View xForm - IRB Application

One Form to Rule Them All

Application Data Entry

Basic Study and PI Information

Basic Study Information

Submitter
User, IRB

<table>
<thead>
<tr>
<th>Email:</th>
<th>Phone:</th>
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Title of Project

No answer provided.

Please enter the email address of the principal investigator.

If you are the principal investigator, please enter your own email address.

No answer provided.

CITI Human Subjects Training

Additional PI and Study Information

PI Level
No answer provided.

PI's Department Chair
N/A

Note about Recruitment Registries or Data/Specimen Repositories:

- A stand-alone IRB protocol is required when establishing a recruitment registry AND/OR data or specimen repository.
- If you are obtaining data from an existing repository, or using an existing recruitment registry as part of a Human Subjects Research Project, check "Human Subjects Research Project".

This application is seeking IRB approval for:

No answer provided.

Is or will the project be externally funded?

No answer provided.

External funding may come from federal funds, state or local government agencies, non-profit institutions, or for-profit businesses. Internal department funding is not considered "external" funding.
**Does this project involve collaboration with researchers at another institution?**

No answer provided.  
Select "yes" if individuals at other institutions will be involved as researchers on the project.  
Select "no" if you are conducting research at a collaborating site, but the only role of persons at that site is to serve as research participants.

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### Key Personnel

Key personnel include any other individuals who will be involved with collecting data from participants, involved with recruitment or obtaining informed consent, or who have access to their private and identifiable data. For more information, please see Human Subjects – Persons Required to Obtain IRB Training.

Key personnel other than the PI and/or Supervising Investigator working on this study will need to be listed in response to one of the two questions below. Please be sure to select the appropriate table for the personnel:

- ISU Faculty and P&S staff, OR
- Other Personnel (i.e., research assistants, student personnel, hourly staff, transcribers, coders, non-ISU investigators, etc.)

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**Will there be any other ISU Faculty or P&S Staff Investigators (not the PI or Supervising Investigator) responsible for the design, conduct, or reporting of the findings of this protocol of the study?**

No answer provided.

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**Non-ISU Contacts:** If the contact you wish to include is outside of ISU and you receive an error upon entering the email address, please click the link below to add them to the system. A form will open in a new tab or window for you to enter their contact information. Once the information is entered in the form and it is submitted, you will be able to come back to this page and add them to the study.

Click to Add New Non-ISU Contact

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**Will there be any other individuals (not already listed) who will be involved with the human subjects research activities (e.g., research assistants, student personnel, hourly staff, transcribers, coders, non-ISU investigators, etc.)?**

No answer provided.

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### General Overview - Purpose and Expected Benefits

**Research Objectives - Briefly explain in language understandable to a layperson the purpose and specific aims(s) of the study.**

No answer provided.
Broader Impacts/Significance - Explain in language *understandable to a layperson* why this research is important and how the information gained in this study is expected to advance knowledge and/or serve the good of society.

*Be sure to include justification as to why this study is necessary.*

No answer provided.

Benefits to Participants - Are there any expected direct benefits to research participants from participation in the research?

*Compensation (i.e., monetary, course credit, etc.) is *not* considered to be a benefit of participation in research.*

No answer provided.

Research Plan - Participant Characteristics

Inclusion Criteria - Describe the specific characteristics of persons that will be included in your study, and provide justification for these requirements.

No answer provided.

Exclusion Criteria - Describe the characteristics of any persons who will not be allowed to participate in your study, and provide justification for their exclusion.

No answer provided.

Do you intend, or is it likely that your study will include any persons from the following populations? Please check all that apply.

No answer provided.

Participant Enrollment

Please indicate the maximum number of participants you expect to enroll in your study. This number should include the total number of participants across all groups and account for any enrollment that may be needed due to attrition, withdrawals, screen failures, etc.

No answer provided.

Please include details about the planned enrollment numbers such as how many you expect to include in any groups or conditions, how many you expect to screen versus fully enroll in the study, etc.

No answer provided.

