Cayuse IRB Application Question Guide for Initial Submissions

Contents

Tip: Look for the  icon throughout the application for definitions and additional information.

Students: Your advisor should be involved in this application process. This is your first time going through this process, it is not their first time and they can help you. There is only one IRB administrator, please ask your advisor before asking the IRB office.

Section A. Primary Investigator and Application Selection

1. **Principal Investigator (PI)**

   As the person submitting the application, you are most likely the Principal Investigator (PI). The PI is the person proposing the research and will collect informed consent, collect data, and analyze data.

   Students conducting a thesis/dissertation or McNair project should be listed as the PI.

2. **Primary Contact (PC)**

   The Primary Contact (PC) is normally the same person as the PI as this person needs to receive ALL notifications from the software regarding resubmission requests, approvals, renewals, etc.

3. **Are you receiving funding to conduct this study?**

   If you are receiving external or internal funding for any costs related to this human subjects research, please check "yes" and list the funder. External funding information MUST be disclosed in your informed consent form.

4. **Please select the type of research you are proposing to conduct:**

   Select either human or animal research. This selection will take you to the appropriate form. This guide is only for the Human Subjects Application.

Section 1 Human Subjects Application

1. **Co-Principal Investigator/ Faculty Advisor**

   If you have a Co-PI from Sac State, please use the Find People to search for them and add them to your application. This allows them to see the application.

   Students MUST list their thesis or dissertation committee chair as the Faculty Advisor. Search by first or last name and add them to the application. Your advisor should help you with this application and will be required to certify this application.

2. **Will there be additional investigators?**

   Any additional investigators/ assistants can be listed on your application through the Find People function or by writing in their name. Anyone helping you with obtaining 1) informed consent, 2) collecting data, or 3) analyzing identifiable data MUST take the CITI training.

3. **What is your status at Sac State?**

    a. Faculty & Staff – verify that you are conducting "research" that will contribute to or develop generalizable knowledge. Then verify that you have complete the CITI training. If you have not completed training, do this before you submit the application or it will be sent back!
    b. All students – select the most appropriate circumstance for this submission. Verify that you have completed training.

Section 2 Project Information

1. **Anticipated Start Date**

    If you are ready to begin your research, enter a start-date of two weeks from your submission date to give the IRB time for review. If you do not anticipate starting the study until the next month or next semester, enter your best estimated start date.

    1.a. This question is asking how long you anticipate working with people to collect data from them and working with that data during analysis. For example: I anticipate collecting survey responses for 2 weeks and analyzing the data for another 2 weeks, so my data collection and analysis should take about 1 month. Once my data analysis is complete, I will be working on completing my thesis and writing up results, but this is NOT included in my estimate.

2. **Review Category Requested:**

    This is an important one!

    - **Exempt** - Please read the Exempt category carefully and click the " ? " icon to the right to learn about Direct and Indirect identifiers to determine if you will be collecting individually identifiable information. Most data is **NOT considered anonymous**. That's OK. As long as the information is low in risk, you can request an Exempt review.
        - **This selection will lead you to Section 3 and will be the last section in the application**.

    - **Expedited** –
        - if you are conducting research that will collect identifiers and the data could potentially be harmful to the participant if that information were to accidentally be linked to them and disclosed, it will be Expedited.
        - If you are collecting blood, saliva, or other biospecimens, you will need to request Expedited review.
        - If you are asking *healthy* participants to complete **moderate** exercise you will request Expedited review (does NOT include Max V02 testing or other intense exercise that a normal healthy adult would consider more than moderate).

- **This selection will lead you to Section 4-6.**

- **Full** –
  - If you are asking healthy adults to complete a max V02 test,
  - Intense exercise for a healthy participant
  - Moderate or less than moderate exercise for unhealthy participants

  - Collecting potentially identifiable data about a person and, if that information were to be accidentally disclosed with a link to that person, could result in deportation, arrest, or trigger self-harm.

  - **This selection will lead you to Section 4-6.**

- **Secondary Data Analysis ONLY -**
  - if you are working with data that already exists, select this option and then select the best option that describes the dataset.
  - Depending on your response, it may lead you to a one-page application requiring IRB approval, or it may lead you to a statement about not working with "human subjects."
  - Either way, the IRB will be in contact with you via the Cayuse software.

3. Purpose and Objectives of the Research

This is the "so what?" statement. The IRB wants to know why you are doing the study. What is the gap in research that you aim to fill? Who will it benefit? What are the potential implications of this research?

Please do not copy and paste from a thesis/dissertation – please be concise.

If the objective of the research does not reach beyond a specific program, then you may not be conducting "research," rather you are conducting a "program evaluation." However, many evaluations can have far-reaching benefits and apply to other programs. If your research can be replicated by other programs who can experience the same results, and that is your intent, then you are conducting research.

4. Main Research Question(s) or Study Hypothesis(es)

Students, these should be the same questions you pose in your thesis/dissertation.

The IRB will want to see how the purpose/objectives and methods tie in with your hypothesis/RQ's. If your methods will not answer your questions/hypothesis, the IRB may question whether the benefits of conducting the study outweigh the risks.

