To facilitate the review of your proposed research project, Sections A – E must be completed. Additional information, depending on your specific project, may also be required. All required documents must be included in a single email. **This form should be submitted as a word document (so that it can be revised directly if revisions are required).** All other forms should be attached and labeled according to what they are (e.g., “Informed Consent” or “Signed Research Agreement” or “Recruitment flyer” or “Jones CITI”). Additional required forms may be submitted as word documents or .pdfs; formats should be accessible to a standard PC operating system. All forms should be included in a single emailto irb@calbaptist.edu

**SECTION A: Researcher Information**

**Principal Investigator (PI) Information**

|  |  |
| --- | --- |
| PI Name | Click here to enter text. |
| PI Preferred Salutation | Choose an item. |
| PI College/School at CBU | Choose an item. |
| *If other, please specify* | Click here to enter text. |
| PI Position | Choose an item. |
| *If other please specify* | Click here to enter text. |
| If you are a graduate student, please indicate your degree program | Click here to enter text. |
| If you are a graduate student, please indicate your degree program **director** (check with your advisor if you are unsure) | Click here to enter text. |
| PI Email | Click here to enter text. |
| PI Phone | Click here to enter text. |
| PI Date of most recent CITI HSR Certification\* | Click here to enter text. |
| Date of Application | Click here to enter text. |

**Co-PI Information** (delete this section if there is no Co-PI; copy if additional PIs need to be listed).

|  |  |
| --- | --- |
| Co-PI Name | Click here to enter text. |
| Co-PI Preferred Salutation | Choose an item. |
| Co-PI College/School at CBU | Choose an item. |
| *If other, please specify* | Click here to enter text. |
| Co-PI Position | Choose an item. |
| *If other please specify* | Click here to enter text. |
| If you are a graduate student, please indicate your degree program | Click here to enter text. |
| If you are a graduate student, please indicate your degree program director | Click here to enter text. |
| Co-PI Email | Click here to enter text. |
| Co-PI Phone | Click here to enter text. |
| Co-PI Date of most recent CITI HSR Certification\* | Click here to enter text. |

**Faculty Advisor Information** (delete this section if there is no faculty advisor; *all student research requires a faculty advisor*.)

|  |  |
| --- | --- |
| Faculty Advisor Name | Click here to enter text. |
| Faculty Advisor Preferred Salutation | Choose an item. |
| Faculty Advisor College/School at CBU | Choose an item. |
| *If other, please specify* | Click here to enter text. |
| Faculty Advisor Position | Choose an item. |
| *If other please specify* | Click here to enter text. |
| Faculty Advisor Email | Click here to enter text. |
| Faculty Advisor Phone | Click here to enter text. |
| Faculty Advisor Date of most recent CITI HSR Certification\* | Click here to enter text. |

**Research Assistant (RA) Information** (delete this section if there are no RAs on this project; copy if additional RAs need to be listed.)

*Note:* A research assistant includes any person who will assist in recruitment of human participants, data collection, data entry/cleaning, data analysis, etc. Engaging in a literature review or write up of results (already analyzed) does not constitute IRB-regulated research assistant activities.

|  |  |
| --- | --- |
| RA Name | Click here to enter text. |
| RA Email | Click here to enter text. |
| RA Date of most recent CITI HSR Certification\* | Click here to enter text. |

\*The IRB requires a current CITI Certification in either the Biomedical Researchers (Basic or Refresher Course) or the Social-Behavioral-Educational Researchers (Basic or Refresher Course) Course. Please email irb@calbaptist.edu if you have questions. We will accept non CBU CITI courses on a case-by-case basis.

