**Purpose:** This application is used to request continuing IRB approval of previously expedited with the condition of continuing review or full board human subject research.

**Instructions:** Information reported on this form should reflect activities having occurred over the course of the most recent approval period unless otherwise specified. ***Approval period*** *refers to the time since the initial approval (if this is the first continuing review for this protocol)* or *since the last continuing review approval.* Submit this application and all applicable research materials solicited in the checklist at the end of the form to [Progress Report/Continuing Review Electronic Application Form](https://cphsadmin.wufoo.com/forms/z1ln3ivr0ll72wy/) or <https://cphsadmin.wufoo.com/forms/z1ln3ivr0ll72wy/>.

* This form must be submitted in its original format, MS Word format. The IRB will not accept this form in pdf or google docs format.
* The Principal Investigator (PI) is responsible for maintaining IRB approval and must provide the IRB with all required materials to request continuing review in a timely manner (a minimum of 45 days in advance of the IRB approval expiration date).
* Allowing a protocol to expire is considered non-compliance. The project must either be continued or closed to maintain compliance. If a project is allowed to expire, a new Initial Review Application and supporting materials will need to be submitted an IRB approval obtained before resuming human subject research activities.
* Changes cannot be incorporated into the continuing review materials. In order to be in compliance with federal regulations and institutional procedures an Amendment Submission must be submitted for separate review of proposed changes.

Direct any question regarding this form or human subjects research to the IRB by email at irbadmin@campbell.edu or phone (910) 893-7780.

|  |  |
| --- | --- |
| **SUBMISSION DATE:** | Enter a date |

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| **PART 1: PROJECT AND INVESTIGATOR INFORMATION** |
| Project Title: Title |
| Principal Investigator (PI): | Name | School/Department: | School/Department |
| PI CU Email: | Email address | PI Telephone: | Number |
| Role at CU: | Role | If other, specify role: | Text |
| Co-PI/Student: | Name | School/Department: | School/Department |
| Co-PI/Student CU Email: | Email address | Student Telephone: | Number |
| **Research Status (check one)** |
| * Select one of the following to indicate the project status:
 |
| [ ]  Recruitment not yet started[ ]  Recruitment started; no participants enrolled |
| [ ]  Participants enrolled; recruitment ongoing[ ]  Enrollment closed to new subjects, participant research activities/interventions are ongoing[ ]  Research is permanently closed to enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects[ ]  Activities limited to data analysis only and identifiable participant information and/or code key/link to participant identifiers exists. |
| **PART 2: PROGRESS REPORT** |
| 1. **Provide a brief summary of the project’s progress and describe preliminary observations/findings during the last approval period.**
 |
| Enter text |
| 1. **In the next year of the project, do you anticipate any major design changes or new phases of the research will commence?** *NOTE: This is only to assess the project progress. An amendment request will need to be submitted for review and approval in advance of implementing any changes.*
 |
| [ ]  Yes [ ]  No | If “Yes,” explain in the text box below: |
| Enter text. |
| 1. **State the anticipated end date for human subject research activities, including analysis of *identifiable* participant data, if applicable.**
 |
| Month and year: Enter text. |
| 1. **New and relevant information since the last approval period:**
 |
| 1. **Has there been any new and relevant information published or unpublished since the last approval period (i.e., as a result of this research or within the field)?**
 |
| [ ]  Yes [ ]  No | If “Yes,” explain and attach any abstracts, list of citations, or other relevant information: |
| Enter text. |
| 1. **Does the project progress or any preliminary findings, or new information from the field suggest a change in previously assess risk to participants?**
 |
| [ ]  Yes [ ]  No | If “Yes,” explain and attach any abstracts, lists of citations, or other relevant information: |
| Enter text. |
| 1. **Have there been any changes in the Principal Investigator’s situation or qualifications that would impact the ability of the investigator to carry out this research in accordance with the approved protocol?**

