

<b>For IRB Use Only</b>	Review Date: _____	IRB ID: _____
	Approval Date: _____	Length of Approval: _____
	Approval Expiration Date: _____	FULL Committee Review: _____
	EXEMPT per 45 CFR 46.101(b): _____ Date: _____	Minimal Risk: _____
	EXPEDITED per 45 CFR 46.110(b) Category _____, Letter _____	More than Minimal Risks: _____
		Project Closed Date: _____

## INSTITUTIONAL REVIEW BOARD (IRB) Application for Approval of Research Involving Humans

### SECTION I: GENERAL INFORMATION

Principal Investigator (PI):		Phone:	Fax:
Degrees:	Correspondence Address:		
Department:	Email Address:		
Center/Institute:	College:		
PI Level: <input type="checkbox"/> Faculty <input type="checkbox"/> Staff <input type="checkbox"/> Postdoctoral <input type="checkbox"/> Graduate Student <input type="checkbox"/> Undergraduate Student			
Alternate Contact Person:		Email Address:	
Correspondence Address:		Phone:	
Title of Project: [ ]			
Project Period (Include Start and End Date): [mm/dd/yy][ ] to [mm/yy/dd][ ]			

**Comment [MJM1]:** Think carefully about your title!

**Comment [MJM2]:** Give yourself plenty of time to complete your project. Better to anticipate too much time than not enough

<b>FOR STUDENT PROJECTS</b>	
Name of Major Professor/Supervising Faculty:	Signature of Major Professor/Supervising Faculty: [ ]
Phone:	Campus Address:
Department:	Email Address:
Type of Project: (check all that apply)	
<input type="checkbox"/> Research	<input type="checkbox"/> Thesis <input type="checkbox"/> Dissertation <input type="checkbox"/> Class project
<input type="checkbox"/> Independent Study (490, 590, Honors project)	<input type="checkbox"/> Other. Please specify: _____

**Comment [MJM3]:** Don't forget to get your major prof's signature

### KEY PERSONNEL

List all members and relevant experience of the project personnel. This information is intended to inform the committee of the training and background related to the specific procedures that each person will perform on the project.

NAME & DEGREE(S)	SPECIFIC DUTIES ON PROJECT	TRAINING & EXPERIENCE RELATED TO PROCEDURES PERFORMED, DATE OF TRAINING
[ ]		

**Comment [MJM4]:** Put all the people who will be working on your project here. Think: transcribers, undergrads who are working with you, colleagues, your major prof, yourself

To list additional personnel please attach separate sheet.

**FUNDING INFORMATION**

<input type="checkbox"/> Internally funded, please provide account number:
<input type="checkbox"/> Externally funded, please provide funding source and account number:
<input type="checkbox"/> Funding is pending, please provide OSPA Record ID on GoldSheet: Title on GoldSheet if different from above:
<input type="checkbox"/> Other: (e.g., funding will be applied for later)
<input type="checkbox"/> Student Project—no funding or funding provided by student

**Comment [MJM5]:** Be sure to check something here. There are more specific requirements for federally funded projects.

**SCIENTIFIC REVIEW**

Although the assurance committees are not intended to conduct peer review of research proposals, the federal regulations include language such as “consistent with sound research design,” “rationale for involving animals or humans” and “scientifically valuable research,” which requires that the committees consider in their review the general scientific relevance of a research study. Proposals that do not meet these basic tests are not justifiable and cannot be approved. If an assurance review committee(s) has concerns about the scientific merit of a project and the project was not competitively funded by peer review or was funded by corporate sponsors, the project may be referred to a scientific review committee. The scientific review committee will be an ad hoc and will consist of your ISU peers and outside experts as needed. If this situation arises, the PI will be contacted and given the option of agreeing that a consultant may be contacted or withdrawing the proposal from consideration.

Yes  No Has or will this project receive peer review?

**Comment [MJM6]:** The answer to this in our department is typically “no”

If the answer is “yes,” please indicate who did or will conduct the review:

If a review was conducted, please indicate the outcome of the review:

**COLLECTION OR RECEIPT OF SAMPLES**

Will you be: (Please check all that apply.)

