Instructions: Use this form for closure of previously approved exempt, expedited or full board human subject research.

For projects previously reviewed and approved by the IRB or determined exempt, the study can be closed if you have finished obtaining data through intervention or interaction with subjects or obtaining/using identifiable private information about the subjects. Use this form to request closure. The closure review will determine if the research is eligible for closure and notification of the determination will be provided to the investigator. Save this form before proceeding and reopen using MSWord to ensure data entered will be saved properly.

Submit this form by filling out an application for IRB review here: <https://cphsadmin.wufoo.com/forms/z11p9hrl0nitqni/>

|  |
| --- |
| Section 1: Study and Investigator Information |
| **IRB Protocol Number:** | **Number** |
| **Project Title:** | *Title* |
| **Date:** | Date |
| **Principal Investigator:** | Name |
| **Faculty Advisor:** | Name |
| **School/Department:** | School/Department |
| Section 2: Request |
| * Select one of the following:

[ ]  **1. Research has not started** (i.e., no subject enrolled and study never commenced).Explain why this study never commenced below, then skip to Part 4 and submit this form.Enter why study never commenced.[ ]  **2. 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 is 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.[ ]  **3. Project complete or discontinued/data analysis is complete.*** *All of the following conditions must apply*

[ ]  No information and/or biospecimens is 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 study, CU site is no longer engaged.[ ]  **4. Project complete or discontinued/data analysis is complete.*** *All of the following conditions must apply*

[ ]  No information and/or biospecimens is being obtained through intervention or interaction with subjects, ***and***[ ]  Maintaining individually identifiable private information but no longer using, studying, or analyzing the data.If wishing to retain identifiable information, this must have been explained in the approved protocol and informed consent document. If this was not previously approved, contact the IRB for guidance.[ ]  **5. Project ongoing. CU IRB no longer providing oversight for this study.*** *One of the following conditions must apply*

[ ]  Principal Investigator no longer affiliated with CU and research will be overseen by another institution or IRB.[ ]  This is a collaborative project and the CU IRB has deferred oversight for this study to another IRB.[ ]  Other. Describe in textbox below.Describe |
| Section 3: 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 research observations/findings and/or relevant information published or unpublished:** |
| Provide a brief summary of the projects goals and progress here. |
| **2. Participant enrollment (if project only involves records or biospecimens review, skip to 5 of Section 3.** |
| **(2a)** Maximum number of participants approved by the IRB to be enrolled | Enter Number |
| **(2b)** Number of participants enrolled since the start of this research: | Enter Number |
| **(2c)** Does the number of participants enrolled exceed the number of participants approved by the IRB? | [ ]  Yes [ ]  No If yes, explain and submit a Reportable Event or specify if a Reportable Event has previously been submitted.Explain here. |
| **(2d)** Number of signed consent documents obtained? | Enter Number |
| **(2e)** Does the number of signed consent documents match the number of enrolled subjects? | [ ]  Yes [ ]  No If no, explain and submit a Reportable Event or specify if a Reportable Event has previously been submitted.Explain here. |
| **3. Participant withdrawals:** |
| **(3a)** Number of participant withdrawals during the last approval period: | Enter Number |
| **(3b)** Explain the reason for each participant withdrawal (i.e., dissatisfaction, relocation, etc.): | Explain here. |
| **(3c)** Have a greater number of participants than expected withdrawn from the project? | [ ]  Yes [ ]  No If yes, explain:Explain here. |
| **4. Participant complaints:** |
| **(4a)** 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 if a Reportable Event has been submitted.Explain here. |
| **5. Record/Biospecimen Collection:** (skip this section if project did not involve record review and/or biospecimens review/collection) |
| **(5a)** Maximum number of records/biospecimens approved by the IRB to collect/use:  | Enter Number |
| **(5b)** Number of records/biospecimens collected/used since the start of this research: | Enter Number |
| **(5c)** Does the number of records/biospecimens collected/used since the start of this research exceed the number of records/biospecimens approved by the IRB? | [ ]  Yes [ ]  No If yes, explain and submit a Reportable Event or specify if a Reportable Event has previously been submitted.Explain here. |
| **(5d)**. Where any records/biospecimens reviewed/collected and not used for the project? | [ ]  Yes [ ]  No If yes, explain and submit a Reportable Event or specify if a Reportable Event has previously been submitted.Explain here. |
| **6. Events such as unanticipated problems, adverse events, and/or occurrences of non-compliance:** |
| **(6a)** During the last approval period, have any Reportable Events (REs) been submitted to the IRB? | [ ]  Yes [ ]  No If yes, explainExplain here. |
| **(6b)**. During the last approval period have there been any events not reported to the IRB? | [ ]  Yes [ ]  No If yes, explain and address any impact or increased risk to participants.Explain here. |
| **7. Investigation drug(s) and devices:** |
| **(7a)** Did this research involve an investigation drug(s)? [ ]  Yes [ ]  NoIf yes, indicate one of the following:[ ]  All unused supplies of the investigational drug have been returned to the sponsor/IND holder.* If the sponsor is the investigator, explain how unused supplies are managed:

Explain how unused supplies are managed here.-OR-[ ]  Unused supplies do not expose humans to risks from the drug and alternative disposition has been arranged for unused supplies.* Explain how unused supplies are managed:

Explain how unused supplies are managed here. |
| **(7b)**. Did this research involve an investigational device(s)? [ ]  Yes [ ]  NoIf yes, indicate one of the following:[ ]  All devices have been used for the research or returned to the appropriate entity (e.g., sponsor, manufacturer, etc.).-OR-[ ]  Devices have not been returned, but do not expose humans to risk.* Justify why devices remain with local investigator.

Justify why devices remain with local investigator. |
| **8. Investigator and Faculty Advisor Check-off****Principal Investigator:**[ ]  I certify that I conducted this research as approved by the Campbell University IRB.[ ]  I verify that the information provided in this closure submission form is accurate and complete.**Faculty Advisor:**[ ]  I attest that I have reviewed the information reported in this application and agrees that this research was conducted as approved by the Campbell University IRB.[ ]  I verify that the information provided in this closure submission form is accurate and complete. |