University of Redlands Institutional Review Board

Application to Use Human Subjects in Research

(Form revision date: April 22,2021)

**Section A. Identification Information**

|  |  |
| --- | --- |
| Current date: |  |

|  |  |
| --- | --- |
| Target start date for project: |  |

|  |  |
| --- | --- |
| Title of project: |  |

|  |  |
| --- | --- |
| Name of principal investigator (PI): |  |

|  |  |
| --- | --- |
| Email of PI: |  |

|  |  |
| --- | --- |
| Telephone number of PI: |  |

|  |  |
| --- | --- |
| Highest degree held by PI: |  |

*If PI does not hold a degree, enter “None.”*

|  |  |
| --- | --- |
| Department or major of PI: |  |

|  |
| --- |
| Position held by PI: |

[ ] full time faculty

[ ] part time faculty

[ ] visiting faculty

[ ] adjunct faculty

[ ] administrator

[ ] staff

[ ] student

A.1. Has the PI completed the Collaborative Institutional Training Initiative (i.e., CITI training)?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If you answered “Yes,” attach the certificate of completion for each required module to this application (i.e., “Investigators – Human Subjects” basic course and “Social and Responsible Conduct of Research”).

*** If you answered “No” to the previous question, stop completing this application until you complete the CITI training. Do not submit the application for IRB review.***

A.2. If PI is a student, complete the following: (If not, go to A.3.)

|  |
| --- |
| Student’s status: |

[ ] undergraduate

[ ] master’s level graduate

[ ] doctoral level graduate

[ ] other

|  |  |
| --- | --- |
| Name of faculty or administrator sponsor: |  |

|  |  |
| --- | --- |
| Email of sponsor: |  |

|  |  |
| --- | --- |
| Telephone number of sponsor: |  |

|  |  |
| --- | --- |
| Highest degree held by sponsor: |  |

|  |  |
| --- | --- |
| Department or office of sponsor: |  |

|  |
| --- |
| Position held by sponsor: |

[ ] full time faculty

[ ] part time faculty

[ ] visiting faculty

[ ] adjunct faculty

[ ] administrator

Has the faculty/administrator sponsor completed the CITI training?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If you answered “Yes,” attach the certificate of completion for each required module to this application (i.e., “Investigators – Human Subjects” basic course and “Social and Responsible Conduct of Research”).

** ***If the answer to the previous question was “No,” stop completing this application form until your faculty/administrator sponsor completes the CITI training. Do not submit the application for IRB review.***

A. 3. List the names and departments/offices of all other project personnel (e.g., co-investigators, administrative assistants) and anyone else who will have contact with subjects or identifiable data from subjects. If none, go to A.4.

|  |  |  |
| --- | --- | --- |
|  | Name | Department/Office |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |
| 5 |  |  |
| 6 |  |  |

 Has everyone listed above completed the CITI training?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If you answered “Yes,” attach the certificates of completion for each required module to this application (i.e., “Investigators – Human Subjects” basic course and “Social and Responsible Conduct of Research”).

** ***If you answered “No” to the previous question, stop completing this application until everyone above completes the CITI training. Do not submit the application for IRB review.***

A.4. Is the proposed project a collaborative, multi-institutional study?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No (go to A.5.)  |

If “Yes,” state the name of the collaborating researchers and institution(s)

|  |  |  |
| --- | --- | --- |
|  | Name | Institution |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |

Has the proposed study been approved by the IRBs of the institutions listed above?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If “Yes,” specify the IRB approval number(s):

|  |  |  |
| --- | --- | --- |
|  | IRB Approval Number | Institution |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |

A.5. Who or what is the funding source for the proposed study?

[ ] departmental

[ ] University of Redlands faculty research grant

[ ] federal government or agency (e.g., NSF)

 *Specify*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ] state or local government or agency

 *Specify*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ] private foundation (e.g., Carnegie)

 *Specify*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ] industry/business (e.g., ESRI)

 *Specify*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ] personal

[ ] no cost study

[ ] other

 *Specify*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Section B. Abstract of the Study**

In lay language, summarize the purpose and rationale of the proposed project. **Summaries should specify clearly who the subjects are and the major criterion or dependent variables and the major predictor or independent variables.** Do not exceed 200 words. There will be a place in the application to describe the project in greater detail.

**Section C. Review Category Requested**

C.1. Has this project been approved by the IRB before?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If “Yes,” give previous IRB Approval Number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

C.2. Which type of review are you requesting? Check only one. *Note: Expedited or Exempt reviews are based on the criteria outlined in 45 CFR 46; these types of reviews are not granted on the basis of how quickly a PI wants to begin collecting data or the PI’s schedule.*

[ ] Full IRB review (go to Section D.)

