

**Institutional Review Board (IRB) Resource Guide**

**FORM 1: INSTITUTIONAL REVIEW BOARD APPLICATION**

**\*\*This form is required for every IRB application. Do not delete any content from Form 1**

1. The information provided in each section must be very detailed so the reviewer has a clear understanding regarding what you plan to do with the participants and what you plan to do with the data you are collecting. The study procedure needs to be written step by step. Write as if you are expecting someone else to follow your instructions if you are absent.
2. Each section offers information to help assist you in responding to that section, please review
3. You may respond to each section in paragraph form or use bullet points

**Form 1 subsections with helpful guidance:**

**Subsection: Purpose of the study**

* Only need to include a brief statement for the purpose

**Subsection: State the Hypotheses, Research Question, or Practice Question**

**Subsection: Description of Subjects**

* Need to include the exact target sample size *“the target sample size is XX”*
* State how and where you will screen for eligibility for the study
* State the inclusion criteria for the participants *(*for example *“age 19 and older, male and females, no chronic diseases”)*

**Subsection: How Subjects Will Be Selected and Recruited**

* State sampling method, such as random or convenience sampling
* Include the recruitment materials in your application, such as flyers, email scripts, social media messages, if recruitment is conducted face-to-face include the verbal script you will use
* State where recruitment will take place and who will do the recruitment
* Basically describe how the prospective participant will learn about the study and be asked to participate

**Subsection: Background and qualifications of the principal investigator and additional personnel directly involved in the research:**

* Identify all team members who will be engaged in the research (engaged: such as obtaining consent, collecting data or conducting the experiments, working with identified data, etc)
* For each member who is engaged, state where they work or where they are a student, and add their credentials; *do not include their resume or CV.*
* Attach each team member’s CITI certificates. The 4 required CITI training certificates include: Human Subject Researcher, Responsible Conduct for Research, Conflict of Interest, and Export Compliance.

**Subsection: Description of Procedure**:

* This section needs to show what specific steps will be taken once informed consent has been obtained.
* Could begin this section by stating *“once consent is given the participant will…..”* then list **each step** the participant will do, such as completing surveys, performing tasks, be specific here. This needs to be written in a step by step order.
* Describe the location where the study will take place (for example: the lab, classroom, waiting room, private room, researcher’s private office, participant’s home, online)
* Describe when and how the surveys will be administered by the team members
* If the participants will be receiving incentives such as gift cards/cash etc, describe how the gift cards/cash etc will be distributed to the participants. For example, who will provide the incentive to the participant and how will the participant receive the incentive (pick up or email). If someone who is not on the research team will be distributing the incentives describe who this person will be and how they will have access to the participants so they can deliver the incentive to the participants.
* Also include the steps the research team members will do once they have collected the data
	+ Include how the data will be collected and where it will be stored (such as *“data will be collected in person and then transcribed to a spreadsheet that has been de identified, the data (*list the type of data*) will be stored on a password protect computer only accessed by the team members”).*
	+ State who will have access to the data
	+ State how long the data will be stored and how it will be destroyed, for example *“the data will be stored for 3 years and then all papers copies will be shredded and all electronic files will be deleted”*

**Subsection: Instrumentation**

* Describe each survey/tool/instrument in detail and list what type of data will be collected, For example: “*Demographic data will include: age, ed level, years at institution, number of employees under your supervision, etc*.
* Include each survey/tool/instrument in your submission either as an appendix or as an attachment in the submission email

**Subsection: Duration of Study**

 a. **Total amount of time with each subject**: this only includes the participants time such as *“5 minutes to complete the demographics, 40 minutes to perform the tasks, 5 minutes to complete the survey, total time will be 50 minutes per participant*

 b. **Time to complete study**: this includes your timeline, that will include conducting the study from time of imitation to completion of data analysis for example *“6 months”*

**Subsection: Benefit(s) of the Study**

* Briefly describe what the participant will gain and what may be the benefit to society from the results of your study.

**Subsection: Compensation and Incentives with Monetary Value** (be sure to review what is written in red on form 1 for this section)

* Be specific regarding what incentive will be given to the participant, for example: a gift card and how much or how they will receive xx number of research points in a class
* Note that either all will receive an incentive or no one will receive an incentive. Could state *“there is no incentive given to participate in this study.”* Or just state *“none”*
* If you can only give a limited amount of incentives to a few participants (such as cash or gift cards) there needs to be a qualifying event for the participant to enter into a drawing. Can state *“if you wish to participate in a drawing to receive a XX$ gift card please answer the following question…..*this question can be very easy and to your choosing,then state *once you have answered the question your name will be entered into the drawing.”*
* Describe how the incentive will be given to the participant, this section should match what is described in the procedure section of form 1.

**Subsection: Possible Risks to Subject(s) and Precautions Taken to Avoid Risks**

* There may be some minimal risk, if so list those
* If there are risks such as emotional or physical describe how the risk, if encountered, will be addressed and or what resources will be offered to the participants, such as UAH counseling center, etc.

**Subsection: How You Will Ensure Confidentiality/Anonymity**

* Describe how you will de identified the data and how the data will be recorded/documented
* State how long the data will be stored and how it will be destroyed

**Subsection: Procedures for Obtaining Informed Consent or Assent**

* Describe how you will obtain consent, state where consent will be obtained.
* If you are not obtaining written consent but obtaining consent electrically such as through Qualtrics then you are required to also include **FORM 11: Request for Waiver of Written Documentation of Informed Consent.** Youcan state the following in form1:
	+ When using Qualtrics can state: “Potential participants will be presented with a recruitment email containing a link to the Qualtrics survey.  If interested, the individual will click on the link and will be presented with an informed consent document via Qualtrics.  Participants will acknowledge their consent by clicking on an “Agree or Disagree” radio button. In order to complete the survey participants will have to click the “agree” button. No identifying information will be captured. All information gathered in this study will be kept as confidential as possible. No IP addresses, names, or other information that could be used to identify participants will be collected or linked to the data.
* If you are waiving consent describe why and include **FORM 8 Request to Waive Informed Consent**
* Must use the current consent form found on the IRB website title: Sample consent form.
* State if consent will be obtained following recruitment or will there be a delay in consenting.