted without medical and/or scientific justification.

6. **Vulnerable Subjects:** Will subjects from any vulnerable group be included in the subject population?

- Under 18
- Cognitive impairment
- Economically or educationally disadvantaged
- Residents in Total institutional care
- Prisoners
- Non-English speakers
- Terminally Ill patients
- ER patients
- Other

Note: Examples of vulnerable subjects include children (under age 18), the elderly, pregnant women, fetuses, cognitively impaired individuals, persons with severe psychological disorders, terminally ill patients, emergency room patients, institutional residents, prisoners, parolees, non-English speaking subjects, etc.

7. **Method of Subject Identification and Recruitment:** What method(s) will be used to identify and recruit prospective subjects? Attach a copy of any planned advertisements, notices, emails and or letters that will be sent to prospective subjects.

8. **Payment for Participation:** Describe all plans to pay subjects, in cash or in kind. If no payment is planned, that should be stated. Information regarding payment consideration should include: Will subjects receive any financial inducement or payment for participation? Will they receive services or other benefits instead of cash? Will they be reimbursed for travel or other expenses? What conditions must be fulfilled by subjects to receive either full or partial payment?

Note: The FDA encourages a prorated system of payment whereby subjects who do not finish the protocol are paid in proportion to the part completed. The amount of payment must be justified and not constitute undue inducement of the subject to participate in the research. If a non-prorated system of payment will be used, this should be justified in this section.

9. **Methods and Procedures Applied to Human Subjects:** Describe the study design and all procedures (sequentially) to which human participants will be subjected. Identify all procedures that are considered experimental and/or procedures performed exclusively for research purposes.

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10. Data Collection, Storage, Confidentiality and Data Disposition:

- a) How will the data be collected and recorded? Will it be associated with personal identifiers or coded to protect personal privacy? How will the data be coded?
- b) Where will the data be stored during the study and how will it be secured?
- c) Who will have access to the data and/or the codes? If data with subject identifiers will be released, specify the person(s) or the agency to who this information will be released?
- d) How long will data be stored and what will be done with it at the end of that period?

Note: The principal investigator is responsible for taking all necessary steps to maintain confidentiality of the data. This includes coding data and choosing an appropriate and secure data storage mechanism that will prevent unauthorized access to the data. Where appropriate, the principal investigator should seek a certificate of confidentiality from the Federal government.

11. Potential Risks and/or Discomforts: What are the potential risks and/or discomforts associated with this research? If data are available, estimate (a) the probability that a given harm may occur, (b) its severity, and (c) its potential reversibility.

Note: A risk and/or discomfort is a potential harm associated with the research that a reasonable person would consider important in deciding whether to participate in the research. Risk and/or discomforts can be generally categorized as physical, psychological, sociological, economic, or legal.

13. Risk Classification: What is the overall risk classification of the research?

- Minimal Risk meaning probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological exams or tests.
- Greater than minimal risk
- Significant
- Unknown risks and discomforts cannot be considered minimal

14. Minimizing Risks: What procedure(s) will be utilized to prevent/minimize any potential risks or discomforts?

Note: All potential risks and discomforts must be minimized to the greatest extent possible by using procedures such as appropriate monitoring and withdrawal of the subject upon evidence of specific events or signs. This section should reflect that all appropriate steps will be taken to protect subjects from harm.

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15. Potential Benefits:

a) What potential benefits may individual subjects receive as a result of their participation in this research?

Note: Please state that there are no benefits to the individual if your research does not help or enrich the participant directly.

b) What benefits to society may reasonably be expected from this research?

16. Therapeutic Alternatives: What therapeutic alternatives are reasonably available in the non-research and/or research context that may be of benefit to the potential subjects?

Note: This section only applies to studies testing therapies or diagnostic methods.

17. Financial Obligations of the Subjects: What financial obligations will subjects incur as a result of participating in this research, such as travel costs and parking fees? Will subjects have to pay for any treatment(s) they receive or tests performed in the research?

