



CARDINAL STRITCH UNIVERSITY

Institutional Review Board (IRB)
Human Participants Research Protocol (HPRP)

Protocol #: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_
IRB use only

1. INVESTIGATORS

Principal Investigator

Name
Address
Phone
Email address
Department College
Student Faculty Staff

Other Investigators (if applicable)

Name
Address
Phone
Email address
Department College
Student Faculty Staff

Advisor (if applicable)

Name
Address
Phone
Email address
Department College

2. PROJECT

Project title
Application date
Anticipated beginning date of participant recruitment and data collection
Anticipated ending date of participant recruitment and data collection
Funding source
Personal
Grant (state source)
Other (provide explanation)
Funding is not required

### 3. PARTICIPANTS

#### a. Describe the pool of participants

1) **Gender** (if one gender, justify your exclusion of the other) \_\_\_\_\_

2) **Age range** \_\_\_\_\_

3) **Race/ethnic group**

\_\_\_\_\_ No ethnic group will be specifically chosen or excluded

\_\_\_\_\_ This study will target specific ethnic groups

Identify the groups and describe the reason for choosing these groups and excluding others \_\_\_\_\_

4) **Number/sample size** (provide exact or maximum number) \_\_\_\_\_

5) **Physical and mental health**

\_\_\_\_\_ Participants will not be chosen or excluded based on their physical or mental health

\_\_\_\_\_ Participants will be required to have a specific physical or mental status

Describe here, including the method for determining this status. \_\_\_\_\_

6) **Protected populations**

a) Do the targeted participants belong to any of the following protected populations? Note that a participant may belong to one or more of these categories by chance (e.g., a participant might be pregnant). However, do not check "Yes" unless you are a) specifically targeting that population or b) if there is a high likelihood certain participants will belong to a protected population, even if not specifically targeted.

\_\_\_\_\_ No participants belong to a protected population. Skip to *b. Participant Recruitment*

\_\_\_\_\_ All participants belong to one or more protected populations. Complete the section below.

\_\_\_\_\_ Some, but not all, participants belong to one or more protected populations. Please explain and complete the section below.

Check all that apply.

(1) \_\_\_\_\_ Minors (17 years or younger)

(2) \_\_\_\_\_ Pregnant women and fetuses

(3) \_\_\_\_\_ Prisoners

(4) \_\_\_\_\_ Individuals on probation or parole

(5) \_\_\_\_\_ Persons with mental disabilities: Describe

(6) \_\_\_\_\_ Persons with learning, emotional, or cognitive disabilities: Describe

(7) \_\_\_\_\_ Any individual not listed above who might not be capable of making an informed decision concerning participation. Please explain.

b) If the participants are from a protected population, justify the necessity of their participation.

(1) Why are you using this group?

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(2) Why cannot “non-protected” adults be used?

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c) Does your research take place in a classroom setting involving children with disabilities?

No \_\_\_\_\_ Skip to *b. Participant recruitment*

Yes \_\_\_\_\_

(1) Do these children participate in “normal classroom activities” with few adaptations? If yes, explain.

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(2) Do these children have current Individualized Educational Plans (IEPs) that specify participation in “normal classroom activities”? If yes, explain.

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## b. Participant recruitment

1) **Affiliation** of participants with institutions, agencies, schools, hospitals, or the general public.

That is, from where will you recruit your participants? Check all that apply. If more than one source is checked *and* if participant characteristics are different for each source (e.g., participants older than 17 will be recruited from Cardinal Stritch University and participants 17 or younger will be recruited from a high school), explain the participant differences.

\_\_\_\_\_ Participants will be recruited from Cardinal Stritch University.

a) Describe how participants will be contacted and recruited. \_\_\_\_\_

\_\_\_\_\_ Participants will be recruited from an institution, school, agency, business, organization, etc. other than, or in addition to, Cardinal Stritch University.

a) Provide the name and full address of the institution. \_\_\_\_\_

b) Describe how participants will be contacted and recruited. \_\_\_\_\_

c) Complete an *Affiliation Agreement* (<http://www.stitch.edu/Offices-and-Services/Institutional-Review-Board/>), showing you have permission to recruit from this institution, even if you are employed at that institution.

