**Committee on the Use of Human Subject in Research**

**Application for Approval of Using Human Subjects in Research**

**INSTRUCTIONS**

1. **Submit a current Curriculum Vita for the PI & Co-PI.** If you have submitted a CV within 3 years, it should be on file and a new one is not needed. Student investigators do not need to send a CV, however the faculty person associated with the research should have a CV on file. Please send to [cuhsr@fsmail.bradley.edu](mailto:cuhsr@fsmail.bradley.edu). This can be sent with your application.

2. **Submit evidence of ethical training for the study team.**  CITI training and certification is acceptable and is good for three years. We will check if CITI certificates are on file. The review process will not begin until we have evidence of ethical training. Please send to [cuhsr@fsmail.bradley.edu](mailto:cuhsr@fsmail.bradley.edu). This can be sent with your application.

3. **Submit an application form (next page) with required signatures and required attachments.** Include: 1) the application form (excluding the directions), and if applicable, 2) copies of questionnaires, surveys, data collection forms, and educational materials, 3) recruitment materials, 4) any letters that give special permission to investigate certain populations or use certain locations for the investigation, 5) letters of approval from an institutional privacy board if using protected health information, and 6) consent forms.

4. **Send an email to** [**cuhsr@fsmail.bradley.edu**](mailto:cuhsr@fsmail.bradley.edu) **with all your materials in #3 above as an attachment. The attached documents must be easily readable and can be sent as a single PDF.** The signature page may be copied and sent separately as a PDF with the appropriate signatures.

6. **Deadlines:** Studies that will likely be reviewed under an exempt or expedited process can be sent anytime. For studies that may require full committee review, the materials with signatures must be sent to cuhsr@fsmail.bradley.edu by 12:00 noon 10 days prior to a scheduled meeting. This is typically two Wednesdays prior to a Friday meeting.

7. **Process:** Bradley’s CUHSR does not have a dedicated full-time staff to handle protocols. They will be handled by the committee members as they arrive, expeditiously as possible, given the limited time of the reviewers. Be aware there are times of the year (typically September, November and April) in which there tends to be a high volume of protocols being submitted. During these times of high volume, it will take more time to process your study. Protocols that are well thought out and completely developed will take less time to review. Complex studies or studies using sensitive or protected information will take longer. Reviewers may contact the investigators with questions and may request additional materials. Investigators are asked to reply as soon as they can. If a reviewer does not receive the requested material within a month, the investigators may be asked to withdraw their study. Plan well ahead of time to get your material submitted well in advance of the target date to start data collection. Generally, we can begin the review process within a month of your submission. But to be guaranteed a timely approval, a protocol should be submitted before the midterm of the semester before a researcher wishes to collect data. For example, if data collection begins in the spring the protocol should be submitted before midterm in the fall. Be aware that it is unlawful to begin collecting data on human-subjects in research without a formal letter of approval from CUHSR. The committee does not meet over breaks and over the summer. Exempt and expedited studies can be reviewed over breaks contingent of the availability or the reviewers. However, a study requiring a full committee review can only be reviewed during a convened committee meeting during the academic year. When your study is approved, you will receive an email letter of approval from the CUHSR chair, CUHSR staff, or a designated committee member.

8. All correspondences will occur via email. After the submission of the application a CUHSR protocol number will be assigned. All correspondence regarding protocol must be have the CUHSR number in the subject line.

**DO NOT INCLUDE THIS PAGE OF INSTRUCTIONS WITH YOUR APPLICATION**

**Committee on the Use of Human Subject in Research**

**Application for Approval of Using Human Subjects in Research**

Instructions-Fill out the following form, **begin typing after the colon**. Small font directions can be eliminated.

**PROTOCOL TITLE:**

**STUDY TEAM –** **Check the appropriate box and** **please read the following:**

FOR STUDIES WITH FACULTY OR STAFF AS LEAD - Studies must have a Principle Investigator (PI) who has the ultimate responsibility for the study. The PI **must** be Bradley Faculty or Staff.

