

To apply for the IRB to consider your research protocols, please use the following link:
<https://forms.gle/hEavXNcgpKRQF2wAA>

The form is complex, and while many answers provide a predetermined choice, some require a carefully thought out narrative. This document offers you the form prompts so you know what to expect. We suggest that you use these prompts to write your narrative answers in a separate document, make sure everything is accurate and error-free and then copy and paste the information into the form. For any questions, please contact irb@caldwell.edu

The prompts are:

EXEMPT and EXPEDITED REVIEWS:

Valid email address

Name of the Principle Investigator, Status at Caldwell, Department information

Information about additional investigators, if any

Information about the CITI training and certificate of completion (should be attached to the application)

Project title and type

Information about your project such as review category, research summary and objectives, involvement of minors, types of consent, and so on.

Answer the questions about the intended participants and recruitment, attach recruitment materials

Provide the necessary consent process information; attach all necessary forms.

Provide necessary methodology information, attach the instruments you will be using

Explain the confidentiality or anonymity and how you will protect it.

Provide explanations of risks and how they will be mitigated

Explain what the benefits of the study will be

Provide assurances, your signature and insert the date.

Submit your form.

<div style="border: 1px solid #ccc; padding: 10px;"> <p>Email *</p> <p>Your email _____</p> <p> This is a required question</p> </div>	<p>Insert your valid email address, the one you use and check often. For Caldwell students, faculty, and staff, make sure this is your Caldwell address.</p>
<div style="background-color: #4a4a9a; color: white; padding: 5px;">PI INFORMATION</div> <div style="border: 1px solid #ccc; padding: 10px; margin-top: 10px;"> <p>Name of the PI *</p> <p>ENTER YOUR NAME HERE _____</p> </div> <div style="border: 1px solid #ccc; padding: 10px; margin-top: 10px;"> <p>Are you a student, CU faculty, or staff? *</p> <p><input checked="" type="radio"/> Yes</p> <p><input type="radio"/> No</p> </div> <div style="border: 1px solid #ccc; padding: 10px; margin-top: 10px;"> <p>PI Department/Program *</p> <p><input type="radio"/> Applied Behavior Analysis</p> <p><input type="radio"/> Business/Computer Science</p> <p><input checked="" type="radio"/> Education</p> <p><input type="radio"/> Nursing/Public Health</p> <p><input type="radio"/> Psychology/Counseling</p> <p><input type="radio"/> Sociology/Criminal Justice</p> <p><input type="radio"/> Sciences</p> <p><input type="radio"/> Other</p> <p><input type="radio"/> Not affiliated with Caldwell University</p> </div>	<p>Enter the name of the Principle Investigator (PI) and mark other appropriate choices to tell us more about the PI on the project.</p>
<div style="background-color: #4a4a9a; color: white; padding: 5px;">Additional investigators</div> <div style="border: 1px solid #ccc; padding: 10px; margin-top: 10px;"> <p>Is there an additional investigator on this project? *</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p> </div>	<p>Tell us if there are any additional investigators on the project. If there are, fill out their information.</p>

ADDITIONAL INVESTIGATOR(S) INFORMATION

Who else is affiliated with the project and how? *

Your answer



PROTECTION OF HUMAN SUBJECTS TRAINING

Date of completion of the latest CITI training. The basic CITI training for the Caldwell University IRB purposes is Social-Behavioral-Educational (SBE) Comprehensive training for non-nurses and Biomedical (biomed) Comprehensive for nursing students/faculty. The CITI training must be completed within past three years).

Date

10/03/2022

Additional Training, date of completion

Date

mm/dd/yyyy

Please include proof of CITI training(s) for all researchers and/or faculty sponsors involved with the project. Completion date must be within past three years.

PDF citiCompletionCe... X

Add file

PROJECT INFORMATION

Project title *

ENTER THE TITLE OF YOUR PROJECT HERE.

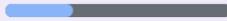
Tell us about the completion of CITI training for you and other researchers on the project. Make sure that you and everyone on your team complete the appropriate CITI course:

- Non-nurses should complete Social-Behavioral-Educational (SBE) Comprehensive course.
- Nurses should complete Biomedical (Biomed) Comprehensive course.

