

Case Western Reserve University

Worksheet for Determining Whether a Proposed Activity Meets the Definition of Human Research

To determine whether your proposed activity meets the definition of human research (and therefore **may** need to be reviewed by Case IRBs or an IRB at one of Case's affiliated hospitals), please answer the following questions.

1. Is the proposed activity a systematic investigation? Yes No

A systematic investigation is one that involves a predetermined method for studying a specific topic, answering a specific question(s), testing a specific hypothesis(es), or developing theory.

Examples of systematic investigations include, but are not limited to, observational studies, interview (including those that are open-ended) or survey studies, group comparison studies, test development, program evaluation, interventional research.

Examples of activities that would **not** normally be considered systematic investigations include, but are not limited to, training activities (e.g., human subjects being trained to perform a certain technique or therapy such as art therapy, psychoanalysis, oral history techniques), classroom exercises involving human subjects or human subject data where the objective of the activity is to teach proficiency in performing certain tasks or using specific tools or methods.

2. Will the proposed activity develop or contribute to generalizable knowledge? Yes No

To develop or contribute to generalizable knowledge requires that the results (or conclusions) of the activity are intended to be extended beyond a single individual or an internal program.

Examples of activities that are typically not generalizable include biographies and service or course evaluations, unless they can be generalized to other individuals, services, courses or concepts **and there is an intention to do so**. In addition, classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices would also not typically be considered generalizable.

Activities involving human subjects or human subjects data where there is an intention to publish the results in a peer-reviewed journal or to present at a regional or national meeting are generally assumed to be generalizable. In addition, theses or dissertation projects conducted to meet the requirements of a graduate degree are usually considered generalizable.

3. Will the proposed activity involve collecting data through an interaction or intervention with a living individual? Yes No

Examples of such interactions or interventions include interviews, questionnaires, surveys, observations, manipulation of subject behavior or environment, physical measurements, specimen collection (e.g., blood, tissue), administration of experimental drugs or devices. Please note that the activity must involve a **living individual**.

4. Will the proposed activity involve collecting private identifiable information about a living individual? Yes No

Private identifiable information includes **individually identifiable** information from a **living individual**:

- a) about behavior when the individual can reasonably expect that no observation or recording is taking place;
- b) or information that has been provided for specific purposes that the individual can reasonably expect will not be made public (e.g., medical record, employee or student records)

Examples of individual identifiers include the subject's name, address, phone number, social security number, medical record number, student or employee identification number, or, in some cases, the combination of data such that they can identify a single individual through deductive reasoning. For example, data about employer, job title, age and gender may not individually identify a subject, but, when combined, could in certain cases identify a specific individual.

If the information can not be linked to a living individual, or is considered public or is given with the expectation that it will be made public and that it will be linked to the individual (e.g., biography, news story), then it would not be considered private identifiable information.

5. Will the proposed activity involve the use of a drug on one or more human participants, other than the use of a marketed drug in the course of medical practice? Yes No

A **drug** is defined as an article (or a component of an article) intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals or, other than food, intended to affect the structure or any function of the body of humans or other animals or recognized in the official U.S. Pharmacopoeia, official U.S. Homoeopathic Pharmacopoeia or official National Formulary (or their supplements).

6. Will the proposed activity involve the use of a medical device on one or more human participants, other than the use of a marketed medical device in the course of medical practice,? Yes No

A **medical device** is one that is 1) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease in humans or other animals or, 2) intended to affect the structure or any function of the body of humans or other animals and which does achieve any of its primary intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes, or 3) recognized in the official U.S. Pharmacopoeia or official National Formulary (or their supplements).

7. Will the proposed activity involve the use of a medical device on human specimens, other than the use of a marketed medical device in the course of medical practice, where the activity is being done to determine the safety or effectiveness of the device and data from the activity will be submitted to, or held for inspection by, the FDA? Yes No

8. Will the proposed activity involve the use of one or more of the following FDA-regulated articles on one or more human participants and produce data that will be submitted to, or held for inspection by, the FDA? Yes No

- Food or dietary supplement that bears a nutrient content or health claim
- Food or color additive for human consumption
- Infant formula
- Biologic product for human use
- Electronic product for human use
- Other article subject to the Food, Drug and Cosmetic Act

Use of this worksheet:

If you have checked “yes” to any of the questions above, please review the information below to determine if your activity is considered **Human Research**. If your activity is **Human Research**, you will need to contact an IRB office to determine the next level of review required.

Your activity is **Human Research** if:

- Question 1 and Question 2 are both checked “yes” and either Question 3 is checked “yes” or Question 4 is checked “yes”

Your activity is **Human Research** if:

- Question 5 is checked “yes”, or
- Question 6 is checked “yes”, or
- Question 7 is checked “yes”, or
- Question 8 is checked “yes”

Application of Worksheet to Selected Activities

1. Biography of Winston Churchill

This activity is not human research, since the individual is no longer alive. [It may also not meet the definition of human research since the results of the activity are not intended to be generalizable beyond Winston Churchill].

2. Biography of Bill Clinton

This activity is not human research, since the results of the activity are not intended to be generalizable beyond Bill Clinton.

3. Study of the impact of the Great Depression on the lives of African Americans by interviewing a sample of African Americans in Cuyahoga County using an open-ended interview methodology

This is human research, since it is a systematic investigation that intends to produce generalizable results and identifiable data will be collected from living individuals.

4. Study of the population trends and the economic viability of major American cities using 1990 and 2000 census data without any unique subject identifiers.

This is not human research since no individually identifiable information is being used.

5. The development of a training videotape showing how to conduct a structured interview to assess mood disorders

This is not human research, since it is not a systematic investigation.

6. Study of the media preferences and communication styles of normal adults using a mailed questionnaire

This is human research since it is a systematic investigation to yield generalizable knowledge by interacting with living individuals

7. Study of communication styles of politicians by analyzing content and delivery of videotaped public speeches of regional and national politicians.

This is not human research, since it does not use private identifiable information. The data is derived from public speeches.

8. A study to evaluate the effectiveness of the delivery of social services to home-bound senior citizens by analyzing data collected by the Ohio Department of Health and Human Services and conducting telephone interviews with a sample of senior citizens.

This is human research since it is a systematic investigation that is generalizable and interactions with living individuals are planned. In addition, the ODHHS data may also contain subject identifiers.

9. A study of the lives of early Amish settlers in Pennsylvania and Ohio by analyzing diaries, letters, and other written communications.

This is not human research since it does not involve living individuals.

10. A study of consumer behaviors while shopping on-line for fashion apparel, and a comparison of satisfaction with the consumption experience of apparel between products purchased on-line and at retail stores.

This is human research since it is a systematic investigation that is intended to yield generalizable knowledge and it involves collecting data through interactions with living individuals.

11. A study of whether a particular protein is a biological risk factor for breast cancer by examining tissue discarded from breast biopsies where the identity of the person from whom the biopsy is taken is unknown. However, whether the individual did or did not have breast cancer is known.

This is human research since it is a systematic investigation that is intended to yield generalizable knowledge and it involves collecting data through an interaction with a living individual.