[ ] Expedited review

[ ] Exempt from review

C.3. If requesting an expedited review or to be exempt from review, include justification by making explicit reference to the information in 45 CFR 46.

**Section D. Information About Research Methods**

For each part of Section D, be succinct but complete. Unless requested to do otherwise, do not include a grant proposal, thesis proposal, or any similar material with the IRB application. Do not exceed 200 words in any subsection (e.g., Research Objectives, Design and Methodology).

**Research Objectives**

In lay language, describe the research objectives. Being sure to describe and justify the conceptual, theoretical, practical, or educational value of the proposed project. The IRB needs to understand the value of the proposed project to judge the risks and benefits to the research subjects. *Cite literature related to the project and root the study in unanswered conceptual, theoretical, or practical issues.*

**Design and Methodology**

In lay language, describe and justify the design and methodology. *Explicitly state how the methodology will be carried out and permit the goals of the research/educational objectives to be adequately met*.

**Debriefing Procedure and Disclosure of Results**

Describe how subjects will be debriefed and what will be included as part of the debriefing procedure. Include the following information: the study’s rationale, the person who subjects can contact with future questions, and whether subjects can obtain a copy of the results (and, if so, how they do so). Where appropriate, include or attach a copy of the debriefing script. *If you do not plan to use a debriefing script, describe the rationale for not doing so and how subjects will be provided the other required information listed above. If you do not plan to disclose the results of the study to subjects, describe the rationale for not doing so.*

**Data Analysis**

In lay language, describe how the qualitative and/or quantitative data will be analyzed. Explain how the sample size is sufficient to achieve the study’s aims. This explanation might include a formal power calculation or an explanation of why a small sample is sufficient (e.g., qualitative research, pilot studies).

**Project Materials**

Include copies of all materials used in this study (e.g., surveys, interview questions), and information about the source of these instruments (e.g., who developed the instrument, where additional information about the instrument’s reliability and validity can be found, etc.).

**Deception**

Does the research use deception?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If “Yes,” provide the justification for the use of deception.

**Audio and Video Recording**

Does the research use audio recording of subjects?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If “Yes,” provide the justification for the use of audio recording, indicate how the recording will take place and how the recording will be safeguarded to protect participants’ privacy.

Does the research use video recording of subjects?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If “Yes,” provide the justification for the use of video recording, how the recording will take place and how the recording will be safeguarded to protect participants’ privacy.

**Hazardous Materials**

Will drugs or hazardous substances be used as a part of this study?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If “Yes,” explain.

**Section E. Description of Subjects**

E.1. Do the PI, faculty sponsor, or other research personnel have an existing relationship with any of the subjects?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If “Yes,” describe the nature of the relationship.

E. 2. Describe the subject population even if your study does not involve direct interaction with them (e.g., archival data).

|  |  |
| --- | --- |
| Total number of subjects |  |
| Age range of subjects |  |

E.3. Does the proposed study target any social, ethnic, religious, medical, or other group of individuals (e.g., NCAA athletes, Chinese-Americans, Catholics, HIV positive individuals)?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If “Yes,” specify the group(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E.4. Will the subjects consist of University of Redlands students?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

E.5. Will the subjects consist of any persons from protected groups as per 45 CFR 46 (e.g., children under 18 years of age, prisoners, cognitively impaired persons, individuals who are institutionalized, pregnant women)?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If “Yes,” specify the protected group(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E.6. Will any of the subjects be currently living live outside of the United States?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If “Yes,” specify the country or countries where they live: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

** ***Research involving human subjects living outside of the United States is difficult for the IRB to evaluate and requires special attention on the part of the PI (e.g., with regard to the cultural climate in these other countries). In the appropriate sections of this application, the PI should describe clearly whether there are any aspects of the cultural, political, or economic climate in the country where the research will be conducted that might present unique risks for subjects in comparison to what subjects in the United States might experience if they participated in a similar study. If there are unique risks, the PI should describe how she or he will mitigate these risks. The PI also must describe how she or he will deal with 45 CFR 46’s requirement that all human subjects in research be given the opportunity to ask questions, how the PI will address the requirement that all human subjects be given the PI’s contact information during the consent process, and how other requirements of 45 CFR 46 will be met. Investigators conducting research outside of the United States should consult the Department of Health and Human Services information about international human subjects protections at http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html.***

E.7. What will be the duration of an individual subject’s participation?