PI and Co-PI have similar responsibilities in the development and execution of the protocol and in responsible conduct of the research. For Co-PI or Co-I collaborating with Bradley Faculty/Staff from another institution include name of institution.

Co-I and Student Investigators have limited participation in the investigation.

**PRINCIPAL INVESTIGATOR (PI)**

**Name:**

**Email**:

**Department or division**:

**CO-PRINCIPAL INVESTIGATOR (Co-PI)**

**Name:**

**Email**:

**(Name or institution if not formally associated with Bradley):**

**CO-INVESTIGATORS (Co-I):**

**Names:**

**Emails:**

**(Name or institution if not formally associated with Bradley):**

**STUDENT INVESTIGATORS (SI):**

**Names:**

**Emails:**

In some cases (example graduate students) can be a student principal investigator (SPI). **SPI MUST** **have a Bradley Faculty or Staff as a Co-PI**. SPI and Co-PI have similar responsibilities in the development and execution of the protocol and in responsible conduct in research. Students are not allowed to lead a study with more than minimal risk.  
**STUDENT PRINCIPAL INVESTIGATOR (SPI):**

**Name:**

**Email:**

**Department or division**:

**CO-PRINCIPAL INVESTIGATOR with student PI (Co-PI):**

**Name:**

**Email:**

**Department or division**:

**Students**: is this being done for a course requirement Yes No; For a Thesis requirement Yes No

**EXPECTED DATE TO BEGIN DATA COLLECTION (Month/Day/Year):**

**EXPECTED DATE TO COMPLETE DATA COLLECTION (Month/Day/Year):**

**FINANCIAL SPONSER** (if any, corporate or government grants, etc.)**:** Describe, include any conflict of interest):

**FUNDING SOURCE FOR PARICIPANT INCENTIVE, COMPENSATION, REIMBUSEMENT or APPRECIATION** (could include self-funding, department funding, or financial sponsor above):

**MUST ANSWER: Is this study supported by any Federal agency?** Yes No

**YES NO**  **CITI Certificates** (or ethics training certificates) are on file for all on the study team or attached with submission (*The application will be returned to the PI if CITI Certificates are missing*). CITI training expires after 3 years.

**YES NO**  **Curriculum Vita** of the PI is on file or attached with this application *(The application will be returned to the PI if the CV is not on file – CV should be sent as a separate file).*

**SIGNATURE PAGE: Please fill in the information below. Read the statements carefully and check the boxes before signing the document. This page with the signatures can be scanned separately and sent as a separate PDF.**

**PROTOCOL TITLE**:

**BRIEF PURPOSE (less than 50 words)**:

**BRIEF SYNOPSIS: In the space below provide a synopsis of the human-subjects interaction of your protocol (fewer than 50 words)** Example 1 – workers at an insurance company will take an anonymous survey to determine their satisfaction with HR practices. Example 2 – elderly participants will be assessed for balance impairments, undergo balance exercise and reassessed for balance to determine the effectiveness of the intervention.

By signing below, I, the **principal investigator**, or **student principal investigator** acknowledge that I have reviewed the proposal and deem it to be ready for review by the *Committee on the Use of Human Subjects in Research*. Specifically, this proposal **(please check in the check boxes):**

(1) clearly identifies the **variables being assessed and the measurement devices employed** to measure them, as appropriate,

(2) contains an evidence-based **rationale** for the study,

(3) identifies the **number of participants** to be used and **how those participants will be recruited**, and includes **sample recruitment material or invitation to participate script**, and

(4) clearly outlines the **procedures and methods** used to obtain information from those participants,

(5) includes copies of all **relevant instruments** (unless copyrighted, in which a description of the measure and a sample of the type of items should be included),

(6) has **Informed Consent documentation** that contains all of the elements necessary for this particular type of study, or has requested alterations or waivers of informed consent, or waivers of documentation of informed consent.

(7) is complete and ready for review in all other ways not specified.