5. **Methodology**

   This text box is big so that you can fill it up! This is your beginning to end research design. Please follow the sub-categories to walk you through what the IRB needs to know:

   1) *Study Design* - What methods will be used? mixed? Quantitative and/or qualitative? Are you using a survey, interviews, focus groups, experiment?

   2) *Sampling* - who do you need to participate in your study in order to have a representative sample? How will you reach that audience?

   3) *Data Collection* – how will you obtain the information you need from your participants? Go beyond "a survey" and tell us when you plan on collecting the data, where you will collect it, how long it will take (if it involves several sessions, please break this up by session), and what you are collecting. We want to see that every detail has been planned and thought-through.

   4) *Data Analysis* – How will you analyze the data you obtain in order to answer your research question? Will you need to use any tools or services (SPSS, transcription services, etc.) to analyze data?

   5) *Reporting of Results* - how do you plan on disseminating your results to peers in your discipline? Additionally, please describe whether participants will be identified individually **or as a group** in results or how they will be protected (i.e. the population will be described as students at a Northern CA Community College and the real college name and location will not be revealed; all data will be reported in aggregate in charts and graphs; personal quotes will be linked to a pseudonym and no real names will be used).

6. **Potential Benefits**

   Anticipated benefits may be directly to the subject (although rare), the population from which the subject was drawn, scientific knowledge, or society. Normally, research benefits will not be realized by participants (hence, incentives are offered). However, the IRB must see that benefits can potentially reach a population or society in order to balance the risks.

Section 3 Exempt Application*

*If you selected *Expedited, Full, or Secondary Data* you will **NOT** see this section. Go to Section 4 Participant Experience (Expedited and Full Board Application) to continue this guidance.

1. **How will participants be recruited?**

Not only does the IRB need to know your method of recruitment, we need to know how you are going to carry it out. Who is helping you reach your population? Are you obtaining emails or is someone forwarding a flyer? Are you posting paper flyers somewhere? Are you visiting certain organizations, classrooms, or groups to announce your study?

1.a. Conflicts of interest

- Are you being paid to conduct this research? By whom? Will that be disclosed in your informed consent form?
- Are your subjects subordinates? Do you have any control over your research subjects' grades, financial standing, employability, etc.? If so, how do you plan on mitigating the potential for coercion?
    - If you are conducting a survey, having a neutral third-party disseminate the survey on your behalf and drop-off the completed surveys in a sealed envelope will ensure that you will not know who participated and who did not (if the survey is anonymous).
    - If you are collecting course documents and data, ensure that you are obtaining student's consent to allow you to access that data for research purposes. Collect the informed consent forms in an envelope and don't open it until the final grades are posted. This ensures that participation will not affect their grade.

2. Attach recruitment letter, flyer, or letter(s) of support here, when applicable:

If you are using a flyer (by email or paper) or a recruitment letter/email, it must be attached to the application. If you are contacting potential participants by phone, create a script and attach it. Your application will be returned if written communication with participants is described and nothing is attached here.

If you are posting flyers on campus, the specific Department or Student Organizations office need to approve it prior to posting.

3. Will any incentives be offered to participants?

An incentive is useful for gaining participants when the study will take time or when you suspect little interest in the study.

a. Raffle, lottery, or drawing – California law requires that those who don't want to participate in a study must be able to enter a raffle/lottery/drawing when it is offered as an incentive (similar to "no purchase necessary"). You cannot limit the raffle to participants only. THIS IS LAW.
    i. In your informed consent form you must describe the incentive. If you are offering a raffle, add the statement, "If you do not want to participate in the study but would like to be entered into the drawing, please email me at (enter email address here)." This statement alone grants access to all potential participants and makes the lottery legal.

b. Gift cards – these are great, especially if everyone who participates gets one and it's given right after participation. If everyone gets the same incentive, you can require participation in order to receive the incentive.

c. Extra credit – when extra credit is offered as an incentive, there must be an alternative extra credit option for those who do not want to participate in the research. This alternative option cannot also be available to those who participate in the research, it must be one or the other. This means that all students must have access to the same amount of extra credit points, whether they participate in the research or not. For example, if I want to participate in the research for 5 points, I cannot also have access to the alternative assignment for another 5 points, totaling 10 points. The person who does not want to participate in the research will only have access to 5 points, not 10.

d. Please be sure that your incentive matches the time and effort required of the participant. An inappropriate incentive can cause coercion. For example, a $10 gift certificate for a 5 minute survey is too much. A $5 - $10 gift certificate for a 1.5-2 hour interview is more appropriate.

4. How many participants will be enrolled?

If you are working with multiple subject populations, or multiple data collection methods (survey/ interview), you need to split up the numbers by population and method. For example, 300 students for the survey and 10 faculty for the interviews.

5. Data collection method

Check the application data collection methods that you will use. If you are conducting online surveys, you will select Electronic/online. If you are audio recording interviews you will check audio recording.

- Paper-based – you are only collecting data from paper surveys or hand-written notes
- Electronic/online – you are only collecting data from online surveys or notes written electronically
- Audio recording/ video recording

  Using this method automatically links the individual to their responses and is not anonymous.