Yes  No Receiving samples from outside of ISU? See examples below.  
 Yes  No Sending samples outside of ISU? See examples below.

Examples include: genetically modified organisms, body fluids, tissue samples, blood samples, pathogens.

If you will be receiving samples from or sending samples outside of ISU, please identify the name of the outside organization(s) and the identity of the samples you will be sending or receiving outside of ISU. If the outside organizations have not been identified, please check no for both questions above.

**Comment [MJM7]:** Be sure to put n/a “not applicable” for all empty boxes like this, so the committee knows you haven’t ignored this

Please note that **some samples may require a USDA Animal Plant Health Inspection Service (APHIS) permit**, a USPHS Centers for Disease Control and Prevention (CDC) Import Permit for Etiologic Agents, a Registration for Select Agents, High Consequence Livestock Pathogens and Toxins or Listed Plant Pathogens, or a Material Transfer Agreement (MTA) [EH&S Website](#)

**ASSURANCE**

- I certify that the information provided in this application is complete and accurate and consistent with any proposal(s) submitted to external funding agencies.
- I agree to provide proper surveillance of this project to ensure that the rights and welfare of the human subject or welfare of animal subjects are protected. I will report any problems to the appropriate assurance review committee(s).
- I agree that I will not begin this project until receipt of official approval from all appropriate committee(s).
- I agree that modifications to the originally approved project will not take place without prior review and approval by the appropriate committee(s), and that all activities will be performed in accordance with all applicable federal, state, local and Iowa State University policies.

**CONFLICT OF INTEREST**

A conflict of interest can be defined as a set of conditions in which an investigator’s or key personnel’s judgment regarding a project (including human or animal subject welfare, integrity of the research) may be influenced by a secondary interest (e.g., the proposed project and/or a relationship with the sponsor). ISU’s Conflict of Interest Policy requires that investigators and key personnel disclose any significant financial interests or relationships that may present an actual or potential conflict of interest. By signing this form below, you are certifying that all members of the research team, including yourself, have read and understand ISU’s Conflict of Interest policy as addressed by the ISU Faculty Handbook (<http://www.provost.iastate.edu/faculty>) and have made all required disclosures.

- Yes  No Do you or any member of your research team have an actual or potential conflict of interest?  
 Yes  No If yes, have the appropriate disclosure form(s) been completed?



**SIGNATURES**

\_\_\_\_\_  
Signature of Principal Investigator                      Date

\_\_\_\_\_  
Signature of Department Chair                                      Date

**Comment [MJMB]:** Be sure you sign, and get the dept chair’s signature

The Major Professor/Supervising Faculty member must sign the cover page in the section entitled “For Student Projects”.

**PLEASE NOTE:** Any changes to an approved protocol must be submitted to the appropriate committee(s) before the changes may be implemented.

Please proceed to SECTION II.

## SECTION II: IRB SECTION - STUDY SPECIFIC INFORMATION

Please complete all of the following questions.

### STUDY OBJECTIVES

Briefly explain in **language understandable to a layperson** the specific aim(s) of the study.

### BENEFITS TO SOCIETY AND PARTICIPANTS

Explain in **language understandable to a layperson** how the information gained in this study will advance knowledge, and/or serve the good of society. Please also describe the direct benefits to research participants; if there are no direct benefits to participants, indicate that. **Note:** monetary compensation cannot be considered a benefit to participants.

### PART A: PROJECT INVOLVEMENT

- 1)  Yes  No Is this project part of a Training, Center, Program Project Grant?  
Director Name: \_\_\_\_\_ Overall IRB ID: \_\_\_\_\_
- 2)  Yes  No Is the purpose of this project to develop survey instruments?
- 3)  Yes  No Does this project involve an investigational new drug (IND)? Number: \_\_\_\_\_
- 4)  Yes  No Does this project involve an investigational device exemption (IDE)? Number: \_\_\_\_\_
- 5)  Yes  No Does this project involve existing data or records?
- 6)  Yes  No Does this project involve secondary analysis?
- 7)  Yes  No Does this project involve pathology or diagnostic specimens?
- 8)  Yes  No Does this project require approval from another institution? Please attach letters of approval.
- 9)  Yes  No Does this project involve DEXA/CT scans or X-rays?