**SECTION B: RESEARCH INFORMATION**

|  |  |
| --- | --- |
| Research Project Title | Click here to enter text. |
| Type of Research (select one) | Choose an item. |
| Research Funding (select one) | Choose an item. |
| *If funded, provide agency name and grant number* | Click here to enter text. |

|  |
| --- |
| **California Baptist University’s IRB follows the guidelines set out by the Office of Human Research Protection (OHRP), a division of Health and Human Services (HHS), in determining the category for IRB review (exempt, expedited, full board). Please review the options below and select the criteria true for your research application. A full description of these categories is available in the IRB handbook in the “Categories of Human Subject Research” section. This section of the handbook should be referenced before selecting and submitting here.***Within this section*, applications submitting for Exempt Review will complete Section 1, applications submitting for Expedited Review will complete Section 2, and applications submitting for full board application will complete Section 3. You will only complete **one** of the three sections below. If your application is for an external review (external researcher or you have approval from an external IRB, please use the appropriate forms posted on InsideCBU.Not sure which category applies? Review the HHS Decision Charts [here](https://calbaptist.box.com/s/zvgbnag1wrg4jn1rf3wi8d8hdvpllf3u). |

|  |  |
| --- | --- |
| **SECTION 1: Exempt Qualification** |  |

Please indicate which of the 6 criteria (45 CFR 46.104) qualifies this research for exempt status.

|  |  |  |  |
| --- | --- | --- | --- |
| *(Check here)* | Exempt Category | Subcriteria | Abbreviated Description |
|[ ]  1 | -- | Educational practices |
|[ ]  2 | i | Tests, surveys, or observation of public behavior, *no* identifiers |
|[ ]  2 | ii | Tests, surveys, or observation of public behavior, *no* risk |
|[ ]  2 | iii | Tests, surveys, or observation of public behavior, identifiers *with* limited IRB review (provisions for confidentiality/privacy) |
|[ ]  3 | i(A) | Benign behavioral interventions, *no* identifiers |
|[ ]  3 | i(B) | Benign behavioral interventions, *no* risk |
|[ ]  3 | i(C) | Benign behavioral interventions *with* limited IRB review (provisions for confidentiality/privacy) |
|[ ]  4 | i | Secondary research, publicly available information *with* identifiers |
|[ ]  4 | ii | Secondary research with information recoded with *no* identifiers |
|[ ]  4 | iii | Secondary research with identifiable health information |
|[ ]  4 | iv | Secondary research for a federal agency |
|[ ]  5 | -- | Public benefit research and demonstration projects |
|[ ]  6 | -- | Taste and food quality studies |

**Exempt Status Checklist—**Please review this short checklist to ensure that aspects of the research that may require expedited or full board review are not present in the proposed project. ***All*** of the items listed below must apply to qualify for exempt status.

|  |
| --- |
|[ ]  This research does NOT involve participants who are prisoners as a target population, individuals with diminished capacity, or vulnerable populations. |
|  |  |
|  |  |
|[ ]  This research does NOT involve the collection of sensitive information (including information about illegal behavior, abuse, or sexual behavior/orientation).  |
|  |  |
|[ ]  This research does NOT involve deception (OR, if there is deception for exempt category 3(iii), the informed consent documents clearly inform the participant that they will be unaware of/misled regarding the nature/purposes of the research). |
|  |  |
|[ ]  This research is specifically limited to individuals 18 years and older, as indicated in all necessary consent documents and research descriptions (OR, application is seeking exemption for categories 1; 2(i) and 2(ii) when the researcher is using an educational test or observing public behaviors but does not participate in the observed behaviors; 4; 5; 6). |
|  |  |

|  |  |
| --- | --- |
| **SECTION 2: Expedited Review Qualification** |  |

Please indicate which of the 7 criteria applies to the research described in this proposal. The activities listed do not necessarily constitute minimal risk simply because they are included on this list; Inclusion on this list merely means the activity is *eligible* for review through the expedited review procedure.

|  |  |  |
| --- | --- | --- |
| *(Check here)* | Expedited Category | Abbreviated Description |
| [ ] \* | 1 | Clinical studies of drugs and medical devices (with conditions) \* |
| [ ] \* | 2 | Blood samples (with conditions) \* |
|[ ]  3 | Noninvasive, prospective collection of biological specimens  |
|[ ]  4 | Noninvasive data collection via routine clinical practice (excluding x-rays/microwaves) |
|[ ]  5 | Research involving secondary data that is not exempt |
|[ ]  6 | Voice, video, digital, or image recording for research |
|[ ]  7 | Research on individual or group characteristics or behavior that is not exempt |

*\* If you are applying under expedited category 1 or 2, please address how the conditions stipulated with these categories have been satisfied in the proposed research. Indicate “NA” if you are applying under a different category.*

Click here to enter text.