Research Plan - Data Collection Procedures
Research Procedures - Using layperson's terminology, please describe in detail your plans for collecting data from participants. Include a description of 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, observation protocols, sensors to be worn, amount of blood drawn, etc.).

When referencing attached documents (i.e., surveys, interview protocols, copies of stimuli, instructions for tasks, etc.), please ensure that each attachment is clearly labeled and clearly referenced in this section.

No answer provided.

Will your research include any types of recordings that may capture private or identifiable information?

These selections must be described in detail in the research procedures above.

No answer provided.

Secondary Use of Data or Information from Records, Repositories, Databases, or Similar Sources

Does your study involve obtaining information or data about people from records, (e.g., student records, medical records, etc.), repositories (e.g., tissue banks, biospecimen repositories, etc.), or other similar sources (e.g., government databases, data from other studies, etc.)?

No answer provided.

Will any devices be used for data collection (i.e., eye trackers, activity monitors, heart rate monitors, EEG, MRI, DEXA, other sensors, etc.)?

No answer provided.

Does the research involve collection of data from observation of people's behaviors or activities?

No answer provided.

Will participants be deceived or misled about anything during the study, and/or do you plan to intentionally withhold information from participants, such as the full purpose of the study, a full description of procedures, etc.? Check all that apply.

No answer provided.

Will your participants consume any substances for purposes of your research (e.g., food, beverage, dietary supplements, drugs, vitamins, etc.)?

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

No answer provided.

Will the research take place in an international setting?

No answer provided.

Do you believe your study may qualify for exemption?

No answer provided.

Data Collection Materials

Attach any materials related to the data collection and screening procedures (e.g., survey questions, interview questions, medical history questionnaire, focus group protocols, descriptions of stimuli, descriptions of tasks, etc.) you will use for this study.

Note: If you have already attached data collection materials (i.e. observation protocol, etc.) as a response to another question, you do not need to upload it here.

No answer provided.

Clinical Trials

There are special requirements related to conducting Clinical Trials, including training on Good Clinical Practices, trial registration and results-reporting at ClinicalTrials.gov, and in some cases, approval from the Food and Drug Administration. These requirements differ depending on the funding agency and/or type of clinical trial. The following questions are intended to identify research that is subject to these requirements.

Does your study involve research on any of the following:

No answer provided.

Please answer the following questions to assess whether or not your study meets the NIH definition of a Clinical Trial:

Is your study funded in whole or in part by the National Institutes of Health?

No answer provided.

Is your study an Applicable Clinical Trial, for which registration at www.ClinicalTrials.gov is required? Please check this flowchart or work through this interactive flowchart before responding.

No answer provided.
### ClinicalTrials.gov Registry

If you plan to publish the results in a member journal of the International Committee of Medical Journal Editors (ICMJE), please be aware that ICMJE requires clinical trial registration in a public registry such as [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) to be a condition for publication. For more information see: [http://icmje.org/about-icmje/faqsclinical-trials-registration/](http://icmje.org/about-icmje/faqsclinical-trials-registration/).

### Discomfort or Risk to Participants

#### Discomfort or Risk

**Are there any foreseeable discomfort or risk to participants from taking part in your research?**

Yes

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**Do you foresee any physical discomfort/risk to participants?**

*Examples may include: injury, bruising from a blood draw, pain, side-effects from drugs administered, allergic reactions, etc.*  
No answer provided.

**Do you foresee any psychological discomfort/risk to participants?**

*Examples may include: emotional discomfort from answering questions, stress or anxiety from procedures, mood alterations, viewing offensive or "shocking" materials, etc.*  
No answer provided.

**Do you foresee any informational or social discomfort/risk to participants?**

*Examples may include: harm if information collected about the participant were disclosed or overheard, such as embarrassment, retribution, harm to reputation or stigmatization, disruption of personal or family relationships, disruption of employment or workplace relationships, etc.*  
No answer provided.

**Do you foresee any legal discomfort/risk to participants?**

*Examples may include: criminal liability if information about participants' illegal behaviors is collected, etc.*  
No answer provided.