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Signature or Principal Investigator or Student PI Printed name of the Principal Investigator or Student PI Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Co-Principal Investigator if Student is PI Printed name of Co-Principal Investigator if Student is PI Date

By signing below, I, the department chair (or division director), confirm that this proposal is **fully developed** and ready for review by the *Committee on the Use of Human Subjects in Research*. Further, I affirm that the **resources required for satisfactory completion** of this project are available to the investigator.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Dept. Chair/ Division Director Printed Name of Dept. Chair / Division Director Date

**Instructions:** Begin typing after the heading – example **2.0 Purpose of the study**: (start typing here) **Remove all instructions.** Depending on the nature of your protocol, some sections may not be applicable. If so mark as “NA.”

**1.0 Protocol Characteristics –** use the check boxes and check which most closely applies

**1.1 Type of Study:** Social/Behavioral Biomedical Scholarship of Teaching and Leaning Quality Improvement (Quality improvement projects should use the alternate application) Other**:**

**1.2 Primary Type of Interaction** Check (click on box) any that apply **–**

Anonymous Survey (no link to personal data),

Confidential Survey

Individual Interviews

Focus Groups

Physical Assessment Cognitive Assessment Physical Task

Cognitive Task

Behavioral Assessment Review of established records

Collection of Bio specimens

Application of physical or psychological stressors (Example: mild shocks as punishment)

Taking a drug, supplement, or food substance (oral, topical, or injection)

Application of an experimental substance or procedure

Application of a standard clinical procedure Prospective assignment into placebo or control groups to determine the effectiveness of an intervention

Use of deception,

Other

**1.3 Primary Type of Data -**

Opinion

Disclosure of Past/current Behaviors

Sensitive informationTask Performance by observation

Behavioral observation

Video/audio recording

Data from physical instrumentation applied to the subject or remote sensors Indefinable personal information

Indefinable Bio specimens Protected Health information (HIPAA),

Protected student records (FERPA)

De-identified personal information

De-identified Bio specimens

Other

**1.4 What type of review are you anticipating: See the CUSHR website for the description of EXEMPT vs EXPEDITIED vs FULL Review and the description of the categories.**[**https://www.bradley.edu/academic/cio/osp/studies/cuhsr/categories/**](https://www.bradley.edu/academic/cio/osp/studies/cuhsr/categories/)

**Exempt – Category 1, 2, 3, 4, 5, 6, 7, 8**

**Expedited – Category 1, 2, 3, 4, 5, 6, 7, 8, 9** (must be no more than minimal risk and fall into one of the categories - *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests 45 CFR 46.102(j). Anything beyond minimal risk will undergo a full review. Harm or discomfort can be psychological, social, legal. economic and reputational as well as physical.

**Full review** (usually more than minimal risk, and/or does not fit into one of the expedited categories)

**1.5  YES NO Has this study been approved by an IRB at another institution or will you be seeking IRB approval or a reliance agreement at another institution?** If yes, explain why in the space provided. Provide the name of the other institution.

**2.0 Purpose of the study**: begin typing here – you should eliminate the instructions under each heading.

2.0 Briefly describe the proposed purpose or objectives. State the research question or hypothesis that will guide the study. Reviewers will consider the scientific merit of the research and if the merit warrants the involvement of human subjects. Reviewers will consider if the methodologies achieve the stated purpose.

**3.0 Background/literature review/rational for the study**: begin typing here -

3.0 Provide a brief statement (~500 words or less) that gives context of the study. What is the rationale for the proposed research? What is the background on the existing literature. How will your research add to the current knowledge? **Cite and provide several relevant references.** Reviewers may be familiar with the general disciple but not necessarily your specific area of expertise. Please avoid professional jargon and do not assume abbreviations will be understood. **Students – DO NOT** attach your entire research proposal submitted for course work. It will not be considered as part of this application. Cite the validity and reliability of the measures used if they are known.

**4.0 Participant selection and inclusion/exclusion criterion**: begin typing here -

4.0 Briefly describe your participants as it is related to your research question. Describe their characteristics for inclusion (such as age, gender, health condition, etc.). Describe any exclusion criteria. How will you determine and document that they meet the inclusion/exclusion criteria? Most researchers state the criteria on the consent form. For more complex studies, researchers may use a screening form. Please include your form if using one. If your research could provide some benefit or result in harm, describe how your inclusion/exclusion criteria is equitable and thus not limiting benefit to some groups or potentially producing harm to other groups.

