**Purpose:** The of this worksheet is to help you determine whether or not you project constitutes research involving human subjects, according to regulatory definition of these terms.

Special Considerations:

* If you study involves human biological or genetic material, or repositories, please contact the IRB Office for specific instructions (the information provided in this worksheet may not apply to your research).
* In general, activities undertaken for the fulfillment of a single course requirement and not the development of or contribution to generalizable knowledge (e.g., public presentation or publication) do not require IRB review. Please check the [Campbell IRB website](https://www.campbell.edu/about/leadership/provost/institutional-review-board/) for further information regarding undergraduate classroom human subjects research projects for more information.

**Instructions:** Complete this worksheet to determine whether or not your research is human subjects research and therefore requires review and approval by the IRB.

If your answers reveal that your project is human subjects research, you must complete and submit a New Protocol Submission Form to the IRB Office for review prior to commencing any research activities involving interaction with human subjects.

If your answers reveal that your project is not human subjects research, you must submit a Not Human Subjects Research (NHSR) Submission Form to the IRB Office for determination prior to commencing any research activities. The IRB Office will provide you with a formal letter documenting that your project is not human subjects research.

If you need assistance please contact the IRB office at 910-893-7780 or irbadmin@campbell.edu.

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| Section 1: Determination of Research. (45 CFR 46.102) |
| * Human subjects research regulations apply only to activities that meet the federal definition of ***research***.
* ***Research*** is a “systematic investigation”, including research development, testing and evaluation, designed to develop or contribute to “generalizable knowledge”. Answer questions 1 and 2 below to determine whether or not your project meets this definition of research.
 |
| 1. **Is the project a systematic investigation? Systematic means having or involving a system, method or plan**
 |
| * Examples of projects that are systematic include, but are not limited to, those which:
* Gather information for the purpose of hypothesis building or testing.
* Ask individuals the same sets of questions or obtain the same kind of information from them.
* Apply the same measures in gathering the data – whether through interaction, observation or experiment.
* Utilize data collection methods that can be replicated.
 |
| [ ]  Yes [ ]  No |
| 1. **Is the project designed to contribute to generalizable knowledge?**
 |
| * Your project contributes to generalizable knowledge if you intend for finding from it to be applicable to a larger population, or otherwise make the findings of it available for the development of knowledge beyond the scope of the project.
* If the project activities involving people are conducted solely for the purpose of fulling a course requirement, they are not generally considered research because they are not designed to contribute to general knowledge. However, activities involving people that are conducted in conjunction with the requirements of a thesis or dissertation is by definition to make a contribution to general knowledge.
 |
| [ ]  Yes [ ]  No |
| * The following activities are deemed not to be research:
* Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship) including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
* Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.
* Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
* Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
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| * If you answered “No” to ***either*** question 1 ***or*** 2, STOP. Your project is not considered research.
* If you answered “Yes” to questions 1 ***and*** 2, continue to Section 2.
 |
| Section 2: Determination of Human Subjects. (45 CFR 46.102) |
| * Human subjects protection regulations apply only to research involving ***human subjects***.
* ***Human subject*** is a living individual about whom an investigator (whether professional or student) conducting research:
1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
2. Obtains, uses, studies, analyzes, or generates identifiable private information identifiable biospecimens.
* Answer the questions below to determine if you research involves human subjects.
 |
| 1. **Does the research involve obtaining information about and/or biospecimens from living individuals?**
 |
| * Information about and/or biospecimens from an individual includes, but is not limited to the following:
* Ideas, attitudes, opinions, feelings, experiences, thoughts, beliefs, assessments, reflections, etc., reported by an individual, even when the individual provides the information while working in a professional capacity.
* Information about living individuals that was gathered by another researcher or source.
* Information about living individuals gathered through the use, analysis or harvesting of cell lines, tissue, or the products of labor and delivery.
* Samples of material, such as urine, blood, tissue, cells, DNA, RNA, and protein.
 |
| [ ]  Yes [ ]  No |
| 1. **Does the research involve obtaining information and/or biospecimens through intervention or interaction with individuals and uses, studies, or analyzes the information and/or biospecimens?**
 |
| * ***Intervention*** includes:
* Both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
* E.g., drawing blood from subjects, timing subjects running laps, recording brain activity during sleep, etc.
* ***Interaction*** include:
* Communication or interpersonal contact between investigator and subject.
* E.g., A street interview, an online survey, recording posts on a blog or listserv, a mailed questionnaire, etc.
 |
| [ ]  Yes [ ]  No |
| 1. **Will you obtain, use, study, analyze, or generate *identifiable private information* and/or *identifiable biospecimens* from individuals?**
 |
| * Private information includes:
* Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place.
* Information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., medical records, emails, certain listserv communications, student records (grades, class papers, etc.), etc.
* ***Identifiable private information*** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
* Biospecimens include;
* Samples or specimens of material, such as urine, blood, tissue, cells, DNA, RNA, and protein.
* ***Identifiable biospecimen*** is a biospecimen for which the identity of the subject is or may be readily ascertained by the investigator or associated with the biospecimen.
 |
| [ ]  Yes [ ]  No |
| * If you answered “No” to questions 4 and 5, STOP, your project is considered Not Human Subjects Research. You should complete and submit an NHSR Submission Form to the IRB Office.
* If you answered “Yes” to either question 4 or 5, your project does involve human subjects and you must complete and submit a New Protocol Submission Form to the IRB Office.
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