**Purpose:** This application is designed to facilitate the Institutional Review Board (IRB) review of proposed human subjects research. The IRB serves to protect the rights and welfare of human subjects in research in accordance with federal, state, and institutional regulations and policy.

**Instructions:** Complete this application as part of the initial protocol submission. A complete protocol submission initiates the IRB review of research involving human subjects. Submit this application (including the checklist on the last page) and all applicable research materials (research protocol, attachments, consent form(s), surveys, interview guides, etc.) using the [New Protocol Electronic Application Form](https://cphsadmin.wufoo.com/forms/zkthc20k1gury/) found on the [IRB website](https://www.campbell.edu/about/leadership/provost/institutional-review-board/).

Please note:

* Remember this form should be written in lay terms and define specific terms prior to using initials. Please double check your submission for completeness and accuracy prior to submission. Please read the [IRB Investigator Manual](https://assets.campbell.edu/wp-content/uploads/2018/09/CUIRB-Investigator-Manual-2020.pdf) and IRB SOPs for Investigators on the [IRB website](https://www.campbell.edu/about/leadership/provost/institutional-review-board/) prior to completing this form.
* Incomplete submissions will be placed **ON HOLD**, if a submission is incomplete it will not be processed until **all** required documents and criteria have been submitted or met.
* This form should be accompanied by a [Research Plan](https://assets.campbell.edu/wp-content/uploads/2018/09/Research-Plan-Template.v1.docx). Please use the template and guidance document located on the [IRB website](https://www.campbell.edu/about/leadership/provost/institutional-review-board/). All project personnel must have completed human subjects research training and received certification, prior to the submission of any research protocol for IRB review. Please see the [IRB website](https://www.campbell.edu/about/leadership/provost/institutional-review-board/) for further information. This form guides you to many other documents/forms on the IRB website. Links are embedded in this form.
* 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](mailto:irbadmin@campbell.edu) or phone (910) 893-7780.

**THE REMAINDER OF THE PAGE IS LEFT BLANK INTENTIONALLY.**

**PROCEED TO THE NEXT PAGE.**

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| **SUBMISSION DATE:** | Click or tap to 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 |

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| 1. **Research Request (select one of the following):** | | | | |
| **INITIAL REVIEW OF NEWLY PROPOSED RESEARCH PROJECT OR BANK** | | | | |
| **INITIAL REVIEW FOR EXPIRED RESEARCH** – *For review of research that as previously approved by the IRB that has now expired.* Answer the question below:   1. State reason for lapse in approval:   Enter text | | | | |
| 1. Describe the plan to prevent future lapses in approval:   Enter text | | | | |
| 1. Has the project sponsor or funding agency been notified of the lapse in approval period?   Yes  No  N/A (no sponsor involved/not required)  If “No”, explain: Enter text | | | | |
| 1. Has any human subject research activity been conducted after the IRB approved expiration data?  * Once there is a lapse in IRB approval of research, investigators must stop all human subject research activities, including intervening or interacting with subjects an obtaining or analyzing identifiable private information about human subjects.   Yes  No If “Yes”, submit a [Reportable Event Submission Form](https://assets.campbell.edu/wp-content/uploads/2019/03/Reportable-Event-Submission-Form.docx) describing the number of subjects enrolled, the research interventions/activities conducted and/or the data analyzed. | | | | |
| 1. **Provide the anticipated start and end date for human subject research (month/year):**  * *The expected end date is when all project procedures (e.g., follow-up and data analysis) have been completed.* * *For multi-site industry-sponsored projects, uninterrupted IRB approval should extend until the sponsor has completed a close-out visit and all the data at this site are “locked down”.* | | | | |
| Start (month and Year) | | Month, Year | End (month and year) | Month, Year. |
| 1. **Complete the Research Personnel Form. All research personnel, including the Principal Investigator, Co-Investigators, and research staff members must be listed.** | | | | |
| Research Personnel Form attached to [New Protocol Electronic Application Form](https://cphsadmin.wufoo.com/forms/zkthc20k1gury/). | | | | |
| 1. **Is this research funded or sponsored from and internal CU or external source?** | | | | |
| Yes  No | If “Yes,” complete and attach the Funding and Sponsorship Form to [New Protocol Electronic Application Form](https://cphsadmin.wufoo.com/forms/zkthc20k1gury/) in Wufoo. | | | |