  - What device are you using to record the interviews? Is it password protected?
  - Once the interview is complete, please transfer the file to a hard-drive and remove the audio from the recording device (unless you used a laptop to record).
  - How long will transcription take? Once transcription is complete, the audio file should no longer be needed and it should be erased from the hard-drive.
    - Now you have a de-identified interview transcript and you can keep that transcript as long as you like, but no less than 3 years.

6. **Attach survey, interview questions, rubric, inter-rater reliability datasheet, other data collection tools:**
   You MUST attach your data collection tool (i.e. your survey instrument, interview questions, rubric, etc.). If you are collecting data from participants or using an instrument to recording information about participants, it needs to be attached or the application will be returned.

7. **Will you be collecting any direct identifiers other than audio/video?**

   You are collecting direct identifiers if you are asking participants to enter their name, email, or other unique identifiers like a student ID# directly on the data collection tool, or asking for contact information that will not be linked to their research data.

   a. **What** identifiers are you collecting and **why** are they needed?

      Why is it necessary to collect the identifiers? Are you linking the information to someone? What identifiers exactly are you collecting?

   b. Will identifiers be included in the data collection tools or in the dataset?

      If you are asking participants to provide their name, email, phone, or other identifiable info directly on the data collection tool (i.e. a survey form or health evaluation screening form), you are linking the individual to their responses. You are not collecting "anonymous" data.

      i. If you are collecting names or other identifiable info, can you download the dataset and, once you link the data as needed, remove the column of identifiable information?

         If you are collecting a contact list, it's as easy as deleted that list once you no longer require contact with participants. In some instances, you will need to erase any texts, calls, or emails made to participants in order to erase any link of that person to your study.

      ii. Protection of participants during reporting of results means that you are reporting in aggregate so that individual results are not being shared, or through the use of pseudonyms or vague descriptions. For example, do not share that students interviewed were from Sacramento State, rather they are students from a four-year higher educational institution in Northern California. This could be any CSU in the norther region and helps to de-identify your subject group.

8. **Will you be collecting demographic information (indirect identifiers)?**

   Demographics are identifiers that cannot directly identify someone:
   a. Gender/ sex
   b. Age

c. Ethnicity
d. Employment status
e. Income status
f. Status as a student, faculty, employee, etc.
g. Other identifiers that define a group (i.e. students at a university in Northern California)

9. **How will raw research data be stored and protected** during and after **your study?**

Data storage –

- The best way to protect data, whether in written or electronic form, is by limiting access to the data.
- Paper- store in locked drawers/ cabinets/ offices where only you and the research team have access.
- Electronic - store on a hard-drive (no cloud storage yet) in encrypted or password protected files.

10. **How long do you anticipate** retaining raw data **after the completion of your study?**

Data retention timeline –

a. How long will you store identifiable data vs. de-identified data? For example, how long will you keep audio recordings vs. transcriptions?
b. Only keep the data and miscellaneous information needed to reconstruct your study, such as relevant statistics and analyses, notes, or observations. If they can be de-identified, do so prior to long-term storage. Tell the IRB when you plan on removing identifiers and then how long you will store the de-identified data.
c. Make sure these timelines are consistent with what you are telling participants in your informed consent form. You need to address both identifiable data retention vs. de-identified data retention.
d. You can keep de-identified data indefinitely. But if you will not, you need to keep it for at least 3 years. Why? Because someone might challenge your research or try to replicate it and you need to have your data to back-up your work.

11. **How will raw research data be** destroyed**, if applicable?**

Data destruction –

a. We don't need timelines here, many inconsistencies come from providing information that we are not asking for.
b. Effective data destruction ensures that information cannot be extracted or reconstructed. Shredding paper files and erasing electronic files from a hard-drive are necessary. Sometimes deleted data can be recovered, please ensure you know how to delete items from your hard-drive or ask I.T. for help.

12. **Please check all potential *minimal risks* presented to participants:**

a. MOST research includes the risk of loss of confidentiality. You might think you are collecting "anonymous" data, but if you are obtaining contact information, audio recording, or collecting enough demographics from a small population, you are not collecting anonymous data. Examine closely what you are collecting.
b. Please address all risks in the study.

13. If risks are present, describe how each risk identified above will be mitigated or eliminated.

Any risks checked in question 12 MUST be accompanied with an explanation in this text box. We also want to know how you will mitigate the risk (we understand that not all risks can be eliminated. We are not risk averse).

14. Informed Consent

PLEASE use the sample document linked in the application. This is the most up-to-date form that follows current standards. Pay close attention to whether you are collecting anonymous or private information. Most research is not collecting data anonymously, so Option #1 is usually the safest bet. You must include all options that apply to your study. You do NOT, however, need to include any options text in blue if it does not apply. For example, if you do not have an incentive, you do not need to tell participant's that you do not have an incentive for them. Just remove the text. All red and black text is required and must stay in the form. Do not leave the highlighted sections or the "(Exempt Research Template)" text at the top. This is the form your participants will see, make sure it is clean and uniform.

a. Students – please request your advisor to review your consent form for typos.

15. Notify your Department Chair

You are required to send a copy of the PDF to your department chair. Please follow the instructions in the application to complete this task. You may need to disable pop-up blockers for the Cayuse site in order to download the PDF.

This is the end of the Exempt application. Please use the first-time submission guide under the Investigator drop-down for submission instructions: www.csus.edu/research/irb/submit.html.