The CITI training must be completed within the past three years).

Add certificates indicating the completion of training when prompted to do so.

Tell us about your research project, provide the title and mark what type of project that is.

<p>Type of project *</p> <ul style="list-style-type: none"><input type="radio"/> Individual Research Project<input type="radio"/> Class Project<input checked="" type="radio"/> Thesis/Dissertation<input type="radio"/> Course Exemption (please note that only faculty teaching courses may apply for course exemption)<input type="radio"/> Course Exemption (Action Research ONLY)	<p>Choose the type of project</p>
<p>Review category</p> <p>Predicted level of review *</p> <ul style="list-style-type: none"><input checked="" type="radio"/> Exempt<input type="radio"/> Expedited<input type="radio"/> Full <p>Back Next  Page 9 of 30 Clear form</p>	<p>Choose the level of the review</p>
<p>EXEMPT REVIEW CATEGORY</p> <p>Exempt review category (for description of the exempt review categories, * please use this link: https://oprs.usc.edu/irb/exempt-level-of-review/)</p> <ul style="list-style-type: none"><input checked="" type="checkbox"/> #1<input type="checkbox"/> #2<input type="checkbox"/> #3<input type="checkbox"/> #4<input type="checkbox"/> #5<input type="checkbox"/> #6<input type="checkbox"/> #7<input type="checkbox"/> #8 <p>Back Next  Page 23 of 30 Clear form</p>	<p>Chose one or more categories of the review. For the complete list and explanations of categories, please visit https://oprs.usc.edu/irb/exempt-level-of-review/</p>

<p>PROJECT INFORMATION, CONTINUED</p> <p>Please provide a brief summary of research objectives and significance of the proposed research. *</p> <p>ENTER YOUR SUMMARY HERE</p> <hr/> <p>Does this research involve minors? *</p> <p><input type="radio"/> yes</p> <p><input checked="" type="radio"/> no</p>	<p>Provide project information as requested by the prompts. Here, provide the research summary, research objectives significance.</p> <p>Mark whether your research involves minors.</p>
<p>Untitled Section</p> <p>Does this research involve other vulnerable populations (i.e. individuals with impaired decision-making ability, prisoners, etc.)? *</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p>	<p>Provide project information as requested by the prompts. Most of the information is choice filled by clicking on the options provided.</p>
<p>Is the study likely to involve participants who are not fluent in English? *</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p> <p>PARTICIPANT INFORMATION</p> <p>Approximate number of participants *</p> <p>Your answer <input type="text" value="14"/></p> <p>Participant age range *</p> <p><input type="checkbox"/> Adults age 18 and older</p> <p><input type="checkbox"/> Children under the age of 18</p>	<p>Continue discussing the participants and their selection in these questions.</p>

Will any ethnic group or gender be excluded from the study pool? *

- Yes
- No

Does this study involve participants located outside of the US? *

- Yes
- No

Participant selection *

Your answer



Participant recruitment *

Your answer



Please attach your recruitment materials. The file(s) should be labeled with your name and the words "ATTACHMENT 2". If you are attaching more than one recruitment document, please label each accordingly (e.g., Smith, ATTACHMENT 2, social media recruitment).

[Add file](#)

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INFORMED CONSENT INFORMATION

Type of consent *

- Adult, written, online
- Adult, written, hard copy
- Adult, waived
- Child assent
- Broad consent

Please provide the explanation how the participants will be selected. Explain any exclusion criteria and why these apply. Provide a narrative explaining how the participants will be recruited. Attach the recruitment materials to the form

Provide the information on the informed consent.

Please enter the Flesch-Kincaid grade level score for your consent documents *

(The Flesch Kincaid Grade Level is a readability formula which assesses the approximate reading grade level of a text. Federal Government requires the readability of consent forms to be at about eighth grade level. You can use this calculator: <https://charactercalculator.com/flesch-reading-ease/> to calculate the level)

Your answer



Please attach your consent and assent forms and, if using alterations, waivers, and broad consents, any explanations to the efficacy of their use. The file(s) should be labeled with your name and the words "ATTACHMENT 1". If you are attaching more than one consent form, please label each accordingly (e.g., Smith, ATTACHMENT 1, PARENTAL CONSENT).

