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| **Wayne State University Institutional Review Board** | |
| **Subject** | **01-4 Human Participant Research: How is it Defined?** |
| **Form Date** | Rev. March 2015 |
| **Approvals** | Rev. March 2015. Administrative Review 7/2024 |

Please see the **Human Research Participant Determination Tool** available on the IRB website for guidance in determining if a study is considered human participant research. Other resource documents are also available on this topic on the website.

**Is this research? The decision process:**

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| 1 | The first question a principal investigator (PI) must ask is whether or not a “research activity”  is being proposed. Contact the IRB Education Office should assistance be required in making this determination. (Note: An investigator cannot exempt his/her research project from IRB review and concurrence. Instead, the IRBchairperson or his/her designee must determine that a project is eligible for exemption. (See IRB Policy/Procedure “Exempt Procedures”). |
| 2 | The second question is whether or not the “research activity” involves interacting or intervening with living individuals or their identifiable private information (see Part A #3  below). |
| 3 | If the activity involves the FDA, Part B (below) provides the appropriate definition. |
| 4 | If the activity involves the Department of Defense (DoD) or one of its components, the definition of “Experimental Subject” should be used in determining if the research meets the  criteria for human subject research. |
| 5 | When the questions in Part A or Part B (below) can be answered “yes,” a research proposal must be submitted to the IRB for review. |

Criteria for initial IRB review and approval of research protocols are set forth by HHS regulations at 45 CFR

46.111, 38 CFR 18.111, FDA regulations at 21 CFR 56.111, DoD Directive 3216.02, and include:

determining the level of risk to the participant, potential benefits, informed consent process and documentation, and safeguarding the participant’s rights and welfare (i.e., safety monitoring, equitable selection, protection of privacy and confidentiality and special protections for vulnerable populations). Criteria for review, based on the type of protocol being submitted, will also comply with regulations or guidance for a specific federal agency, as appropriate (i.e., ICH-GCP, Department of Defense, the Department of Education, the Department of Energy, the Department of Justice, and the Environmental Protection Agency).

**Definitions**

***Experimental subject*** *(as defined by the Department of Defense)* – “An activity for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction (32CFR.210.102 (f) reference (c). Examples of interventions or interactions include, but are not limited to: a physical procedure, a drug, a manipulation of the subject or subject’s environment, the withholding of an intervention that would have been undertaken if not for the research purpose.”

***Generalizable knowledge*** – Determination as to whether the activity will contribute to “generalizable knowledge” is often based on whether the data will be dissemination by means of publication or presentation. This should not be the sole factor used to make determination. In general, OHRP gives guidance that if the data will be used to draw conclusions related to a larger entity, then the activity is considered “research.”

***Systematic investigation*** – A systematic investigation may include research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

**PART A:**

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| **A.** | The activity is “Human Participant” (subject) research according to the Department of Health and Human Services (DHHS) regulations when either 1 and 2 below are true  Or 1 & 3 below are true. |
| 1. | The activity is a systematic investigation including research development, testing and evaluation and is designed **OR** contributes to generalizable knowledge  **AND** |
| 2. | The data the PI is planning to obtain are about living individuals obtained through any or all of the following means:  o Physical procedures performed on individuals  o Manipulation of individuals  o Manipulation of individuals’ environments  o Communication with individuals, **OR**  o Interpersonal contact with individuals  **OR** |

3. The data is individually identifiable because:

o The identity of the participant is or may readily be ascertained by the PI **OR**

o The identity of the participant is or may readily be associated with the information

**And** the data is private because:

o It is about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place **OR**

o The individual has provided information for specific purposes and can reasonably expect that the information will not be made public (i.e., medical record).