The following sections will only appear in Expedited and Full Board applications.

Section 4 Participant Experience (Expedited and Full Board Application)

1. How will participants be recruited?

Recruitment – not only does the IRB need to know your method of recruitment, we need to know how you are going to carry it out. Who is helping you reach your population? Are you obtaining emails or is someone forwarding a flyer? Are you posting paper flyers somewhere? Are you visiting certain organizations, classrooms, or groups to announce your study?

1.a**. Attach recruitment letter, flyer, or letter(s) of support here, when applicable:**

If you are using a flyer (by email or paper) or a recruitment letter/email, it must be attached to the application. If you are contacting potential participants by phone, create a script and attach it. Your application will be returned if written communication with participants is described and nothing is attached here.

If you are posting flyers on campus, the specific Department or Student Organizations office need to approve it prior to posting.

2. **How many (maximum) participants will be enrolled?**

If you are working with multiple subject populations, or multiple data collection methods (survey/ interview), you need to split up the numbers by population and method. For example, 300 students for the survey and 10 faculty for the interviews.

3. **Are there any special criteria for selection or exclusion of participation in your study?**

Inclusion and exclusion criteria –
most research is about a specific population. What are the requirements for being eligible to participate?

Those studies requiring certain health criteria should have a health screening form to ensure eligibility. That form does not need to collect names or other contact information. If you need that information, create a master key that links a person to a participant number. Only the participant number should be on health forms and other research data.

4. **Are there** monetary costs **associated with participating in the research? For example, travel costs, parking costs, co-pay for a required doctor's visit, etc.**

If you are asking non-Sac State affiliated to come onto campus, will you pay them back for a parking pass? What other costs might they incur from participating in your study? Who is covering those costs? **This information needs to be very clear in the informed consent form. Especially if the cost is on the participant to pay.**

5. **Will an** incentive **be offered for participation?**

An incentive is useful for gaining participants when the study will take time or when you suspect little interest in the study.

a. Raffle, lottery, or drawing – California law requires that those who don't want to participate in a study must be able to enter a raffle/lottery/drawing when it is offered as an incentive (similar to "no purchase necessary"). You cannot limit the raffle to participants only. THIS IS LAW.
    i. In your informed consent form you must describe the incentive. If you are offering a raffle, add the statement, "If you do not want to participate in the study but would like to be entered into the drawing, please email me at (enter email address here)." This statement alone grants access to all potential participants and makes the lottery legal.

b. Gift cards – these are great, especially if everyone who participates gets one and it's given right after participation. If everyone gets the same incentive, you can require participation in order to receive the incentive.

c. Extra credit – when extra credit is offered as an incentive, there must be an alternative extra credit option for those who do not want to participate in the research. This alternative option cannot also be available to those who participate in the research, it must be one or the other. This means that all students must have access to the same amount of extra credit points, whether they participate in the research or not. For example, if I want to participate in the research for 5 points, I cannot also have access to the alternative assignment for another 5 points, totaling 10 points. The person who does not want to participate in the research will only have access to 5 points, not 10.

d. Please be sure that your incentive matches the time and effort required of the participant. An inappropriate incentive can cause coercion. For example, a $10 gift certificate for a 5 minute survey is too much. A $5 - $10 gift certificate for a 1.5-2 hour interview is more appropriate.

6. As a researcher, will any real or perceived conflicts of interest **or** coercion **be present?**

Conflicts of interest -

- Are you being paid to conduct this research? By whom? Will that be disclosed in your informed consent form?
- Are your subjects subordinates? Do you have any control over your research subjects' grades, financial standing, employability, etc.? If so, how do you plan on mitigating the potential for coercion?
    - If you are conducting a survey, having a neutral third-party disseminate the survey on your behalf and drop-off the completed surveys in a sealed envelope will ensure that you will not know who participated and who did not (if the survey is anonymous).
    - If you are collecting course documents and data, ensure that you are obtaining student's consent to allow you to access that data for research purposes. Collect the informed

consent forms in an envelope and don't open it until the final grades are posted. This ensures that participation will not affect their grade.

7. **Approximately** how long **will participation in the study take for each individual subject?**

   If participation is over the course of several days/months, state how long each session will be, and the frequency of sessions, over the course of those days/months. Note that this question is not asking how long it will take YOU to complete the study, this is only about the participant experience.

8. Where **will the study take place?**

   Research that could potentially be harmful to a subject's social standing or reputation should consider private locations for data collection rather than public locations. Off-site study locations should have letters of support from the location and should be attached in Question 1 of this section. Please be a bit specific about locations, for example, a private room in the library rather than saying CSUS campus.

9. From the participant's perspective**, describe what their participation entails, beginning with the informed consent process through completion of participation:**

   This text box is asking you to put on your participant's shoes. The IRB finds a lot of gaps and inconsistencies in this section because the researcher hasn't planned out all the details yet or hasn't thought about the study from the participant's point of view. If you were your own participant, what steps would they go through in order to complete informed consent (are you being emailed, called, or talked to in-person?), what they will be asked to do as part of their participation, and how/when they will receive their incentive. Is the researcher going to contact the participant multiple times? How? Walk us through the steps.

