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

**Application for Approval of Using Human Subjects in Quality Assurance and Quality Improvement Projects - INSTRUCTIONS**

1. **Submit a current Curriculum Vita for the PL & Co-PL.** 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. This can be sent with your application.

2. **Submit evidence of ethical training for the project 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. This can be sent with your application.

3. **Submit an application form 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, and 5) letters of approval from an institutional privacy board if using protected health information.

4. **Send an email to** **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.

5. **Deadlines:** Projects that will likely be reviewed under as Quality Improvement or Quality Assurance can be sent anytime. 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.

6. **Process:** Bradley’s CUHSR does not have a dedicated full-time staff to handle protocols. The committee members will handle them 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 projects. 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 prior to the target date to start data collection. 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 without a formal letter of approval from CUHSR. The committee does not meet over breaks and over the summer. Exempt and expedited studies can possibly 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.

7. 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 WITH YOUR APPLICATION**

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

**Application for Approval of Using Human Subjects in Quality Assurance and Quality Improvement Projects**

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

**PROJECT TITLE:**

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

FOR PROJECTS WITH FACULTY OR STAFF AS LEAD - Studies must have a Principle Leader (PL) who has the ultimate responsibility for the project. The PL **must** be Bradley Faculty or Staff.

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

PM and Student Project Members have limited participation in the investigation.

[ ] **PRINCIPAL LEADER (PL)**

 **Name:**

 **Email**:

 **Department or division**:

[ ] **CO-PRINCIPAL LEADER (Co-PL)**

 **Name:**

 **Email**:

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

[ ] **PROJECT MEMBERS (PM):**

 **Names:**

 **Emails:**

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

[ ] **STUDENT PROJECT MEMBERS (SPM):**

 **Names:**

 **Emails:**

In some cases (example graduate students) can be a student principle investigator (SPL). **SPL MUST** **have a Bradley Faculty or Staff as a Co-PL**. SPL and Co-PL 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 LEADER (SPL):**

 **Name:**

 **Email:**

 **Department or division**:

[ ] **CO-PRINCIPAL INVESTIGATOR with student PL (Co-PL):**

 **Name:**

 **Email:**

 **Department or division**:

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

**EXPECTED DATE TO BEGIN DATA COLLECTION:**

**EXPECTED DATE TO COMPLETE DATA COLLECTION:**

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

**MUST ANSWER: Is this project 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.**

**PROJECT TITLE**:

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

**In the space below provide a synopsis of the human subjects’ interaction or review of records of your project (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 – Nurses in a clinic will be trained in reducing vaccination errors. Retrospective chart reviews will occur measuring vaccination errors before and after the training.

By signing below, I, the **principal project leader**, or **student principal project leader** 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 project, 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, 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 **PROJECT DETERMINATION** & **CHARACTERISTICS** Is your project QI/QA or is it research. Answer the following questions.

1.1 Must Check:[ ]  **YES** [ ] **NO**  HUMANS SUBJECTS: Will the project be obtaining information about living individuals or biospecimens? [Checking yes mean the project involves human subjects]

 1.1.1 Must Check:[ ]  **YES** [ ] **NO**  Will the project obtain information or biospecimens through intervention (physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment) and uses, studies, or analyzes the information or biospecimens?

 1.1.2 Must Check:[ ]  **YES** [ ] **NO**  Will the project obtain information or biospecimens through interactions (communication or interpersonal contact between investigator and subject) and uses, studies, or analyzes the information or biospecimens?

 1.1.3 Must Check:[ ]  **YES** [ ] **NO**  Will the project obtain, use, study, analyze, or generate identifiable private information or identifiable biospecimens (identifiable: that which the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

1.2 Must Check:[ ]  **YES** [ ] **NO**  RESEARCH: Is the intent of your project to systematically [systematic: could mean hypothesis testing, randomization, concern for validity] investigate a question including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge [generalizable – widely applicable], typically, but not always, culminating by sharing the results in a public presentation or publication? [Checking yes indicates that your project is research defined by the federal government. If 1.1 and 1.2 are affirmed, then you project is considered human subjects research and must be reviewed as research by an IRB. **STOP HERE** and fill out a CUSHR application for research or contact the chair of CUHSR]

1.3 Must Check:[ ]  **YES** [ ] **NO**  Will the project use and experimental drugs, devices or biologicals?

1.4 Must Check:[ ]  **YES** [ ] **NO**  Will individual’s identities be readily ascertained or associated with the information gathered or with the biospecimens?

