

DOES IRB REVIEW APPLY? DETERMINING IF ACTIVITIES INVOLVE HUMAN SUBJECTS RESEARCH



This checklist is intended to assist investigators in determining if their activity is considered human subjects research and would therefore require IRB review. This checklist does not address whether research may be FDA-regulated. **This checklist does not need to be submitted to the IRB.** If there is any doubt as to whether or not your activities could qualify as human subject research or if your activities involve an [FDA-regulated](#) test article, please contact the IRB Chair at irb@cocc.edu.

SECTION A: Is the Activity Not Considered Research?

The following activities are deemed NOT TO BE RESEARCH per the 2018 Common Rule:

- (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.

Note: This category concerns scholarly and journalistic activities that focus directly on the specific individuals about whom information is collected and used to provide an accurate portrayal of the individuals involved, without extending that information to draw generalizations about other individuals or groups.

- (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).

Public Health Authority means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

- (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 [Federal] agency) in support of intelligence, homeland security, defense, or other national security missions.

Does your activity fall wholly within one or more of the above exclusions from the definition of research?

YES

NO

If you answered NO, continue to section B to determine if your activity falls within the definition of research provided in the 2018 Common Rule.

If you answered YES, your activity is not research and IRB review is not required.

SECTION B: Is it Research?

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102 (I)).

Generalizable Knowledge: Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population) or inform practice or policy.

Is your activity a systematic investigation designed to develop or contribute to generalizable knowledge?

YES

NO

If you answered YES, your activity is considered research. Continue to section C to determine if your research involves human subjects.

If you answered NO, your activity is not research and IRB review is not required.

SECTION C: Does Your Activity Involve Human Subjects?

Is the data about (or biospecimens from) living individuals?

YES

NO

If you answered NO, your research does not involve human subjects and IRB review is not required. If your research includes decedent protected health information (PHI) or decedent biospecimens labeled with PHI, HIPAA requirements may apply. Please consult with the Privacy Office of the entity providing the information or specimens.

If you answered YES, continue to the next question.

Does the activity involve obtaining information or biospecimens through intervention or interaction with the individuals, and using, studying, or analyzing the information or biospecimens?

Intervention includes both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject e.g., surveys, focus groups, interviews). (45 CFR 46.102(e)(2) and (3))

YES

NO

If you answered YES, your research does involve human subjects and IRB review is required.

If you answered NO, continue to the next question.

Does the activity involve obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens?

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen. (45 CFR 46.102(e)(4), (5), and (6))

YES

NO

If you answered YES, your research does involve human subjects and IRB review is required.

If you answered NO, your research does not involve human subjects and no IRB review is required.

Please note there are other activities that are not considered Human Subjects Research:

Classroom activities solely to fulfill course requirements or train students in the use of particular methods/devices, and for which you have no desire to publish or share this information outside the classroom (e.g., at a conference).

Internal data collection for Central Oregon Community College departmental, school, or other institutional administrative purposes only (e.g., teaching evaluations) and for which you have no desire to share or publish.

Information-gathering where questions focus on things, products, or policies rather than about people or their thoughts. (e.g., canvassing about rising journal costs).

If there is any doubt as to whether or not your activities could qualify as human subject research, please contact the IRB Chair at irb@cooc.edu.