



Protocol Review

Payment Information

Review fee: \$ _____ (per fee for services quote)

Bill to Purchase Order No. _____ or

Check made payable to "Heartland IRB" _____ (ck #), in the amount of \$ _____ mailed on _____.

Department of Health and Human Services regulations require review and approval of all research involving human subjects. Approval of Heartland Institutional Review Board must be obtained **PRIOR** to the involvement of any human subjects. HIRB will not review protocols for projects if projects were initiated prior to submission of forms to HIRB for review.

PROJECT TITLE

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PRINCIPAL INVESTIGATOR

First Name:		Last Name:		
Street Address:	City:	State:	ZIP:	
Phone Number:		E-mail:		

CO-RESEARCHER(S)

First Name:		Last Name:		
Street Address:	City:	State:	ZIP:	
Phone Number:		E-mail:		

SPONSOR CONTACT (If research is being sponsored or funded by a third party.)

First Name:		Last Name:		
Street Address:	City:	State:	ZIP:	
Phone Number:		E-mail:		

If the study will be funded by a grant, indicate the name of the funding agency.

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DOCUMENT DISTRIBUTION: Please identify individuals below to whom you authorize access to documents related to this application. HIRB will send an email notification to the individuals below when a document is posted on the portal.

Name	Email address

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How did you learn of HIRB?

- Have previously been a client
- Sponsor/CRO recommendation
- Tradeshow
- Industry Publication
- Internet/Website
- Other:

TRANSFER/DESIGNATION OF IRB SERVICES

Through an agreement by the IRB Chairperson or designee, the Principal Investigator must actively designate Heartland Institutional Review Board as the IRB of record for the study. This section must be completed if a site is under the jurisdiction of a local IRB.

I am aware that study-related procedures for the above referenced research will be conducted at our institution, and I hereby defer authority to Heartland Institutional Review Board.

Name of Institution

Printed Name of IRB Chairperson or designee

Signature of IRB Chairperson or designee

Date

SCREENING TOOL

Directions: Please, review each item and answer each by placing an “X” in the appropriate box to the right. Use “N/A” for any item that is “not applicable” to your proposed research study. Then follow the directions at the bottom of this page.	YES	NO	N/A
1) Is this research designed to study typical educational practices (e.g., instruction, classroom management)?			
2) If so, will the research occur in an established educational setting?			
3) Will the research consist <u>solely</u> of standardized tests, surveys, interviews, or tracking public behavior?			
4) Will subjects have anonymity? (If participant names appear on consent forms, if research involves interviews, or if the investigator can link a number with a name then subjects will not have anonymity.)			
5) If information about subjects is disclosed, can you ensure they will not be at risk for damage to their financial standing, employability, or reputation?			
6) Will you collect or study existing data, documents, records, pathological or diagnostic specimens from publicly available sources?			
7) Will you collect or study existing data, documents, records, pathological or diagnostic specimens so that data cannot be linked to identifiable subjects?			
8) Will the study use deception (i.e., withholding information or giving false or misleading information to subjects)?			
9) Will procedures cause any degree of discomfort, harassment, invasion of privacy, risk of physical injury, threaten the dignity, or otherwise potentially harm subjects?			
10) Has another IRB declined to review or approve this protocol?			
11) Has another IRB terminated this research?			
12) Will subjects be drawn from any of the categories listed below? a) Minors (individuals not of age under State law to consent) b) Prisoners or persons who are under criminal sanctions c) Persons with diminished mental capacity (retardation, neurological, psychiatric, or related disability) d) Persons in a residential program (hospital, developmental center, group home, nursing home, etc.) e) Clients of a human service program (e.g., counseling center, clinic, etc.) f) Children who are wards of State g) Non-English speaking h) Adults who do not read or write i) Educationally disadvantaged j) Economically disadvantaged k) Employees or family members of the Principal Investigator or Sponsor l) Students of the university or the Principal Investigator participating in this research			

Directions:

- If you answered “yes” to any of the questions 1 through 7 and “no” to all the questions 8 through 12, complete the Basic Review Form.
- If you answered “yes” to any of the questions 8 through 12, complete the Advanced Review Form.

