

[https://www.memphis.edu/research/researchers/compliance/irb/decision\\_guide.php](https://www.memphis.edu/research/researchers/compliance/irb/decision_guide.php)

## Decision Guide – Do I need IRB review?

### IRB Determinations

An IRB determination process reviews proposed research to determine whether a study meets the regulatory definitions of human subjects research that requires IRB review.

#### To submit for IRB Determination:

- 1) If you have never logged into CayuseIRB, request access with an email to [cayusesupport@memphis.edu](mailto:cayusesupport@memphis.edu), include your full name and Memphis.edu email address. It will take a server reset overnight to gain access once you have been added to the system.
- 2) Cayuse IRB for Researchers Presentation will walk you through the determination submission starting at slide 30.
- 3) An official determination will be emailed to the investigator advising that the work is not human subjects research or that the work is human subjects research requiring IRB review and full protocol submission based on the definitions below.

**Commented [BJ1]:** Link to <https://memphis.cayuse4242.com>

**Commented [BJ2]:** Link to 022619DeterminationTrainingSlide30.pdf

#### Regulatory definitions of human subjects research that requires IRB review:

##### Human Subjects

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

- (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

##### Research

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

Additionally, the regulations outline what is **not research** requiring IRB review:

- (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

(m) Written, or in writing, for purposes of this part, refers to writing on a tangible medium (e.g., paper) or in an electronic format.

If you need to report a study-related injury, or if you have questions, please contact the IRB Administrator at [irb@memphis.edu](mailto:irb@memphis.edu) or 901/678-2705.

If you have any concerns regarding integrity and ethics in research and scholarship at UofM, please do not hesitate to call 901/678-4786 or email [researchcompliance@memphis.edu](mailto:researchcompliance@memphis.edu). The confidentiality of anyone who contacts the office will be protected under the Whistleblower Protection Act. Working together we will promote the highest standard of integrity and ethics in research and scholarship.

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