Section 5 Data Protection (Expedited and Full Board Application)

2. **Mark all data collection methods that apply:**
   - Paper-based – you are only collecting data from paper surveys or hand-written notes
   - Online survey/questionnaire – you are only collecting data from online surveys or notes written electronically
   - Notetaking with notebook or computer – during interviews or observations, for example.
   - Rubric or checklist – for inter-rater reliability, for example
   - Audio recording/ video recording

     Using this method automatically links the individual to their responses and is not anonymous.

     - What device are you using to record the interviews? Is it password protected?

- Once the interview is complete, please transfer the file to a hard-drive and remove the audio from the recording device (unless you used a laptop to record).
- How long will transcription take? Once transcription is complete, the audio file should no longer be needed and it should be erased from the hard-drive.
    i. Now you have a de-identified interview transcript and you can keep that transcript as long as you like, but no less than 3 years.

3. Attach all data collection tools:

You MUST attach your data collection tool (i.e. your survey instrument, interview questions, rubric, etc.). If you are collecting data from participants or using an instrument to recording information about participants, it needs to be attached or the application will be returned.

4. Will you be collecting any direct identifiers other than audio/video?

You are collecting direct identifiers if you are asking participants to enter their name, email, or other unique identifiers like a student ID# directly on the data collection tool, or asking for contact information that will not be linked to their research data.

a. **What** identifiers are you collecting and **why** are they needed?

   Why is it necessary to collect the identifiers? Are you linking the information to someone? What identifiers exactly are you collecting?

b. Will identifiers be included in the data collection tools or in the dataset?

   If you are asking participants to provide their name, email, phone, or other identifiable info directly on the data collection tool (i.e. a survey form or health evaluation screening form), you are linking the individual to their responses. You are not collecting "anonymous" data.

   i. If you are collecting names or other identifiable info, can you download the dataset and, once you link the data as needed, remove the column of identifiable information?

      If you are collecting a contact list, it's as easy as deleted that list once you no longer require contact with participants. In some instances, you will need to erase any texts, calls, or emails made to participants in order to erase any link of that person to your study.

   ii. Protection of participants during reporting of results means that you are reporting in aggregate so that individual results are not being shared, or through the use of pseudonyms or vague descriptions. For example, do not share that students interviewed were from Sacramento State, rather they are students from a four-year higher educational institution in Northern California. This could be any CSU in the norther region and helps to de-identify your subject group.

5. **Will you be collecting demographic information (indirect identifiers)?**

   Demographics are identifiers that cannot directly identify someone:
   - Gender/ sex
   - Age
   - Ethnicity
   - Employment status
   - Income status
   - Status as a student, faculty, employee, etc.
   - Other identifiers that define a group (i.e. students at a university in Northern California)

6. How **will *raw research data* be stored and protected** during and after **your study?**

   Data storage –
   - The best way to protect data, whether in written or electronic form, is by limiting access to the data.
   - Paper- store in locked drawers/ cabinets/ offices where only you and the research team have access.
   - Electronic - store on a hard-drive (no cloud storage yet) in encrypted or password protected files.

7. **How long do you anticipate** retaining raw research data **after the completion of your study?**

   Data retention timeline –
   - How long will you store identifiable data vs. de-identified data? For example, how long will you keep audio recordings vs. transcriptions?
   - Only keep the data and miscellaneous information needed to reconstruct your study, such as relevant statistics and analyses, notes, or observations. If they can be de-identified, do so prior to long-term storage. Tell the IRB when you plan on removing identifiers and then how long you will store the de-identified data.
   - **Make sure these timelines are consistent with what you are telling participants in your informed consent form. You need to address both identifiable data retention vs. de-identified data retention.**
   - You can keep de-identified data indefinitely. But if you will not, you need to keep it for at least 3 years. Why? Because someone might challenge your research or try to replicate it and you need to have your data to back-up your work.

8. **How will data be** destroyed**, if applicable?**

   Data destruction –
   - We don't need timelines here, many inconsistencies come from providing information that we are not asking for.

- Effective data destruction ensures that information cannot be extracted or reconstructed. Shredding paper files and erasing electronic files from a hard-drive are necessary. Sometimes deleted data can be recovered, please ensure you know how to delete items from your hard-drive or ask I.T. for help.

9. **Will medical records covered by a HIPAA entity be accessed that require HIPAA Authorization or Waiver?**

   This is only required if you are working with official medical records. If you are obtaining medical records for research you must have an HIPAA Authorization or Waiver signed by participants. This document should be separate from your informed consent form.

Section 6 Risks and Informed Consent (Expedited and Full Board Application)

1. **Please check all risks that may be present due to participating in your study:**
   - MOST research includes the risk of loss of confidentiality. You might think you are collecting "anonymous" data, but if you are obtaining contact information, audio recording, or collecting enough demographics from a small population, you are not collecting anonymous data. Examine closely what you are collecting.
   - Please address all risks in the study. Assess whether that risk is "minimal" (i.e. a risk that most people encounter daily) or "more than minimal" (i.e. a risk that most people do not encounter daily).
     i. If your study involves "more than minimal" risk, it will be reviewed by the Full Board.
   - Please be sure to address how the risks will be mitigated. This usually involves your data security plan, and/or an emergency plan in the event of physical risks.

