Instructions:

* Prior to the initiation of any human research activity, investigators are required to submit and the IRB is required to review Human Research for which Campbell University is engaged.
* The term “*Human Research*” is defined below for you to consider in Section 1.0.
* In addition, Section 2.0 below contains some examples of activities that are generally considered not to be Human Research.
* If, after reading through Sections 1.0 and 2.0, you are not certain whether your activity is Human Research OR you would like for the IRB office to review your protocol (Section 3.0 below) and evaluate your research and provide documentation of that the IRB agrees your project is not human research, complete the information in Section 3.0.

NOTE: the IRB can only make this determination **prior** to the beginning of the research activity. The IRB will not make a determination after the activity has already begun. The IRB Office uses the “Human Research Determination Worksheet” to make its Human Research determinations. Please consult the worksheet as a guide for the information you provide in Section 3.0, if you choose to submit to the IRB.

* After completing Section 3.0, submit using the [**New Protocol Electronic Application**](https://cphsadmin.wufoo.com/forms/zkthc20k1gury/) link located on the IRB website and upload this document in lieu of an **Initial Protocol Submission Form**.
* If while reviewing this determination form, you discover that an activity is Human Research, please submit your protocol as described on the IRB website.
* If you need assistance please contact the IRB office at 910-893-7780 or irbadmin@campbell.edu.

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| Section 1: Definitions |
| *Review the following definitions to determine whether your activity is Human Research. Note that* ***publication is not a determining factor*** *for whether an activity is Human Research requiring review and approval by the IRB.* |
| **1.1 “Human Research”** (according to DHHS): The definition includes two components:* “Research”: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
* “Human Subject”: A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through Intervention or Interaction with the individual, or (2) or identifiable private information. For the purpose of this definition:
	+ - Intervention: Physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
		- Interaction: Communication or interpersonal contact between investigator and subject.
		- Private Information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).
		- Identifiable Private Information: Private Information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

If your activity does not meet both of these components, then it is not Human Research according to DHHS. Please see below for the FDA definition. |
| **1.2 “Human Research”** (according to FDA) The definition includes two components:* **“Research”**: Any experiment that involves a test article and one or more Human Subjects, and that meets any one of the following:
	+ Must meet the requirements for prior submission to the US Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;
	+ Must meet the requirements for prior submission to the US Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR
	+ Any activity the results of which are intended to be later submitted to, or held for inspection by, the US Food and Drug Administration as part of an application for a research or marketing permit.
* **“Human Subject”:** An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

If your activity is **not research** or is **research that does not involve human subjects**, then it is not Human Research according to FDA. |
| **If your activity does not meet either DHHS or FDA definitions for “Human Research”, then you do not need to submit anything to the IRB Office for review. Consult “Human Research Determination Worksheet” for further clarification if needed.** |
| Section 2: Examples of activities that are generally considered not to be Human Research |
| The following are examples of activities that are generally considered not to be Human Research according to the definitions in Section 1.0. If your activity is limited to one of the examples below, then it is likely not Human Research which would need to be reviewed by the IRB. Note that **publication is not a determining factor** for whether an activity is Human Research. |
| **2.1 Program Evaluation/Quality Assurance Review/Quality Improvement Project**: The activity is limited to program evaluation, quality assurance, or quality improvement activities designed specifically to evaluate, assure, or improve performance within a department, classroom, or hospital setting.Note: The purpose of a QA study is to assure known quality. The purpose of Program Evaluation (PE) is to assess that a program is doing what it is intended to do. Generally, QI is designed for the purpose of improving the quality of a service, a program, a process, etc. A QA, QI or PE study should present NO CHANGE in RISK to participants. These studies are mechanisms to assure that a service, a program or process functions optimally. Such projects are usually for internal auditing purposes only.If you can answer "yes" to all of the following questions, the activity is most likely not human research: 1. Will you simply monitor an existing process for which there will be no manipulation of the existing process?
2. For biomedical or Social Behavioral QA or PE studies, will physicians or caregivers (parents, teachers, therapists, etc.) provide usual and customary care regardless of the conduct of the study?
3. Does the study involve collection of data to which the investigator routinely has access as part of his or her responsibilities within the institution to monitor data associated with, for example: treatment, cost containment, performance, or compliance?