 Add file

Are any of the participants not legally able to provide consent? *

Yes

No

Will participants be compensated for participation? *

Yes

No

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METHODOLOGY

Does the study involve deception? *

Yes

No

Use this website: : <https://charactercalculator.com/flesch-reading-ease/> to calculate the readability of your consent documents. The consent documents should be written at about 8th grade level regardless of the education level of the intended participants.

Please attach the consent forms/assent forms here.

Continue filling out the form by choosing the options here.

Methodology: Please provide a brief but complete description of how the research will be conducted, including what participants will be told and what they will be doing. *

Your answer



Please attach your data collection instruments. If you collect data by using software (e.g., games), please provide a detailed description of the tool and its functions explaining the type of data being captured. The file(s) should be labeled with your name and the words "ATTACHMENT 3". If you are attaching more than one instrument, please label each accordingly (e.g., Smith, ATTACHMENT 3, motivation questionnaire). *

 Add file

Does your study involve transferring identifiable information and/or biospecimens to and/or from a European Country (e.g., an online survey open to participants in Europe) *

Yes

No

Estimated date of project completion *

Date

mm/dd/yyyy 

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DATA COLLECTION INFORMATION

Will your data be collected anonymously or confidentially? *
(for definitions of these terms, please consult <https://www.evergreen.edu/humansubjectsreview/confidentiality>)

The data will be anonymous

The data will be confidential

My study is multi-phased. Some of the data will be anonymous and some data will be confidential.

Provide a description of the data collection methodology you propose to use during the study.

Attach your data collection instruments here.

Provide the approximate date of the completion of the project (this includes data collection, analysis, and reporting)

The next few questions have to do with anonymity/confidentiality. To read up on this, please go to

<https://www.evergreen.edu/humansubjectsreview/confidentiality>

Will any of the data be audio/video recorded? *

Yes

No

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Confidentiality/Risks/Benefits explanations

Confidentiality Statement: Please provide a brief but complete description of how confidentiality of participants and their data will be maintained before, during, and after data collection. *

(Please note: even if you are planning to collect anonymous data, this section still needs to be completed for data handling, maintenance and storage during and after your study.)

ENTER YOUR EXPLANATION HERE

Risks to participants - please describe *

ENTER YOUR EXPLANATION HERE

Management of risk, including COVID mitigation - please describe *

ENTER YOUR EXPLANATION HERE

Will the participation in the study interfere with participants' normal routines in the settings you are using for your study? *

Yes

No

Benefits to participants - please describe *

ENTER YOUR EXPLANATION HERE

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Please explain how you will ensure the confidentiality of the data once it is collected.

Please speak about the risk and risk mitigation in these two sections.

Please describe the benefits to the participants in this study

Assurances:

I, the investigator (and if applicable, the faculty sponsor), certify that to the best of my knowledge the research described above qualifies for review under

45 CFR§4. I agree that any changes to the project will be submitted to the Institutional Review Board before they are implemented, and that any adverse events will be reported in a timely manner. I also recognize that the Institutional Review Board is only responsible for ensuring the safety and integrity of human participants. I recognize that I am responsible for ensuring this research complies with the mission statement of the University.

Assurances

- I agree to the assurances listed above
- I do not agree to the assurances listed above

Signature

This application requires an electronic signature, provided by typing your * name in the box below. By providing your signature, you are certifying that (1) the information provided in the application is accurate and complete, (2) that you understand that research described in the application, including the recruitment of participants, may not begin until full approval has been granted by the CU IRB, and (3) that the research will be conducted in accordance with the above-listed assurances.

Your answer 

Today's date *

Date Time
mm/dd/yyyy  : AM 

Provide assurances, signature, date in the next few sections

You can click the back button at any time to make sure your application is complete and accurate.

CLICK SUBMIT ONCE YOU ARE DONE.