**5.0 Justification for any use of special/vulnerable population**: begin typing here -

5.0 Indicate whether you will include or exclude any special population and provide a justification. Research with special populations will not be included in exempt research and may require a full review. Maters of consent will have to be handled carefully. These population are typically considered special: 1) Adults unable to consent (impaired decision-making capacity), 2) Individuals who are not yet adults (under 18 years of age), 3) Pregnant women (where the activities of the research may affect the pregnancy or the fetus), 4) Prisoners or other detained individuals. There addition instructions for special circumstances and special populations in items 20-23 on this form.

**6.0 Sample size**: begin typing here -

6.0 Describe the total number of participants included in the study. Provide a justification for the sample size.

**7.0 Recruitment methods**: begin typing here -

7.0 All material aimed at recruiting participants must be reviewed by CUHSR. Issues like overstated benefit or incentive, prominent compensation statement, vague inclusion/exclusion criteria are concerns. Please attach to this application any flyers, email scripts, written invitation, audio or video scripts or any other recruitment items. **Required elements:** The words “research”, “Bradley University”, the name of the PI, basic eligibility criteria, contact information, and incentives or compensation are required. Recommended elements: purpose of the study, time commitment and location of the research.

**8.0 Research location**: begin typing here -

8.0 Provide a brief description of the physical location of the research. Is the location conducive to safely carry out the procedures and is amenable to the subject population? (Example, if children are involved, is it a “kid friendly” environment. If disabled individuals are involved, is location accessible). If you are doing research in a specific location not related to Bradley, do you have permission from the appropriate authorities to do the study at that location (example, a public school, or a nursing home). Please provide written proof that you have permission to conduct research at the facility. If you are using protected health information from a health care facility, you will need to seek approval of your study from that facility’s privacy board and provide a letter to CUHSR. If your location does not have a privacy board, then CUHSR will determine if your treatment of protected health information meets the HIPAA standards. Identify how any public health standards will be deployed (example COVID protocols).

**9.0 Study design**: begin typing here -

9.0 Provide a brief statement about your design as it is related to the purpose of your study (randomized placebo controlled trial, correlational, repeated measures, descriptive, etc.). If the study fits the definition of a clinical trial you may have to register it with Clinicaltrials.gov depending on the nature of the intervention and/or your funding source.

**10.0 Procedures Involved**: begin typing here -

Provide a description of all research procedures and activities. **Relay in chronological order** the research activities of the participants including the **duration of an individual’s involvement**. Describe any source records or measures that will be used to collect data about the participants. **Attach to the end of this application ALL surveys, interview scripts, data collection forms**, etc. If using instrumentation be sure to include a description (or a sample data sheet) of all the variables collected. Indicate if audio/video recording or photography will be used. If their use is mandatory, provide a rationale. Permission to use recordings or photographs will have to **be explicitly stated in the consent with explicit statements regarding how it will be handled and the individual’s privacy protected**. Indicate if any of the procedures are experimental. Indicate if any of the procedures are standard practice in your professional context. Describe any equipment, devices, or substances that will be used, particularly as it relates to its purpose and its introduction of risk, harm or discomfort to participants. If applicable, describe its safety profile or provide evidence of its safety. If your procedures involve tests and measures that could identify a health condition previously unknown to the participant, the researcher must have procedures in place to deal with this situation. This might involve a referral to an appropriate professional service. The potential of identifying a health condition will typically be addressed in the consent. Studies involving individuals who are vulnerable or susceptible to coercion or undue influence should include procedures that assure additional safeguards to protect their rights and welfare.