2. **Will informed consent forms be** signed **by participants?**

   In most cases, you MUST collect signed consent forms from participants. Here are some instances when the IRB does NOT want you to collect signatures (but you are still required to provide an informed consent *sheet* that participants get to keep):
   - Research about undocumented individuals
   - Research about individuals involved in illegal activities

   Why don't you collect signatures? Because this adds another layer of identifying the individuals who are participating in your study. If these forms were to be found and posted online with participant signatures, it would link a person to the study and could affect their reputation, for example.

3. **Informed Consent**

PLEASE use the sample document linked in the application. This is the most up-to-date form that follows current regulatory requirements. You must include all options that apply to your study. You do NOT, however, need to include any options in blue text if it does not apply. For example, if you do not have an incentive, you do not need to tell participant's that you do not have an incentive for them. Just remove the text. All red and black text is required and must stay in the form. Do not leave the highlighted sections or the "(Regulated Research Template)" text at the top of the form. This is the form your participants will see, make sure it is clean and uniform.

- Students – please request your advisor to review your consent form for typos.

4. **Notify your Department Chair**

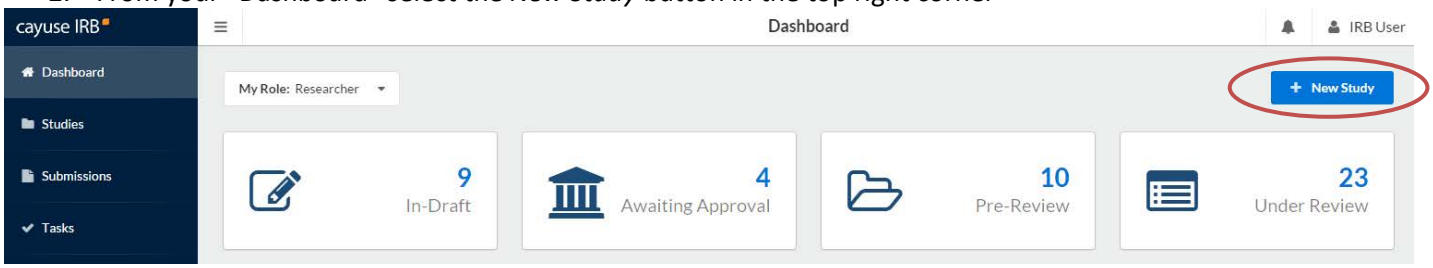
   You are required to send a copy of the PDF to your department chair. Please follow the instructions in the application to complete this task. You may need to disable pop-up blockers for the Cayuse site in order to download the PDF.

This is the end of the Expedited/ Full application. Please use the first-time submission guide under the Investigator drop-down for submission instructions: www.csus.edu/research/irb/submit.html.

Submit a New Study in Cayuse IRB

1. Login using your saclink username and password here: https://csus.cayuse424.com/rs/irb

2. From your "Dashboard" select the *New Study* button in the top right corner



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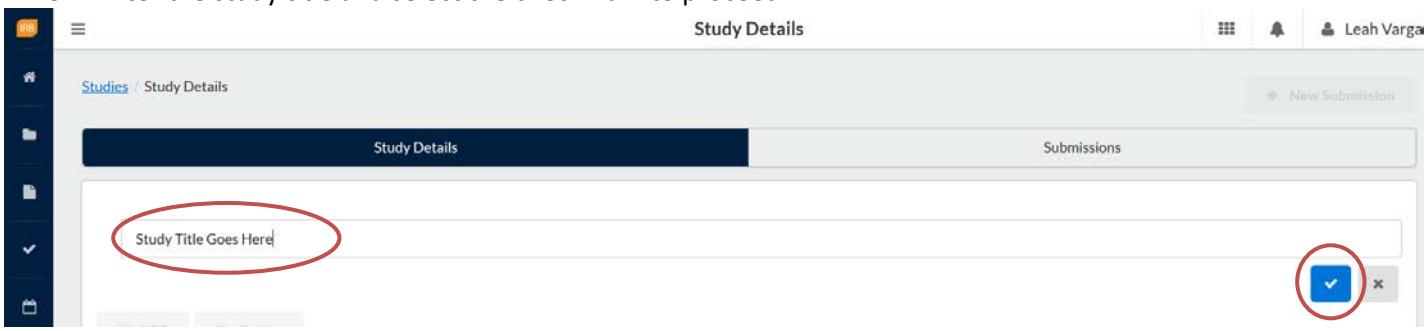
3. Enter the study title and select the checkmark to proceed.