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| **PART 2: RISK ASSESSMENT** | |
| * ***Minimal risk*** *means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.* | |
| **In the Principal Investigator’s opinion, this research presents (select one of the following):** | |
| No greater than minimal risk; **briefly justify in the text box below.**  Enter text | |
| Greater than minimal risk; **briefly justify in the text box below.**  Enter text | |
| **PART 3: RESEARCH PLAN** | |
| 1. **Develop a Research Plan using the** [**Research Plan Guidance**](https://assets.campbell.edu/wp-content/uploads/2018/09/IRB-Guidance_-Research-Plan.v2.pdf) **and** [**template**](https://assets.campbell.edu/wp-content/uploads/2018/09/Research-Plan-Template.v1.docx)**. Grant, thesis, dissertation, or course work proposals may NOT be submitted in lieu of the Research Plan** | |
| * See [IRB website](https://www.campbell.edu/about/leadership/provost/institutional-review-board/) and the [IRB Investigator Manual](https://assets.campbell.edu/wp-content/uploads/2018/09/CUIRB-Investigator-Manual-2020.pdf) for guidance; be sure to include all relevant information in the Research Protocol/Plan. | |
| Research Plan Attached to [New Protocol Electronic Application Form](https://cphsadmin.wufoo.com/forms/zkthc20k1gury/). | |
| 1. **Answer “Yes” or “No” to ALL the following questions.** | |
| * If the answer to any of the following questions is “Yes,” incorporate relevant information into the Research Plan and attach applicable appendix. * *All applicable appendices must be submitted with the initial protocol submission and each subsequent submission of the Research Plan.* | |
| 1. Does this research involve the access, use or collection of Protected Health Information (PHI)? | |
| Yes  No | If “Yes,” Attach [Appendix A – HIPAA – Use of PHI](https://assets.campbell.edu/wp-content/uploads/2018/09/Appendix-A-HIPAA-Use-of-PHI.v1.docx) |
| 1. Does this research involve banking of data or biospecimens for research? | |
| Yes  No | If “Yes,” Attach [Appendix B – Banking Project](https://assets.campbell.edu/wp-content/uploads/2018/09/Appendix-B-Banking-Projects.v1.docx) |
| (c) | |
| Yes  No | If “Yes,” Attach [Appendix C – Genetic Materials/Information/Tests](https://assets.campbell.edu/wp-content/uploads/2018/09/Appendix-C-Genetic-Materials_Information_Tests.v1.docx) |

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| **Part 4: RECRUITMENT AND SUBJECT POPULATION** | | |
| * Copies of all recruitment materials must be submitted with this submission form (e.g., flyer, email text, verbal recruitment scripts, etc.) * The IRB cannot approve protocols involving prisoners as research subjects at this time. * If your research involves pregnant women or fetuses, contact the IRB Office. These groups are federally regulated and require additional protections. | | |
| 1. **Maximum number of participants to be enrolled (include breakdown for all groups as applicable):** | | |
| Click or tap here to enter text. | | |
| 1. **Does this project involve minors?** | | |
| Yes  No | If “Yes,” state the minimum and maximum ages: Enter ages | |
| 1. **Does this project involve adults?** | | |
| Yes  No | If “Yes,” state the minimum and maximum ages: Enter ages | |
| 1. **Indicate how the participants will be recruited (check all that apply):** | | |
| No recruitment activities, study uses existing data  Email  Flyer  In Person  Database or record review  Professional referrals | | Online  Telephone  Mail  Recruitment Bank  Professional referrals  Other: Explain |
| 1. **Will all research be conducted in English?** | | |
| Yes  No | If “No,” state what language(s) will be used in the text box below.  Enter text. | |
| Note: See [IRB SOP: Recruitment and Enrollment of non-English or Limited English-Proficient Subjects](https://assets.campbell.edu/wp-content/uploads/2018/09/HSR630-IRB-SOP-Investigator_Recruitment-and-Enrollment-of-NEP-or-LEP-Subjects.pdf)*.* | | |