### PART B: MEDICAL HEALTH INFORMATION OR RECORDS

- 10)  Yes  No Does your project require the use of a health care provider's records concerning past, present, or future physical, dental, or mental health information about a subject? The Health Insurance Portability and Accountability Act established the conditions under which protected health information may be used or disclosed for research purposes. If your project will involve the use of any past or present clinical information about someone, or if you will add clinical information to someone's treatment record (electronic or paper) during the study, you must complete and submit the Application for Use of Protected Health Information.

**PART C: ANTICIPATED ENROLLMENT**

<b>Estimated number of participants to be enrolled in the study</b>		Total:	Males:	Females:
Check if any enrolled participants are:		Check below if this project involves either:		
<input type="checkbox"/> Minors (Under 18)		<input type="checkbox"/> Adults, non-students		
Age Range of Minors:		<input type="checkbox"/> Minor ISU students		
<input type="checkbox"/> Pregnant Women/Fetuses		<input type="checkbox"/> ISU students 18 and older		
<input type="checkbox"/> Cognitively Impaired		<input type="checkbox"/> Other (explain)		
<input type="checkbox"/> Prisoners				
<b>List estimated percent of the anticipated enrollment that will be minorities if known:</b>				
American Indian:		Alaskan Native:		
Asian or Pacific Islander:		Black or African American:		
Latino or Hispanic:				

**Comment [MJM9]:** Make sure you check all the appropriate boxes. Any boxes checked on the left will trigger more stringent requirements for review.

**PART D: PARTICIPANT SELECTION**

Please use additional space as necessary to adequately answer each question.

11. Explain the procedures and rationale for selecting participants, including the inclusion and exclusion criteria (e.g., where will names come from, what persons will be included or excluded and why, etc.).

**Comment [MJM10]:** The committee is looking for equitable selection of participants. For example, if only studying men, be sure to say why that is. Make sure you are clear about your inclusion/exclusion criteria.

12. Describe the procedures for contacting participants (e.g., letter, email, flyer, advertisements, phone call, etc.). Attach copies of any letters, scripts, flyers, or advertisements that will be used. Recruitment materials should include a statement of the voluntary and confidential nature of the research.

**Comment [MJM11]:** Think of all the ways you will recruit participants, and include them here, even if you may not use that method of recruitment.

**PART E: RESEARCH PLAN**

Include sufficient detail for IRB review of this project independent of the grant, protocol, or other documents.

13. The information needed here is similar to that in the “methods” or “procedures” sections of a research proposal—it should describe the flow of events that will occur during your interactions with subjects. Please describe in detail your plans for collecting data from participants, including all procedures, tasks, or interventions participants will be asked to complete during the research (e.g., random assignment, any conditions or treatment groups into which participants will be divided, mail survey or interview procedures, sensors to be worn, amount of blood drawn, etc.). This information is intended to inform the committee of the procedures used in the study and their potential risk. Please do not respond with “see attached” or “not applicable.”

**Comment [MJM12]:** This is perhaps the most important part of the form, and must be consistent with what is in the consent document. It doesn't have to be *identical*, though. Have someone who doesn't know about your study review this part to see if it makes sense. This is the part that causes the most confusion and generates the most questions from the committee.

14. For studies involving pathology/diagnostic specimens, indicate whether specimens will be collected prospectively and/or already exist “on the shelf” at the time of submission of this review form. If prospective, describe specimen procurement procedures; indicate whether any additional medical information about the subject is being gathered, and whether specimens are linked at any time by code number to the participant’s identity. If this question is not applicable, please type N/A in the response cell.

