Introduction:

* Some institutions do not have a policy which allows them to enter into a reliance agreement with another IRB, this will require the investigator to file a separate IRB application to the external institution(s) IRB(s) as well as submitting an application to the CU IRB. Some institutions will require that CU IRB will cede to their IRB. If you think that your project may fall into one of these situations, please contact the IRB of each institution for their reliance agreement policy.
* IRB reliance only applies to human subject research. If you suspect your project may qualify as a QA/QI project or might not qualify as human subject research, please consult with your home institution’s IRB Office before completing and submitting this reliance request.
* The purpose of this Investigator Reliance Agreement Form is to inform the CU IRB of your intention of submitting an IRB application for a multi-site project where an IRB Reliance Agreement may be required. This Investigator Reliance Agreement Form can be used for initial submissions or when adding other institutions to an already IRB-approved project.
* If you are using this Investigator Reliance Agreement Form, do not submit your IRB application to the CU IRB until you receive a response from the IRB Administrator from the external institution(s) regarding if they require the CU IRB to cede to their IRB (no CU IRB application will be required) or if they will require a separate IRB submission to their institution’s IRB (a CU IRB application will need to be submitted).
* This Investigator Reliance Agreement Form is NOT and IRB application.

Instructions:

1. Complete this form with the requested information and submit only to the CU IRB Office as soon as you know what the other site(s) IRBs require.
2. Complete the form fully to allow the IRB to process your request quickly. If sections are incomplete, the form will be retuned for completion.
3. If the external site(s) IRB requires the CU IRB to cede to their IRB. Attach **the Investigator Attestation for Ceded Projects** and return it with the external site(s) Reliance Agreement. *Please note that all Reliance Agreements require the Signatory Officer’s signature and this can take up to or more than a month to complete. If you need the Reliance Agreement signed in order to secure funding please submit these documents to the CU IRB Office as soon as possible, so as to not lose funding.*
4. If funding is granted through CU is involved, you will be required to contact Sponsored Programs directly. The CU IRB Office will only contact for Sponsored Programs for verification when federal funding is involved.

Note: This form must be completed in sufficient detail in order for the CU IRB to make a determination on engagement and IRB oversight. Please answer all questions completely and in sufficient detail.

|  |
| --- |
| 1. **Basic Study Information**
 |
| Study Title: ***Click or tap here to enter text.*** |
| Is the investigator or student doing the work on a dissertation or thesis? [ ]  Yes [ ]  NoIf yes, specify with which institution the student is affiliated:If yes, Provide name & contact information for faculty advisor: |
| Funding:[ ]  No funding[ ]  There is funding and the source is: Click or tap here to enter text. | Awardee Institution:Has the funding been awarded? [ ]  Yes [ ]  No |
| Is there a subcontract or sub-award? [ ]  Yes [ ]  NoIf yes, specify with which institution: Click or tap here to enter text.  |

|  |
| --- |
| 1. **Project Status**
 |
| [ ]  Yes [ ]  No | Does this project already have IRB approval? |
| [ ]  Yes [ ]  No | Has the project already been submitted to an IRB? |
|  | If yes to either of these questions, specify which IRB: Click or tap here to enter text.  |
|  | If yes to either of these questions, specify IRB assigned project/study number: Click or tap here to enter text. |

|  |
| --- |
| 1. **Subject Populations (check all that apply)**
 |
| [ ]  healthy subjects [ ]  inpatients [ ]  outpatients [ ]  decisionally impaired [ ]  Non-English proficient[ ]  pregnant women [ ]  residents/students/employees [ ]  minors (anticipated % minors: %age)[ ]  other: Click or tap here to enter text. |