**Expedited Status Checklist**—Please review this short checklist. ***All*** items **must** apply to this research to submit an expedited status application. If one or more of these do not apply, please submit a full IRB review application.

|  |
| --- |
|[ ]  This research does NOT involve participants who are prisoners, fetuses, pregnant women, disadvantaged or vulnerable adults. |
|[ ]  This research does NOT involve the collection of sensitive information (including information about illegal behavior, abuse, or sexual behavior/orientation).  |
|[ ]  This research is specifically limited to individuals 18 and older, as indicated in all necessary consent documents and research descriptions. |

|  |  |
| --- | --- |
| **SECTION 3: FULL BOARD REVIEW** |  |

**Full Board Review Status Checklist**—Some research, by virtue of the intended sample or the nature of the protocol, requires full board review (including review by a non-scientist). Please indicate the elements of your research that merit full board review.

*Research involves vulnerable populations:*

 [ ]  Minors

 [ ]  Fetuses

 [ ]  Pregnant women

[ ]  Individuals/Groups with diminished capacity to provide consent

[ ]  Individuals/Groups otherwise considered to be at high risk

*\*Federal definitions and requirements for research involving prisoners requires IRB expertise that is currently not available to the CBU IRB. Thus, we cannot serve as the IRB of record for research involving prisoners. Details on these policies are available on HHS (*[*https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/prisoner-research/index.html*](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/prisoner-research/index.html)*). Researchers looking to conduct research with prisoners may secure appropriate IRB elsewhere and complete an external researcher/IRB form to the IRB.*

*Research involves sensitive topics:*

[ ]  Sexual orientation, attitudes, preferences, or practices

[ ]  Illegal or punishable conduct, including use of alcohol, drugs, or other addictive products

[ ]  Information that could damage an individual’s financial standing, employability, or reputation, if released

[ ]  Traumatic experiences, including physical, emotional, or sexual abuse and veteran/wartime experience

**SECTION C: SIGNATURES**

Typed signatures are sufficient for IRB submission; severe penalties are enforced when false signatures are typed by someone other than the named individual. Delete any unnecessary fields; duplicate signature fields as necessary. A signature is required from every PI/Co-PI, the PI’s faculty advisor (when a student is the listed PI), and the PI’s dean.

*As the* ***PI****, I/we certify that this application and the attachments are an accurate and complete description of the proposed research and we agree to protect the rights and welfare of all human* participants *involved in the research as described herein. If RAs are involved in this project, I certify that I/we will oversee their work to ensure the proper protocols are being conducted.*

**PI Signature and Date:** Click here to enter text.Click here to enter a date.

**Co-PI Signature and Date:** Click here to enter text.Click here to enter a date.

*As the* ***faculty advisor****, I agree to supervise this student’s research and ensure the rights and welfare of all human participants are protected, as described in this protocol.*

**Faculty Advisor and Date:** Click here to enter text. Click here to enter a date.

*As the* ***dean****, I have reviewed and support this research for IRB review. I am aware that my signature indicates that I approve of research of this nature proceeding. I also understand the IRB does not represent the viewpoint of the University; the IRB will review this research to ensure there are appropriate protocols in place for the ethical treatment of human participants according to federal regulations.*

**Dean Signature and Date:**  Click here to enter text.Click here to enter a date.

**SECTION D: NOTE FOR APPLICANTS (Response Required)**

The IRB is an intentionally multidisciplinary committee charged with the review of proposals for research with human participants. *The primary role of the IRB is to assess potential risks of the proposed study, examine steps that the research team has taken to mitigate these risks/protect potential participants, and to weigh these risks against the benefit of the research* (in general and/or to specific participants). As such, a full and complete description of the research is required. The IRB evaluates the research as described to assess the risk of the study relative to its potential contributions and to assess the extent to which the principles of respect for persons, beneficence, and justice are achieved in the research proposal. Please see the IRB handbook sections explaining the role and function of the IRB for additional context.