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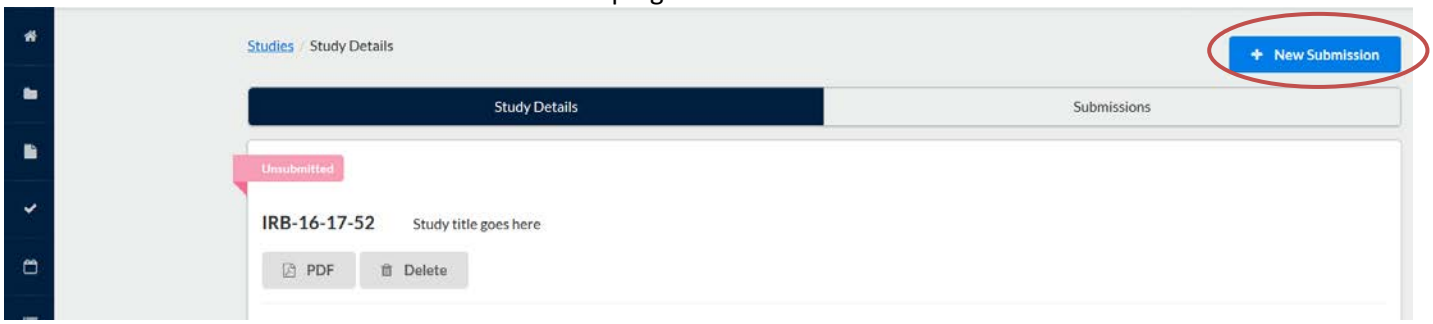
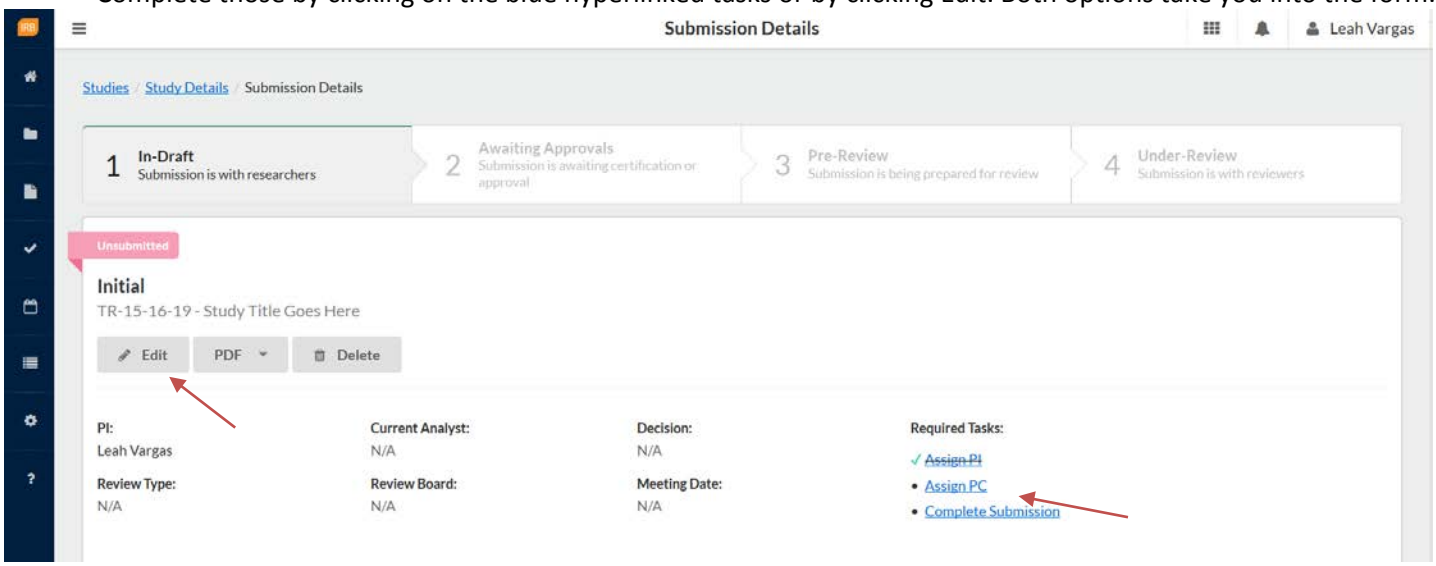
4. Select the *New Submission* button at the top right corner



5. Select *Initial* from the dropdown menu. This is creating your initial submission form.

6. Several tasks will be listed under *Required Tasks* that must be completed before a submission can be made. Complete those by clicking on the blue hyperlinked tasks or by clicking Edit. Both options take you into the form.



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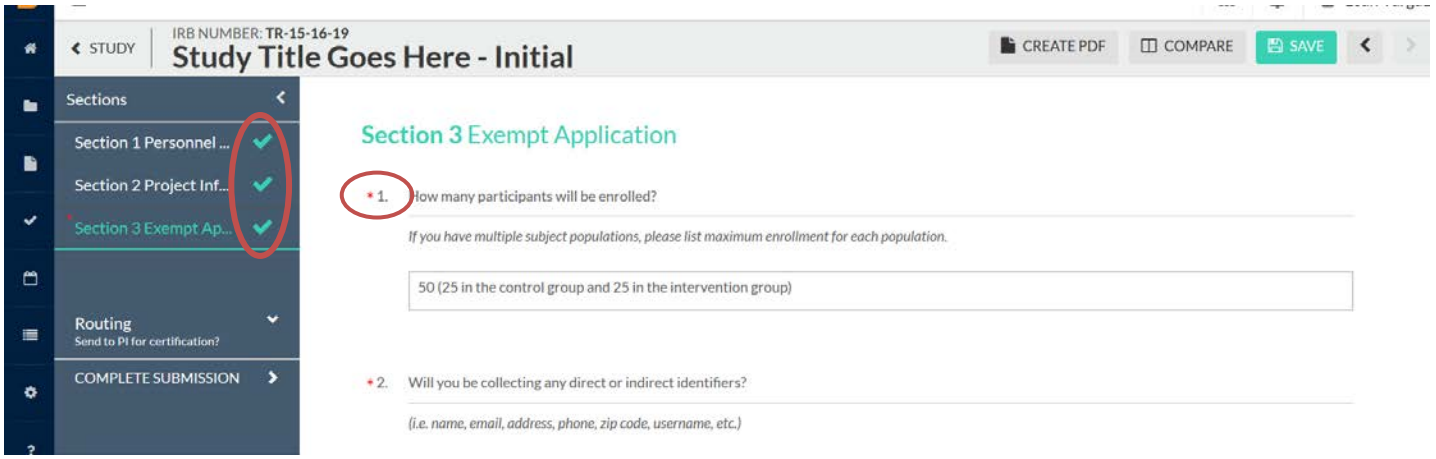
7. A Primary Contact (PC) *must be assigned*, and this is normally the PI.

