**RAP Worksheet  
Human Subjects Research Determination**

|  |
| --- |
| **Purpose:** The purpose of this worksheet is to help you determine and record whether or not your project constitutes research involving human subjects, according to regulatory definitions of these terms.  Special Considerations:   * If your study involves human biological or genetic material, or repositories, please contact Research Compliance Services (RCS) 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. |

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

* If your answers reveal that your project **is** human subjects research, you must complete and submit a New Study activity through the Research Administration Portal (RAP) for review and approval prior to commencing any interaction with human subjects.
* If your answers reveal that your project is not human subjects research, you do not need to submit an application, but you should keep this worksheet with your records.
* If you are unsure of your self-determination or if you would like a formal letter from RCS documenting the determination, complete the supplemental information requested on the last page of this form. Upload your completed form to the Basic Study Info page of the submission activity in the IRB Module of the RAP. Upload all applicable research materials as prompted throughout this application and within the electronic application pages in the RAP.

**General information for investigator’s reference (optional):**

|  |  |  |  |
| --- | --- | --- | --- |
| Principal  Investigator (PI): |  | Faculty Advisor: |  |
| Study Title: |  | | |

|  |  |
| --- | --- |
| 1. Determination of Research. ([45 CFR 46.102](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#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 study a systematic investigation? Systematic means having or involving a system, method, or plan. | |
| * Examples of studies 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 | **Explain your answer in the textbox below:** |
|  | |
| 1. Is the study designed to contribute to generalizable knowledge? | |
| * Your study contributes to generalizable knowledge if you intend for findings 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 study. * If the study activities involving people are conducted solely for the purpose of fulfilling a course requirement, they are not 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 generally are research because the purpose of the thesis or dissertation is by definition to make a contribution to general knowledge. | |
| Yes  No | **Explain your answer in the textbox below:** |
|  | |
| * 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. | |
| * If you answered “No” to ***either*** question 1 ***or*** 2, STOP - you do not need to complete the rest of this form. Your study is not considered research. * If you answered “Yes” to questions 1 ***and*** 2, continue to Part II. | |

|  |  |  |
| --- | --- | --- |
| 1. Determination of Human Subjects. ([45 CFR 46.102](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102)) | | |
| * Human subjects protection regulations apply only toresearch 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 or identifiable biospecimens.”  * Answer the questions below to determine if your research involves human subjects. | | |
| 1. Does the research involve obtaining information about or biospecimens from living individuals? | | |
| * Information about 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 | | **Explain your answer in the textbox below:** |
|  | | |
| * If you answered “No” to question 3, STOP - you do not need to complete the rest of this form. Your project is not considered research involving human subjects. * If you answered “Yes,” continue to questions 4 ***and*** 5 below. | | |
| 1. Does the research involve obtaining information 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. * ***Interactions*** 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 | | **Explain your answer in the textbox below:** |
|  | | |
| 1. Will you obtain, use, study, analyze, or generate identifiable *private information* 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., a medical record, emails, certain listserv communications, class papers and exams, 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 | | **Explain your answer in the textbox below:** |
|  | | |
| * If you answered “No” to questions 4 ***and*** 5, STOP - you do not need to complete the rest of this form. * If you answered “Yes” to ***either*** question 4 ***or*** 5, your project **does** involve human subjects and you must complete an IRB application (available on the RCS website). | | |

|  |
| --- |
| 1. What’s Next? |
| * If your answers indicate that your project does involve human subjects research, you must complete and submit an application for review to RCS. An exempt determination or IRB approval is required before any research activities – including recruitment – with human subjects may begin. Complete and submit an application according to instructions provided on the [website](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/application-research-human-subjects). * If your answers reveal that your project is not human subjects research, keep a copy of this worksheet with your records. * If you would like a formal letter from RCS documenting that your project is not human subjects research, please provide the supplemental information requested on the next page and submit it with your answers above to RCS. * If you are not sure if your project is human subjects research or if you have any questions, contact RCS at 541-346-2510 or [ResearchCompliance@uoregon.edu](mailto:ResearchCompliance@uoregon.edu). |

**Instructions:**

If you have completed the above worksheet and have self-determined that your project does not involve human subjects research and you need formal documentation of this determination, complete the following and submit to RCS via the RAP.

If your answers above indicate that your project involves human subjects, please fill out an [application](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/application-research-human-subjects) for review.

|  |  |
| --- | --- |
| 1. Briefly describe the project, and what you expect to do with your findings: | |
|  | |
| 1. Briefly describe the study population or subject of the research: | |
|  | |
| 1. Briefly describe the data collection methods to be used: | |
|  | |
| 1. Is this project funded or sponsored from an internal UO or external source? | |
| Yes  No | If “yes," complete and attach the [Funding and Sponsorship Form](https://research.uoregon.edu/sites/research2.uoregon.edu/files/2020-12/rap_form_-_funding_and_sponsorship.docx). |