The IRB is not prescriptive (e.g., there is not “one right way” to conduct a research project). Instead, the role of the IRB is to assess whether the researcher(s) have satisfactorily prepared their research project to meet or exceed the ethical standards that guide the IRB’s operations. Researchers will be more successful in their applications if they have thoroughly read the IRB handbook, recently engaged the required CITI training, and have clearly and sufficiently described the details of their project in the attached application. All materials necessary to conduct the proposed project (e.g., recruitment scripts, informed consent, data gathering tools/surveys) are required. The IRB approves detailed research proposals, not general research ideas. Additional documentation beyond this application may be required.

To submit an IRB application, please complete this and any additional forms required for IRB review (e.g., CITI Certificate), attaching all forms in a single email to irb@calbaptist.edu. Please submit this form as a **word document** (so that the document can be directly edited and resubmitted if revisions are necessary).

Once a *complete* application is received via e-mail (IRB@calbaptist.edu), the submitter will receive an e-mail noting that the submission has been received and what the expected timeline for review is. The typical review time is approximately 3 weeks. After this review, the PI/Co-PI should expect an e-mail indicating that (a) the application has been approved to proceed or (b) requesting revisions to the protocol.

***□ As the PI, I have read and I understand these instructions.***

## **SECTION E: RESEARCH PROPOSAL**

The Research Proposal is a detailed description of the purpose and procedure for the proposed research. The proposal needs to address information about how some research choices were made (e.g., why are you recruiting X number of participants? Why was survey Y selected for use in this research?) as well as a detailed description of all the steps of the research (e.g., how many times will you contact a participant to invite them to participate? Where and how will the data be stored?). The IRB can only assess your proposal based on the information that you provide; you should be thorough and complete, providing sufficient information for the IRB to assess your proposed research from start to finish.

*Important tips for a successful proposal:*

* Be specific, avoid technical jargon, and proofread your application.
* Remove any inconsistencies that may be introduced while revising an application. One common reason applications are returned for revisions is the inconsistency between answers (e.g., indicating one recruitment strategy in one question and a different strategy elsewhere).
* Use concise, short answers when they are clear and provide enough information for someone not engaged in your research project to understand and assess.
* Write for a multidisciplinary group of scientists and non-scientists who may not be familiar with your academic discipline.
* Remember your audience; you are not writing a thesis proposal but a detailed explanation of planned research activities.
* Responses should be in size 12 font.
1. **State the research/project title (this should describe your project and is not necessarily the same title your participants will see).**

Click here to enter text.

1. **In the following space, provide the various elements of your research abstract. Each section can include several sentences. Though the abstract should be brief (e.g., not several pages of literature review), you should provide enough information to address the question. Questions below will allow for an elaboration of each of these points; the goal here is to provide a succinct overview of the basic elements of your research proposal.** You can find examples of how to construct research abstracts online, such as the one available [here](https://writing.wisc.edu/handbook/assignments/writing-an-abstract-for-your-research-paper/).
	1. **Background.**

Click here to enter text.

* 1. **Purpose.**

Click here to enter text.

* 1. **Methods.**

Click here to enter text.

* 1. **Participants.**

Click here to enter text.

* 1. **Data analytic plan.**

Click here to enter text.

1. **List the research question(s), hypotheses, and/or goals.**

Click here to enter text.

1. **Is the proposed research *qualitative, quantitative,* or *mixed methods?***

Choose an item.

1. **Are you using secondary data (data that has already been collected)?**

Choose an item.

|  |
| --- |
| ***IF YES, you are only using secondary data, skip questions 6-37. Answer questions 38-44.*** * *If you are using secondary and primary data, answer all questions.*

***IF NO, you are not using secondary data, answer all questions except questions 38-44.*** *(This is noted again before these questions.)* |

1. **Describe the sample you plan to recruit from** (Who are your potential participants?)**.**

Click here to enter text.

