**Calvin University Institutional Review Board (IRB)**

**Form A – Cover Sheet**

**All investigators must submit Form A**. Investigators requesting the designation of *Course-based Research* (as defined on the IRB website) or *Center-based Research* must **also** submit Form B.

|  |
| --- |
| **1. Type of approval requested**  **New**    In addition to this form, you must provide information requested in the IRB document  **"Information to include with a new proposal"** posted on the IRB website.  **Continuing / Renewal**    ***Please insert your assigned IRB# at the top of each page*. Expiration date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  Have any amendments been filed *since* your last approval/renewal? \_\_\_\_ Yes \_\_\_\_ No  In addition to this form, you must provide information requested in the IRB document  **"Information to include with a renewal"** posted on the IRB website.  **Revision**    ***Please insert your assigned IRB# at the top of each page*. Expiration date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  If your revision is minor enough to explain on the lines provided below you may do so (e.g., *Please add*  *one student to my list of research assistants, CITI certificate attached.*) If your revision is more  substantial, please resubmit your original proposal with the revised portions and additions highlighted.  Minor revision: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |
| --- |
| **2. Information for Primary Investigator**  **Only Calvin faculty and staff can serve as the primary investigator.** Even if the majority of activity associated with the project is undertaken by a student or investigator from outside the Calvin community, a Calvin faculty or staff must assume responsibility for supervising the project and be listed as the primary investigator.  **Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Credentials:** Doctorate/Terminal Degree Masters' DegreeOther \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_        **Department:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Phone:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Email:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date of Completion for CITI or NIH Human Subjects training**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  The link for the training is: **https://about.citiprogram.org/en/homepage/**  The date of completion is listed on the certificate that appears when you finish the course. Certificates must be dated within three years of the date your IRB proposal is *approved* (i.e., please be sure you still have at least a month of eligibility when you submit your proposal).  **3. Information for project**  **Project title:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Funding agency (if applicable):**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Project timeline for contact with human subjects:**  Start date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_ End Date:\_\_\_\_\_\_\_\_\_\_\_\_\_  **Is this project associated with a Calvin course or independent study for which student(s) will receive**  **academic credit(s)?** No Yes: List course number (e.g., Psyc 356) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_      **Are you also filing Form B?** No Yes |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **4. Information for all Co-investigators.** Include all Calvin and external affiliates who will have access to human subjects OR to data on human subjects that have not been deidentified. ***Unless you are filing Form B,*** you must **also list all students and staff as co-investigators.**  **All co-investigators must complete CITI training.**   |  |  |  |  | | --- | --- | --- | --- | | **Co-Investigators** | **Category**  (faculty, staff,  student, other) | **Institutional affiliation**  (if other than Calvin) | **NIH or CITI training completion date** | | 1. |  |  |  | | 2. |  |  |  | | 3. |  |  |  | | 4. |  |  |  | | 5. |  |  |  | | 6. |  |  |  | | 7. |  |  |  | |

|  |
| --- |
| **5. Conflict of Interest**  Beyond customary academic scholarship and potential publication revenues, do any of the investigators associated with this proposal have any financial or other conflict of interest related to this project? (Check all that apply).  No    Yes, investigator(s) listed (and/or their organization) have been hired to conduct this research for a client.    Yes, investigator(s) listed have other interests in this research (e.g., product test for a company in which    the investigator owns shares). Please describe this interest in a separate document. |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **6. Investigator assurance**   |  | | --- | | **Who needs to sign the assurance?**  For a **new proposal,** all co-investigators listed in Part 4 must sign the assurance. If some investigators are off campus and it is difficult to circulate a single form, the primary investigator may duplicate this page as necessary, sign each, and send to off-campus investigators to obtain their signatures. The primary investigator's signature must appear on each copy of this page. The signatures of co-investigators should appear on ONLY one copy of this page.  For a **renewal or revision** that does NOT involve new co-investigators, only the primary investigator must sign.  For a renewal or revision that does **involve new co-investigators**, the primary and all new co-investigators must sign. |   **In making this application, I certify that:**  1. I agree to abide by all Calvin University and CITI policies and procedures governing human subjects research.  2. The attached information accurately describes the proposed research project.  3. There will be no contact (verbal or written) with human subjects until the project has been approved by the IRB.  4. NIH or CITI training in human subject protection has been completed by all investigators who will have:  a.) contact with human subjects and/or b.) access to data that have not been deidentified.  5. Written approval will be obtained prior to changing procedures or adding new investigators (including students).  6. During the course of the project, I will report to the IRB any unanticipated problems, adverse effects, or findings that may affect the risks or benefits to my participants.  7. Records of all IRB-approved documents and consent forms will be retained for a minimum of three years following the close of the project *and* until dissemination has ceased. The primary investigator will produce these documents upon request of the IRB.  8. I agree to maintain the standards of anonymity or confidentiality guaranteed in the proposal.  9. I understand that this project is subject to continuing review of the IRB. Initial approval is good for one year. Requests to renew must be made annually.  10. This proposal involves no conflict of interest (unless specified).   |  |  |  |  | | --- | --- | --- | --- | |  | **Signature** | **Printed name** | **Date** | | **Primary investigator** |  |  |  | | **Co-investigator** |  |  |  | | **Co-investigator** |  |  |  | | **Co-investigator** |  |  |  | | **Co-investigator** |  |  |  | | **Co-investigator** |  |  |  | | **Co-investigator** |  |  |  | | **Co-investigator** |  |  |  | |

|  |
| --- |
| **7. Signature of your Department Chair (required for new proposals, renewals and major revisions)**  *I have reviewed this proposal (all forms and supporting documents) and support this project.*    **Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Printed name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

**Instructions for submission**

1. If this is a renewal or revision, insert the assigned IRB# at the top of each page.

2. Scan the following, in this order, **in a single pdf file.**

a.) Pages 1-3 of Form A

b.) Additional copies of page 3 from external affiliates (as needed)

c.) Page 4 of Form A

d.) Form B (as needed)

e.) CITI certificates for the primary and all co-investigators, in the same order as they appear in the proposal (Note: Certificates are required for new proposals and renewals, but not revisions.)

3. **Name the scan** with the last name of the primary investigator, like this.

If new: *Smith NEW forms and certificates*

If renewal or revision: *Smith 17-098 RENEWAL 2018 forms and certificates*

4.Send the scan and other required components of the proposalto [IRB@calvin.edu](mailto:IRB@calvin.edu) *and* send a courtesy email to the chair of the IRB.

|  |
| --- |
| ***For IRB use only:***  As a reviewer, are you an investigator, consultant, collaborator, or study personnel on the proposed study; do you have a financial interest in the study; or do you have any other conflict of interest with this study?  No Yes—*If Yes, do not perform the review and contact the IRB chair.*      Exempted, no further review needed unless protocol changes  Approved as Specific Project  Approved as Course-based Research (proposal includes Form B)  Approved as Center-based Research (proposal includes Form B)  Approved as Grant Proposal. Specific project approval needed prior to data collection  Approved with special conditions, see attachment  Approved by the IRB. Investigator must also obtain approval from the Dean of Research prior to surveying members of the Calvin Community.  Not approved  **Institutional Review Board Member Signature** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Institutional Review Board Member Printed Name** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ IRB Approval of this project expires: \_\_\_\_\_\_\_\_\_\_\_\_\_ |