15. For studies involving deception or where information is intentionally withheld from participants, such as the full purpose of the study, please explain how persons will be deceived or what information will be withheld. Additionally, a waiver of the applicable elements of consent will be needed. Please complete the "Waiver of Elements of Consent" form (available at the IRB website). If this question is not applicable, please type N/A in the response cell.

**Comment [MJM13]:** If you are using deception in your study, describe that here, and complete the extra form.

#### PART F: CONSENT PROCESS

A copy of any translated informed consent documents and an English version should be submitted with the application. Provide the name of the individual who translated the consent documents, their qualifications for translating documents, and in particular informed consent documents, below.

If the consent process does not include documented consent, a waiver of documentation of consent must be requested. If any information about the study is intentionally withheld or misleading (i.e., deception is used), a waiver of the elements of consent must be requested. Forms for requesting waivers are available at the IRB website.

16. Describe the consent process for adult participants (those who are age 18 and older).

**Comment [MJM14]:** This also causes confusion. Be sure you are clear about how you are obtaining consent, and clearly communicate that to the committee.

17. If your study involves minor children, please explain how parental consent will be obtained prior to enrollment of the minor(s).

18. Please explain how assent will be obtained from minors (younger than 18 years of age), prior to their enrollment. Also, please explain if the assent process will be documented (e.g., a simplified version of the consent form, combined with the parental informed consent document). According to the federal regulations assent "...means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent."

#### PART G: DATA ANALYSIS

19. Describe how the data will be analyzed (e.g. statistical methodology, statistical evaluation, statistical measures used to evaluate results).

**Comment [MJM15]:** Sometimes this has caused problems. Be sure you have enough participants to analyze the data.

#### PART H: RISKS

The concept of risk goes beyond physical risk and includes risks to participants' dignity and self-respect as well as psychological, emotional, legal, social or financial risk.

20.  Yes  No Is the **probability** of the harm or discomfort anticipated in the proposed research greater than that encountered ordinarily in daily life or during the performance of routine physical or psychological examinations or tests?

21.  Yes  No Is the **magnitude** of the harm or discomfort greater than that encountered ordinarily in daily life, or during the performance of routine physical or psychological examinations or tests?

22. Describe any risks or discomforts to the participants and how they will be minimized and precautions taken. Do **not** respond with N/A. If you believe that there will not be risk or discomfort to participants, you must explain why.

23. If this study involves vulnerable populations, including minors, pregnant women, prisoners, the cognitively impaired, or those educationally or economically disadvantaged, what additional protections will be provided to minimize risks?

**Comment [MJM16]:** This is a question the committee must answer—whether the study poses minimal risk to participants. One question we often ask is: are the study procedures similar to what people do in their everyday lives? If you think the study is more than minimal risk, be sure to address this issue; better to address it and be wrong than to not address it and the committee believe that it is more than minimal risk.

#### PART I: COMPENSATION

24.  Yes  No Will participants receive compensation for their participation? If yes, please explain.

Do not make the payment an inducement, only a compensation for expenses and inconvenience. If a person is to receive money or another token of appreciation for their participation, explain when it will be given and any conditions of full or partial payment. (E.g., volunteers will receive \$5.00 for each of the five visits in the study or a total of \$25.00 if he/she completes the study. If a participant withdraws from participation, they will receive \$5.00 for each of the visits completed.) It is considered undue influence to make completion of the study the basis for compensation.

**Comment [MJM17]:** Be sure the amount of money offered isn't an undue influence on participants (not a typical problem!).

Payments of \$75 or more required participants to provide Social Security Numbers.

#### PART J: CONFIDENTIALITY

25. Describe below the methods that will be used to ensure the confidentiality of data obtained. (For example, who has access to the data, where the data will be stored, security measures for web-based surveys and computer storage, how long data or specimens will be retained, anticipated date that identifiers will be removed from completed survey instruments and/or audio or visual tapes will be erased, etc.)

**Comment [MJM18]:** This is another important consideration for the committee. Describe how you will maintain confidentiality.