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| **Part 5: CONSENT, ASSENT, AND PERMISSIONS** | |
| 1. **Considering all participant groups, indicate the consent/assent process(es) involved in the research (check all that apply)** | |
| In Person  Remote: (e.g. online, phone, Skype, etc.)  Other: Enter text | |
| 1. **Will the consent process include all the elements of informed consent?** | |
| Yes  No | If “No,” a waiver of informed consent or an alteration of the elements of informed consent must be approved by the IRB. Provide justification in the **Research Plan**. See, [IRB Guidance: Informed Consent and Waivers](Informed%20Consent%20and-Waivers) for a list of required elements. |
| 1. **Will the consent and/or assent process be document using a written consent form that will be signed by the subject or the subject’s legally authorized representative?** | |
| Yes  No | If “No,” a waiver of documentation of informed consent must be approved by the IRB. Provide rationale for not obtaining signed written consent in the **Research Plan**. |

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| **PART 6: COMPENSATION AND REIMBURSEMENT** |
| * If compensating participants using funds distributed through a CU department, consult with the department administrator to clear the method of payment and develop a tracking system in compliance with Campbell University’s procurement procedures. |
| 1. **Will the participants be compensated and/or reimbursed for their participation?** |

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| Yes  No | If “Yes,” proceed to question 2 and 3 below. If “No,” proceed to next section. | |
| 1. **For what are the participants being compensated/reimbursed (check all that apply):** | | |
| Time  Travel  Expenses | | General incentive to participate  Meals  Other: Enter text |
| 1. **Method of compensation/reimbursement (check all that apply):**   See, [IRB Investigator Manual](https://assets.campbell.edu/wp-content/uploads/2018/09/CUIRB-Investigator-Manual-2020.pdf) and [IRB SOP: Compensation of Research Subjects](https://assets.campbell.edu/wp-content/uploads/2018/09/HSR380-IRB-SOP-Investigator_-Compensation-of-Research-Subjects.v2.pdf), for further details regarding the usage of the following types of compensation. | | |
| Cash  Check  Gift Certificate/Card | | Gift Item  Drawing  Academic/extra credit |

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| **PART 7: OTHER INSTITUTIONS, PERFORMANCE SITES, AND NON-CU PERSONNEL** |
| * If another institution is engaged in this research and it has an IRB, approval must be obtained from that institution’s IRB. Otherwise, and IRB Authorization Agreement must be executed to defer IRB oversight. To request a deferral, submit and [IRB Institutional Authorization Agreement Request Form](https://assets.campbell.edu/wp-content/uploads/2018/09/IRB-Institutional-Authorization-Agreement-Request-Form.v1.docx) for review, prior to submitting this submission form. * If a site/organization does not have an IRB, site/organization permission (Letters of Support) may need to be obtained and an [IRB Individual Investigator Agreement Request Form](https://assets.campbell.edu/wp-content/uploads/2018/09/IRB-Individial-Investigator-Agreement-Request-Form-CU-IRB-of-Record.v1.docx) may be required. * Documentation of IRB determinations and Authorization Agreements must be in place ***prior*** to engaging in associated human subject research activities. * See the [IRB website](https://www.campbell.edu/about/leadership/provost/institutional-review-board/), [IRB Investigator Manual](https://assets.campbell.edu/wp-content/uploads/2018/09/CUIRB-Investigator-Manual-2020.pdf) or [IRB SOP: Reliance Agreements for Multi-Site Projects](https://assets.campbell.edu/wp-content/uploads/2018/09/HSR710IRB-SOP-Investigator_Reliance-Agreements-for-Multi-Site-Projects.pdf) and [Conducting Multi-site (sIRB) Research and Investigator Responsibilities](https://assets.campbell.edu/wp-content/uploads/2018/09/HSR720-IRB-SOP-Investigator_Conducting-Multi-site-SIRB-Research-and-Investigator-Responsibilities.pdf). * Please contact the IRB before submitting a new protocol submission form that includes non-Campbell sites * Please note that approval of research involving non-Campbell sites likely increases time to approval. Plan accordingly |
| 1. **Will *individuals* from other site(s)/organizations(s) (e.g., universities, hospitals, clinics, etc.) with an IRB be engaged in this research?** |