1. **How many participants do you plan to recruit for participation?** Remember that this number serves as a recruitment limit, if approved by the IRB.

Click here to enter text.

1. **Describe how you arrived at the number indicated in the previous question** (Power analysis, saturation, etc.). The IRB cannot approve a research study with a sample size that is unexplained/arbitrary.

Click here to enter text.

1. **Describe the demographics of your intended participants:**
2. **Age:** Click here to enter text.
3. **Gender:** Click here to enter text.
4. **Ethnicity:** Click here to enter text.
5. **If there are there additional selection criteria for your intended participants, please describe those criteria here (e.g., “mothers” or “competitive athletes”).**

 Click here to enter text.

1. **From where do you intend to recruit potential participants?**

 Click here to enter text.

1. **Do you have any relationship with potential participants** (e.g., former work supervisor, employee at the company in a different region, friends from church)**?**

 Choose an item.

* 1. **IF YES, please explain the nature of the relationship and address what steps have been taken to reduce potential coercion (real or perceived) for participation.**

 Click here to enter text.

1. **Describe the recruitment process. Include any recruitment scripts.** (If included as an attachment to the application, please indicate so here.)

 Click here to enter text.

1. **If you are recruiting participants through planned points of contact (e.g., emailing invitations to participate or direct calling), specify the number of times you will contact and at what frequency.** In other words, if you are directly contacting someone, how many times will you contact them before you understand their non-response as a “decline to participate”?

Click here to enter text.

1. **Are participants recruited from or in cooperation with an organization/individual who will provide you access to participants *or* provide you contact information to facilitate recruitment?** If yes, a signed Research Agreement with the organization/individual should be mentioned in this question and attached as part of the IRB application. If the signed research agreement is contingent on IRB approval, please indicate that and provide the unsigned research agreement to be signed for IRB review.

 Click here to enter text.

1. **Are participants recruited from a CBU classroom?** Please note that faculty can share research opportunities with students via announcement in class/on Blackboard without requiring a Research Agreement. A Research Agreement is required if faculty are offering course/extra credit for participation.

Choose an item.

* 1. **IF YES, please describe the specific steps that have been taken to reduce the potential for coercion to participate.**

 Click here to enter text.

* 1. **IF YES, is course/extra credit being offered? If so, describe the equitable alternatives to participation and how information about participation is reported to faculty.**

 Click here to enter text.

1. **Describe the *process* of obtaining informed consent (e.g., describe how you go from potential participant, described in the recruitment process, to a participant who has provided informed consent to participate).**

Click here to enter text.

1. **Copy and paste the text of your informed consent under this question. You may also attach the informed consent documents to your IRB application (a word document labeled “Informed Consent” attached to the submitted email) if the formatting is changed in the copy/paste process.**

Click here to enter text.

1. **Please complete this informed consent checklist, ensuring that your informed consent has all the required elements.**