[ ] Less than 30 minutes

[ ] 30 minutes to 60 minutes

[ ] 1 hour to 2 hours

[ ] Greater than 2 hours *Specify duration:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E.8. Will there be any inducement for participation (money, extra credit, course requirement)?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If “Yes,” describe the inducement. *Inducements should not be so large as to be considered coercive.*

E.9. Where will the subjects be studied? Please provide the general location (name of building/department, address, office/lab/classroom number, etc.). If the subjects will be studied in a public setting, provide information about the setting (e.g., San Bernardino National Forest, Santa Monica pier). If there will be no specified location (e.g., online data collection), then state so.

**Section F. Information About Recruitment of Subjects**

F.1. Specify all methods that will be used in the recruitment of subjects:

[ ] Newspaper

[ ] Internet (websites, social media)

[ ] Email (personal or mass mailing)

[ ] Letter (personal or mass mailing)

[ ] University common area bulletin board (e.g., Hunsaker Commons, Armacost Library)

[ ] University departmental bulletin board (e.g., Appleton, Hall of Letters)

[ ] University dorm or residential area bulletin board

[ ] Publicly posted notice outside of the University of Redlands

[ ] Flyers

[ ] Radio

[ ] Television

[ ] Telephone

[ ] Other *Specify:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Describe how you will be recruiting subjects. In the description, include how you will be obtaining any contact information used for recruitment and specific recruitment methods (e.g., Reddit, common area bulletin board in Greek housing). Attach a copy of any document or script that will be used to recruit subjects, including any non-English speaker versions (or insert below).

F.2. Does the PI, faculty sponsor, or other person who will be obtaining informed consent have an existing relationship with any of the subjects (select N/A if collecting consent online)?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Yes |  | No |  | N/A |

If “Yes,” describe the nature of the relationship and what steps will be taken to prevent undue influence or coercion.

F.3. Did you append a letter from an appropriate gatekeeper (i.e., school principal, facility director, hospital administrator, Vice President of Student Life) that states clearly that you have permission to recruit participants and/or collect data from the population specified previously? *The letter from the gatekeeper must be on official stationery with letterhead and the letter must contain the gatekeeper’s name and contact information. [NOTE: Whether gatekeeper permission is necessary depends on the proposed methods for recruiting, including obtaining contact information, and collecting data (i.e., the location where subjects will be studied). Gatekeeper permission is required if you are not using publicly available contact information and/or posting your study on a public website, stating that you have permission to access/use private contact information and/or the proposed recruitment procedure. Gatekeeper permission would also be required if you are collecting data in a private location not open to the public stating that you have permission to use the space to collect data.]*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If you answered “No” to the previous question, explain why you did not.

**Section G. Information About The Consent Process and Documentation**

The standard consent process is for all subjects to sign a document containing all the elements of informed consent as specified in 45 CFR 46. Some or all of the elements of consent, including signatures, may be altered or waived under certain circumstances (as discussed in 45 CFR 46). *Under no circumstances can informed consent include false or misleading statements for the purpose of deception.*

G.1. The standard consent process is for all subjects to sign a document containing all elements of informed consent. The subject is given a copy of the consent form or computerized equivalents. If the project is being conducted with an online platform, the consent information should be the first page of the survey. All consent forms (or digital files) must be securely stored for three years after the conclusion of the study. Will informed consent be obtained according to these requirements and all others specified in 45 CFR 46?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**** If you answered “No,” then complete the sections below *Justification for a waiver of written (i.e., signed) consent* and/or *Justification for a full or partial waiver of consent*. If you answered “Yes,” do not complete the sections *Justification for a waiver of written consent* or *Justification for a full or partial waiver of consent*.**

**Obtaining informed consent**

Describe who will be obtaining consent (or permission). In the description, include discussion of when/how consent will be collected and the steps that will be taken to minimize coercion or undue influence. If children will be enrolled as subjects, describe how parental permission will be obtained and by whom. Also, describe how assent of the child will be obtained. If cognitively-impaired adults will be used as subjects, describe how permission will be obtained from a legally authorized representative. If non-English speaking subjects will be recruited, explain how consent in their native language will be obtained and by whom.

Attach a copy of the informed consent or parental consent (including forms for non-English speakers).

For subjects under the age of 18 years, attach a copy of form that will document assent of the child.

**Justification for a waiver of written (i.e., signed) consent**

Is either or both of the following true? Check all that apply.

[ ] The only record linking the subject and the research would be the consent document and the principle risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether she or he wants documentation linking him or her with the research, and the subject’s wishes will govern.

[ ] The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

**Justification for a full or partial waiver of consent**

A waiver might be requested for research involving only existing data or human biological specimens. More rarely, it might be requested when the research design requires withholding some study details at the outset (e.g., behavioral research involving deception).