Note: This section should clarify who will pay for procedures associated with the study as well as financial responsibility for care. Insurance and other third-party payers may not cover costs associated with research (even if they might pay for these same services when not associated with research). All costs to be incurred by subjects should be carefully explained and justified.

18. Process of Consent: How and where will the consent process take place? How will it be structured to enhance independent and thoughtful decision making? What steps will be taken to avoid coercion and undue influence? How, and by whom, will it be determined whether the subjects or their legally authorized representatives understand the information provided?

Note: Consider: (a) the environment and location where informed consent will be solicited; (b) the timing of the process (e.g., in relation to the beginning of data collection); (c) the involvement of someone other than the investigators to help explain the research; and, (d) opportunity for the prospective subject/representative to discuss participation in the research with family, friends, or their advisors before signing the consent form. This section should clearly document that the investigator has an adequate plan in place to assure existence of an acceptable level of comprehension before consent is documented. The principal investigator (or approved designee) is responsible for assuring that prospective subjects or their representatives have sufficient understanding of the research to make an informed decision about participation. It is important that they understand the purpose of the research, the nature and the duration of

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the procedures, any risks and/or discomforts, the possible benefits to subjects and to others, and their right to withdraw consent at any time without penalty. Willingness to sign the consent form is not an adequate demonstration of their understanding. Some investigators try to determine the level of comprehension of prospective subjects= by questioning them about the research. (This approach is useful with children and adolescents, as well as with adults of uncertain capacity to consent.)

19. Capacity to Consent: Will all adult subjects have the capacity to give informed consent? If not, describe the likely range of impairment and explain how, and by whom, their capacity to consent will be determined.

Note: In research involving more than minimal risk, capacity to consent should be determined by a qualified person (psychiatrists, psychologist, etc.) not otherwise connected with the research. Individuals who lack capacity to consent may participate in research if consent is given on their behalf by a legally authorized representative.

20. Information Withheld From Subjects: Will any information about the research purpose and design be withheld from potential or participating subjects? If so, explain and justify the non-disclosure and describe the post-study debriefing.

Note: Any non-disclosure must be approved by the HSC and may not exclude information that a reasonable person would want to know in order to decide whether to participate in the research. In addition, the alteration in the consent procedures must be approvable under 45 CFR 46.116(d): (1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration, and (4) whenever appropriate the subjects will be provided with additional information after participation (debriefing).

21. Personnel Inviting Participation: Who will invite subjects to participate and what will they say? Identify by name and training the individual(s) authorized to describe the research to subjects/representatives and to invite participation.

Note: Only those individuals authorized to solicit consent may sign the consent form confirming that the prospective subject was provided the necessary information and that any questions asked were answered.

22. Consent/Assent Forms: Specify the form(s) that will be used among the following

- Youth Assent Form (ages 13-18) and Child Assent Form (ages 7-12)
- Adult Consent Form

**INVESTIGATIONAL DRUG INFORMATION RECORD
(Complete only if applicable to research)**

INSTRUCTIONS: Attach copy of the Investigators Brochure. Provide the following information on each investigational drug that is not approved by the Food and Drug Administration (FDA) for the use outlined in the study protocol. If you intend to use an approved drug in an unapproved way (e.g., different dosages or routes of administration, new age groups, new indications, etc.) in research and if you are planning to use the results to seek approval from the FDA, you must submit an IND application to the FDA and complete this section.

Part A:

1. List all participating investigators authorized to prescribe the investigational agent:
2. Sponsor=s name, address and telephone number.
3. Will any approved drugs be used for unapproved purposes (new indications) or in unapproved ways (e.g., different dosages or routes of administration, new age groups)?
Yes No Please explain.
4. Identification of study design (check appropriate categories):
Single blind
Double blind
Open trial
Cross over
Placebo control
Drug control
Other (Explain; be specific)
4. Approximate duration of investigation:
5. Approximate number of subjects required:

Part B:

1. Name of holder of the IND:
2. IND number:
3. Generic drug name and synonyms:
4. Source of drug:
5. Dosage form(s) and strength(s):
6. Special storage requirements (if any):
7. Stability information (if applicable):
8. Indications for the use of the drug:
9. Mechanisms of action:

