**Introduction:**

* This form should only be used for collaborative research when research will be conducted at an institution which does not have a Federalwide Assurance/IRB.
* The purpose of this Individual Investigator Agreement (IIA) Request Form is to request that the CU IRB serve as the the IRB for a multi-site/collaborative project. This Request Form can be used for initial/new submissions or when adding other institutions to an already IRB approved project.
* This Request Form is NOT an IRB submission/application. Information in this form will be used to make a decision by the CU IRB. Be sure to complete all sections thoroughly.

**Instructions:**

1. Complete this form and submit, along with the *Research Plan* to the CU IRB Office via the email address provided below. Complete the form fully to allow the IRB to process your request quickly. If sections are incomplete, the form will be retuned for completion.
2. Complete the form fully to ensure the IRB(s) to process your request as quickly as possible. If sections are incomplete, the form will be returned for completion.
3. ***Please note that all IIAs require the Signatory Officials’ signature and this can take up to or more than a month to complete. If you need the IAA 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 you have questions about the multi-site IRB process or the Request Form, contact the IRB Office at irbadmin@campbell.edu.

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| 1. **Basic Study Information**
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| Study Title: ***Click or tap here to enter text.*** |
| PI of entire project: Click or tap here to enter text.CU Investigator: Click or tap here to enter text. |
| Funding:[ ]  No funding[ ]  Funding is being sought at this time and the funding source is: Click or tap here to enter text. Awardee Institution or primary wardee on grant application: Click or tap here to enter text.[ ]  There is existing funding and the funding source is: Click or tap here to enter text.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.  |
| Funds will leave CU through: [ ]  direct award/contract [ ]  sub-contract [ ]  service agreement  [ ]  Not funded |

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

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

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| 1. **Project Sites, Personnel, Activities (indicate which institution/site will be involved in the study for each activity)**
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| 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/biospecimens 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 | [ ]  | [ ]  | [ ]  | [ ]  |

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| 1. **Responsible investigator and key personnel**
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| 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.) |
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| 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).**
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| 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.  |
| 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:

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| Name of individual | Institution/Site |
| Click or tap here to enter text. | Click or tap here to enter text. |
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| 1. **Conflict of Interest Disclosure**
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| 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 |

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| 1. **Project Team Point of Contact Information**
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| 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. |

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| 1. **External Site Information**
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| Name of collaborate/external research institution: Click or tap here to enter text. |
| Name of 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. |
| Recruitment procedures will be conducted at external site as outline in the *Research Plan*, if applicable:Will external site researchers review medical records prior to consent to determine eligibility? [ ]  Yes [ ]  No If yes, specify source of records? Click or tap here to enter text.  |
| Consent process will be conducted at external site as outline in the protocol? [ ]  Yes [ ]  NoIf not included in the *Research Plan* or if different than in the *Research Plan*, explain the process for the external site: Click or tap here to enter text.  |

**Submit this entire form along with the *Research Plan*\*, to** **irbadmin@campbell.edu****.**