Note that an evaluation, assurance review, or improvement project designed specifically for a particular setting may yield useful information for similar entities, and may still not meet one of the definitions for Human Research in Section 1.0. |
| **2.2 Case Report:** The project consists of a case report or series which describes an interesting treatment, presentation, or outcome. A critical component is that nothing was done to the patient(s) with prior “research” intent.Note that HIPAA or other state or local laws may still apply to this activity. Please consult the entity from which you received or accessed the information contained in the report for further guidance. |
| **2.3 Course-Related Activity:** The project is limited to one or more course-related activities designed specifically for educational or teaching purposes where data are collected from and about students as part of routine class exercises or assignments and otherwise do not meet either of the definitions of Human Research in Section 1.0.Note that some course-related activities, even those conducted by students, may yield information suggesting additional investigation or analysis. If an additional activity entails Human Research, then it must be submitted to the IRB Office for review. |
| **2.4 Journalistic or Documentary Activity (including Oral History):** The activity is limited to investigations or interviews (structured or open-ended) that focus on specific events (current or historical), views, etc. Such investigations or interviews may be reported or published in any medium, e.g, print newspaper, documentary video, online magazine. |
| **2.5 Research Using Public or Non-Identifiable Private Information about Living Individuals:** The activity is limited to analyzing data about living individuals (1) where the data have been retrieved by the investigator from public, non-restricted data sets or (2) where the private data have been provided to the investigator without any accompanying information by which the investigator could identify the individuals.Note that “de-identified data” according to HIPAA may be identifiable according to the DHHS definition of “Human Subjects” above. Please consult “Human Research Determination Worksheet” for clarification and contact the IRB Office with any questions regarding research with data. |
| **2.6 Research Using Health Information from Deceased Individuals:** This activity is limited to analyzing data (identifiable or not) about deceased individuals.Note that deceased individuals cannot be Human Subjects according to DHHS, but they may be Human Subjects according to FDA. Please review the definitions above for clarification. Note also that HIPAA or other state or local laws may still apply to this activity. Please consult the entity from which you received or accessed the information contained in the report for further guidance. |
| **2.7 Instrument/Questionnaire Development:** This activity is limited to interacting with individuals in order to obtain feedback on the types of questions which could or should be used to develop an instrument or questionnaire. The focus is on the development and construction of a data collection tool and not on the individuals who are providing the feedback on the questions being developed. This will be true even when the feedback may be specifically sought from an identified group of people most likely to be affected by the topic of the instrument, survey or questionnaire. The instrument/questionnaire development process will apply to many aspects of reliability and validity testing of the instrument or questionnaire. Note that once the process gets to the level of testing discriminant, concurrent or predictive validity, the activity may need to be reclassified as human subject research.Note: If the participant is asked to provide additional information unrelated to instrument/questionnaire construction, such as demographic information, that will be analyzed as part of a research study, the project may need to be submitted to the IRB for review. |
| If, after reviewing the information above, (1) you are unclear as to whether your activity is Human Research and would like for the IRB Office to make a determination for you or (2) you believe that your activity is not Human Research but would like for the IRB Office to provide documentation that it agrees with your assessment, then please complete the information in Section 3.0. |

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| Section 3: Description of Activity |

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| **3.1. 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 |
| Faculty Advisor: | Name | Faculty Advisor Department: | Department |
| Faculty Advisor CU Email: | Email address | Faculty Advisor Telephone: | Number |
| **3.2 Purpose** |
| Click or tap to describe the purpose, specific aims or objectives of the project.  |

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| **3.3 Procedures** |
| Click or tap to describe the procedures used to obtain information from the individuals with whom you will interact or intervene for this activity, including communication or interpersonal contact with individuals and physical procedures, if any. |

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| **3.4 Data and/or specimens:***Describe the data and/or specimens that you will gather about individuals, including names of datasets you will access and links to data sources.* |
| **Data and/or Specimen Collection and Analysis**  |
| Click or tap here to enter text.  |
| **Data and/or Specimen Collection Method** |
| Click or tap here to enter text.  |
| * **Level of Identity of Data or Specimens** *(Indicate the level of “subject identification” required to being this work)*

[ ]  **Identified Data:** Utilizes one or more identifiers, including those defined by HIPAA Privacy Rule and FERPA but not using a “limited data set”.[ ]  **Coded data, Key held by project team:** Data is coded; **and** key code held by any person at CU whether or not they are part of the project team.[ ]  **Coded data, Key not held by project team:** Data is coded; key code not held by any CU faculty member, employee, fellow, resident, or student; key code not held by any member of the project team; **and** they key code will never be accessible to any member of the project team.[ ]  **Limited data set:** The only HIPAA identifiers utilized are dates or certain allowable geographic subdivisions; an IRB “limited data set” data use agreement has been executed by the PI; and is uploaded into the application.[ ]  **De-Identification Process:** The application describes how the project team will de-identify data in one of two approvable methods: 1) reliance on a CU-sanctioned “honest broker” or 2) receiving coded data/specimens without identifiers and without a key code. To use these options, no code keys may be created or saved and the resulting dataset can never be re-identified. In addition, a complete list of project variables, e.g., data recording sheet, must be included.[ ]  **Anonymized:** The investigator receives data in anonymized form and no other party has the potential to re-identify data (i.e., no code key exists anywhere in the world). In this case, the IRB application must include a detailed description of how the data was collected, e.g., anonymous surveys, or who provided the anonymized data or biospecimens, so the IRB can verify the source and the irreversibility of anonymization. In addition, a complete list of variables, e.g., data recording sheet, Case Report Form, anything that summarized all the information that will be recorded, must be included. |