HRP-310 | 7/31/2024

WORKSHEET: Human Research Determination

The purpose of this worksheet is to provide support for individuals in determining whether an activity is Human Research or how it is regulated [[1]](#endnote-2).

This is a diagram that shows the process of Human Research Determinations based on DHHS and FDA definitions.

For an official IRB determination of whether your research activities are Human Subjects Research, please complete the NHSR Determination Form (HRP-503c – TEMPLATE - DETERMINATION).

1. Research as Defined by DHHS Regulations[[2]](#endnote-3) (Check if “Yes”)

☐Is the activity an investigation? (Investigation: a searching inquiry for facts; detailed or careful examination.)

☐Is the investigation systematic? (Systematic: having or involving a system, method, or plan.)

☐Is the systematic investigation designed to develop or contribute to knowledge? (Designed: observable behaviors used to develop or contribute to knowledge. Develop: to form the basis for a future contribution. Contribute: to result in. Knowledge: truths, facts, information.)

☐Is the knowledge the systematic investigation is designed to develop or contribute generalizable? (Generalizable: universally or widely applicable.)

1. Human Subject Under DHHS Regulations (Check if “Yes”)

☐ Is the investigator conducting the Research gathering information or biospecimens *about living* individuals?

1. Human Subject Under DHHS Regulations (Check if “Yes”)

☐ Will the investigator use, study, or analyze information or biospecimens obtained through either of the following mechanisms? Specify which mechanism(s) apply, if yes:

☐ Physical procedures or manipulations of those individuals or their environment for Research purposes (“Intervention”).

☐ Communication or interpersonal contact with the individuals. ("Interaction”).

1. Human Subject Under DHHS Regulations (Check if “Yes”)

☐ Will the investigator gather data that is either identifiable or private? Specify which category(s) apply(ies) if yes:

☐ The data are about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place (i.e. “Private information”).

☐ Individuals have provided the data for specific purposes in which the individuals can reasonably expect that it will NOT be made public, such as a medical record (i.e. “Private information”).

☐ Can the individuals’ identities be readily ascertained or associated with the information by the investigator (i.e. “Identifiable Private Information”)?

☐ Can the individuals’ identities be readily ascertained or associated with the biospecimens (i.e., “Identifiable Biospecimen”)?

**If all items are checked under 1, 2, and 3 or 1, 2, and 4, the activity is Human Research under DHHS regulations.**

1. Human Research Under DHHS Regulations (Check if “Yes”)

☐ Has a department or agency head, covered by the Common Rule, retained final judgment (consistent with the ethical principles of the Belmont Report) that the activity is Human Research under DHHS regulations?

**If checked, the activity is Human Research under DHHS regulations.**

1. Human Research Under FDA Regulations (Check if “Yes”)

☐ Does the activity involve any of the following? (Check all that apply)

☐ In the United States: The use of a drug [[3]](#endnote-4) in one or more persons other than use of an approved drug in the course of medical practice [[4]](#endnote-5).

☐ In the United States: The use of a device [[5]](#endnote-6) in one or more persons that evaluates the safety or effectiveness of that device.

☐ Data regarding subjects or control subjects submitted to or held for inspection by FDA [[6]](#endnote-7).

☐ Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by FDA [[7]](#endnote-8).

**If “Yes”, the activity is Human Research under FDA regulations.**

1. Human Research under Organizational Policy

**If the activity is Human Research under DHHS regulations or under FDA regulations, it is Human Research under organizational policy.**

1. Engagement (Complete if the activity is Human Research. (Check if “Yes”)

☐ The organization is engaged in Human Research. Use HRP-311 - WORKSHEET - Engagement Determination.

1. Comments

Comments:Click or tap here to enter text.

Below we provide a table of common research projects an whether they require IRB involvement. Please note that any uncertainty should warrant, at minimum, correspondence with the IRB administration ([irbadmin@auburn.edu](mailto:irbadmin@auburn.edu)). If an investigator is unsure of whether their research activities constitute human subjects research, or when they anticipate that correspondence from the IRB will be require to satisfy funding agency requirements or for presentation and/or publication purposes, they should submit HRP-503c – TEMPLATE – Human Subjects Research Determination through Endeavor.