1.5 Must Check:[ ]  **YES** [ ] **NO**  Will any disclosure of the participants response outside of the project place the participant at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation?

[If YES is checked to 1.3, 1.4, 1.5, it may not be considered QI/QA depending on the nature of the interaction. **STOP HERE** and fill out a CUSRH application for research or contact the chair of CUHSR]

In any QI or QA project the human interaction should be below the level of or minimal risk and should generally, if submitted as human subject research, be exempt from the standards of the federal regulations regarding human subjects research. However, participants in QI/QA projects are still afforded basic human protections (informed consent and protection of privacy).

1.6 Must Check:[ ]  **YES** [ ] **NO**  Will the human interaction involve vulnerable populations (such as children under 18 years old, impaired decision-making capacity in adults, pregnant women, disabled individuals, prisoners). [depending on the nature of the interaction it may or may not qualify for QI/QA – additional safeguards will need to be in place]

1.7Must Check:[ ]  **YES** [ ] **NO**  Will the human interaction with the participants be reasonably free from harm and discomfort and any harm or discomfort be no more than a person might experience in daily life (Harm or discomfort can be psychological, social, legal, economic and reputational as well as physical)?

1.8 Must Check:[ ]  **YES** [ ] **NO**  Is the intent of your project to gather information in order have a better understanding of a process or to understand how a process may be improved, typically applicable to a single setting. [This intent is typical of a QI/QA project].

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

[ ] Anonymous Survey (no link to personal data)

[ ] Confidential Survey

[ ] Review of established records

[ ] Physical Assessment

[ ] Cognitive Assessment

[ ] Physical Task

[ ] Cognitive Task

[ ]  Behavioral Assessment

[ ]  Behavioral Observation

[ ] Collection of Biospecimens

[ ] 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 of subjects into placebo or control groups to determine the effectiveness of an intervention\*

[ ] Use of deception\*

[ ]  Other

 Items marked with \* may not qualify for QA/QI project

**1.12 Primary Type of Data –** (click on box) any that apply **–**

[ ] Opinion

[ ] Past/current Behaviors

[ ] Task Performance by observation

[ ] Behavioral observation

[ ]  Video/audio recording

[ ] De-identified personal

Information,

[ ] Protected Health information (HIPAA)

[ ] Protected student records (FERPA)

[ ]  De-identified Biospecimens

[ ]  Data from physical

instrumentation applied to the subject or remote sensors\*

[ ] Identifiable personal information\*

[ ]  [ ] Identifiable Biospecimens \*

[ ] Sensitive information\*

[ ]  Other

Items marked with \* may not qualify for QA/QI project

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

**2.0 Purpose of the project**:

Describe the proposed purpose or objectives as it relates to the specific institution and purpose. State the project goals that will guide the study. Explain how the results will be used for the improvement /assessment in the specific setting. Reviewers will consider the merit of the projects 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 project**:

Provide a brief statement (~500 words or less) that gives context of the project. What is the rationale for the proposed project? What is the background on the existing literature. How will your project add to the current processes? 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 project proposal submitted for course work. It will not be considered as part of this application.

**4.0 Participant selection and inclusion/exclusion criterion**:

Briefly describe your participants as it is related to the purpose of your project. 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? If your project 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**:

Indicate whether you will include or exclude any special population and provide a justification. Projects with special populations might not qualify for QI/QA projects. Maters of consent will have to 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.

**6.0 Number of participants**:

Describe the total number of participants included in the projects. Include the number or records that will be review is applicable.

**7.0 Recruitment methods/Invitations to participate**:

All material aimed at recruiting participants should be reviewed. 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 “Quality Improvement (or assessment) project”, the name of the PL, eligibility criteria, contact information, and incentives or compensation are required. Recommended elements: purpose of the study, time commitment and location of the project, Bradley University DNP student.

**8.0 Project location**:

Provide a brief description of the physical location of the project. Is the location conducive to safely carry out the procedures and is amenable to the subject population? (Example, If disabled individuals are involved, is location accessible). If you are doing a project in a specific location not related to Bradley, do you have permission from the appropriate authorities to conduct the project at that location (example, a public school, or a nursing home). Please provide written proof that you have permission to conduct project 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 you project involves patient records and is considered quality improvement, provide a letter from the facility management that the patient record potion of your project falls under the normal operations of the covered entity. You must indicate if you as the project leader are considered a covered entity and as a part of normal operations you have access and permission to look at protected health information (Quality Assurance/Improvement is considered to be under normal operations).

