Definitions and Categories of Research

Definition of Research

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

Not-Research:
Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection of use of information, that focus directly on the specific individuals about whom the information is collected are not considered research. [§45 CFR 46.102(l)]

> ***Quality improvement and quality assurance*** activities conducted solely for the intent of maintaining or improving quality of services provided by an institution, are not considered research activities. However, if the data collected are generalizable and are to be shared outside of the institution through presentation or publication, the activity qualifies as research.

If a project does not meet the "systematic investigation" part of the definition of human subject research, then it does not matter if it is presented or published.

Human Subject means a living individual about whom an investigator (whether professional or student) conducting research obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens or Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. [§45 CFR 46.102(e)(1)]

Identifiable private information is private information for which the identity of the participant is or may readily be ascertained by the investigator or associated with the information. [§46.102(e)(5)]

If you are unsure of whether or not your project requires IRB review, see the IRB Decision Tree or contact the IRB Office at 386.226.7179 or teri.gabriel@erau.edu.

Exempt Research

Exempt research is research with human participants that generally involves no more than minimal risk. It is "exempt" from the provisions stated in the Federal regulations. An exempt research project does not require ongoing review by the IRB, unless the project is amended in such a way that it no longer meets the exemption criteria. The IRB is required to determine if a research project falls under one of the following exempt categories listed in the Federal regulations [§45 CFR 46.104]:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices including regular or special education instructional strategies and research

on the effectiveness or on the comparison among instructional techniques, curricula, or classroom management methods.
This exemption applies to minors.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording). *This exemption applies to minors if the information obtained is recorded in such a manner that the identity of the participant cannot be readily identified.*

3. Research involving ***benign behavioral interventions*** in conjunction with the collection of information from an adult subject through verbal or written response (including data entry) or audiovisual recording if the participant prospectively agrees to the intervention.
This exemption does <u>not</u> apply to Minors.

   Benign behavioral interventions is defined as "being brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the participant, and the investigator has no reason to think the participants will find the interventions offensive or embarrassing." Examples include playing an online game, solving puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. [§46.104(d)(3)]

4. Secondary research using identifiable private information or identifiable biospecimens for which consent is not required if the identifiable private information or identifiable biospecimens are publicly available or information is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained directly or through identifiers linked to the participant and the investigator does not contact or re-identify the participant. *This exemption applies to minors.*

5. Research and demonstration projects that are conducted or supported by a Federal department or agency and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs. This includes internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants.
This exemption applies to minors.

6. Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
This exemption applies to minors.

7. Storage or maintenance of identifiable private information or identifiable biospecimens for which broad consent is required for potential secondary research use if a ***Limited IRB*** review is conducted.
This exemption applies to minors.

8. Research involving the use of identifiable private information or identifiable biospecimens for secondary research use if broad consent for the storage, maintenance, and secondary research use was obtained; documentation or a waiver of informed consent was obtained; a ***Limited IRB*** review is conducted to determine that the research is within the scope of the broad consent and the investigator does not include returning individual research results to subjects as part of the study plan.
   This exemption applies to minors.

Research that meets the requirements of 'Exempt' may be reviewed by the IRB within approximately two to four weeks.

Limited Review of *EXEMPT* Research

New Category of Exempt Review is required in some instances to ensure there are adequate confidentiality and privacy safeguards. ***Limited IRB*** review is required for "broad consent" in studies involving identifiable private information or identifiable biospecimens. ***Limited IRB*** review involves making and documenting the determination that adequate provisions are in place for protecting privacy and maintaining confidentiality.

Expedited Research

Research activities involving "no more than minimal risk" and in which the only involvement of human participants will be in one or more of the following categories may be reviewed using an expedited procedure. These categories are listed in the Federal regulations [§45 CFR 46.110]:

1. Non-exempt research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing surveys, interviews, or human factors evaluation and any other research activity that poses no more than minimal risk to participants;
2. Minor changes in previously approved research during which approval is authorized;
3. Research for which ***Limited IRB*** review is a condition of exemption.

Research that meets the requirements of 'Expedited' may be reviewed by the IRB within approximately three to six weeks.

Research requiring Full IRB Review

Research that does not meet the requirements of 'Exempt' or 'Expedited' must be reviewed at a fully convened IRB meeting and can take anywhere from one month to three months to review.