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| Yes  No | If “Yes,” list the site(s)/organization(s) below. | | |
| Name of site(s)/organization(s) | Enter name | Approval Status: | Enter |
| Name of site(s)/organization(s) | Enter name | Approval Status: | Enter |
| Name of site(s)/organization(s) | Enter name | Approval Status: | Enter |
| If no approval required, explain: Explain | | | |

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| 1. **Will research *activities* occur at other site(s)/organizations(s) (e.g., universities, hospitals, clinics, etc.) that have an IRB be engaged in this research?** |

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| Yes  No | If “Yes,” list the site(s)/organization(s) below. | | |
| Name of site(s)/organization(s) | Enter name | Approval Status: | Enter name |
| Name of site(s)/organization(s) | Enter name | Approval Status: | Enter |
| Name of site(s)/organization(s) | Enter name | Approval Status: | Enter |
| If no approval required, explain: Enter name | | | |

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| 1. **Will *individuals* from other site(s)/organizations(s) (e.g., universities, hospitals, clinics, etc.) without an IRB be engaged in this research? An Individual Investigator Agreement (IIA) will need to be executed.** |

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| Yes  No | If “Yes,” list the names of researchers, site(s)/organization(s) below. | | |
| Name of researcher(s), site(s)/organization(s) | Name researcher/Name site/organization | | |
| Name of researcher(s), site(s)/organization(s) | Name researcher/Name site/organization | | |
| Name of researcher(s), site(s)/organization(s) | Name researcher/Name site/organization | | |
| 1. **Will the research be conducted with any site(s)/organizations(s) other than Campbell University (e.g., public schools, tribes, non-profit organizations, companies, etc.) that do not have an IRB?** [**Letters of Support**](https://assets.campbell.edu/wp-content/uploads/2018/12/Guidance-Letters-of-Support-from-External-Sites.pdf) **will be required.** | | | |
| Yes  No | If “Yes,” list the site(s)/organization(s) below. | | |
| Name of site(s)/organization(s) | Name site/organization | Permission Status | Enter |
| Name of site(s)/organization(s) | Name site/organization | Permission Status | Enter |
| Name of site(s)/organization(s) | Name site/organization | Permission Status | Enter |
| If no permission required, explain: Explain | | | |
| 1. **Does this research involve activities outside of the United States?** | | | |
| Yes  No | If “Yes,” list the country (ies) below. | | |
| Name of country (ies): | Name of country (ies) | Permission Status | Enter |
| **Note:** See the [IRB website](https://www.campbell.edu/about/leadership/provost/institutional-review-board/) and [IRB SOP: International Research](https://assets.campbell.edu/wp-content/uploads/2018/09/HSR730-IRB-SOP-Investigator_International-Research.pdf) for additional guidance on documentation requirements.  If no permission required, explain: Enter | | | |
| 1. **Does this research require approval/permission from a CU department or service (e.g., Registrar’s Office, Athletic Director, Campus ListServ, etc.)?** | | | |
| Yes  No | If “Yes,” inquire with the applicable office and attach documentation of permission to [New Protocol Electronic Application Form](https://cphsadmin.wufoo.com/forms/zkthc20k1gury/). | | |
| Name of department(s)/  service(s): | Name of dept./service | Permission Status | Enter |
| Name of department(s)/  service(s): | Name of dept./service | Permission Status | Enter |
| If no permission required, explain: Explain | | | |