*Please consider each of these elements of informed consent and indicate whether it is included, it does not apply (NA), or an alteration is being requested. Please see the Informed Consent section of the IRB handbook for a more detailed description of these elements of informed consent.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Included** | **NA** | **Alteration** | **Abbreviated Description of Informed Consent Element** |
| ***Key Elements*** |
|[ ] [ ] [ ]  Clear and concise presentation of key information at beginning of document  |
|[ ] [ ] [ ]  Consent for voluntary research participation |
|[ ] [ ] [ ]  Purpose, duration, and procedures of research |
|[ ] [ ] [ ]  Reasonable foreseeable risks/discomforts *(this should include relevant follow-up procedures, as applicable. Note that if the counseling center is a relevant resource for your study that the CBU Counseling Center is only available to CBU students.)* |
|[ ] [ ] [ ]  Benefits to participants/others *(Note: If you cannot guarantee benefits to potential participants, this should be indicated.)* |
|[ ] [ ] [ ]  Alternative procedures available *(including when course/extra credit is offered for other studies/activities)* |
| ***Basic Elements*** |
|[ ] [ ] [ ]  Research purposes, duration, and procedures (if additional information required) |
|[ ] [ ] [ ]  Reasonable foreseeable risks or discomforts (if additional information required) |
|[ ] [ ] [ ]  Benefits to participant/others (if additional information required) |
|[ ] [ ] [ ]  Disclosure of alternative procedures (if additional information required) |
| [ ]  |[ ] [ ]  Extent of confidentiality |
|[ ] [ ] [ ]  Compensation or remuneration if injury occurs |
|[ ] [ ] [ ]  Who to contact for questions about the research or to report an adverse experience *(Typically this includes the IRB with a statement such as “If you have questions about your rights as a research participant, would like to talk with someone about this research other than the researchers, or would like to report an adverse experience, you can contact the IRB, the ethics committee that oversees research at CBU, at* *irb@calbaptist.edu**.”)*  |
|[ ] [ ] [ ]  Statement that participation is voluntary, there is no penalty for decision to participate or not, and that the research can be discontinued at any time |
|[ ] [ ] [ ]  For research involving private information or identifiable biospecimens, a statement about whether the information will be shared with other researchers or not, once de-identified |
| ***Additional Elements*** |
|[ ] [ ] [ ]  Some treatments may involve risks if the participant becomes pregnant |
|[ ] [ ]   | Circumstances under which participant’s participation may be terminated by the researcher |
|[ ] [ ] [ ]  Additional costs that may result from participation |
|[ ] [ ] [ ]  The consequences of withdrawing from the research *(including implications when course/extra credit is offered in exchange for participation)* |
|[ ] [ ] [ ]  A statement that new findings that may impact participants’ willingness to continue will be reported to participants |
|[ ] [ ] [ ]  The approximate number of participants involved in the study |
|[ ] [ ] [ ]  That biospecimens may be used for commercial profit and that the participant will/will not share in this profit |
|[ ] [ ] [ ]  Whether clinically relevant results will be disclosed to participants and under what conditions |
|[ ] [ ] [ ]  Whether research with biospecimens may include whole genome sequencing in the future |

1. If you are conducting a survey, are responses to the questions required? (i.e., is the survey software set to force a response to a question, or are participants allowed to advance in the survey without answering questions?)

Choose an item.

* 1. If you require responses to some/all survey questions:
		1. How much of the survey is a “required response” to get to completion?
		2. Please copy and paste the language in the informed consent that notifies participants of this requirement here.
		3. Please address what steps have been taken to reduce the potential coercion implied by forcing responses to these questions. Coercion is increased when there is an inducement for or direct benefit of participation.
1. Documentation of consent involves collecting participant signatures (physical or digital). If you are *not* planning to collect participant signatures (e.g., if your research involves selecting “I agree to participate” on a survey instead of collecting names), you will need to request a waiver for the *documentation of consent.* There are three circumstances where a waiver of the documentation of consent can be approved. **Are you applying for a waiver of documentation and, if so, under which justification?**

Choose an item.

* 1. **IF YES, please select and provide a justification below.** See the IRB handbook section on Informed Consent/Waiver of Informed Consent for more information.
		1. Choose an item.
	2. **If additional explanation of this selection is required, please do so here:**
		1. Click here to enter text.
1. A waiver or alteration of informed consent is when an IRB waives the requirement to obtain informed consent or waives elements that are otherwise required for inclusion in the informed consent. There are several, specific instances in which a waiver or an alteration of informed consent may be approved by the IRB. **Are you requesting a waiver or alteration of consent?**

Choose an item.

* 1. **IF YES, please indicate which circumstance from the handbook applies (see “Waiver of Informed Consent” section) and explain how this applies to your proposed research.**

Click here to enter text.

1. **If your study includes minors, please include the process for participant assent. Please attach any assent documents, being sure to address the requirements as outlined in the IRB handbook.** Enter N/A if no minors are involved in this research.

Click here to enter text.

1. **Is there an inducement (e.g., financial incentive, course/extra credit) provided for participation? If so, please describe the inducement and the requirements for receipt of the inducement.** Enter N/A if there are no inducements involved in this research.

