**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 often be a difficult and confusing task. This worksheet**[[1]](#footnote-1)** is provided to assist investigators in making that determination.

**NOTE**: *The 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.*

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**When and How to Use this Form**

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| **When to use this form.**   * Prior to initiating activities subject to this determination outcome. * If you are unsure whether or not you need to submit your activity to the IRB for review. * If you are unsure if your activity is research. * If you are unsure if your research involves human subjects. * **This form cannot be used to request an exemption or IRB approval**. * If you need a **formal documented determination of “IRB Review Not Required”**. Increasingly sponsors (e.g., funding agencies, device and drug manufacturers, etc.), administrators, collaborators, vendors or journal editors want verification from an impartial source that activities do not (or did not) require IRB approval.   **How to use this form.**   * This form must be typed if it will be submitted to the IRB. * Consider and answer each question in the order presented. * The term “**data**” for the purpose of this worksheet refers to information of any type (e.g., records, data sets, recordings, photos, scans, etc.) **including** specimens. * To obtain a **formal determination of “IRB Review Not Required”** in writing, please submit this completed and signed form to the HRPP office either via hardcopy or electronically as an email attachment to [irb@purdue.edu](mailto:irb@purdue.edu). * **Please contact us if you have any questions**. Reach us by phone 765-494-5942, by email [irb@purdue.edu](mailto:irb@purdue.edu) or in person during our walk-in hours: Mondays and Thursdays 9:30am - 11:30am; Tuesdays 2pm - 4pm.   **Submit this form ONLY if the project DOES NOT require IRB review.** For information about which review type or application form to use, please refer to our [guidance](https://www.irb.purdue.edu/approval.php). |
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**Contact Information** (*Complete this section only if submitting to the IRB*)

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|  | **Contact Person Name and Title** | **Campus** | **Department** | **Phone** | **Email** |
| Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
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**Activity/Project Information** (*Complete this section only if submitting to the IRB*)

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|  | **Activity/Project Title** | |
| Click here to enter text. | |
| **Funding Source** (select all that apply) | **If Sponsor-External, Identify Sponsor Below:** |
| Choose an item. | Click here to enter text. |
| **Purpose of Activity/Project and Intended Use of Its Results** (Describe in lay terms, 3-5 sentences) | |
| Click here to enter text. | |
| **Description of Activity/Project** (Provide a brief description of your project) | |
| Click here to enter text. | |
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1. **Is my activity Research as defined by the Common Rule? (DHHS - 45 CFR 46)**

***Check all that apply***

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|  |  | The activity is an **investigation**.  *Investigation: A searching inquiry for facts, or detailed or careful examination.* |
|  | The investigation is **systematic**.  *Systematic: Having or involving a prospectively identified approach to the investigation, based on a system, methods, or plan.* |
|  | The systematic investigation is **designed** to **develop** or **contribute** to **knowledge**.  *Designed: The activity has a predetermined purpose and/or intent.*  *Develop: To form the basis for a future contribution.*  *Contribute: to result in.*  *Knowledge: facts, information, truths.* |
|  | The knowledge the systematic investigation is designed to develop or contribute is **generalizable**.  *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.* |
| **Conclusion:**  If **ALL** boxes are checked: the activity is Research. Proceed to **Section 2**.  If **ALL** boxes are **NOT** checked: proceed to **Section 5** to determine whether the activity is subject to the Food and Drug Administration (FDA) regulations. | |
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1. **Does it involve Human Subjects as defined by the Common Rule: Part 1? (DHHS - 45 CFR 46)**

***Check all that apply***

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|  |  | A. The data include **protected health information (PHI)** that will be used 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).* |
|  | B. The data are **about** individuals, and the individuals are **living**.  *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 regulations. 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.*  ***Examples:***   * *A survey of elementary school teachers that asks them their opinions about the class curriculum would generally be considered to be* ***about*** *the teachers and therefore involves human subjects.* * *A survey of elementary school teachers that asks them factual questions about class size, classroom features, and availability of classroom materials would generally* ***not*** *be considered to be* ***about*** *the teachers and would therefore not involve human subjects.* * *A researcher is developing a new user interface for a computer program. His research uses the “think aloud” method whereby he asks college students to verbally express their thought processes as they use the interface. Though the object of his interest is the interface, not the students, he is nonetheless collecting data* ***about*** *the students and they are human subjects.* * *Suppose you ask individuals, “How does your school respond to confidentiality breaches?” If you are seeking information about the school and are asking people who should know the answer, then the question is* ***not about*** *the person being asked and s/he is not a human subject. If you are seeking how often employees know the correct answer, then the question is* ***about*** *the person and s/he is a human subject.* |
| **Conclusion:**  If **ONLY** box A is checked; your study must be submitted to the IRB. Proceed to **Section 5** to determine whether the activity is also subject FDA regulations.  If **ONLY** box B is checked: proceed to **Section 3**.  If **NEITHER** box is checked: human subjects are not involved, as defined by the Common Rule. Proceed to **Section 5** to determine whether the activity is subject to FDA regulations. | |
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1. **Does it involve Human Subjects as defined by the Common Rule: Part 2?**