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| **ACTIVITY** | **DESCRIPTION** | **IRB DETERMINATION REQUIRED** |
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| Cadaver or autopsy specimens/materials | Research involving deceased individuals does not require IRB oversight. | **NO** |
| Case Report Studies | **Retrospective** review of a medical or other records with intent to document a specific situation or the experience of an individual without intent to form a research hypothesis, draw conclusions or generalize findings. Data is de-identified. | **NO** if using only 1-2 records. |
|  |
| **YES** if using 3 or more records. |
| **Prospective** case study with clear intent, before recruiting or interacting with the participant, to use that data to draw conclusions and will publish or present to external groups. | **YES** |
| Classroom Assignments/Activities | Normal educational activities conducted by the students designed to teach students methods or demonstrate course concepts ***and*** the activities are not designed to create new knowledge ***and*** are not generalized or presented outside the classroom. | **NO** |
| Classroom Activities and Instructional Methods. | Educational activities conducted by faculty or instructors in the classroom or with students and the intent is to generalize the information outside of the classroom or publish. This includes use of student records, interviews, surveys or other student data for prospective or retrospective research. | **YES** |
| Clinical Investigations | Experiments using an intervention, substance or test article on one or more human subjects to evaluate the effects of those interventions, products or test articles on health related biomedical or behavioral outcomes regardless of FDA status or applicability. Products include foods (dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives), drugs for human use, medical or diagnostic devices for human use, biological products for human use, and energy emitting products used on humans. | **YES** |
| Focus Groups and Interviews | When discussing personal experiences or opinions and/or the focus is on people (e.g. how do you rate your ability to handle stress; how often do you run red-lights?) | **YES** |
| When discussing non-human topics and the focus is on things instead of people (e.g. discussions on the differences between product A and product B) | **NO** |
| Human Factors Evaluation | Observing, recording, measuring or testing human behavior, cognition, interaction, performance, psychophysiology or anthropometry in a natural or laboratory environment for research applications. | **YES** |
| Innovative or Novel Procedures, Treatment, or Instructional Methods | Systematic investigation of innovations in diagnostic, therapeutic procedure or instructional methods in multiple participants in order to compare to standard of care or normal procedure. The investigation is designed to test a hypothesis, permit conclusions to be drawn, thus to develop or contribute to generalizable knowledge. | **YES** |
| The use of innovative interventions that are designed solely for therapeutic purposes to enhance the well-being of an individual patient with a reasonable expectation of success. The intent of the intervention is to provide diagnosis, preventive treatment, or therapy to an individual patient. Research is not involved. | **NO** |
| Internet Research | Online websites set up for the purposes of collecting human data regarding a particular topic. This may include the completion of questionnaires/surveys, personal data, etc. | **YES** |
| Harvesting, mining, profiling, observing or recording identifiable data from sites such as blogs, chat rooms, or social media postings, etc.; or entering restricted or pay sites where there are restrictions of use or expectations of privacy/confidentiality; | **YES** |
| Submitting information or interacting with internet sites in order to measure influence on behaviors or other outcomes. | **YES** |
| Literature Review | An assessment of a body of ***published*** material that addresses a research question. Identifies or summarizes what is already known about an area of study or may identify questions a body of research does not answer. | **NO** |
| Pilot Studies | Pilot studies that meet the definition of human research, regardless of the number of subjects enrolled or the duration of the studies. | **YES** |
| Professional Recognition | Employees or agents of Auburn University involved in human research projects carried out at other locations when the services performed merit professional recognition or publication privileges. | **YES** |
| Program Evaluation | Evaluation will be used for internal reporting purposes only or for funding agency reporting and will not be published. | **NO** |
| Evaluation will be disseminated outside of the institution, generalized or published. | **YES** |
| Public Health Surveillance Activities | Limited to those activities necessary to allow a public health authority to provide timely situational awareness or set priorities during an event or crisis that threatens public health. Researchers must have a written request, authorization, or contract from a Public Health Authority. | **NO** |
| Quality Assurance (QA) and Quality Improvement (QI) Activities | Systematic, data-guided activities involving humans designed to implement promising ways to improve outcomes, system performance or professional development and are intended to be generalized or used beyond the local setting **or** have research intent, or address a specific deficit in scientific knowledge. | **YES** |
| The proposed QA/QI activity is confined to the local setting ***and*** the information will not be used or shared beyond the local system. | **NO** |
| **Guidance:** Intent is only one element considered. QI and research often overlap. A QA/QI activity often involves an iterative process that may change over time in response to ongoing feedback. The plan includes mechanisms for assessment, intervention, analysis and implementation. |
| Records, Repositories, Registries or other Data or Biospecimen research; and (Publicly Available Information) | Proposed activity involves accessing student, health or other private records, data banks, repositories or any other mechanism by which identifiable human records, data, tissue, blood, or genetic materials will be obtained. | **YES** |
| Proposed activity involves accessing stored human tissue, blood, genetic material or private identifiable data that will be de-identified by study personnel at the time of collection or when the investigator has access to a code or link that enables re-identification of data or specimens. | **YES** |
| Private information or specimens are being collected specifically for the proposed research through interaction or intervention with living individuals. | **YES** |
| Proposed activity involves accessing biospecimens or cell lines from a commercially operated or established biorepository where the investigator does not receive under any circumstances personal identifiers, or links, or codes that enable identification; | **NO** |
| Proposed activity involves accessing unrestricted ***publicly*** available data/information, public use files (PUFs) or biospecimens that are available to the general public. | **NO** |
| Scholarly and Journalistic Activities (oral history, journalism, literary criticism, historical scholarship, biography, legal research); | Oral histories or journalism that focuses directly on the specific individuals about whom the information is collected and there is no intent to generalize the information to others. Legal research must focus on the circumstances of specific plaintiffs or parties involved in a case; Legal research is not a particular field. | **NO** |
| Scholarly and Journalistic activities that involve the testing or confirmation of a hypothesis that is intended for generalization to others. | **YES** |
| Self - Experimentation | Any human research where the investigator is also a participant in their own study (investigator self-experimentation) requires IRB review and approval. | **YES** |
| Standard Diagnostic or Therapeutic procedures | The collection of data about established and accepted diagnostic, therapeutic procedures, or instructional methods is intended for dissemination or contribution to generalizable knowledge. | **YES** |
| There is an alteration in patient care or assignment for research purposes or the alteration is in a way that standard diagnostic or therapeutic procedures are not completely up to the discretion of a practitioner. | **YES** |
| A diagnostic procedure is added to a standard treatment for the purpose of research. | **YES** |
| An established and accepted diagnostic, therapeutic procedure or instructional method is performed only for the benefit of a patient and not for research purposes. | **NO** |
| Student Conducted Research | Thesis or dissertation projects involving human subjects research conducted to meet the requirements of a graduate degree. | **YES** |
| Surveys | Interacting with participants directly or through third party survey administrators to answer a research question about humans requires submission to the IRB for a determination even if not collecting identifiable information. | **YES** |

