



Originally Issued: September 6, 2016  
Reviewed: January 2019

FOR IRB USE ONLY

IRB # \_\_\_\_\_

Date Submitted: \_\_\_\_\_

Date Approved: \_\_\_\_\_

**Application for Institutional Research**  
***Full or Expedited Review***

Full Review  Expedited Review

Proposed Start Date: [Click here to enter text.](#)

**Project Title:**

**Faculty/Staff Investigator**

**Name:**

**Department/College:**

**Phone Number:**

**Email:**

**Date CITI Training Completed** (*Attach copy of CITI Training Certificate*):

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**Student Investigator, If applicable:**

**Name:**

**Department/College:**

**Phone Number:**

**Email:**

**Date CITI Training Completed** (*Attach copy of CITI Training Certificate*):

**Faculty Advisor Name:**

**Department/College:**

**Phone Number:**

**Email:**

**Date CITI Training Completed** (*Attach copy of CITI Training Certificate*):

**Type of Research**

Thesis

Class Project

Faculty Research (Please see information at the bottom of this form if this research pertains to a grant opportunity)

Other (Please explain):



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**Please check that all of the following items are attached, if applicable BEFORE submitting the application:**

- All research instruments (i.e., tests, surveys, questionnaires, or anything other methods used to collect data.)
- All *informed consent/assent* documents.
- Permission from applicable authorities (i.e., principals of schools, teachers of classrooms, parent(s) permission for videotaping) to conduct your research at their facilities.
- Appropriate permission and signatures from your faculty advisor, if applicable.

**1. Purpose/Objectives of Research:**

(In this section, briefly state the purpose and the problem to be investigated. Also, state the specific hypothesis to be tested or specific research questions to be answered. For pilot or exploratory studies, discuss the way in which the information obtained will be used in future studies so that the long-term benefits can be assessed.)

**2. Relevant Background and Rationale for the Research:**

(In this section, present the context of the work by explaining the relation of the proposed research to previous investigations in the field. Please include citations of relevant research largely focused on peer-reviewed articles.)

**3. Recruitment Procedures & Participant Population:**

(In this section, please address the following questions to the best of your ability.)

- A) Please list the number of expected participants in this study.
  
- B) Describe all characteristics that would be relevant for participants (e.g., demographics, ethnicity, any vulnerabilities, disabilities etc.). Explain *why* you are focused on this particular population group.
  
- C) Indicate if anyone might be *excluded* from participation in this study, justify *why*.



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- D) Explain how you will find, recruit, and/or identify participants for this study? Discuss the selection process? Please attach flyers, posters, or any type of oral/written invitations used to recruit potential participant.
- E) If you are offering any type of incentive (e.g., extra credit)? If YES, please explain.

#### 4. Informed Consent Process

Please complete and attach the *Consent/Assent/HIPAA Authorization to Participate in Research* form. Also complete the questions pertaining to each population that will be participating in your research.

- A) Please describe how and when you will explain the parameters of your study and the required elements of the *Consent/Assent/HIPAA Authorization to Participate in Research*. Provide who will be doing this task.
- Where the consent process will take place and provisions that were made for privacy.
  - Discuss waiting periods between informing the prospective participant and obtaining the consent.
  - Describe processes to ensure ongoing consent throughout the study.
  - Discuss any procedures/testing for ensuring that the consent is fully understood by the participants.
- B) After explaining the parameters of the study, how much TIME will the participants have to consider participating in your study (i.e., upon receipt of consent document, beginning of study)?
- C) If you have participants that are under the age of 18, please discuss how you will explain the parameters of the study to them? How will you handle parental consent and child assent?
- D) If you are requesting a Waiver of Informed Consent, please explain why the waiver is needed. Outline the alternative procedures for obtaining consent or providing study information that you plan to use. Also, please address the following items:
- Attach the written script to be provided orally and assurance that any written information contains ALL of the required elements of informed consent.



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- How does the research meet criteria for minimal risk?
- State if the consent would be the only record that links the participant(s) and that the research data could represent the principal risk of harm that could result in a breach of confidentiality.