**Do you foresee any other discomfort/risk to participants, given the setting of your research?**  
No answer provided.

### Data and Safety Monitoring

#### Is a data safety and monitoring plan required for this study?

No answer provided.

### Recruitment and Informed Consent
Recruitment Process

Describe the process you will use to identify and invite people to take part in your study. Your response should include how you will obtain contact information for your potential participants AND how you will contact them.

Examples of how you will obtain contact information for your potential participants:
- review of public records (e.g., voter lists, utilities lists, phone directory, ISU directory, etc.),
- review of private records (e.g., medical records, student records, etc.),
- purchased mailing lists,
- personal contacts/knowledge,
- “snowball” sampling,
- participant responses to posted advertisements or flyers, etc.

Examples of how you will contact them:
- letter or email,
- phone call,
- posting flyers,
- posting announcement on a website,
- posting on a SONA system,
- distribution of email or ads via Listserves or online bulletin-boards,
- television or radio advertisements,
- personal or verbal announcements,
- informal personal communication, etc.

No answer provided.

Recruitment Materials

Attach all materials you will use to recruit or invite participants to take part in your study.

For example:
- phone scripts,
- advertisements,
- flyers,
- letters,
- emails,
- verbal talking points, etc.

No answer provided.

Participant Eligibility

What is your process for determining whether or not all potential participants are eligible to participate prior to including them in your study?

The information provided here should explain how you will ensure that participants are eligible based on the inclusion and exclusion criteria you have assigned for this study.

Please be sure to include information on any screening procedures you may be conducting prior to enrollment.

If you will obtain information from people or ask them to do something specific prior to their formal enrollment, you must first obtain their informed consent. Your description of the consent process(es) must include plans to obtain consent prior to any screening or eligibility assessment activities.

No answer provided.
CONSENT PROCESS

In most cases, people cannot participate in a research study without first obtaining their informed consent. Obtaining informed consent is much more than asking people to sign a document; in fact, in many instances, no signatures are required. Instead, it is an ongoing process between researcher and participant where information is conveyed, in an appropriate manner and setting, to allow persons to voluntarily consider and choose whether or not to participate.

People can truly give informed consent, only when:

- **Meaningful information** about the study is conveyed in a clear manner, understandable to the participant (e.g., well-organized, concise, no scientific jargon, appropriate reading level and language, etc.)
- The participant has sufficient opportunity to consider the information, ask questions, discuss it with others, etc.
- Consent is given freely, and under the circumstances that eliminate or minimize undue influence or coercion.
- In cases where adult participants are unable to consent for themselves, such as those with impaired decision making capacity due to disease, dementia, life-threatening situations, etc., informed consent must be obtained from the participants' **Legally Authorized Representative**. Additionally, participants must be given an opportunity to assent (affirmatively agree) to the extent possible.

Please describe the **process(es) you will follow** to obtain the voluntary, informed consent of ADULT participants. Your response must include sufficient information regarding how your planned consent process(es) address the points above.

No answer provided.

In very limited instances, human subjects may be involved in research without their informed consent. For example, consent may not be obtained from those who are third-parties in an observation process, or when research involves obtaining existing records, etc. Anytime informed consent will not be obtained, the IRB must grant a waiver of the typical, informed consent requirement. A waiver is generally allowable with sufficient justification that your study meets **special criteria**.

In your study, will informed consent be obtained from ALL participants before they complete any research procedures?

No answer provided.

**Translation**

**Translation of Information or Materials**

In order to facilitate meaningful informed consent, recruitment and informed consent materials must be in a language understandable to the participants. If your study will include individuals who do not read or speak English, recruitment and consent materials must be translated into the appropriate languages.

Please check the following to describe your plans.

No answer provided.
### Compensation

**Will participants receive any compensation (i.e., monetary, course credit, etc.) for their participation in your research?**  
*No answer provided.*

### Privacy

**Describe how participants' privacy will be protected during recruitment and data collection.**

> For example, discussions/procedures will be conducted in private locations, messages regarding the research will not be left on answering machines without permission of participant, how documents or recordings will be kept secure while in the field and during transmission, etc.