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| **Part 8: ADDITIONAL MATERIALS** | | |
| 1. **Does this research involve procedures, materials, and/or a lab space that requires Laboratory Safety Committee or Institutional Biosafety Committee approval, or other special approval(s)?** | | |
| Yes  No | If “Yes,” attach relevant approval documentation to the [New Protocol Electronic Application Form](https://cphsadmin.wufoo.com/forms/zkthc20k1gury/) (e.g., biosafety committee approval, radiation safety approval, etc.) | |
| 1. **Has a Data and Safety Monitoring Plan (DSMP) been created for this research? This is typically required by a sponsor or regulatory agency (e.g., FDA or sponsor)?** | | |
| Yes  No | | If “Yes,” attach a copy of the DSMP to the [New Protocol Electronic Application Form](https://cphsadmin.wufoo.com/forms/zkthc20k1gury/) and address in the **Research Protocol/Plan**. |
| 1. **Has a Data Safety Monitoring Board or Committee (DSMB/DSMC) been established for this research? This is typically required by a sponsor or regulatory agency (e.g., FDA or sponsor)** | | |
| Yes  No | | If “Yes,” attach a copy of the DSMB/DSMC information to the [New Protocol Electronic Application Form](https://cphsadmin.wufoo.com/forms/zkthc20k1gury/) and address in the **Research Protocol/Plan**. |
| 1. **Will this research include obtaining, accessing, or using data from outside sources (e.g., universities, data repositories, government agencies, etc.)?** | | |
| Yes  No | | If “Yes,” If “Yes,” name the source(s) below. |
| Name of outside source(s): List outside sources here | | |
| 1. Are there terms, restrictions, or conditions regarding the data? | | |
| Yes  No | | If “Yes,” describe in applicable sections of the **Research Plan** |
| 1. Does this source require a [Data Use Agreement (DUA)](https://assets.campbell.edu/wp-content/uploads/2018/09/CUIRB-Data-Use-Agreement-01.15.2020.docx) or other agreement to use or obtain access to the data? | | |
| Yes  No | | If “Yes,” attach a copy of the agreement in the [New Protocol Electronic Application Form](https://cphsadmin.wufoo.com/forms/zkthc20k1gury/) and contact General Councils Office to ensure appropriate institutional approval is obtained to enter into the agreement. |
| 1. **Are you requesting the IRB create a secured file for storage of research materials in Egnyte?** | | |
| Yes  No | | If “No,” provide detailed research material/information/data protections and security measures in the **Research Protocol/Plan**. |

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| **Part 9: CLINICAL TRIALS** | |
| * **Does the research meet the definition of clinical trial under NIH or other sponsor requirements and/or FDA, or 2018 HHS regulations? Please see** [**IRB SOP: Definitions**](https://assets.campbell.edu/wp-content/uploads/2018/09/HSR102-IRB-SOP_IRB-Definitions.pdf) | |
| Yes  No | If “Yes,” If “Yes,” the principal investigator is responsible for ensuring the additional requirements related to conduct of clinical trials are met: |
| * For non-exempt federally funded research reviewed under the 2018 Revised Common Rule (45 CFR 46), the informed consent form must be posted to a federal website after the project is closed to recruitment and no later than 60 days after the last project visit by any subject. * For NIH sponsored research that meets the definition of clinical trial and/or FDA regulated research: * The research must be registered with and 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 trials must complete Good Clinical Practice (GCP) training. Current training dates need to be listed in the [Research Personnel Form](https://assets.campbell.edu/wp-content/uploads/2018/09/Research-Personnel-Form.v2.docx). | |