Click here to enter text.

1. **Does your study have a treatment, intervention, or manipulated variable? If yes, please describe.** Enter N/A if there is no treatment, intervention, or manipulated variable in this research.

Click here to enter text.

1. **Indicate whether deception is used. If yes, explain how and when/if/how participants are informed about the research’s true purposes.** Enter N/A if there is no deception.

Click here to enter text.

1. **Identify and describe the data-gathering instruments** (e.g., surveys, interview protocol with questions, explanation of physiological measures)**. Please provide the necessary background to evaluate these data-gathering instruments** (e.g., references for validation studies, reliability measures)**. If the data-gathering measures were developed by the researcher(s), please explain how they were developed.**

Click here to enter text.

1. **Above you have explained recruitment and the process of informed consent. Please connect these processes to the data collection process. Describe the steps taken to go from the recruitment of participants to informed consent to the collected data.** Feel free to number your steps or provide a visual of the process if that helps organize your description for IRB review.

Click here to enter text.

1. **Privacy** concerns participants’ control over the extent, timing, and circumstances of sharing themselves with others. This includes, but is not limited to, the data that participants are asked to share in the research process. For example, privacy also includes the extent to which they can keep their participation in the study at all private, which is relevant to the recruitment process and the process of data collection. **What protections are in place to promote participant privacy?**

Click here to enter text.

1. **Confidentiality** concerns the extent to which the information provided by individual participants will not be disclosed without permission/beyond what is stipulated by the informed consent. Confidentiality is an extension of privacy to data. **What protections are in place to ensure participant confidentiality? Consider how the data are collected, de-identified, stored, and shared.** Keep in mind that *data are only anonymous if they cannot be connected to an individual participant’s identity*.

Click here to enter text.

1. **Identify foreseeable risks or distress to participants during the research process. Remember the IRB is concerned with *potential* or *perceived* risks as well as recognized risks.**

Click here to enter text.

1. **Explain follow-up procedures, if any, including services provided to participants who potentially experience anxiety, stress, physical harm, etc.** Follow-up procedures should match the potential risks and need to be relevant to the intended participants. The CBU Counseling Center, for example, is only available to CBU Students and should not be listed for a community sample.

Click here to enter text.

1. **What are the plans for the analysis of the data, once collected? Please be specific.** (The value of a study, relative to the risk, is related to the potential of the data to answer the questions outlined by the researcher(s). Please describe how your data analytic plan allows you to answer the questions/hypotheses outlined earlier in the research description.)

Click here to enter text.

1. **Describe your plans for the dissemination of the research results.**

Click here to enter text.

1. **Please address your suitability to conduct this research (e.g., describe any special training or experience relevant to your ability to conduct this research, especially for research involving more than minimal risk/with protected populations.).**

Click here to enter text.

1. **Please provide an assessment/statement regarding the scientific merit of this study, especially as related to potential risks.** (Please consider the risk-to-benefit ratio.)

Click here to enter text.

1. **Throughout this research proposal, you may have indicated several documents that will be attached to your submitted IRB application. Please list those documents here in a numbered list.** When submitting these documents as part of your IRB application, please label each attachment clearly (i.e., “Informed Consent” or “Survey”), and in alignment with this list.

Click here to enter text.

|  |
| --- |
| **Answer questions 38-44 *ONLY* if using secondary data**. |

1. **Is the dataset considered public (e.g., anyone can access) or private (e.g., you can access with special permission)?**

Choose an item.

1. **Describe your *permission* to access these data.**

Click here to enter text.

1. ***What* are the data you would like to access (e.g., describe the variables represented in the dataset and the participants who contributed to the dataset)?**

Click here to enter text.

1. ***Who* collected the data originally? Briefly describe how these data were collected, including whether/how informed consent was provided for their collection.**

Click here to enter text.

1. ***Where* are the data stored currently?**

Click here to enter text.

1. ***How* are the data stored (e.g., do they contain private information, is the information linked to participant identities)?**

Click here to enter text.

1. **Describe how you will store the data, once received.**

Click here to enter text.