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| **Overview** |

At first glance the definition of human subjects research seems clear and simple. Yet determining what is human subjects research and what is not can become a confusing task. This document is provided to guide investigators about prospective research activities.

The Purdue Institutional Review Board (IRB) has final authority in determining if an activity is human subjects research requiring IRB review or exemption. A determination of IRB Review Not Required does not absolve individuals conducting the activity of any other ethical or legal responsibilities and obligations that may apply. The following criteria are to be utilized for guidance and does not substitute for a determination from the Purdue Human Research Protection Program (HRPP) and/or IRB.

To accurately utilize this guidance, researchers should consider their proposed activity in relationship to all definitions provided. Please review each section carefully.

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| **Research as defined by the Common Rule**  |

Research is defined as a “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

A **systematic** **investigation** **designed** to develop or contribute to **generalizable knowledge**.

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| **Term** | **Definition as applied to Human Subjects Research** |
| *Systematic* | *Having or involving a prospectively identified approach to the investigation, based on a system, methods, or plan.* |
| *Investigation* | *A searching inquiry for facts, or detailed or careful examination.* |
| *Designed* | *The activity has a predetermined purpose and/or intent.* |
| *Generalizable* | *The data and/or conclusions are intended to apply more broadly beyond the individuals studied, or beyond a specific time and/or location, such as to other settings or circumstances.* |
| *Knowledge* | *facts, information, truths.* |

**If these criteria all apply, the activity is Research.**

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| **Does the proposed activity involve Human Subjects? (Part One)**  |

Researchers **obtaining** data **about** **living** individuals through **intervention** or **interaction** are conducting Human Subjects Research.

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| **Term** | **Definition as applied to Human Subjects Research** |
| *Obtain* | *Record in any fashion (writing, video, email, voice recording, etc.) for research purposes and retain for any length of time.* |
| *About* | *The data relates to the person. Asking individuals what they think about something (asking for an opinion) is almost always about the person. Asking for factual information, or other questions where the answers are expected to be independent of the person being asked, are generally not about the individual.* |
| *Living* | *Individuals who are alive according to applicable local and national definitions. With respect to specimens, data, and other information gathered without direct interaction with the individual: it is assumed that the individuals are living unless there is a reason to think otherwise.* |
| *Interaction* | *Communication or interpersonal contact between a member of the research team and the individual. Surveys – whether in-person, web-based, mail, email, computer/tablet-based, phone, etc. – are an interaction between researchers and individuals. Observing individuals for research purposes is also considered an interaction.* |
| *Intervention* | *Physical procedures, or manipulations of the individuals or the individual’s environment, that are performed for research purposes. Manipulations may be physical, social, psychological, or emotional. “Environment” includes an individual’s social and virtual environments as well as physical environment.* |

**If the activity meets the criteria in this section, the activity meets the definition of Human Subjects and Research as described, the activity requires review by the Purdue Human Research Protection Program. Please submit an application to the IRB.**

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| **Does the proposed activity involve Human Subjects? (Part Two)** |

Researchers obtaining Identifiable Private Information or Protected Health Information are conducting Research with Human Subjects.

Data obtained about Individuals are considered **private information** if any of the following criteria are met

*1. Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place.*

*2. Information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record, an education record or a residual medical specimen that is “leftover” from a health care procedure.*

*3.* *Any information about individuals that is collected specifically for the proposed research study through and interaction or intervention with the individual by the investigator or other research team member is considered to be private.*

*4. Inclusion of protected health information (PHI) for research purposes without the consent of patients (whether s/he is living or deceased) or the patient’s legally authorized representative.*

 *PHI: If your project uses data/specimens obtained from, or held by, a health care provider (including physicians, counselors, medical centers, clinics, hospitals, etc.), health care database, health clearinghouse, health plan or health care related records held by an employer, your project may be subject to the Health Information Portability and Accountability Act (HIPAA).*

**If the activity meets the criteria in this section, the activity involves Human Subjects and requires review by the Purdue Human Research Protection Program.**

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| **Do Food and Drug Administration (FDA) Regulations Apply to the project?** |

The activity meets the FDA’s definition of research if it includes a **drug**, **device**, or **test article**.

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| **Term** | **Definition as applied to Human Subjects Research (FDA)** |
| *Drug* | *Any chemical compound that may be used on or administered to humans as an aid in the diagnoses, treatment, cure, mitigation, or prevention of disease or other abnormal conditions.* |
| *Device* | *A diagnostic or therapeutic article that does not achieve any of its principal intended purpose through chemical action within or on the body.* |
| *Test Article* | *Any drug, biological product, medical device, food additive, color additive, electronic article or any other product, or any other article subject to regulation under the Federal Food Drug and Cosmetic Act, or under sections 351 or 354-360F of the Public Health Service Act.* |

The activity meets the FDA’s definition of human subjects if it involves a living individual who is or becomes a participant in research, either as a recipient and/or whose specimen is used in the research of a test drug, device (including in vitro diagnostics), biologic or as a **control** even if the specimen is **anonymous**.

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| **Term** | **Definition as applied to Human Subjects Research (FDA)** |
| *Control* | *A subject used for comparison who is not given a treatment under the study or who does not have a given disease, condition, background, or risk factor that is the object of study.* |
| *Anonymous* | *Entirely without name or other identifier so the individual can neither be discerned or deduced in any way by anyone. No one can link an individual to his/her data including the investigator.* |

**If the activity meets the criteria in this section, the activity involves Human Subjects and requires review by the Purdue Human Research Protection Program. Please submit an application to the IRB.**

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| **Review by Purdue HRPP/IRB** |

Researchers must initiate review by submitting an application or a request for exemption to the Purdue University HRPP/IRB. Purdue University Researchers are not authorized to conduct research that meets the definition of Human Subjects Research without review and approval or exemption by the Purdue HRPP/IRB.

The Purdue University HRPP/IRB website, [www.irb.purdue.edu](http://www.irb.purdue.edu) consists of the most up-to-date information and is regularly updated to reflect any changes to processes, systems, or regulations. The information provided does not substitute for IRB review or exemption. Investigators are encouraged to contact the Purdue HRPP for guidance.

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| **Activities Not Considered to be Research** |

Beginning July 19, 2018 with revision to the U.S. federal rules that prescribe protections for human participants in research (collectively known as the Common Rule), the definition of “Research” to remove the following activities from IRB review:

1. certain scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship);
2. public health surveillance activities ordered, required, or authorized by a public health authority necessary for assessing or monitoring public health outbreaks;
3. collections/analyses by law or court order solely for criminal justice or criminal investigative purposes for criminal justice or criminal investigative purposes;
4. federal agency-authorized activities in support of specified missions of intelligence, homeland security, defense, or other national security missions.

Researchers planning to undertake such activities are encouraged to discuss potential projects with the HRPP to be certain the project’s scope falls within permissible parameters.