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| **Part 10: 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 Human Subjects Conflict of Interest (COI) form. 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 Human Subject COI forms for their records. * The PI must submit with this application IRB Human Subject COI forms only for those individuals who have identified a real, perceived, or potential conflict of interest on their form. | |
|  | No conflicts are identified  Yes, conflicts are identified and [IRB Human Subject COI form](https://assets.campbell.edu/wp-content/uploads/2018/09/IRB-COI-Form.v1.docx)(s) are attached for the following individuals: |
| Enter name(s) here | |

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| **Part 11: ATTACHED DOCUMENTS** |
| When attaching documents please use the appropriate prefix listed below in the title of the document. For example, ICF-(informed consent form) |
| RP – Research Plan  PRO – Sponsor’s protocol, protocol summary or narrative  IA – Campbell IRB Investigator Agreement  ADV – Advertisements and Recruitment Materials  ICF – Informed Consent Form/Project Information Sheet  DCT – Data Collection Tool  SUR – Surveys/Questionnaires/Interviews  INF – Informational Material for subjects  TBL – Activity table, schedule of assessments  IB – Investigator Brochure  SMP – Safety Monitoring Plan  DM – Device Manual  LET – IND/IDE/HDE or 510(k) documentation, communications from/with the sponsor, IRB approvals or administrative letters from other institutions  LOS – Letters of Support from sides that do not have an FWA and IRB  IAA – Institutional Authorization Agreement  IIA – Individual Investigator Agreement  DA – Data Agreements or contracts  OTHER(S) – (SPECIFY) *Other items may include; study journals or forms* |

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| * **Please attach signed** [**IRB Investigator Agreement**](https://assets.campbell.edu/wp-content/uploads/2018/09/IRB-Investigator-Agreement-Form.v2.docx) **to the** [**New Protocol Electronic Application**](https://cphsadmin.wufoo.com/forms/zkthc20k1gury/) **form.** |

**Instructions:**

The purpose of this checklist is to identify all items necessary to compile a complete protocol submission. Submit all protocol materials including the checklist using [Initial/New Protocol Electronic Application Form](https://cphsadmin.wufoo.com/forms/zkthc20k1gury/) found on the [IRB website](https://www.campbell.edu/about/leadership/provost/institutional-review-board/). Contact the IRB Office by [email](mailto:irbadmin@campbell.edu) or phone (910-893-7780) with any questions.

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| Attached | N/A | Document | |
|  | -- | Initial/New Protocol Submission Form | |
|  | -- | Investigator Agreement, signed by the Principal Investigator and, if applicable, the student. | |
|  | -- | Research Personnel Form and required applicable training documentation. | |
|  |  | Human Subject Conflict of Interest Form | |
|  |  | Funding and Sponsorship | |
|  | -- | A Research Protocol/Plan and applicable appendices (grant applications or excerpts from a grant will NOT be accepted as a Research Protocol/Plan | |
|  |  | Attached | N/A |
|  |  |  | Appendix A –HIPAA and Use of PHI |
|  |  |  | Appendix B – Banking Projects |
|  |  |  | Appendix C – Genetic Materials/Information/Tests |
|  |  | Recruitment Materials: Emails, letters, scripts, flyers, posters, brochures, etc. | |
|  |  | Informed Consent/Assent Materials | |
|  |  | Debriefing Materials | |
|  |  | Declarations of Translation and Back-Translations for non-English speaking documents | |
|  |  | Data Collection Materials (questionnaires, surveys, data collection forms, focus group/interview scripts, case report forms, etc.) | |
|  |  | Data Safety Monitoring Board/Committee information | |
|  |  | Data Use Agreement(s)/Transfer of Materials Agreement | |
|  |  | Permissions, letters of support, and IRB approval documentation as identified in Part 7 of this form | |
|  |  | Clearance or approval documentation from applicable CU oversite authority/committee | |
|  |  | For funded and/or sponsored research: The human subjects portion of the grant proposal | |