Instructions: Use this form to request continuing IRB approval of previously expedited or full board human subject research. 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.*

* 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 lapse (expire) is considered non-compliance. The study must either be continued or closed to maintain compliance. If a study is allowed to expire, a new Initial Review Application and supporting materials will need to be submitted and IRB approval obtained before resuming human subject research activities.
* If no longer intervening/interacting with subjects and/or analyzing identifiable participant information, this study may be eligible for closure, see the [CU IRB website](https://www.campbell.edu/about/leadership/provost/institutional-review-board/) for more detail.
* Changes cannot be incorporated into the continuing review materials. In order to be compliant with federal regulations an Amendment Application and Submission Form must be submitted for separate review of proposed changes.

Submit this application and all required protocol materials (see Part V: Protocol Materials) to the IRB Office by using the Continuing Progress Report Application Form found at <https://cphsadmin.wufoo.com/forms/z1ln3ivr0ll72wy/>. Save this form and reopen using MSWord before proceeding to ensure your information will be saved properly.

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| Section 1: Protocol Information | |
| **IRB Protocol Number:** | **Number** |
| **Project Title:** | *Title* |
| **Date:** | Date |
| **Principal Investigator:** | Principal Investigator |
| **Faculty Advisor:** | Faculty Advisor |
| **School/Department:** | School/Department |
| **1. Research Status (check one)** | |
| Recruitment not yet started  Recruitment started, no participants enrolled or  No data/biospecimens collected  Participants enrolled, recruitment ongoing  Data/biospecimens are being collected  Collection of data/biospecimens, research activities are 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. | |

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| Section 2: Progress Report | | |
| **1. Provide a brief summary of the project’s progress and describe preliminary project observations/findings during the last approval period:** | | |
| Enter brief summary of project’s progress and other information here. | | |
| **2. 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 major design changes here. | | |
| **3. State the anticipated end date for human subject research activities, including analysis of identifiable participant data:** | | |
| Month and year: Month and year | | |
| **4. New and relevant information since the last approval period?** | | |
| (a) 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:  Explain here. | | |
| **5. Participant Enrollment (if project only involves records or biospecimens review, skip to 9):** | | |
| (a) Maximum number of participants currently approved to enroll: | | Number |
| (b) Number of participants enrolled during the last approval period: | | Number |
| (c) Number of participants enrolled since the start of this research: | | Number |
| (d) Does the number of participants enrolled (3c) exceed the number of participants approved by the IRB (3a) above?  Yes  No  If “yes,” explain:  Explain here. | | |
| **6. Consent Documents (if applicable):** | | |
| (a) Total number of signed consent documents: | | Number |
| (b) Number of signed consent documents during the last approval period: | | Number |
| (c) Does the total number of signed consent documents (6a) match the number of number of enrolled since start of this research (5c)?  Yes  No  If “no,” explain:  Explain here. | | |
| **7. Participant Withdrawals:** | | |
| (a) Number of participant withdrawals during the last approval period: | | Number |
| (b) Explain the reason for each participant withdrawal (e.g., dissatisfaction, relocation, etc.):  Explain reason(s) for participant withdrawal | | |
| (c) Number of participant withdrawals since the start of the project: | | Number |
| (d) Have a greater number of participants than expected withdrawn from the project?  Yes  No  If “yes,” explain:  Explain here. | | |
| **8. Participant Complaints:** | | |
| (a) 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:  Explain here. | | |
| **9. Record/Biospecimens Collection:** (skip this section if project did not involve record review and/or biospecimens review/collection) | | |
| (a) Maximum number of records/biospecimens approved by the IRB to collect/use: | Enter number | |
| (b) Number of records/biospecimens collected/used since the start of this research: | Enter number | |
| (c) 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 | |
| (d) Were 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 | |
| **10. Events such as unanticipated problems, adverse events, and/or occurrences of non-compliance:** | | |
| (a) During the last approval period, have there been any events reported to the IRB?  Yes  No  If “yes,” explain:  Explain here. | | |
| (b) During the last approval period, have there been any events not reported to the IRB?  Yes  No  If “yes,” explain:  Explain here. | | |
| **9. Have there been any approved changes to you research project during the last approval period?** | | |
| **NOTE: No new changes may be incorporated with the continuing review application materials. Any newly proposed changes will require an Amendment Application** | | |
| Yes  No  If “yes,” explain:  Explain here. | | |

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| Section 3: Funding | | | | | |
| **Has funding or sponsorship been associated with this research?** *No new funding may be added with the continuing progress review application. Funding not previously associated with the protocol requires an Amendment Application.*  Yes  No | | | | | |
| If “yes,” list all funding sources, include internal and external sources and indicate if funding is active: | | | | | |
| **Active** | **Inactive** | | **Source Name** | | **Grant #** |
|  |  | | Source Name | | Grant number |
|  |  | | Source Name | | Grant number |
|  |  | | Source Name | | Grant number |
| Section 4: Human Subjects Conflict of Interest | | | | | |
| **Have there been any changes to any research personnel’s real, perceived, or potential conflicts of interest related to this research during the last approval period?**  No changes have been identified during the last approval period.  Yes, changes were previously reported for the following individuals. Briefly describe and provide date reported. | | | | | |
| Section 5: Protocol Materials | | | | | |
| **1. The following materials, if applicable to the protocol, must be submitted with this application:** | | | | | |
| **Attached** | | **N/A** | | **Material Types** | |
|  | |  | | Revised Initial/New Protocol Submission Form.   * *Attach the most current approved version* | |
|  | |  | | Recruitment Materials   * *“N/A” only acceptable for studies that are closed to enrollment of new subjects* | |
|  | |  | | Informed Consent/Assent/Debriefing Materials   * *Attach current approved 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 documentation; and/or (2) the project status was reported as data analysis only for the last continuing review.* | |
|  | |  | | External/Non-CU IRB Approval(s) – documentation of continuing review | |
|  | |  | | Data Safety Monitoring Plan (DSMP) | |
|  | |  | | DSMB/DMC/Independent Monitoring – progress report and/or interim analysis | |
|  | |  | | Protocol Document, if applicable | |
| List other: | | | | List other | |
| List other: | | | | List other | |
| **2. Describe any previously approved research activities/procedures completed or that will not continue:** | | | | | |
| Describe here. | | | | | |
| **3. List all previously approved materials no longer in use:** | | | | | |
| List previously approved materials no longer in use here. | | | | | |

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| Part 6: Investigator and Faculty Advisor Signatures |
| **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. |