***Check if “YES”***

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|  |  | The data are obtained through **intervention**.  *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.*  *Obtain:* *Record in any fashion (writing, video, email, voice recording, etc.) for research purposes and retain for* ***any*** *length of time.*  **Note:** Individuals who “screen out” of a study because an intervention or interaction (such as a screening phone call or lab test) reveals that they do not meet the study eligibility criteria are still considered human subjects if they meet all of the criteria outlined in this Worksheet. |
|  | The data are obtained through **interaction**.  *Interaction:* *Communication or interpersonal contact between a member of the research team and the individual. Surveys – whether in-person, web-based, mail, email, phone, etc. – are an interaction between researchers and individuals.*  *Obtain:* *Record in any fashion (writing, video, email, voice recording, etc.) for research purposes and retain for* ***any*** *length of time.*  *This includes so-called “****third party****” or “****secondary subject****” situations in which researchers obtain information about one individual through interaction with another individual.*  ***Example:*** *A researcher is studying married couples where one spouse is the primary caregiver for the other spouse who has Alzheimer’s disease and who is living at home. When the caregiving spouse provides the researcher with individually-identifying private information about the spouse with Alzheimer’s as a required part of the study, then the spouse with Alzheimer’s is a human subject.*  **Note:** Individuals who “screen out” of a study because an intervention or interaction (such as a screening phone call or lab test) reveals that they do not meet the study eligibility criteria are still considered human subjects if they meet all of the criteria outlined in this Worksheet. |
| **Conclusion:**  If **ONE** or **BOTH** boxes are checked: human subjects are involved, as defined by the Common Rule. **DO NOT submit this form to the IRB.** Proceed to **Section 5** to see if the research is subject to FDA regulations. For information about which review type or application form to use, please refer to our [guidance](https://www.irb.purdue.edu/approval.php).  If **NEITHER** box is checked, proceed to **Section 4**. | |
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1. **Does it involve use of a Human Subject as defined by the Common Rule: Part 3?**

***Check if “YES”***

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|  |  | The data obtained about Individuals are **private information**.  *Private information is defined as one or both of the following:*   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.*   *Information: records, specimens, x-rays, photos, scans, recordings and all other types of data.*  *Publicly available data are not considered private.*  *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.*  *If permission is required to obtain/access information, then the information is usually considered private. There are numerous “gray” areas in distinguishing “private” from “non-private”. For example, there are some situations that are best considered “semi-private”. This may include some behaviors, communications, and interactions that occur in electronic or social media. Also, a specific type of information may be considered private for one group of individuals but not for another.* |
|  | The private information is **identifiable**.  *Identifiable: The identity of the individual is or may readily be ascertained or associated with the information by a member of the research team, OR a member of the research team could readily identify the individual through a constellation of the data variables.*  *Research Team: Anyone involved in conducting the research. The act of solely providing coded private information is not considered involvement. However, individuals who provide coded private information are considered involved if they collaborate on other activities related to the research including, but not limited to, (1) study interpretation, or analysis of the data resulting from the coded information; or (2) authorship of presentations or manuscripts related to the research.*  *Obtaining Identifiable private information or specimens includes but is not limited to: using, studying, or analyzing for research purposes identifiable private information of specimens that have been provided to researchers from any source, or that were already in the possession of the researcher.*  ***Examples*** *of some specific circumstances in which the information would not be considered identifiable:*   * *The identifiers or the code key to coded data have been destroyed.* * *The research team has entered into an agreement with the holder of the identifiers or code key that prohibits the release of the identifiers or code key to the research team members.* * *When the data come from a repository or data management center, that repository or center has written policies and procedures that prohibit release of the identifiers and code key to research team members.* * *There are other legal requirements prohibiting the release of identifiers or code key to the research team members.*   ***Note:*** *The definition of “identifiable” is not the same as in the HIPAA regulations about health care records. Information that is considered an “identifier” by HIPAA regulations may not meet the federal human subjects definition of “identifiable”.* |
| **Conclusion:**  If **BOTH** boxes are checked: human subjects are involved, as defined by the Common Rule. **DO NOT submit this form to the IRB.** Proceed to **Section 5** to see if the research is subject to FDA regulations. For information about which review type or application form to use, please refer to our [guidance](https://www.irb.purdue.edu/approval.php).  If **ONE** or **NONE** of the boxes is checked, human subjects are not involved, as defined by the Common Rule. Proceed to **Section 5** to see if the research is subject to FDA regulations. | |
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1. **Is it Human Subjects Research as defined by the Food and Drug Administration?**

