**Purpose:** Use this form for closure of previously approved registration project, exempt, expedited or full board human subject research.

**Instructions:** For projects previously reviewed and approved by the IRB or determined registration project or exempt, the project can be closed if you have finished obtaining data through intervention or interaction with subjects or obtaining/using identifiable private information about the subjects. The closure review will determine if the research is eligible for closure and notification of the determination will be provided to the investigator. Submit this application to [Closure Electronic Application Form](https://cphsadmin.wufoo.com/forms/z11p9hrl0nitqni/). DO NOT EMAIL SUBMISSIONS TO THE IRB.

* Save this form before proceeding so your work will not be lost.
* 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.

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 |

|  |
| --- |
| **PART 1: PROJECT AND INVESTIGATOR INFORMATION** |
| Project Title: Title |
| Principal Investigator (PI): | Name | School/Department: | School/Department |
| PI Campbell Email: | Email address | PI Telephone: | Number |
| Role at Campbell: | Role | If other, specify role: | Text |
| **Project Status (check one)** |
| * Select **one** of the following to indicate the project status: *(do not select more than one box)*
 |
| 1. [ ]  **Research not started (i.e., no subject enrolled and project never started).**

Explain why this project never started, below, then skip to Part 4, sign, and submit this form to the IRB.Explain: Insert explanation1. [ ]  **Enrollment closed; research activities limited to analysis of information and/or biospecimens only.**
* ***All of the following conditions must apply:***
* No information and/or biospecimens are being obtained through intervention or interaction with subjects,
* Information and/or biospecimens are not identifiable (i.e., data has been de-identified and code keys linked with identifiers have been destroyed); *and*
* Only de-identified information and/or biospecimens are being analyzed.
1. [ ]  **Project complete or discontinued/data analysis is complete.**
* ***All of the following conditions must apply:***
* No information and/or biospecimens are being obtained through intervention or interaction with subjects,
* Information and/or biospecimens are not identifiable (i.e., data has been de-identified and code keys linked with identifiers have been destroyed); *and*
* Information and/or biospecimens are not being analyzed; *or*, for multi-site project, CU site is no longer engaged.
1. [ ]  **Project and data analysis complete. Retaining identifiers for possible future use or for safety purposes.**
* ***All of the following conditions must apply:***
* No information and/or biospecimens are being obtained through intervention or interaction with subjects,
* Maintaining individually identifiable private information but no longer using, studying, or analyzing the data.

NOTE: if wishing to retain identifiable information, this must have been included and explained in the approved Research Plan and Informed Consent. If this was not previously approved, contact the IRB for guidance.1. [ ]  **Project ongoing. Campbell IRB no longer providing oversight for this protocol.**
* ***Indicate one of the following and provide explanation below:***
* [ ]  Principal Investigator no longer affiliated with Campbell and research will be transferred and overseen by another institution or IRB.
* [ ]  This is a collaborative project and the Campbell IRB has deferred oversight for this protocol to another IRB.
* [ ]  Other as described below.

Explain:Click or tap here to enter text. |

|  |
| --- |
| **PART 2: PROGRESS REPORT** |
| 1. **Provide a brief summary of the project’s goals and progress over the course of the most recent approval period. Describe preliminary project observations/findings and/or attach relevant information published or unpublished.**
 |
| Enter text |
| 1. **Participant Enrollment:**

**NOTE:** For projects determined to be registration projects or exempt, a response is only required for 2b. Indicate “n/a” for 2a and 2c. *Please refer to your initial IRB determination letter for IRB determination information.* |
| 1. **Maximum number of participants/records/biospecimens currently approved to enroll/collect:** *(****NA*** *is not acceptable for Exempt or Full studies)*
 | Enter number. |
| 1. **Number of participants/records/biospecimens enrolled/collected since the start of this research:**
 | Enter number. |
| 1. **Does the number of participants/records/biospecimens enrolled/collected exceed the number of participants approved by the IRB above?**
 |
| [ ]  Yes [ ]  No | If “Yes,” submit a Reportable Event Submission and briefly explain in the text box below: |
| Enter text. |
| 1. **Participant Withdrawals:**
 |
| 1. **Number of participant/record/biospecimen withdrawals since the start of the research:** *(****NA*** *is not acceptable)*
 | Enter number. |
| 1. **Explain the reason for each participant/record/biospecimen withdrawal (e.g., dissatisfaction, relocation, etc.)**
 |
| Enter text. |
| 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. |

|  |
| --- |
| **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 researcher.*
* 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)*
 |

|  |  |
| --- | --- |
| [ ]  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. |

|  |
| --- |
| **Part 7: Location of Research Materials** |
| * All research materials and source documentation must be retained for 3 to 6 years following completion of research activities.
* Research materials and source documentation should be readily accessible for IRB and external agency review.
 |
| **1.** **Where are the research materials and source documents located?** *Indicate building and room number, name of electronic storage stem, if applicable.* |
| Location(s): Click or tap here to enter text. |

|  |
| --- |
| **Part 8: INVESTIGATOR SIGNATURE** |
| * By signing below I certify this research was conducted as approved by the Campbell University IRB and in accordance with the Investigator Agreement.
* *Electronic signature acceptable.*
* *Must be signed by PI (no student signatures)*
 |
| Click here to type name or insert electronic signature | Click here to enter date |