\_\_\_\_\_ A signed *Affiliation Agreement* is attached.

\_\_\_\_\_ A sample *Affiliation Agreement* is attached. It will be signed at a later date.

\_\_\_\_\_ An *Affiliation Agreement* cannot be obtained. Explain the reason.

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\_\_\_\_\_ Participants will be recruited from one or more social networking sites.

a) Give the names and links of the sites you will use. \_\_\_\_\_

b) Describe how participants will be contacted and recruited. \_\_\_\_\_

\_\_\_\_\_ Participants will be recruited from the general public.

a) Describe where you will recruit these participants. \_\_\_\_\_

b) Describe how participants will be contacted and recruited. \_\_\_\_\_

2) **Recruitment materials:** Will you be using flyer, invitations on social networking sites, or other recruitment materials?

No \_\_\_\_\_

Yes \_\_\_\_\_ Include a copy at the end of the protocol.

3) **Summary of tests or instruments used in preliminary screening of participants:** Will you be performing a preliminary screening in order to choose participants?

No \_\_\_\_\_ Skip to *c. Archival data*

Yes \_\_\_\_\_

1) Describe all instruments used in screening of participants. \_\_\_\_\_

2) Describe how these instruments will be used in your research. \_\_\_\_\_

### c. Archival data

1) Will you be using archival or pre-existing data (data that have already been collected)?

No \_\_\_\_\_ Skip to 4. *PROJECT DESCRIPTION*

Yes \_\_\_\_\_

2) Describe the source of the data. \_\_\_\_\_

3) Will the data be used for a purpose other than that agreed upon by the original participants?

No \_\_\_\_\_

Yes \_\_\_\_\_ Describe the original intent of the data. \_\_\_\_\_

4) Did another institution's IRB approve the original protocol?

No \_\_\_\_\_

a) Please explain the reason. \_\_\_\_\_

Yes \_\_\_\_\_

a) Provide the name of that institution. \_\_\_\_\_

b) Attach an example of the original consent form.

c) Attach a copy of the original signed IRB approval letter.

#### 4. PROJECT DESCRIPTION

Use as much space as needed but do not submit a separate description, proposal, or thesis.

Provide definitions for unfamiliar terms. Note that IRB members might not have expertise in your field.

a. **Purpose, hypothesis, research question or objectives:** Describe the intent of your study.

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b. **Data:** Describe the information to be gathered. If applicable, describe your independent and dependent variables. Describe any tests that might be used.

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#### c. Surveys and interview questions

1) Will you be giving a survey or asking interview questions?

- No \_\_\_\_\_ Skip to *d. Procedure*  
 Yes \_\_\_\_\_ Participants will be given a paper copy of the survey.  
 Yes \_\_\_\_\_ Participants will be given an online link to the survey.  
 Yes \_\_\_\_\_ Participants will be asked interview questions.

2) Source of survey or interview questions

- \_\_\_\_\_ Survey/interview requiring copyright permission. For each survey, give evidence that permission was granted. \_\_\_\_\_  
 \_\_\_\_\_ Publicly available survey/interview that does not require copyright permission  
 \_\_\_\_\_ Researcher prepared survey/interview  
 \_\_\_\_\_ Other (please specify) \_\_\_\_\_

3) Did you attach a copy of your survey or interview questions?

- Yes \_\_\_\_\_ A copy is attached. If you are giving an online survey, also give the link below.  
 \_\_\_\_\_  
 No \_\_\_\_\_ If a copy cannot be attached, please explain. \_\_\_\_\_

d. **Procedure:** Describe how data will be collected and recorded. What will the researchers do? What will the participants do?

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e. **Personnel:** Describe people who are conducting the research, who will be directly or indirectly interacting with the participants, and/or anyone involved in your research who will have access to participants' data.