1. This document satisfies AAHRPP elements I.1.A, III.1.A [↑](#endnote-ref-2)
2. The following activities conducted or supported by the Department of Defense (DOD) are NOT research involving human subjects: Activities carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease in Service members and other mission essential personnel under force health protection programs of the Department of Defense, including health surveillance pursuant to section 1074f of Reference (g) and the use of medical products consistent with DoD Instruction 6200.02. Authorized health and medical activities as part of the reasonable practice of medicine or other health professions undertaken for the sole purpose of patient treatment. Activities performed for the sole purpose of medical quality assurance consistent with 10 USC 1102 and DoDD 6025.13. Activities performed solely for an OT&E project where the activities and project meet the definition of OT&E as defined in 10 USC 139(a)(2)(A). Activities performed solely for assessing compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units, including such activities as occupational drug testing, occupational health and safety reviews, network monitoring, and monitoring for compliance with requirements for protection of classified information. Activities, including program evaluation, customer satisfaction surveys, user surveys, outcome reviews, and other methods, designed solely to assess the performance of DoD programs where the results of the evaluation are only for the use of Government officials responsible for the operation or oversight of the program being evaluated and are not intended for generalized use beyond such program. Survey, interview, or surveillance activities and related analyses performed solely for authorized foreign intelligence collection purposes, as authorized by DoDD 5240.01. [↑](#endnote-ref-3)
3. The term ‘‘drug’’ means:

   articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

   articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

   articles (other than food and dietary supplements) intended to affect the structure or any function of the body of man or other animals; and

   articles intended for use as a component of any article specified in clause (A), (B), or (C). [↑](#endnote-ref-4)
4. “Other than the use of an approved drug in the course of medical practice” refers to a practitioner providing an approved drug to a patient because the practitioner believes the drug to be in the best interests of the patient. If the protocol specifies the use of the drug, it is not in the course of medical practice unless use of the drug is completely up to the discretion of the practitioner. [↑](#endnote-ref-5)
5. The term ‘‘device’’ means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

   recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

   intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

   intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. [↑](#endnote-ref-6)
6. This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement. [↑](#endnote-ref-7)
7. This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement. [↑](#endnote-ref-8)