**11.0 The circumstances or surrounding the consent procedure**:begin typing here -

11.0 Obtaining consent is more than having a participant sign a form. The entire procedure ensures that the participant fully understands what they are consenting to do. They should understand what is expected of them, and any potential risks or harms. Participation should be completely voluntary and the participants are not subject to coercion or excessive incentives. **The consent process and language is heavily scrutinized**. If applicable, describe the following: 1) location where the consent process will take place,2) if there is a waiting period between informing the participant and obtaining the consent,3) the time for devoted for discussion or questions, 4) steps taken to minimize the possibility of coercion or undue influence,5) steps taken to ensure the participants understanding. Refer to the CUHSR website for the General Requirements of Informed Consent and instructions regarding consent in different populations and circumstance (children, international settings, etc.) <https://www.bradley.edu/academic/cio/osp/studies/cuhsr/consent/>.

Applicants should use one of the consent templets provided <https://www.bradley.edu/academic/cio/osp/studies/cuhsr/forms/>. Depending on the nature of your study, CUHSR may require additional elements to the consent. See the CUHSR website for the General Requirements of Informed Consent paragraph c. Using the templates is required unless certain conditions occur where elements of informed consent can be waived or altered upon approval of CUHSR. Exempt studies can have an abbreviated consent statement whereas expedited and full review studies will have extensive consent documents. Please see requests for a waiver or alteration for any elements in 11.1 or 11.2 below. If your research involves protected health information (HIPAA) or official student records(FERPA) additional consent procedures are likely. Should your study involved individuals with impaired decision making please see sections 20.0 and 21.0 below for additional elements of consent. Please see the guideline regarding [SOTL Research and FERPA](https://www.bradley.edu/academic/cio/osp/studies/cuhsr/procedure/protection/) if this applies to your study.

**11.1 Alteration or waiver of informed consent:**

Check YES IF you are requesting to alter the typical consent elements OR requesting to waive (eliminate) the consent. This is typically not requested so in most cases this will be checked NO. Must Check: **YES NO If YES see the instructions below.**

11.1 It is rare that informed consent would be waived. At times, some of the consent elements can be waived. To grant an alteration or waiver of consent ALL the conditions below must be met. You will need to provide a justification here in this section and your justification needs to address these conditions:

-The research involves no more that minimal risk

-The research could not be practicable carried out without the requested waiver or alteration.

-If the research involves identifiable private information or biospecimens the research could not be practicably carried out without using such information in an identifiable format.

- The waiver or alteration will not adversely affect the rights or welfare of the participants.

-Whenever appropriate the participants or LAR will be provided with pertinent information.

**11.2 Waiver or alteration of documentation of informed consent:** Common is some research it may be impractical or may add risk to the study by having the participant sign a consent form. This would be common in anonymous surveys. **By federal regulation documentation of consent must be meet, unless an IRB grants a waiver or alteration. Documentation of consent includes the following elements:**

**1) An approved consent form will be signed by the subject or legally authorized representative (LAR).**

**2) A copy will be given to the person signing he form.**

**3) For minors, appropriate parent/guardian signatures are obtained**

**4) The subject or legally authorized representative has an opportunity to read the consent before signing, or a short form of the element of consent are presented orally with an approved written summary provide with witness signature. Your consent process should explicitly state these elements**.

**YES NO** Will participant be signing a paper copy of the consent (or provided an official certified e-signature). If YES (signature is obtained) proceed to item 12.0. If NO see below.

If NO is checked above, you need to request a waiver or alteration of documentation of consent. This is common in survey research or in cases where complete anonymity is important. Provide your justification here -

To grant a waiver or alteration of the documentation of consent ONE of the following 3 conditions must be met. Your justification should explicitly explain one or more of these conditions.

1. The only record linking the subject and the research would be the informed consent form and the principle risk would be potential harm resulting in a breach of confidentiality.

2.That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required.

3. Participants or LAR are members of a distinct cultural group or community in which signing forms is not the norm and the research presents no more than minimal risk

**12.0 Provision for managing risk and adverse reactions**: begin typing here -

12.0 List the reasonably foreseeable risks, discomforts, hazards or inconveniences to the participants related to participation in the research. Describe the probability, magnitude, duration and reversibility of the risks. Consider physical, psychological, social, legal and economic risks. Consider a breach of confidentiality as a risk in the context of this research.

Identify procedures to minimize any risk (some risk can be avoided by the exclusion factor in subject selection)

Identify any procedures to manage any anticipated adverse reactions.