*Consider changes like an increase in the number of research projects, work status, funding/facilities, etc.* |
| [ ]  Yes [ ]  No | If “Yes,” explain in the text box below. |
| Enter text. |
| 1. **Participant Enrollment:**
 |
| 1. **Maximum number of participants currently approved to enroll:**
 | Enter number. |
| 1. **Number of participants enrolled during the last approval period:**
 | Enter number. |
| 1. **Number of participants enrolled since the start of this research:**
 | Enter number. |
| 1. **Does the number of participants enrolled/collected (5c) exceed the number of participants approved by the IRB (5a) above?**
 |
| [ ]  Yes [ ]  No | If “Yes,” submit a Reportable Event Submission and briefly explain in the text box below: |
| Enter text. |
| * To request an increase of total maximum number of participants, and Amendment Submission must be submitted for review and approval.
 |
| 1. **Participant Withdrawals:**
 |
| 1. **Number of participant withdrawals during the last approval period:**
 | Enter number. |
| 1. **Explain the reason for each participant withdrawal (e.g., dissatisfaction, relocation, etc.)**
 |
| Enter text. |
| 1. **Number of participant withdrawals since the start of the project:**
 | Enter number. |
| 1. **Have a greater number of participants than expected withdrawn from the project:**
 |
| [ ]  Yes [ ]  No | If “Yes,” explain in the text box below: |
| Enter text. |
| 1. **Participant Complaints:**
 |
| 1. **Have there been any complaints about the research and/or the conduct of the research during the last approval period?**
 |
| [ ]  Yes [ ]  No | If “Yes,” explain and specify if a Reportable Event was submitted: |
| Enter text. |
| 1. **Events such as unanticipated problems, adverse events, and/or occurrences of non-compliance:**
 |
| 1. **During the last approval period, have there been any events reported to HRPP and/or the IRB?**
 |
| [ ]  Yes [ ]  No | If “Yes,” explain in the text box below: |
| Enter text. |
| 1. **Have there been any events not reported to HRPP and/or the IRB?**
 |
| [ ]  Yes [ ]  No | If “Yes,” explain and address any impact or increased risk to participants: |
| Enter text. |
| 1. **Have there been any approved changes to your research project since the start of the research?**
 |
| [ ]  Yes [ ]  No | If “Yes,” provide a brief summary of the approved amendments: |
| Enter text. |
| **NOTE:** No new changes may be incorporated with the progress review submission materials. Any newly proposed change will require an Amendment Submission. |

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| **Part 3: FUNDING** |
| **Has funding or sponsorship been associated with this research?** *No new funding may be added with the progress report submission. Funding not previously associated with the protocol requires an Amendment Submission.* |
| [ ]  Yes [ ]  No | If “Yes,” list all funding sources, including internal and external sources and indicate if funding is active: |
| Active | Inactive | Source Name | Grant #, if applicable |
|[ ] [ ]  Enter text. | Enter number |
|[ ] [ ]  Enter text. | Enter number |
|[ ] [ ]  Enter text. | Enter number |

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| **PART 4: CLINICAL TRIALS** |
| When meeting the definition of clinical trial, the principal investigator is responsible for ensuring the additional requirements related to conduct of clinical trials are met:* For expedited with no requirement of continuing review research reviewed under the 2018 Revised Common Rule, the informed consent document must be posted to a federal website and no later than 60 days after the last project visit by any subject. *This applies only to federally funded research.*
* For NIH sponsored research that meets the definition of clinical trial:
* The research must be registered with an any results submitted to clinicaltrials.gov per program requirements. This may be required by other sponsors or federal agencies.
* All individuals involved in the design, conduct, oversight, and management of the clinical trial must complete Good Clinical Practice (GCP) training. Current training dates need to be listed in the Research Personnel Form.
 |
| 1. **Does the research meet the definition of *clinical trial* under NIH or other “sponsor” requirements or 2018 HHS regulations (45 CFR 46)?** *“Clinical trial” means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. 45 CFR 46.102(b)*
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| [ ]  Yes [ ]  No | If “No,” skip the remainder of this section. If “Yes,” review the additional responsibilities noted below and answer questions a-c below. |
| 1. **If required by a sponsor (e.g., NIH) or other regulation(s) has the research been registered with clinicaltrials.gov and any results available been submitted as required.**
 |
| [ ]  Yes [ ]  No [ ]  NA | If “No,” explain in the text box below: |
| Enter text. |
| 1. **Have all individuals involved in the *design, conduct, oversight, and management* of the clinical trial completed Good Clinical Practice (GCP) training?**
 |
| [ ]  Yes [ ]  No [ ]  NA | NOTE: Current GCP training dates need to be listed in the Research Personnel Form.If “No,” explain in the text box below: |
| Enter text. |
| 1. **Is the project now closed to recruitment? Select ONE of the following**
 |
| [ ]  | No, the project is not closed to recruitment |
|[ ]  Yes, the project is closed to recruitment **and** the research was determined to be “registration project” or “exempt”. Posting the consent form is not required for registration projects or exempt research. |
|[ ]  Yes, the project is closed to recruitment **and** the informed consent **was posted** to a federal website no later than 60 days after the last project visit by any subject.* Provide the website address for the informed consent posting in the textbox below:
 |
| Enter text. |
|[ ]  Yes, the project is closed to recruitment **and** the informed consent for **was not** posted to a federal website no later than 60 days after the last project visit by any subject.* Explain why the consent was not posted in the textbox below:
 |
| Enter text. |