**9.0 Project Design**

Describe the basic design of the project. such as pre-test/education intervention/post-test design; opinion gathering; pre-records screen/intervention/post-record screen; behavioral observation etc.

**10.0 Procedures Involved:**

Provide a chronological description of the project procedures and activities that relate to the human interactions, interventions, bio specimens or participant data or records. Describe any source records or measures that will be used to collect data about the participants. Attached to the end of this application ALL surveys interview scripts, data collection forms, etc., as it will appear to the participant. 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 such recording is mandatory for participation a rationale must be provided here. Permission for such recordings will have to be explicitly stated in the consent with explicit statements regarding how it will be handled and how the individual’s privacy will be protected. Procedures that are experimental will not qualify for QI/QA. Indicate if any of the procedures are standard practice in your professional context. Indicate if a process or procedure of your project as implemented is mandatory for all. 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.

**11.0 The circumstances or surrounding the consent procedure**:

Whenever possible individuals should be **fully informed and give their permission to participate** in a quality improvement or assessment project. The consent 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. This section should explain your consent process. Depending on the nature of project, it could be very short and simple or is could be more complex. At the very least it should contain these elements:

 [ ] The consent process will disclose that activity involves quality improvement procedures

 [ ] The consent process will disclose the procedures that are involved

 [ ]  The consent process will disclose the approximate time the participant is involved

[ ] The consent process will disclose that participation is voluntary (if components are mandatory, it is clear as to what component is mandatory and what components are voluntary)

 [ ]  The consent process allows participants to withdraw (or not answer questions)

[ ] The consent process will disclose participation and/or results will have no influence on employment, educational status

[ ] The consent process will disclose how privacy and confidentiality will be maintained

 [ ] The consent process will disclose the name and contact information of the investigator
 [ ]  The consent process provides a statement of agreement

A typical consent document for a quality assurance project could be stated as follows:

*You are invited to participate in a quality improvement project. The purpose of this project is* ***[explain basic purpose of******the study].*** *This project consists of* ***[describe what the project involves (e.g., answering questions on a******survey, or responding to images on a computer screen)].*** *Your participation in this project will take approximately* ***[state duration, e.g. 10 minutes].*** *Your participation in the project and the data collected will remain confidential* ***[or describe confidentiality, e.g., this is an anonymous******survey; there is no link between your name and the research record].*** *Taking part in this project is voluntary. You may choose not to take part or may leave the project at any time.* ***[For surveys you might say: you may******also skip specific questions].*** *Your participation or non-participation will have no effect on your status as an [****employee, student, patient].*** *At the conclusion of the project, the data will be completely de-identified and the de-identified data could be used for future projects* ***[Or the data will be destroyed].*** *Questions about this project may be directed to the* ***[project leader or project advisor]*** *in charge: [Dr. \_\_\_\_\_] at (309) 677 –xxxx. You are voluntarily making a decision to participate in this project. Your submission of the [****survey]******[OR By clicking*** *“****I Agree below”, OR By participating, OR your signature]*** *means that you have read and understand the information presented and have decided to participate. Your submission* ***[or participation]*** *also means that all of your questions have been answered to your satisfaction. If you think of any additional questions, you should contact the project leaders(s).*

\*For studies that involve a management/clinical process that has be implemented and is now being assessed should still have a consent process even though it is mandated. It may sound something like this:

*You are invited to participate in a quality improvement project. The purpose of this project is* ***[explain basic purpose of******the study].******[Management; or the clinic, or administration]*** *has implemented a process change* ***[or example: has mandated attendance regarding education on this process or change****]. Your participation in the project consists of* ***[describe what the project involves (e.g., attending and education session and answering questions on a******survey, or documenting on a patient interaction)].*** *Your participation in this project will take approximately* ***[state duration, e.g. 10 minutes].*** *Your participation in the project and the data collected will remain confidential* ***[or describe confidentiality, e.g., this is an anonymous******survey; there is no link between your name and the research record].*** *Though taking part of the project is mandated, the outcome of the analysis will have no bearing on our employment* ***[status, status as a student, performance evaluation****].**At the conclusion of the project, the data will be completely de-identified and the de-identified data could be used for future projects* ***[Or the data will be destroyed].*** *Questions about this project may be directed to the* ***[project leader or project advisor]*** *in charge: [Dr. \_\_\_\_\_] at (309) 677 –xxxx. Your submission of the [****survey]******[OR By clicking*** *“****I Agree below”, OR By participating, OR your signature]*** *means that you have read and understand the information presented and have decided to participate. Your submission* ***[or participation]*** *also means that all of your questions have been answered to your satisfaction. If you think of any additional questions, you should contact the project leaders(s).*

If your project involves protected health information (HIPAA) or official student records(FERPA) additional consent procedures are likely required.

