**Application Instructions**

**Incomplete applications will be returned to the Principal Investigator (PI) without IRB review.**

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| 1. **Completed IRB Application:**    1. *Exempt request*: Submit exempt application and item numbers 4-6 below.    2. *Expedited or Full Board request*: Submit IRB Application and item numbers 2-6 below. |  |
| 1. Documentation of consent procedures **(ONLY FOR EXPEDITED AND FULL BOARD):** |  |
| * 1. Consent Form |  |
| * 1. Assent Form |  |
| * 1. Parent Permission/Guardian Form |  |
| * 1. Verbal Consent Script |  |
| * 1. Cover Letter |  |
| * 1. Grant application or relevant sections of application (e.g. program narrative) |  |
| 1. All survey instruments or questionnaires to be used |  |
| 1. All interview questions or topics, in as much detail as possible |  |
| 1. All scripts for interviews and focus groups |  |
| 1. All advertisement or recruiting materials |  |
| 1. Addendums |  |
| * 1. Addendum 1: Expedited Categories and Determination **(*Only for Expedited Review*)** |  |
| * 1. Addendum 2: Research with Children |  |
| * 1. Addendum 3: Research with Prisoners |  |
| * 1. Addendum 3a: Research with Prisoner Data Sets Collected for Purposes Other than Research |  |
| * 1. Addendum 4: Alternation or omission of elements from Consent, Permission, or Assent Process |  |
| * 1. Addendum 5: Waiver of Documentation (Signature for Participant) of Informed Consent, Permission, or Assent Process |  |
| * 1. Addendum 6: Waiver of Informed Consent, Permission, or Assent Process |  |
| * 1. Addendum 7: HIPAA Authorization Form and Appendix A |  |
| * 1. Addendum 8: Investigational Drugs, Other Drugs, and Devices |  |
| * 1. Addendum 9: Blood, Tissue, Bodily Fluids, or Other Biological Specimens or Samples |  |
| * 1. Addendum 10: Confidentiality Agreement |  |
| 1. Training Certificates (Copies of CITI training record for PI and all personnel involved in the research (if not previously submitted) |  |

**Instructions**

**How to Submit:**

1. All submissions (Application and the Supporting materials) should be emailed to [CRIHB.IRB@crihb.org](mailto:CRIHB.IRB@crihb.org) Subject line: “IRB Application”
2. All resubmissions must contain the original application with track changes.

**Instructions:**

* All correspondence about IRB decisions will be directed to the PI.
* Do NOT begin data collection prior to IRB approval.
* All materials must be typed; handwritten materials will be returned.
* Do NOT leave a question blank; write "n/a" if a question does not apply to the application.
* If necessary, complete the addendums and submit them along with the application.
* Revisions and resubmissions must contain the original application with all tracked changes.
* *Human Participants Training: The IRB* ***requires all the personnel*** *involved in the research to complete CITI training in the ethical use of human participants in research. The principal investigator (PI) is responsible for ensuring the personnel listed on the application have completed training.* ***Re-training is required every two years****. All personnel must complete the Health Information Privacy and Security Course. Depending upon area of research, the Social Behavioral and Biomedical Research courses are required. For CITI training details visit the CITI website at* [*http://www.citiprogram.org*](http://www.citiprogram.org/) *.*

Research Staff include all individuals who will be involved in this proposed research including, but not limited to, staff that will recruit participants, obtain informed consent, administer surveys/questionnaires, and perform data analysis.

**Types of IRB Review:**

An IRB application submitted for review will fall into one of the categories listed below. The categories reflect the risks for the human subjects participating in the study.

1. **Full Board Review** - Research that involves more than minimal risk. Approval for these studies require that the proposed research be reviewed at a convened meeting with a quorum of IRB members present. IRB approvals are valid for up to one year and require submission of annual renewals and approval for amendments.

* Full Board applications are reviewed at monthly IRB meetings, if and only if the application is received at least 11 working days prior to the meeting date.
* Submit original application and the additional materials

1. **Expedited Review** -Research that involves no more than minimal risk and for minor amendments is approved research. These will be reviewed by one or two members designated by the IRB Chair rather than by the entire convened IRB. Approvals are valid for up to one year and require submission of annual renewals and approval for amendments.

* Expedited applications take approximately 12 working days for review once they have been submitted.

If your study DOES NOT meet the requirements for expedited review criteria, then it qualifies for full board review.

1. **Exempt Certification**- Research considered as minimal risk to human subjects can be exempt under federal regulations; however, the exempt application must be submitted to the IRB for determination. The exempt categories include certain educational practices and tests, study of archived or existing data, public service programs and food evaluation. No renewals are required for a certified exempt activity, although amendments are required to be submitted to the IRB.

* Exempt Certification applications take approximately 10 working days for review once they have been submitted. If your study DOES NOT meet the requirements for an exemption, then it will need to be submitted for Expedited or Full Board Review.

**Common Mistakes to Avoid When Submitting an Application:**

1. Indicating that data are anonymous when it is actually confidential (check definitions).
2. Not providing enough information as to who will have access to the data.
3. Not providing enough information as to how the data will be protected and stored.
4. Stating there are no risks involved in the activity. Even though the risks may be low, they need to be listed on the application.
5. Consent forms, survey, or interview instruments are not attached for review.