BASIC REVIEW FORM

1. State the purpose of the study.
2. Describe your potential subject pool.
3. How will you recruit subjects?
4. Where is the location of the research? (classroom, office, subject's home, via mail)

Directions: Answer each item by placing an "X" in the appropriate box to the right. Use "N/A" if the question is "Not Applicable" to your proposed study.	Yes	No	N/A
5. If subjects will not be identified from public sources, will signed approval to recruit subjects, conduct the study, or use existing data be obtained from the designated authority prior to the research? If no, explain on following page.			
6. Is there a pre-existing researcher-subject relationship? (teacher-student, counselor-client) If yes, explain on following page.			
7. If research occurs in students' classroom or clients in their human service delivery setting, will it require any activity that is not part of the normal class or service delivery? If yes, explain on following page.			
8. If subjects are minors, will parental consent be obtained for participation? If no, explain on following page.			
9. Will subjects be told participation is voluntary and they are free to withdraw at any time? If no, explain on following page.			
10. Will subjects receive compensation for the research (money, extra credit)? If yes, explain on following page.			
11. If extra credit is given, will students choosing not to participate have other opportunities to earn credit? If no, explain on following page.			
12. Will data be recorded so individual subjects cannot be linked to the data? If no, explain on following page.			
13. When study ends, will materials that identify individual subjects (data sheets, audio/video tapes) be destroyed? If no, explain on following page.			

14. Detail study procedures, describing exactly what will be done with the subjects and what measurements will be taken.

15. Use the space below to provide an explanation for any of the questions 5 through 13 from above. Indicate the appropriate question number with each explanation.

ADVANCED PROTOCOL REVIEW

Directions: Answer each question below. Your responses should be concise and, as non-technical as possible. If a question does not apply to your research, answer "N/A" for "Not Applicable."

1. Describe the purpose of the study.
2. Describe your potential subject pool and what determines final choice of subjects.
3. Will any of the below vulnerable populations be in the subject pool? If so, justify allowing these populations into this study and describe additional safeguards to protect their rights and welfare.
 - Minors (individuals not of age under State law to consent)
 - Prisoners or persons under criminal sanctions
 - Persons with diminished mental capacity (retardation, neurological or psychiatric disability, etc.)
 - Persons in a residential program (hospital, developmental center, group home, nursing home, etc.)
 - Clients of a human service program (counseling center, clinic, etc.)
 - Children who are wards of State
 - Non-English speakers
 - Adults who do not read or write
 - Educationally disadvantaged
 - Economically disadvantaged
 - Employees or family members of the Principal Investigator or Sponsor
 - Students of the institution or the Principal Investigator participating in this research
4. How will potential subjects' names be obtained (specific lists, telephone directories, etc.) and how you will have access to these sources?
5. How will subjects be recruited (mail, email, phone, presentation, personal contacts, ads), and by whom?
6. If you are associated with the subjects (your students, employees, clients, patients), explain the association and how a third party will solicit participation.
7. How much time (minutes or hours per day or week) will typically be required for an individual subject's participation?
8. How many subjects will be involved in the study?
9. How many subjects will be in each study group?
10. Will any group receive less than standard practice?
11. Give the approximate dates research subjects will be contacted and when involvement will end.

12. Exactly where will research be conducted (classroom, office, residence, via mail, email, phone, etc.)? What resources are available at this site to support successful completion of the study?
13. If research will be in a classroom or service delivery setting, will it require any activity that is not part of the normal class or service delivery?
14. Will the project use facilities or interact with personnel at another institution or business? (If so, a letter of permission on the institution's letterhead must be sent to HIRB prior to beginning your study.)
15. What will subjects be asked to do?
16. Describe the procedures that the researcher will use with the subjects.
17. Describe any physical, psychological, social, economic, legal or other risks to the subject. (Subjects should be protected against injury and invasion of their privacy, and their dignity should be preserved.)
18. Describe steps that will be taken to minimize risk, including how subjects will be informed of any risks.
19. If subjects will face more than minimal risk (obtaining blood, information on sensitive issues such as illegal drug use, drug treatment, psychological manipulation, more than moderate exercise, etc.), describe procedures in detail, including qualifications/certification of data collectors.
20. Describe your plan for providing emergency medical treatment or psychological support for incidents that may occur during research, and provide the distance from the research site to a facility that can treat medical or psychological emergencies.
21. Describe any electrical equipment to be connected to subjects. (You will need to attach a signed and dated letter from the individual who checked the equipment for electrical safety, including their qualifications and the types and results of the checks.)
22. Describe the need for any audio/video recording of subjects, where recordings will be stored, the specific intended uses of the recordings, the person(s) who will have access to the recordings, and when or if recordings will be destroyed or erased.
23. Describe the nature of any deception used in the study, why it is necessary, and how subjects will be debriefed. Include any feedback – educational or otherwise – subjects will receive.
24. How will subjects indicate consent? (A copy of the consent form or, in the case of a mailed survey, a cover letter explaining the project, must be offered to each subject. HIRB requirements for consent forms are available on the HIRB Web site.) If you are requesting a waiver of the written/signed consent, what other method will be used to obtain consent?
25. Indicate any state or local laws that require additional information in the consent form.
26. Will you obtain consent from anyone other than the participant?