[ ] I am requesting a waiver of some elements of informed consent.

If you checked the above box, describe which elements you are requesting be waived.

[ ] I am requesting a waiver of all elements of informed consent on the basis of the following. Check all that apply.

[ ] The research will involve no greater than minimal risk to subjects or to their privacy.

Explain.

[ ] The waiver will not adversely affect the rights and welfare of subjects. *(Consider the right of privacy and possible risk of breach of confidentiality in light of the information you wish to gather.)*

Explain.

[ ] The research would be impracticable without the waiver.

Explain.

[ ] The risk to privacy is reasonable in relation to benefits to be gained or the importance of the knowledge to be gained.

Explain.

**Section H. Information About Confidentiality**

H.1. As part of the data collection process – excluding information collected solely as part of the consent procedure – will you collect or receive any of the following? *Check all that apply that are collected as part of data collection (e.g., to follow-up with subjects, review transcripts), not information collected as only as part of the consent process.*

[ ] No identifying information will be collected outside of the consent process (skip to H.3.)

[ ] Names

[ ] Telephone numbers

[ ] Any dates related to a subject (e.g., date of birth)

[ ] Current or past addresses

[ ] Fax numbers

[ ] Email addresses

[ ] Social security number

[ ] Account numbers (e.g., bank, health plan)

[ ] License/certificate numbers (e.g., drivers, professional)

[ ] Vehicle Identification Numbers

[ ] URLs

[ ] IP addresses

[ ] Photographs or images of the subject

[ ] Other *Specify:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

H.2. Will any of the identifiers listed above be linked to and/or stored with the research data?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No (skip to H.3) |

 If you answered “Yes” to H.2, specify with whom, excluding research personnel, will identifiable data be shared (i.e., the information listed above)?

|  |  |  |
| --- | --- | --- |
|  | Name | Department/Office |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |
| 5 |  |  |
| 6 |  |  |

If you answered “Yes” to H.2, specify where the identifiers listed above will be stored? Where applicable, list building name/department, address, and office numbers.

|  |  |
| --- | --- |
|  | Department/Office, Address, Office numbers |
| 1 |  |
| 2 |  |
| 3 |  |
| 4 |  |
| 5 |  |
| 6 |  |

H.3. For electronic data stored on a desktop computer or network, check all of the ways in which the data will be secured:

[ ] Secure network

[ ] Password protected computer

[ ] Password protected data files

[ ] Encrypted files

For portable computing and storage devices (e.g., smart phone, laptop computer, flash drives, CDs/DVDs, digital recordings), check all of the ways in which the data will be secured:

[ ] Password protected device

[ ] Password protected data files

[ ] Encrypted files

For hardcopy data (e.g., information recorded on paper, non-digital audio/video recordings), check all of the ways in which the data will be secured:

[ ] Locked office or suite

[ ] Locked storage cabinet

[ ] Data will be kept separate from identifiers listed above

H.4. Will the data eventually be destroyed (including identifiers)?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If “Yes, answer the following:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|

|  |  |
| --- | --- |
| Who will destroy the data? |  |
| How will the data be destroyed? |  |
| When will the data be destroyed? |  |

 |  |  |  |  |  |  |  |

|  |  |
| --- | --- |
| If “No” please give justification. |  |

**Section I. Cost-Benefit Analysis**

I.1. Are there direct and practical benefits to the subjects?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If you answered “Yes” to the preceding question, describe the reasonable, major, practical benefits to individual subjects. *Do not engage in hyperbole.*

I.2. Are there direct and practical benefits for society and/or the discipline/profession?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If you answered “Yes” to the preceding question, describe the reasonable, major, practical benefits to society and/or the discipline/profession. *Do not engage in hyperbole.*

I.3. If the PI is a student, are there direct and practical educational benefits for him or her? *If the PI is not a student, enter “Not applicable”.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Yes |  | No |  | Not Applicable |

If you answered “Yes” to the preceding question, describe the reasonable, major, practical educational benefits. *Do not engage in hyperbole.*

**Analysis of Cost-Benefit Ratio**

Provide an analysis of the cost-benefit ratio and indicate how the potential benefits of the research outweigh any potential costs (or risks). Identify any short-term or long-term risks to subjects and precautions taken to minimize risks. Your response should include information about the risk of psychosocial harm (e.g., emotional distress, embarrassment, breach of confidentiality), economic harm (e.g., loss of employment or insurability, loss of professional standing or reputation, loss of standing within the community), legal jeopardy (e.g., disclosure of illegal activity or negligence), and pain and physical injury. Describe procedures for follow-up, when necessary (e.g., such as when subjects are referred for psychological services). If there is no direct interaction with subjects and risk is limited to breach of confidentiality (e.g., for archival data), then state that this is so.