10. Route of administration:
11. Usual dosage:

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12. Dosage range:
13. Treatment regimen:
14. Possible side effects:
15. Precautions, warnings and contraindications:
16. Restrictions on who may administer the drug:
17. Dispensing instructions to patient (including warnings):
18. Drug-drug interactions (known):
19. Drug-laboratory test interferences (known):
20. Special information for intravenous medications:
 - a. Recommended diluent for reconstitution (if applicable):
 - b. Recommended IV solutions for administration (if applicable):
 - c. Stability when diluted in IV solutions (if applicable):
 - d. Recommended rate of IV administration:
21. Comments

INVESTIGATIONAL MEDICAL DEVICE INFORMATION RECORD
(Complete only if applicable to research)

INSTRUCTIONS: The research investigator or sponsor should make an initial risk assessment (non-significant/ significant risk) of a device based upon the use of the device with human subjects in a research environment. If the HSC determines that the device poses a significant risk to human subjects, the investigator or the sponsor must obtain an IDE number from the FDA and provide a copy of the IDE approval to the HSC.

1. List all participating investigators authorized to use the investigational device:
2. Sponsor's name, address, and telephone number:
3. Approximate duration of the investigation:
4. Approximate number of subjects required:
5. Number of holder of the IDE:
6. IDE Number (if applicable):
7. Manufacturer of the device:
8. Engineering review:
9. Assessment of the risk to participating subjects:
 Non-significant Significant

Please explain the basis for the risk assessment.

10. Possible complications:
11. Precautions, warnings, and contraindications:
12. Comments:

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STUDY OF EXISTING DATA OR BIOLOGICAL SPECIMENS
(Complete only if applicable to research)

Note: This section is constructed to assist the HSC's review of research activities involving the collection of existing data, documents, records, pathological specimens, or diagnostic specimens that are **NOT** exempt from review by the HSC. Federal regulations stipulate that "*research involving the collection or study of existing data, documents, 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 subjects*" may qualify as exempt from HSC review. In accordance with the Federal guidelines, if the data are not publicly available or if the data are recorded with direct or indirect identifying links to subjects, the protocol requires HSC review. For information regarding under what circumstances the study of biological specimens gathered from diagnostic or clinical procedures may be exempt from HSC review, please see *Investigator's Manual on Research with Human Subjects*.

Note: This section is not to be completed when human biological specimens are collected or used for genetic research. There are additional ethical concerns existing for genetic research that may not apply to other types of research with biological specimens.

1. **Purpose:** What are the specific scientific objectives of the research?
2. **Source:** What is the source of the existing data, document, pathological specimens, or diagnostic specimens?
3. **Ownership:** Who possesses control over the data, documents, pathological specimens, or diagnostic specimens?
4. **Type of Biological Specimen:** What is (are) the type(s) of specimen(s) that will be collected/used?
5. **Data Collection, Storage, Confidentiality:**
 - a. What kind of identifying information linked to subjects will be recorded? If you do not plan to maintain an identifier or a link to an identifier of the subjects, please state so.
 - b. If personal identifiers may be recorded, describe how confidentiality of the subject's identity will be maintained and plans for maintaining and destroying data after the study is complete?

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6. Informed Consent: (If you will not maintain an identifier or a link to an identifier of the subjects, state “*NOT APPLICABLE*”).

a. If personal identifiers may be recorded, will the subjects be consented for the involvement of their data or biological specimens in the research? If YES, attach a copy of the informed consent document. If NO, please answer question 6b.

b. Provide justifications to the following questions for requesting a waiver of the informed consent process.

1. Why does the proposed use of existing data, documents, pathological specimens or diagnostic specimens present no more than minimal risk to the subjects?

2. Why could the research not practicably be carried out without the waiver of informed consent?

3. Why will a waiver of informed consent not adversely affect the rights and welfare of the subjects?

4. How will pertinent information be provided to subjects, if appropriate, at a later date?