Determination of UWM IRB Review Guidance

Not all research involving humans will require UWM IRB submission or approval. Only activities meeting the regulatory definitions of **(a)** "**research**" and **(b)** "**human subjects**" and where **(c)** UWM is "**engaged**" in the conduct of human subjects research require UWM IRB review and approval.

Determine if UWM IRB review is required by following the steps below:

Step 1: Does the project meet the definition of "**Research**" as defined by the federal government (and UWM IRB)?

> **"Research"** is *a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.* (source: 45CFR46.102(d))
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> A systematic investigation involves a predetermined method or a plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. A systematic approach incorporates collection of qualitative or quantitative data or specimens using a standardized method, and analysis of the data.
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> Developing or contributing to generalizable knowledge means obtaining scientifically valid results that will be disseminated beyond UWM. Dissemination of results is often done through publication and professional presentations.
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> Therefore, if you are seeking to have a specific question answered (systematic investigation) **and** you intend for the findings to be applied to a broader population (generalizable), the project would then constitute "research."
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> There is often confusion with quality improvement (QI) and program evaluation projects that primarily comes from how they apply to meeting the definition of "research," specifically, the interpretation of "generalizable" knowledge. A question to ask is, "Is the intent to have the data be applied to a broader population, **and** will it have external validity? If yes, then this would be research needing IRB review. Or, will the purpose of the project be to share the findings for internal improvements and use only? If yes, then this would not be research needing IRB review.
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> Please note that QI /program evaluation projects and research are not mutually exclusive. QI/program evaluations can be research. This can happen during the design of the project, i.e., the project is QI but the intent is to also apply it to a broader population, or it can happen after the project is initiated, e.g., researcher finds worthwhile data and intends for it to be generalizable. Once it becomes "research" involving "human subjects", IRB review/approval will be needed.
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> Examples of non-research projects: classroom projects, oral history projects that are only summarizing historical events (and not drawing generalized conclusions), QI or program evaluation activities designed to improve the quality or performance of a department, agency or program.

Step 2: Does the project involve "**human subjects**" as defined by the federal government (and UWM IRB)?

> *"**Human subjects**" are living individual about whom an investigator (whether professional or student) conducting research obtains:*
> 1) *Data through intervention or interaction with the individual, or*
> 2) *Identifiable private information…Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.* (source: 45CFR46.102(f))

About whom means that the researcher is collecting information about a living person. Asking a person about policies, practices or procedures of an organization or business (with no questions specifically about the individual) does NOT meet the definition of "human subjects."

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interventions can be done in person or online.

Interaction includes communication or interpersonal contact between researcher and subject. Examples can include (but are not limited to) surveys, interviews, observations and they may be in person or online.

Identifiable includes when it is possible that the identity of the subject is or may be ascertained by the researcher or associated with the information

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and 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 or educational record information). Private information must be *individually identifiable* through use of identifiers (name, dob, SSN) or through use of a code.

For those research projects using datasets and secondary analysis. Unless the data is "identifiable **and** private," it would not constitute "human subjects" and therefore not need IRB review/approval. For example, research using a public database or de-identified specimens/data would not meet the definition of human subjects provided all identifers have truly been removed. Clarification of de-identified data can be found in the De-identified Data Guidance.

Datasets containing study codes/ID numbers may be considered to be de-identified provided one of the following is true: 1) there is a written agreement prohibiting the UWM researcher and his/her research team from having access to the key linking study IDs to identifiers; 2) there are legal requirements or written policies in place restricting release of the key until the participants are deceased; or 3) it is highly unlikely that the UWM researcher will ever be able to access the key (for example, the key is held by a national data repository or at another institution).

Step 3: Is UWM "**engaged**" in human subjects research?

UWM is considered to be "**engaged**" in human subjects research if its faculty, staff and/or students are involved in any of the following activities for a human subjects research study:

- direct awardee of a federal grant, award, or contract;
- obtaining informed consent;
- performing invasive or noninvasive procedures with subjects;
- intervening for research purposes with any subjects by manipulating the environment;
- interacting for research purposes with any subject; (e.g., conducting research interviews or administering questionnaires); or
  obtaining private identifiable information

UWM is **NOT** considered to be "**engaged**" in human subjects research if its faculty, staff and/or students are ONLY involved in any of the following activities for a human subjects research study:

- performing commercial/service where: (a) the services performed do not merit professional recognition or publication privileges; (b) the services performed are typically performed by those institutions for non-research purposes; and (c) the institution's employees or agents do not administer any study intervention being tested or evaluated under the protocol;
- informing (e.g., distributing recruitment materials, providing a copy of informed consent document or information about contacting the investigator, or obtaining the prospective subjects' permission for investigators to contact them) prospective subjects about the availability of the research but not obtaining subjects' consent for the research or acting as representatives of the investigators; or
- releasing identifiable private information/specimens pertaining to the subjects of the research.

If the activities of your project constitute research; **and** the activities involves human subjects; **and** UWM is engaged then UWM IRB review and approval of your study is required before study activities can begin.

If your project does **not** involve UWM being **engaged** in **human subjects research**, you are **not required** to submit an IRB application. If you would like confirmation and documentation from the IRB staff that your proposed activities do not constitute UWM being engaged in human subjects research, or if you are uncertain if your study meets the definition of human subjects research please complete and submit a word version of the Determination of UWM IRB Submission form to irbinfo@uwm.edu or complete the Qualtrics version of the form.

For instructions and additional information contact the IRB Office at:
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