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|  |  | A. The activity meets the **FDA’s definition of research** if it includes **any** of the following: | |
|  |  | A **drug** (whether approved or unapproved) administered or dispensed to, or used involving, one or more living persons other than the use of an approved drug in the course of medical practice.  *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.* |
|  |  | A **device** (whether approved or unapproved) used with one or more living persons that evaluates the safety or effectiveness of the device.  *Device: A diagnostic or therapeutic article that does not achieve any of its principal intended purpose through chemical action within or on the body.* |
|  |  | Use of a **test article** regulated by the FDA to obtain data regarding subjects or control subjects that are intended to be eventually submitted to or held for inspection by the FDA.  *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.* |
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|  | B. The activity meets the **FDA’s definition of human subjects** if **one** or **both** of the following are true: | |
|  |  | The activity involves a living individual who is or becomes a participant in research, either as a recipient of a test drug, device (including in vitro diagnostics), biologic or as a **control**. The individual may be either a healthy individual or a patient.  *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.* |
|  |  | An individual on whose specimen an investigational device or control is used in the research, even if the specimen is **anonymous**.  *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.* |
| **Conclusion:**  If **BOTH** boxes A and B are checked: the activity is human subjects research as defined by the FDA.  If **ONLY** box A or box B or **NEITHER** is checked, the activity is not human subjects research as defined by the FDA. | | |
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1. **Why are you seeking this determination?** A request for a determination of IRB Review Not Required/Not Human Subjects Research ***rarely occurs unless there has been a request to obtain IRB approval***. These can come from grant administrators, journals, collaborators, etc. If not such request has been made for your activity, you don’t need to submit this questionnaire to the IRB. ***If you do need to obtain an official determination, please take a moment to tell us about your reasons for seeking this determination***. ***Check all that apply***

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|  |  | Not sure if the activity/project is human subjects research or not/for my files. | | | | | |
|  | I hope to publish in a peer reviewed journal and I would like to know that IRB review is not required prior to beginning the study. | | | | | |
|  | Request from Purdue’s Sponsored Program Services (SPS) or other Purdue unit to release award funds. | | | | | |
|  | IRB Review or determination of IRB Review Not Required is a requirement by one of the following: | | | | | |
|  | Sponsor/Funding Agency  Name the Agency below |  | Collaborator or Collaborating Institution |  | Performance Site |
|  | Click here to enter text. |  | Journal |  | Other: Click here to enter text. |
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|  | **Applicant’s Assessment and Assurance** | | | | |
|  | **Submit this form ONLY if the project DOES NOT require IRB review. Forms without that determination will be returned to the contact person and no further action will be taken.** | | | | |
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|  | I assure that the information provided in this document is complete and accurate and have determined that the proposed activity/project: | | | | |
|  | does not involve “research” | | | |
|  | involves research but no “human subjects” | | | |
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| ***I understand that a determination of IRB Review Not Required does not absolve individuals conducting the activity of any ethical or legal responsibilities and obligations that may apply.*** | | | | |
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|  | Signature |  | Date |  |
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|  | FOR IRB USE ONLY: | | | | |
|  | **Reviewer’s Certification** | | | | |
|  | Based on the information provided in this document, the reviewer identifies the activity/project as: | | | | |
|  | not involving “research” under the Common Rule. | | | |
|  | not involving “human subjects” under the Common Rule. | | | |
|  | involving the use of protected health information (PHI) for research purposes. | | | |
|  | involving human subjects research under the Common Rule. | | | |
|  | being subject to FDA regulations. | | | |
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| NOTES: | | | | |
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|  | Signature |  | Date |  |
|  | Click here to enter text. |  | Click here to enter text. |  |
|  | Print Name |  | Title |  |
|  |  |  |  |  |
| **Conditions:** *This determination is for the described activities only. The determination does not render any opinion about the ethical conduct of the activities. If there is a question about the determination, please call us at 765-494-5942.* | | | | |
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1. We extend our gratitude to the University of Washington Human Subjects Division on whose guidance materials this document is based. [↑](#footnote-ref-1)