**11.1 Are you requesting the elimination of the consent process (Alteration or waiver of informed consent):** Must Check:[ ]  **YES** [ ] **NO**

If requesting an alteration or requesting to waive the consent see below and provide what is requested. Only in rare occasions will the consent process be eliminated thus in most cases the NO will be checked above. In most situations participants in you project deserve to be fully informed and have a right to participate or not.

To grant an alteration or waiver of concern all the conditions below must be met your justification needs to address the following conditions: 1) This project involves no more than minimal risk. 2) This project could not practically be carried out without the required waiver for alteration. 3) If the project involves identifiable private information or bio specimens that the project could not practicably be carried out with such information without using such information in an identifiable format. 4) The waiver or alteration will not adversely affect the right or welfare of the participants. Justify your request by stating how it meets the above criteria.

**11.2 Are you altering or eliminating a FORMAL SIGNATURE on a consent form? (Waiver or alteration of documentation of informed consent):** Must Check:[ ]  **YES** [ ] **NO**  If a signed paper copy (or certified electronic copy) is NOT obtained, check **YES** (requesting a waiver or alteration), read below and justify your request. In many cases or QI projects, a signature is not needed.

To grant a waiver or alteration of the documentation of consent ONE of the following conditions must be met. Your justification should explain one or more of these conditions: 1) the only record linking the subject and the project would be thin informed consent form and the principle risk would be potential harm resulting in a breach of confidentiality.

2) that the project presents no more than minimal risk of harm to subjects an involves no procedures for which written consent in normally required, 3) subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm and the project presents nor more than minimal risk.

**12.0 Provision for managing risk and adverse reactions**:

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participants related to participation in the project. 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 the project. Consider any risk to employment status or status as a student or patient should there be any breach in confidentiality. The likelihood of risk should be very low for QI/QA projects.

**13.0 Potential benefit**:

Indicate if there is no direct benefit to participants. Describe the potential benefits to the individual participant experience. Include the probability, magnitude and duration of the potential benefits. Receiving compensation or incentives is not considered a benefit. The benefit relates to the individual’s participation in the project.

**14.0 Provision for the protection of privacy. How will confidentiality be maintained**

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, and data about them). Indicate who on the research team is permitted to access any sources of information about the participant. Describe the process and rationale if subjects 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). Be sure to collect data only related to the goals of the project. For example, do not collect birth date if stated age will be sufficient, or do not collect a specific diagnosis if it is not directly related to the goals of the project.

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.

If using protected health information or official student data, EXPLICITLY state how your project protocol is in compliance with HIPAA and/or FERPA regulations. For HIPAA, you will need to state EXPLICITLY if you are a covered entity or not. If you are not a covered entity you may have to obtain a HIPAA authorization from your participants or request a waiver (or partial waiver of HIPAA authorization) from the local IRB, local privacy board or from CUHSR. You may have to get permission for your project from a local privacy board or from intuitional officials.

**15.0 Incomplete disclosure or deception:**

Describe any incomplete disclosure or deception and provide a rationale explaining why it is necessary to the research. Typically projects with incomplete disclosure or deception will not qualify as QA or QI projects.

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**:

Describe any financial or other compensation that will be provided. Include the method of payment, how much money or what gift will be provided for which activities and the timing of the compensation. Will the compensation be prorated if there are multiple research activities or if the participant withdraws from the study before finishing?

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.

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

**18.0 Qualification of the research team to conduct the research**:

Briefly describe the qualification of the project 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**:

See below for attachments that might relate to special circumstances.

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

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

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

4. Approval letters from a local human protections committee/entity.

5. Approval letters from a local privacy board

**Students – DO NOT attach your entire proposal for a course project.**

**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 study and should not be done if the study could be carried out with individuals who are not impaired. In some cases, the focus of the project will in purpose involve those with decision impairments (such as individuals with dementia). Several considerations should be addressed:

1. Will the project 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 participant 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 project 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 project leader have an invitation to conduct QI in this community? If yes, provide documentation. If no, how will the project leader 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 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 project leader or someone that is part of the project team has to conduct cross-cultural studies on this culture.  Such qualifications/capabilities could include coursework, past experience, training, or being a member of the intended culture.
2. Does the project leader have an invitation to conduct QI in this community? If yes, provide documentation. If no, how will the project leader 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 project, and how these issues will be handled.

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