**PART K: REGISTRY PROJECTS**

26. To be considered a registry: (1) the individuals must have a common condition or demonstrate common responses to questions; (2) the individuals in the registry might be contacted in the future; and (3) the names/data of the individuals in the registry might be used by investigators other than the one maintaining the registry.

Yes  No Does this project establish a registry?

If “yes,” please provide the registry name below.

**Checklist for Attachments**

Listed below are the types of documents that should be submitted for IRB review. Please check and attach the documents that are applicable for your study:

- A copy of the informed consent document **OR**  Letter of introduction containing the elements of consent
- A copy of the assent form if minors will be enrolled
- Letter of approval from cooperating organizations or institutions allowing you to conduct research at their facility
- Data-gathering instruments (including surveys)
- Recruitment fliers, phone scripts, or any other documents or materials participants will see or hear

The original signed copy of the application form and one set of accompanying materials should be submitted for review.

**Federal regulations require that one copy of the grant application or proposal be submitted for comparison with the application for approval.**

**Comment [MJM19]:** Attach all your documents, including informed consent, advertisements, surveys, etc.

**FOR IRB USE ONLY:**

Action by the Institutional Review Board (IRB):

- Project approved. Date: \_\_\_\_\_
- Project is exempt. Date: \_\_\_\_\_
- Project not approved. Date: \_\_\_\_\_
- IRB approval is not required. Date: \_\_\_\_\_
  - Project is not research according to the federal definition.
  - Project does not include human subjects as defined by the federal regulations.

\_\_\_\_\_  
IRB Approval Signature

\_\_\_\_\_  
Date

**SECTION III: ENVIRONMENTAL HEALTH AND SAFETY INFORMATION**

Yes  No Does this project involve human cell or tissue cultures (primary OR immortalized), or human blood components, body fluids or tissues?

**PART A: HUMAN CELL LINES**

Yes  No Does this project involve human cell or tissue cultures (primary OR immortalized cell lines/strains) that have been documented to be free of bloodborne pathogens? If the answer is “yes,” please answer question 1 below and attach copies of the documentation.

1) Please list the specific cell lines/strains to be used, their source and description of use.

CELL LINE	SOURCE	DESCRIPTION OF USE

Add New Row

2) Please refer to the ISU “Bloodborne Pathogens Manual,” which contains the requirements of the OSHA Bloodborne Pathogens Standard. Please list the specific precautions to be followed for this project below (e.g., retractable needles used for blood draws):

--

**Anyone working with human cell lines/strains that have not been documented to be free of bloodborne pathogens is required to have Bloodborne Pathogen Training annually. Current Bloodborne Pathogen Training dates must be listed in Section I for all Key Personnel. Please contact Environmental Health and Safety (294-5359) if you need to sign up for training and/or to get a copy of the Bloodborne Pathogens Manual (<http://www.ehs.iastate.edu/cms/default.asp?action=article&ID=214>)**

**PART B: HUMAN BLOOD COMPONENTS, BODY FLUIDS OR TISSUES**

Yes  No Does this project involve human blood components, body fluids or tissues? If “yes,” please answer all of the questions in the “Human Blood Components, Body Fluids or Tissues” section.

1) Please list the specific human substances used, their source, amount and description of use.

SUBSTANCE	SOURCE	AMOUNT	DESCRIPTION OF USE
<i>E.g., Blood</i>	<i>Normal healthy volunteers</i>	<i>2 ml</i>	<i>Approximate quantity, assays to be done.</i>

Add New Row

2) Please refer to the ISU “Bloodborne Pathogens Manual,” which contains the requirements of the OSHA Bloodborne Pathogens Standard. Specific sections to be followed for this project are:

**Anyone working with human blood components, body fluids or tissues is required to have Bloodborne Pathogen Training annually. Current Bloodborne Pathogen Training dates must be listed in Section I for all Key Personnel. Please contact Environmental Health and Safety (294-5359) if you need to sign up for training and/or to get a copy of the Bloodborne Pathogens Manual (<http://www.ehs.iastate.edu/cms/default.asp?action=article&ID=214>).**