1) Principal investigator

a) Describe this individual's particular role (how he or she will interact with participants)

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b) Qualifications (educational background, training, etc.) \_\_\_\_\_

2) Other individuals interacting, directly or indirectly, with participants. This includes any individuals who will have access to the participants' data.

a) Name \_\_\_\_\_

b) This individual's particular role (how he or she will interact with participants)  
\_\_\_\_\_

c) Qualifications (educational background, training, etc.) \_\_\_\_\_

**f. Location**

1) Describe the location where the participant involvement will take place.  
\_\_\_\_\_

2) If an interview will be conducted, how will privacy be maintained during the interview?  
\_\_\_\_\_

g. **Time:** Estimate the total amount of time required of each participant. \_\_\_\_\_

h. **Compensation or incentives:** Will participants be compensated or given incentives for their involvement?

No \_\_\_\_\_

Yes \_\_\_\_\_ Describe the compensation. \_\_\_\_\_

**i. Deception**

1) Deception is defined as

- Giving participants partial or false information about their role, treatment or expectations in the study in order to gain cooperation from the participant.
- Not letting a person know they are part of a research study.

2) When might deception allowable?

- If revealing the complete or true nature of the study could invalidate the research.
- If there are no alternative procedures for data collection not involving deception.
- If the deceptive procedures will not place participants at significant financial, physical, psychological, or social risks.
- Careful debriefing whereby the participants are fully informed of the nature and purpose of the deception will follow the data collection/experiment.

3) Deception is *not* allowable if disclosure would simply inconvenience the investigator.

Will deception be involved?

No \_\_\_\_\_ Skip to *i. Sensitive Topics*

Yes \_\_\_\_\_

1) Describe the deception. \_\_\_\_\_

2) Justify the use of deception. \_\_\_\_\_

3) How and when will participants be debriefed (told) about the deception? \_\_\_\_\_

j. **Sensitive topics:** Does the study involve any sensitive topics that might adversely affect the participant's psychological well-being or their reputation, character, or employment if their identity was known (e.g., sexual or illegal behaviors)?

No \_\_\_\_\_ Skip to *j. Confidentiality*

Yes \_\_\_\_\_ Please describe \_\_\_\_\_

- If the study involves a sensitive topic and the participant could potentially be identified, a signed [Informed Consent Form](#) must be submitted. Note that a participant could not be identified if completing an anonymous survey and thus a signed Informed Consent form would not be required.
- If the researcher believes that information collected from a participant could have adverse effects on the participant if the researcher is compelled by a legal agency to reveal that information, a *Certificate of Confidentiality* should be filed (<http://www.hhs.gov/ohrp/policy/certconpriv.html>)

### k. Confidentiality

1) **Can individual participants be identified** by you (or anyone else collecting data) by name, appearance, or some other means? Note that a participant potentially CAN be identified if he or she hands a survey to you, places a survey in an envelope where another person would have access to that survey, or if you conduct a face-to-face interview, even if you do not know that person's name.

No \_\_\_\_\_ Yes \_\_\_\_\_

2) Will your participants' identities be

Anonymous \_\_\_\_\_ Confidential \_\_\_\_\_ Publicly available \_\_\_\_\_

Note that **anonymous** data have no identifying information that can link the participants to their data (the researcher will not know the participants' identities), whereas **confidential** data means the researcher may know the participants' identities and could link the participant to their data, but the researcher will not share the participants' data with anyone except in aggregate or group form.

3) Unless the participants' identities will be publicly available, describe specific procedures to be used to ensure the anonymity or confidentiality of the participants' data. \_\_\_\_\_

l. **Use of information:** How will the information obtained from the participants be used?

1) \_\_\_\_\_ Information will only be used in the classroom and will not be made public.

2) \_\_\_\_\_ Information will be made public (conference presentation, publication, thesis, etc.).

3) \_\_\_\_\_ Other (please explain). \_\_\_\_\_

Note that if you decide to use the information at a later date for a purpose not listed here, you must contact the IRB for approval.

m. **Records:** How will participants' records be stored and safeguarded?

1) Discuss how you will handle the data *during* your study. Where will it be stored?

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2) Discuss how you will handle the data after the *completion* of your study. How and where will it be stored, will it be destroyed, etc.?

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Note

- In research involving protected populations, sensitive issues, risk, deception, or federal funding, identifiable data (data that are linked with a person's name or other means of identification) need to be securely stored for a period of at least **three years** after completion of the research. Data may not be destroyed before three years.
- Research NOT involving protected populations, sensitive issues, risk, deception, or federal funding may be destroyed at any time.
- Secure storage consists of locked desks, cabinets or rooms to which only the principal investigator (or other listed investigators) has access. Give the location of the secure storage.

n. **Risks:** Will the participants be subjected to physical, psychological, social, legal, or economic risks, immediate or long-range, that are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests?