[Click here to enter text.](#)

- E) Non-English Speaking Participants: Indicate the primary language(s) of your participants. If any of the participants are not fluent and comfortable with English, please explain how you will ensure that each participant has an understanding of the activities for which they are giving consent.
- F) Cognitively Impaired Adults/Use of a Legally Authorized Representative: Indicate if you are working with Cognitively Impaired Adults and plan to use a Legally Authorized Representative.
- Describe the process you plan to use to determine whether an individual is capable of consent.
  - Describe how the participant's decisional capacity will be assessed throughout the study in order to evaluate any deterioration in the participant's level of consent capacity.
  - Will the participant's decisional capacity be assessed as the study proceeds in order to evaluate any improvement in the participant's level of consent capacity?
  - List the individuals from whom permission will be obtained (i.e., close relative, legal guardian) and explain the process for assent of these research participants.
  - Explain how this authority to provide consent will be confirmed.
- G) HIPAA Authorization: If you are collecting Personal Health Information (PHI), please include a detailed list of identifiers that will be part of the study data.
- Include justification for use of the PHI that you plan to collect.  
Provide and attach HIPAA authorization form for collection of PHI. (*Consent/Assent/HIPAA Authorization to Participate in Research*)
  - If you are requesting a Waiver of HIPAA or a Waiver of HIPAA for recruitment purposes only, please address the following items:
    - Discuss how the use of PHI involves no more than a minimal risk to the privacy of the research participants based on one of the following:
      - Describe an adequate plan to protect the PHI
      - Describe an adequate plan to destroy PHI at the earliest opportunity, unless there is reason to obtain it (please justify this decision)
      - Provide assurance that PHI will not be re-used or disclosed inappropriately.
      - Provide justification that the waiver will not adversely affect rights of participants.
      - Provide justification that research could not be practically carried out without waiver.



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- Describe steps that would be taken to minimize possibility of coercion or undue influence.
- Describe steps that would be taken to ensure the participant(s) understanding.

**5. Procedures and Methodology:**

(In this section, please provide a detailed description of each procedure and each population group, if applicable.)

- A) Describe the study design and why this design should be capable of meeting the study objectives.
  
- B) Please provide a detailed description of all study procedures, assessment and participant activities in a sequential format. Attach assessment document(s) as an appendix. Please consider using a table describing each session and corresponding assessment – if your study has multiple sessions.
  
- C) Where will the research be conducted? Are there any risks or confidentiality issues that would be related to this location?
  
- D) State the specific dates/timeframe in which you plan to conduct your research (i.e., duration). Consider including a flow diagram to improve clarity.

**6. Participant Compensation:**

(In this section, please describe any time of reimbursement/compensation to participants including amounts and payment schedule (i.e., class credit, merchandise cards, transportation).

- Describe why the proposed amount is reasonable and appropriate for the participant's time.



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- If the study includes multiple visits, include your description of prorating and equal payment.

### **7. Risks and Safeguard Procedures**

(In this section, you need to discuss all possible risks and discomforts a participant might experience, indicating both severity and likelihood of occurrence for each. Remember, that risks may range from physical to psychological. Keep in mind that inconvenience, travel, or boredom may also be considered risks of participation in a study. You will NEED to discuss the methods that will be used to minimize these risks remembering that many studies hold the potential for loss of privacy and even confidentiality. Such concerns NEED to be noted in this section. It is especially important that participants from vulnerable populations, or if risks are more than minimal, you will NEED to describe what additional safeguards will be taken when implementing this study.

### **8. Privacy/Confidentiality:**

(In this section, please describe in detail whether this research would involve any observation in situation where participants have a reasonable expectation of privacy. If you plan to use identifiable existing records, has appropriate permission been sought (i.e. institutions, participants, physicians)? What provisions are to be made to protect the confidentiality of sensitive information about individuals? Are the research records anonymous? Please provide information on how records will be coded and where and how they will be stored. Please note where and how signed consent forms will be maintained. If video or audiotapes will be made as part of the study, disposition of these tapes should be discussed. Discuss how research tapes will be permanently destroyed once needed data has been transcribed and if only restricted study personnel will be allowed access to the tapes. List the names of individuals who will have access to names and/or data.

### **9. Unanticipated Problems:**

(In this section, describe the process for monitoring and reporting any unanticipated problems or adverse event to ASU IRB within 7 calendar days.)

### **10. Participant Complaints/Withdrawal:**

(Please describe procedures for handling participant complaints or request for information about the research. Such procedures will need to be safe and confidential. If a participant withdraws during data collection, what





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**If this research pertains to a grant opportunity:  
Funding Agency & ID Number:**

**Grant submission deadline:**

Application reviewed by Provost/Vice President for Academic Affairs

X

Approved    Denied  
Signature of IRB Administrator

X

Next Project Review Date: \_\_\_\_\_