What procedures are in place to deal with emergent adverse events and non-emergent adverse events?

What procedures are in place that monitor the subject and the data (if the research is conducted overtime) to ensure the safety of participants? (What mechanisms are in place for the participants to realize they may be having an adverse reaction? What data are reviewed to ensure safety? What is the frequency of that data collection? Are there any triggers that immediately suspend the research?)

What mechanisms are in place for individual who may feel psychological distress?

Describe anticipated circumstance under which participants will be withdrawn from the research without their consent.

**13.0 Potential benefit**: begin typing here -

13.0 Indicate if there is no direct benefit to participants. Describe the potential benefits that the individual participants may experience. Include the probability, magnitude and duration of the potential benefit. **Receiving compensation or incentives is NOT considered a benefit.** The benefit relates to the research procedure.

**14.0 Provision for the protection of privacy. How will confidentiality be maintained** begin typing here -

14.0 Describe the steps that will be taken to protect the participants’ privacy interests (privacy in regard to their personal space and exposure to others, their ability to place limits on whom they interact or whom they provide information). Indicate who on the research team is permitted to access any sources of information about the participant. Describe the process and rationale if participants will be re-contacted for any reason (this needs to be disclosed on the consent form). What information will be included as data. Where and how will it be stored (including electronic storage). How long will it be stored? Who will have access to the stored data? Will the data be de-identified with no linkage back to the identifiers? If the data is linked, describe the nature of that linkage (example - coded data with codes/identifiers stored separately with limited access; only link to the name is the consent form that is coded). Describe any other steps to secure the data (training, passwords, physical controls, encryption). If doing online surveys, provide the settings used and the meaning of those settings (feel free to directly quote the survey application site). Researchers should **clarify the use of demographics** with regard to their purpose and how they will be handled. In a small and diverse sample, demographic information, if linked to the data, could inadvertently re-identify a subject when reporting the data. Be sure to clarify what demographics are variables of interest (linked to the data) and what demographics are used to describe your sample and not linked specifically to the data. Describe **what you will do with the data when the study is over.** You will have to identify this in the consent. Possibilities include the data will be destroyed after the study [identify the amount of time], the data will be de-identified and used for future research or it the data will be de-identified and shared with other researchers). Bradley University will not participate in the regulatory provision of Broad Consent, which is an entirely separate consent process allowing investigators to share identifiable private information or biospecimens for other studies without obtaining a consent in the future.

**15.0 Incomplete disclosure or deception:** begin typing here -

15.0 Describe any incomplete disclosure or deception and provide a rationale explaining why it is necessary to the research.

Describe the debriefing process that will be used to make participants aware of the incomplete disclosure or deception, including the right to withdraw any record of their participation

**16.0 Inducements, extra credit, rewards, compensation, extra cost**: begin typing here -

16.0 Describe any financial or other compensation, reimbursement, appreciation, or incentive that will be provided. Include the method of payment, how much money or what gift (and the value of the gift) will be provided for which activities and the timing of the payment. Will the payment be prorated if there are multiple research activities or if the participant withdraws from the study before finishing? Payments of any amount that use Bradley funds need to be reported. [Please see the Guideline for Payment to Research Participants](https://www.bradley.edu/academic/cio/osp/studies/cuhsr/procedure/compensation/). Payments from participating in research are typically tax deductible. There should be a statement regarding this in the consent form. Please see the suggested consent language provided on the [Guideline for Payment to Research Participants.](https://www.bradley.edu/academic/cio/osp/studies/cuhsr/procedure/compensation/)

If extra credit is offered in a classroom setting, an alternative extra credit activity of equal value (and related intensity) must be offered to those who do not wish to participate in research. Please see the guidelines for [SOTL Research](https://www.bradley.edu/academic/cio/osp/studies/cuhsr/procedure/protection/) for clarification.

Describe any cost the subject may be responsible for as a participant in the research.

If the research involves more than Minimal Risk, describe the available compensation, if any, in the event of the research related activity.