No \_\_\_\_\_ Skip to n. *Benefits*  
 Yes \_\_\_\_\_

1) Describe these risks and how they will be assessed. \_\_\_\_\_

2) Describe the necessity of such risks. \_\_\_\_\_

3) Describe the alternative research methods that were or will be considered. \_\_\_\_\_

4) Describe why alternative research may not be feasible. \_\_\_\_\_

5) Will risks be reversed before the participant leaves the study? For example, pain or anxiety will be significantly reduced or removed.

No \_\_\_\_\_ Explain why not \_\_\_\_\_  
 Yes \_\_\_\_\_ Explain how this will be done \_\_\_\_\_

6) Will you provide a resource or contact for the participant if risks are possible (e.g., a crisis line).

No \_\_\_\_\_ Explain why not \_\_\_\_\_  
 Yes \_\_\_\_\_ Identify the resource \_\_\_\_\_

**o. Benefits**

- 1) Describe the benefits to the *participants* to be gained from this research (please state if benefits are unknown or if there are none). \_\_\_\_\_
- 2) Describe the benefits to *society* or segments of society to be gained from this research (please state if benefits are unknown or if there are none). \_\_\_\_\_
- 3) If there are *risks* associated with your study, describe why you believe the value of the information to be gained outweighs the risks. \_\_\_\_\_

**p. Cooperating institutions**

- 1) Will you be conducting research at an institution other than Stritch (e.g., a school or hospital) or asking permission to use participants from another institution?

No \_\_\_\_\_  
 Yes \_\_\_\_\_

- a) If you are simply asking an institution's permission to use their employees, clients, or students as participants and will NOT be conducting research in cooperation or partnership with that institution, attach a copy of an [Affiliation Agreement](#) on that institution's letterhead.
- b) For school-based research, provide a signed approval form from the principal or other authorized person on that school's letterhead in addition to the *Affiliation Agreement Form*.

- 2) Will you be conducting research in cooperation or in partnership with another institution?

No \_\_\_\_\_  
 Yes \_\_\_\_\_

- a) Attach a copy of a [Cooperative Research Agreement](#) on that institution's letterhead.
- b) Note that the principal investigator is responsible for ensuring that all collaborating institutions operate under Stritch's IRB guidelines.

**q. Information given to potential participants**

Please check which form you have included.

- \_\_\_\_\_ *Participant Information Statement* (describes the research and participant expectations)  
 \_\_\_\_\_ *Informed Consent* (describes the research and participant expectations; requires a signature from the participant or legal guardian)  
 \_\_\_\_\_ *Informed Consent in Survey Research* (describes the research and participant expectations, with a statement that completing the survey signifies consent to participate in the study)

**r. Ethics training certificate**

## 1) Principal investigator

\_\_\_\_\_ The recommended National Institutes of Health training certificate is attached  
 (<http://phrp.nihtraining.com/users/login.php>).

\_\_\_\_\_ An alternative training certificate is attached.

## 2) Other investigators (including faculty advisors)

\_\_\_\_\_ The recommended National Institutes of Health training certificate is attached  
 (<http://phrp.nihtraining.com/users/login.php>).

\_\_\_\_\_ An alternative training certificate is attached.

Note that even if a training certificate was submitted to Stritch's IRB on a previous date, we will need to see a copy of that certificate for the current protocol. An updated certificate is required every three years.

**5. PRINCIPAL INVESTIGATOR ASSURANCE**

I have read the Stritch [Standards for the Protection of Human Participants of Research](#), including the obligation to obtain informed consent from participants, when appropriate, and I will comply.

Signed \_\_\_\_\_ Date \_\_\_\_\_  
 Principal Investigator (student, faculty, or staff)

Signed \_\_\_\_\_ Date \_\_\_\_\_  
 Major Advisor (if applicable)

If a student has a major advisor, both signatures are required on the *same* document. Typed names are not acceptable.