|  |
| --- |
| 1. **Study Sites, Personnel, Activities (indicate which institution/site will be involved in the study for each activity)**
 |
| Name of institution or site where research activities will be conducted | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Handing out flyers about the study, emailing subjects | [ ]   | [ ]   | [ ]   | [ ]   |
| Reviewing medical records/databases before informed consent to determine eligibility | [ ]   | [ ]   | [ ]   | [ ]   |
| Obtaining informed consent | [ ]   | [ ]   | [ ]   | [ ]   |
| Interacting with subjects, including interviews, surveys, focus groups | [ ]   | [ ]   | [ ]   | [ ]   |
| Testing, designing, or developing equipment | [ ]   | [ ]   | [ ]   | [ ]   |
| Intervening with subjects (e.g. collecting blood or saliva for research purposes, administering drugs or other investigative articles, manipulating the subject or subjects’ environment | [ ]   | [ ]   | [ ]   | [ ]   |
| Use of ancillary services (e.g. biostatistics, pharmacy, nursing, etc.) or institutional equipment | [ ]   | [ ]   | [ ]   | [ ]   |
| Use of scanning equipment (e.g. ex-ray, CT, US, DEXA, MRI, etc.) | [ ]   | [ ]   | [ ]   | [ ]   |
| Use, storage or banking data/biospecimens | [ ]   | [ ]   | [ ]   | [ ]   |
| Origin of data/biospecimens to be reviewed | [ ]   | [ ]   | [ ]   | [ ]   |
| Data/specimen analysis | [ ]   | [ ]   | [ ]   | [ ]   |
| Conducting research in a lab | [ ]   | [ ]   | [ ]   | [ ]   |

|  |
| --- |
| 1. **Responsible investigator and key personnel**
 |
| Name(s) of key personnel at each institution, including a responsible investigator if there are multiple personnel at an institution or site | Home institution for each individual listed | Role in project (e.g. responsible investigator, study coordinator, etc.) |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

|  |
| --- |
| 1. **Project Summary (explain the purpose for the study, activities checked in section 4 in more detail, and who at each site will conduct those activities).**
 |
| Briefly state the broad research goal and specific aims of the study in lay terms:Click or tap here to enter text.  |
| Describe (a) the procedures to be used to meet the specific aims of the project, (b) at which site they will be conducted, and (c) who will be performing those procedures:Click or tap here to enter text.  |
| If the projected is federally funded, identify the coordinating site for the project: |
| For more than minimal risk studies, list the individuals at each site who will be responsible for evaluating and responding to subject complaints and reporting unanticipated events to the reviewing IRB:

|  |  |
| --- | --- |
| Name of individual | Institution/Site |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |

 |

|  |
| --- |
| 1. **Conflict of Interest Disclosure**
 |
| Do any key personnel who will be engaged in the proposed research activity or their family members have a potential conflict of interest that requires disclosure as required by the individual’s institutional conflict of interest policy?[ ]  Yes [ ]  NoIf yes, list the individual and institution: Click or tap here to enter text. If yes, has this conflict of interest been reported to the individual’s institution? [ ]  Yes [ ]  No |

|  |
| --- |
| 1. **Project Team Point of Contact Information**
 |
| Identify the person who will serve as the project team point of contact for this request. This person is responsible for communicating questions and IRB decisions to project team members at all sites. (The project team Point of Contact could be the Principal Investigator or an individual coordinating the project.)Name: Click or tap here to enter text.Email: Click or tap here to enter text.Phone Click or tap here to enter text. |

**When requesting that CU rely upon (cede to) another IRB complete the following additional section. Then submit this entire form along with the protocol\* and consent form, if applicable, to** **sleming@campbell.edu****.**

|  |
| --- |
| 1. **Proposed reviewing IRB information**
 |
| Name of proposed reviewing IRB: Click or tap here to enter text.IRB FWA#: Click or tap here to enter text. |
| Name of IRB contact: Click or tap here to enter text.Email address: Click or tap here to enter text.Phone: Click or tap here to enter text. |
| **Funding Information** |
| Funds will come to CU through: [ ]  direct award/contract [ ]  sub-contract [ ]  service agreement  [ ]  Not funded |
| **Local Information** |
| Recruitment procedures will be conducted at CU as outline in the protocol, if applicable:Will you review medical records prior to consent to determine eligibility? [ ]  Yes [ ]  No If yes, specify source of records (e.g. Harnett Health, Wake Medical, etc.)? Click or tap here to enter text.  |
| Consent process will be conducted at CU as outline in the protocol? [ ]  Yes [ ]  NoIf not included in the protocol or if different than in the protocol, explain the process for this site: Click or tap here to enter text.  |
| **Activities at local site** |
| Briefly describe all study activities to be conducted at CU: Click or tap here to enter text.  |

\*Protocol summaries, narrative or grant applications should include (at minimum) the following sections:

 Purpose, Aims, Research Design, and Procedures to be conducted at each site.