27. Who will present consent documents and/or conduct consent interviews with potential participant?
28. What steps will you take to minimize the possibility of coercion or undue influence?
29. Will prospective participants be allowed to take consent documents away from the site to discuss with their family members, legal counsel, doctors or others?
30. Describe desired timeframe between approaching prospective participants and obtaining consent.
31. Who will assist the Investigator in ensuring consent is appropriately obtained and documented?
32. What language(s) are spoken by those obtaining consent and prospective participants?
33. In your state, what is the legal age to consent to this research?
34. In your state, are both parents required to consent on behalf of the child?
35. Other than parents, who is legally authorized in your state to consent on behalf of a child?
36. Describe community attitudes (religious, ethnic, etc.) about your research that may affect the study.
37. What specific aspects of this study may be most sensitive to this community?
38. How will/have you obtained permission to access existing/secondary data. (A letter of permission must also be attached. See required attachment checklist at the end of this form.)
39. Where are the existing/secondary data files kept and who will gather the information?
40. Do the subjects (and/or their parents or guardians) know that these files will be read? If not, explain.
41. Will you access subjects' protected health information?
42. What processes will ensure that persons assisting in the study are adequately informed about the protocol/study plan, and their study related duties and functions?
43. How will you ensure anonymity or confidentiality during and after the study? (Substituting numbers for names, locking or password-protecting data files, confidentiality contracts with staff, not identifying individuals in reports, etc.) **NOTE:** Social Security numbers may NOT be used.
44. If you use a code numbers linked to identifying names...
 - Will you keep the code listing and data in separate and secure locations?
 - Will you destroy the code list when the study is complete?
 - Who will have access to the code list and data?
45. Will results be disseminated to subjects (and/or their parents or guardians)? If so, explain the qualifications of the person(s) interpreting the results.

- 46. What will you do with the data collected (publish data, present paper)?
- 47. Is a follow-up anticipated, and if so, for what reason?
- 48. Will subjects receive any compensation (money, grade, extra credit, etc.)?
- 49. If participants will be paid, indicate how they will be paid in the table below. (Add lines if needed.)

Visit Number/Type	Amount to be paid

- 50. When should participants expect payment? (At each visit, at final visit, upon completion of study, etc.)
- 51. Will an end-of-study bonus be offered to participants, and if so, what will be the amount?
- 52. What is the maximum total potential compensation for completion of protocol/study plan requirements?
- 53. If extra credit or a grade is given, how will students who choose not to participate get other chances to receive extra credit or an equivalent grade?

CERTIFICATION STATEMENT and SIGNATURE

I certify that the information provided within this report is true and accurate, and represents my intent to pursue review of this research by Heartland Institutional Review Board. My signature below indicates that I understand that it is my obligation to review the reporting responsibilities, as provided on the Heartland Institutional Review Board website and to me in printed form. I understand I may contact Heartland Institutional Review Board at any time with questions or concerns about these requirements. I understand that failure to comply with the above requirements may result in regulatory action by Heartland Institutional Review Board. By signing this agreement, I grant Heartland Institutional Review Board the authority to approve and oversee the above referenced research investigation.

Printed Name of Investigator (Single Site PI submissions)

Signature

Date

ATTACHMENTS

In addition to answering the questions in this application, the following materials must be attached where applicable.

- Questionnaires
- Surveys
- Measurement instruments
- Interview protocols
- Documents that will be distributed or read to subjects
- Recruitment scripts or other recruitment material or advertisements
- Consent forms, assent forms or cover letters
- Tests with sensitive questions, such as illegal behavior, sexual behavior, illness, disease, and disability. (Tests that generally do not involve sensitive questions, such as cognitive, vocational, career, speech and language, and educational tests do not have to be submitted. For further assistance, contact HIRB).
- Documentation of Primary Investigator and staff's human subjects protection training
- Documentation related to any pending or active legal, regulatory, or professional actions or restrictions related to practice of medicine at the site
- Documentation related to discipline or restrictions on Principal Investigator or any member of the research staff by FDA, DHHS or other regulatory agencies
- Documentation of inspection within the last two years by FDA, DHHS or other regulatory agency
- Request for a Waiver or Alteration of Informed Consent
- Request for a Waiver of Documentation of Informed Consent
- Participant diaries
- Participant education material
- The current protocol or study plan (and any amendments)
- Any follow-up materials
- If DHHS funded, a copy of the grant (if your company holds the grant)
- Statement from a person qualified to evaluate risks involving visual or auditory stimuli, chemical substances, or other measures might affect the health of subjects
- Debriefing statement – if project involves deception.
- Letter of permission to use existing/secondary data