*No answer provided.*

### Data Security

**Minimum Data Security Standards**

Iowa State University established a [data security policy](#) in 2015, which establishes minimum security standards. The policy has established four classifications of data (Restricted, High, Moderate, Low). Research data is classified as “moderate”, as such, [security standards](#) outlined for moderate level data apply – unless the research data includes information that falls into one of the higher levels of classification (e.g. FERPA protected, HIPAA protected, etc.) Investigators should follow the [Minimum Security Standards](#) appropriate for the classification of their data.

You will first select the classification level that applies to your research. Appropriate classification is based on the nature and sensitivity of the data. You will next be asked to confirm your agreement to implement the applicable minimum security standards that apply to the data classification level selected for your research project. **Principal Investigators and Supervising Investigators are responsible for ensuring correct implementation of these standards.** You are strongly encouraged to work with departmental, college, or University IT staff as needed.

**Please select from the options below to indicate the sensitivity level/data classification that applies to your study.**

*No answer provided.*

### Confidentiality
Identifiers

Will you obtain any of the following identifiers about participants at any stage of the research (e.g., recruitment, data collection, from existing records, etc.)? Please select from the list below.

No answer provided.

Describe the reason it is necessary to obtain this identifiable information and how it will be used (e.g., recruitment, matching data across time points, only to verify informed consent, follow-up or reminders, etc.). Please be sure to indicate if this information will ever be linked to participant responses, even temporarily.

No answer provided.

Describe your process for ensuring confidentiality of participant identifiers during all stages of the research. This includes removing participant identifiers from the study data, secure disposal of any recruitment lists, etc. If any of the data cannot be fully de-identified (e.g., video recordings, photographs, detailed case study information, etc.), please explain.

The description should include but is not limited to:

- Timing of de-identification in relation to data collection,
- Plans to de-identify video recordings or photographs, when applicable,
- Plans to de-identify transcriptions, when applicable,
- Any plans to replace identifiers with ID codes or pseudonyms,
- Whether or not you will retain a key linking identifiers with ID codes,
  - Where the key will be stored to maintain it's security,
  - When the key will be destroyed

No answer provided.

Deductive Disclosure

What specific steps will you take to ensure participants are not identifiable (directly or indirectly via deductive disclosure) when research results are reported? If you cannot or do not plan to maintain confidentiality, please explain.

No answer provided.

Access to Study Data or Records

Will anyone other than those on the research team have access to any identifiable study data or records?

No answer provided.
Certificate of Confidentiality

Certificates of Confidentiality (CoC) are designed to protect identifiable research records against forced disclosure (e.g., subpoena), and may be important to protect certain types of information (e.g., data on illegal behaviors, genetic information, certain kinds of diseases or mental health conditions, etc.). When a CoC is in place, there are restrictions on how identifiable information about research participants may be disclosed or shared. Researchers must comply with these restrictions.

CoCs are obtained in one of two ways:

1. For NIH-funded research - Research that involves collection or use of individually identifiable, sensitive information is automatically issued a CoC from NIH, and is subject to the corresponding disclosure restrictions outlined in NIH Policy.

2. For other research - CoCs can be sought from the National Institutes of Health (NIH) or Centers for Disease Control and Prevention (CDC) in certain circumstances. Visit the Certificates of Confidentiality Kiosk for more information.

Have you or will you obtain a Federal Certificate of Confidentiality for this study?

No answer provided.

Data Sharing

Do you have any plans to share individual-level data from this study with anyone outside of the current research team (e.g., a recruitment registry, data or specimen repository, other researchers for secondary analysis, to meet funding-agency requirements, etc.)?

Be sure participants are informed of any data sharing plans in the informed consent process and/or document.

No answer provided.

Optional - Additional Considerations

Optional: Please share any information that you feel would be appropriate in assisting the IRB with review of your study. Examples may include historical background that is relevant to this study, important information about the research site(s), etc.

Please do not include information that should be included in prior questions within this application.

No answer provided.

Optional: Attach any documents that you wish to share with the IRB to assist with the review of your study. Examples may include permission letters from research sites, supporting literature, etc.

No answer provided.