**PART B:**

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| **B.** | An activity is “Human Research” according to the **FDA regulations** when it involves an FDA  regulated test article because one or more of the following are true: |
| 1. | The activity involves the use of a drug other than the use of a marketed drug in the course of medical practice, with “drug” meaning:  o An article recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them;  o An article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;  o An article other than food that is intended to affect the structure or any function of the body of humans or other animals, **AND**  o The drug is either **not approved** by the FDA for marketing, **or** the drug is **not being used in the course of medical practice**.  **OR** |
| 2. | The activity involves the use of a medical device, other than the use of a marketed medical device in the course of medical practice, with “device” meaning:  o The device is recognized in the official National Formulary, the United States  Pharmacopoeia, or any supplement to them;  o The device is 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;  o The device s intended to affect the structure or any function of the body of humans or other animals, and which does not achieve any of its 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;  **AND**  o The medical device is **not approved** by the FDA for marketing **or** the medical device is **not being used in the course of medical practice.**  **OR** |

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| 3. | The activity is otherwise subject to FDA regulations because:  o Data from the activity will be submitted to, or held for inspection by the FDA;  o The activity involves an FDA regulated article of one or more of the following:  Food or dietary supplement that bears a nutrient content or health claim  Food or color additive for human consumption  Infant formula  Biological product for human use Electronic product for human use Other article subject to the FD&C Act  **AND** |
| 4. | The activity involves human participants because one or more of the following are true:  o The test article will be used on one or more humans; **OR**  o The test article is a medical device, used on human specimens, the activity is 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. |

# Examples of activities that are generally considered not to be Human Research

The following are examples of activities that are generally considered not to be Human Research according to the above definitions. If your activity is limited to one of the examples below, then it is likely not Human Research which would need to be reviewed by the IRB. Note that **publication is not a determining factor** for whether an activity is Human Research.

* + **Grant-only Submission:** The submission includes a grant (without an accompanying protocol) for which you would like acknowledgement of receipt and “proof of concept” review by the IRB Office. Examples include Umbrella Grants, Training Grants, Just-In-Time Grants, etc., that themselves do not include all elements required in order to obtain full IRB approval. Please utilize the **Administrative Application form** located on the IRB website.
  + **Program Evaluation/Quality Assurance Review/Quality Improvement Project**: The activity is limited to program evaluation, quality assurance, or quality improvement activities designed specifically to evaluate, assure, or improve performance within a department, classroom, or hospital setting.  
    Note that an evaluation, assurance review, or improvement project designed specifically for a particular setting may yield useful information for similar entities, but may still not meet one of the definitions for Human Research.
  + **Case Report**: The project consists of a case report or series (up to 3 cases) which describes an interesting treatment, presentation, or outcome. A critical component is that nothing was done to the patient(s) with prior “research” intent.
  + **Classroom-Related Activity**: The project is limited to one or more classroom-related activities designed specifically for educational or teaching purposes where data are collected from and about students as part of routine class exercises or assignments and otherwise do not meet either of the definitions of Human   
    Note that some course-related activities, even those conducted by students, may yield information suggesting additional investigation or analysis. If an additional activity entails Human Research, then it must be submitted to the IRB Office for review.
  + **Journalistic or Documentary Activity (including Oral History)**: The activity is limited to investigations or interviews (structured or open-ended) that focus on specific events (current or historical), views, etc. Such investigations or interviews may be reported or published in any medium, e.g, print newspaper, documentary video, online magazine.
  + **Research Using Public or Non-Identifiable Private Information about Living Individuals**: The activity is limited to analyzing data about living individuals (1) where the data have been retrieved by the investigator from public, non-restricted data sets or (2) where the private data have been provided to the investigator without any accompanying information by which the investigator could identify the individuals.  
    Note that “de-identified data” according to HIPAA may be identifiable according to the DHHS definition of “Human Subjects” above..
  + **Research Using Health Information from Deceased Individuals**: This activity is limited to analyzing data (identifiable or not) about deceased individuals.

Note that deceased individuals cannot be Human Subjects according to DHHS, but they may be Human Subjects according to FDA. Please review the definitions above for clarification

**References**

45 CFR 46. Federal code of regulations (the “Common Rule”)

45 CFR 46.102 (d) Determination of research

45 CFR 46.102(f)(2) Determination if human subjects are involved in research

32 CFR 219 DoD implementation of 45 CFR46, Subpart A – criteria for exemption

DoD Directive 3216.02 DoD defines additional requirements for human subject research supported by the

Department of Defense