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| **Part 5: HUMAN SUBJECTS CONFLICT OF INTEREST** |
| * It is the responsibility of the Principal Investigator (PI) to ensure that nay research personnel, including the PI, **responsible for the design, conduct, and reporting of research** complete the [IRB Conflict of Interest Disclosure form](https://assets.campbell.edu/wp-content/uploads/2018/09/IRB-COI-Form.v1.docx). See, [IRB SOP: Conflict of Interest in Human Subjects Research](https://assets.campbell.edu/wp-content/uploads/2018/09/HSR311-IRB-SOP-Investigator_COI-in-HSR.v1.pdf) for more information.
* The PI must keep completed copies of all IRB COI Disclosure forms for their records.
* The PI must submit with this application IRB COI Disclosure forms only for those individuals who have identified a real, perceived, or potential conflict of interest on their form.
 |
| 1. **Have there been any changes to any research personnel’s real, perceived, or potential conflicts of interest related to the research during the last approval period?**
 |
| [ ]  No changes have been identified during the last approval period.[ ]  Yes, changes were previously reported to the following individuals. Briefly describe and provide date reported. |
| Enter text. |
| **NOTE:** If changes are identified to research personnel’s COI forms that have not been previously reported to the IRB, an Amendment Submission is required. |

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| **Part 6: PROTOCOL MATERIALS** |
| 1. **The following materials, if applicable to the protocol, must be submitted with this Progress Report.**
 |
| *Attached* | *N/A* | *Document* |
|[ ]  [ ]  | Research Plan* *Attach the most current approved version including applicable appendices*
 |
|  |  | Attached | N/A |
|  |  |[ ]  [ ]  Appendix A –HIPAA and Use of PHI |
|  |  |[ ]  [ ]  Appendix B – Banking Projects |
|  |  |[ ]  [ ]  Appendix C – Genetic Materials/Information/Tests |
|[ ]   | Current Research Personnel Form (no new person may be added without an amendment) |
|[ ] [ ]  Recruitment Materials* Note: “N/A” only if the project is closed to enrollment or recruitment materials were not required.
 |
|[ ] [ ]  Informed Consent/Assent/Debriefing Materials* Attach current versions of all consent, assent, parent/guardian permission, and debriefing forms.
* “N/A” only acceptable for projects that: (1) have previously been granted a waiver of informed consent; and/or (2) the project activities were limited to data analysis only during the last approval period.
 |
|[ ] [ ]  External/Non-CU IRB Approval(s) – documentation of continued approval |
|[ ] [ ]  Documentation of continued clearance or approval from local safety committees (e.g., biosafety committee, laboratory safety, etc.) |
|[ ] [ ]  Abstracts, posters, a list of citations, or relevant information. |
|[ ] [ ]  DSMP – Data Safety Monitoring Plan |
|[ ] [ ]  DSMB/DMC/Independent Monitoring – progress report and/or interim analysis |
|[ ] [ ]  List other: | Click or tap here to enter text. |
|[ ] [ ]  List other: | Click or tap here to enter text. |
|[ ] [ ]  List other: | Click or tap here to enter text. |
| 1. **Describe any previously approved research activities/procedures completed or that will not continue:**
 |
| Enter text. |
| 1. **List all previously approved materials no longer in use:**
 |
| Enter text. |

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| **Part 7: INVESTIGATOR SIGNATURE** |
| * By signing below I certify that I will conduct this research as approved by the Campbell University IRB and in accordance with the Investigator Agreement.
* I understand the submission for continued human subject research activities must be reviewed an approved by the Campbell University IRB prior to conducting continued research activities beyond the existing expiration date.
 |
| Click here to type name or insert electronic signature | Click here to enter date |
| * *Electronic signature acceptable.*
 |