8. All required questions are marked with a red asterisk. When sections have all required questions completed, a green checkmark will appear.



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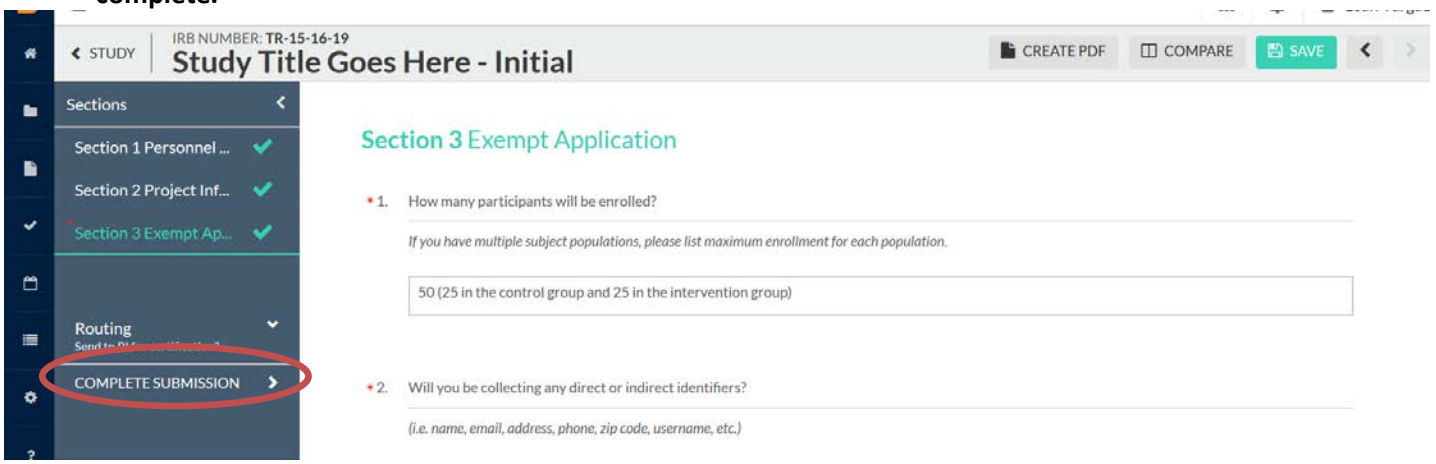
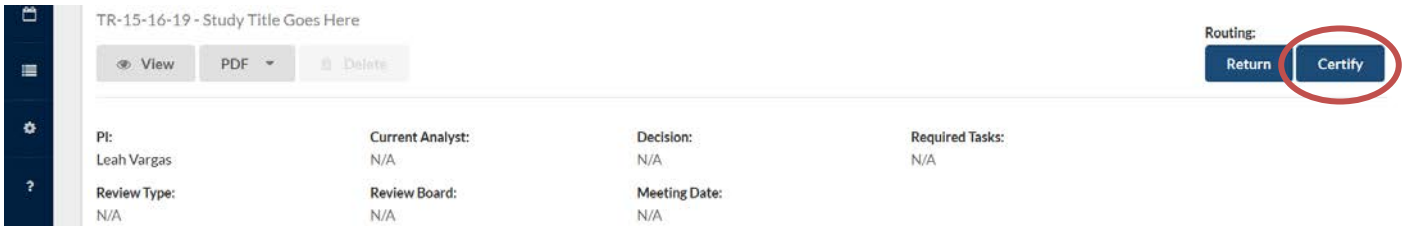
9. Click COMPLETE SUBMISSION > on the left tab if you have completed the application and it is ready to be routed through the approval process. **This will only appear once all required tasks/questions with a red asterisk are complete.**



10. A pop-up will ask you to *Confirm* that you are ready to submit. This will bring you back to the Submission Details.

VERY IMPORTANT!!!

11. Select *Certify* to "sign" and finalize your submission. This step must be completed before the application is received by the IRB.



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12. The application will be routed through the "signature" process, which requires the same Certification process by the Co-PI or Faculty Advisor.

13. Create a PDF of your application and send a copy to the Department Chair/Head as notification of your planned research.

Please contact Leah Vargas at 916-278-5674 or leah.vargas@csus.edu with any questions.