**18.0 Qualification of the research team to conduct the research**: begin typing here -

18.0 Briefly describe the qualification of the research team to conduct this research. CUHSR is looking for information such as areas of expertise, past research experience, relevant certification, etc. If a special or vulnerable population is used, please state team’s qualifications to be attentive to the special needs or environment related to this population.

**19.0 Attachments**:

19.0

1. Attach any consent forms at the end of this document. Reminder – use the templates provided. See below for attachments that might relate to special circumstances.

2. Attach all questionnaires, surveys, interview guides, measures, or data collections sheets.

3. Attach all recruitment materials such as flyers, letters, email scripts, invitations to participate.

4. Attach all letters that give permission for you to have access to any special populations or locations.

**The following sections can be eliminated if they do not apply to your protocol.**

**20.0 Instructions for special circumstances – Impaired decision-making capacity**:

20.0 Involving individuals who have impaired decision-making capacity are usually not recommended for research and should not be done if the research could be carried out with individuals who are not impaired. In some cases, the focus of the research will in purpose involve those with decision impairments (such as individuals with dementia). Several considerations should be addressed:

1. Will the research bring some potential benefit to those involved and what level of risk is involved? What additional safeguards will be provided to limit any risk, harm, or discomfort?

2.Some determination that individuals do not have the capacity to make decisions for themselves should be documented? This could be a firm diagnosis or could require a third-party determination and documentation.

3. A legally authorized representative must be able to provide the consent and sign accordingly. The name of the subject and the name and signature should be on the form.

4. Depending on the level of impairment, an assent process (see below) must be carried out.

5. A witness should be available to sign that they have witnessed the assent process and affirm that a legally authorized representative has signed a consent form.

**21.0 Instructions for special circumstances – Assent process when minors are in involved**:

21.0 Whenever minors are involved in a study, consent must be obtained from the parents or legal guardian, and assent must be obtained from the minor. The assent process varies depending upon the age of the participant. For teenagers, the assent process may resemble the informed consent process used for adults. For young children, a simplified verbal assent process might be appropriate. If you have multiple age groups, multiple assent processes might be appropriate. Address the following points regarding your assent process:

1. The State of Illinois defines a minor as someone under the age of 18. However, the age of majority changes by state and country. If participants are outside of Illinois, state the age of majority and provide documentation of applicable laws.
2. Describe the assent process (e.g., how is it obtained, who obtains assent). Be specific.
3. For written assent, provide the assent form with a space for the signature of participant.
4. For verbal assent, provide the script that will be used and how the verbal assent process will be documented.

If assent is not possible (e.g., infants, Individual with moderate to severe disabilities, etc.), explain why assent is not possible and the procedures that will be used for this situation.

**22.0 Instructions for special circumstances – International Research**:

22.0

1. Describe the qualifications/capabilities that the primary researcher or someone that is part of the research team has to conduct international research.  Such qualifications/capabilities could include coursework, past experience, training, or being a native of the intended area.
2. Does the researcher have an invitation to conduct research in this community? If yes, provide documentation. If no, how will the researcher gain culturally appropriate access to the community?
3. Please describe any cultural differences that may likely impact the intended research, and how these issues will be handled.
4. If the language spoken in the intended research area is different than English, explain how the materials and communications will be handled.

International research projects must be approved by the local equivalent of an IRB before they can receive final approval from CUHSR. When there is no equivalent board or group, investigators must rely on local experts or community leaders to provide approval. Provide documentation of this approval or how the approval will be obtained.

**23.0 Instructions for special circumstances – Domestic Cross-Cultural (such as Native Americans or recent refugees**):

23.0

1. Describe the qualifications/capabilities that the primary researcher or someone that is part of the research team has to conduct cross-cultural research on this culture.  Such qualifications/capabilities could include coursework, past experience, training, or being a member of the intended culture.
2. Does the researcher have an invitation to conduct research in this community? If yes, provide documentation. If no, how will the researcher gain culturally appropriate access to the community? Does this community have the equivalent of an IRB?
3. Please describe any cultural differences that may likely impact the intended research, and how these issues will be handled.

If the language spoken in the intended research area is different than English, explain how the materials and communications will be handled.