**Section J. The Use of Existing Records and Biological Specimens**

J.1. What records, data, or human biological specimens will you be using?  *Check all that apply.*

[ ] None (skip to Section K.)

[ ] Data already collected for another research project

[ ] Data already collected for administrative purposes

[ ] Public records

[ ] Private (i.e., custodial-controlled) records

[ ] Biological specimens

For each of the boxes checked above, summarize how the original data, records, or human biological specimens were collected. The IRB is particularly interested in whether the data or specimens were obtained ethically, especially as regards to issues of informed consent.

For each of the boxes checked in J.1, indicate where specifically these data, records, or human biological specimens currently reside?

Do all of these data, records, or specimens exist at the time of this application?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Yes |  | No |  | Not Applicable |

If not, explain how prospective data collection will occur.

**Section K. Conflict of Interest**

The following questions apply to all investigators and research personnel engaged in the design, conduct, or reporting of the results of this project and/or their immediate family members (e.g., spouse, significant other, dependent children). Currently or during the term of the study, does any member of the research team or his/her family member have or expect to have a …

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| … personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with a sponsor of this study? |  |  |
| … personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with an entity that owns or has the right to commercialize a product, process, or technology studied in this project? |  |  |
| … personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with an entity engaged in the performance of this project as a subcontractor, sub-recipient, or vendor? |  |  |
| … board membership of any kind or an executive position (paid or unpaid) with a sponsor of this study or with an entity that owns or has the right to commercialize a product, process, or technology studied in this project? |  |  |

If the answer to any of the questions above is “Yes,” describe in detail the conflict of interest.

**Section L. Checklist**

Applicants: Please complete the checklist. Do not continue to Section M. without completing this checklist.

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** | **No** | **N/A** | **Item** |
|  |  |  | All questions and items in the IRB application have been answered fully and completely. |
|  |  |  | The IRB approval numbers of collaborating institutions is included. |
|  |  |  | A letter from an appropriate gatekeeper/authority figure specifying that you have permission to recruit subjects in the manner described above has been attached. |
|  |  |  | A letter from an appropriate gatekeeper/authority figure specifying that you have permission to study the subjects at the location(s) described above has been attached. |
|  |  |  | The informed consent has been attached. |
|  |  |  | A copy of the form used for assent of a child is attached. |
|  |  |  | Copies of all instruments, questionnaires, and interview protocols are attached. |
|  |  |  | The debriefing script is attached. |
|  |  |  | Copies of all CITI certificates are attached. |

**Section M. Certification for Research**

*I certify that to the best of my knowledge the information provided above is complete and accurate.*

*I agree to obtain approval from the IRB for any modifications of the above protocol as described.*

*I accept responsibility for ensuring that the rights, welfare, and dignity of the subjects in this study have been protected and are in accordance with applicable federal/state/local laws and regulations and the University's Institutional Guidelines for the Treatment of Human Subjects in Research.*

*I will provide progress reports to the IRB at least annually, or as requested.*

*I will report promptly to the IRB all unanticipated problems or adverse events involving the subjects.*

*I will follow the IRB approved consent process for all subjects.*

*I will ensure that all personnel conducting the work of this protocol have or will receive appropriate training in the use of human participants in experimentation.*

*I certify that this research does not unnecessarily duplicate research already published.*

*I understand that IRB approval is normally for 1 year.*

*I will not collect data after the IRB’s approval has expired.*

*I will submit a request for continuation of approval if I plan to collect data after the IRB’s approval has expired.*

*I will submit a final report once the data have been collected.*

|  |  |
| --- | --- |
|  |  |
| Signature of PI | Date |

|  |  |
| --- | --- |
|  |  |
| Signature of Unit IRB Coordinator | Date |

*Because the PI is a student,* *I accept that I am ultimate responsibility for ensuring that this study complies with all the obligations listed above for the PI.*

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| Signature of Faculty/Administrator/Staff Sponsor | Date |

 *For IRB use only. Do not write or type below this line.*

**IRB Decision**

[ ] Approved

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| --- | --- |
| IRB approval number: |  |

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| --- | --- |
| Date approval starts: |  |

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| Date approval ends: |  |

[ ] Approved with conditions (i.e., the IRB requires as a condition of approval that the investigator make specified changes to the research protocol or informed consent document(s), confirm specific assumptions or understandings on the part of the IRB regarding how the research will be conducted, or submit additional documents)

[ ] Not Approved

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| Signature of IRB Chair | Current date |