FLORIDA ATLANTIC UNIVERSITY
DIVISION OF RESEARCH

Types of IRB Review

FAU HRPP

Background

- The Federal Policy for the Protection of Human Subjects or the “Common Rule” was published in 1991 and codified in separate regulations by 15 Federal departments and agencies;
- The HHS regulations, 45 CFR part 46, include four subparts:
  - Subpart A, also known as the Federal Policy or the “Common Rule”;
  - Subpart B, additional protections for pregnant women, human fetuses, and neonates;
  - Subpart C, additional protections for prisoners;
  - Subpart D, additional protections for children

Background

Research (45CFR46.102.l)	Human Subject (45CFR46.102.e(1))	Intervention (45CFR46.102.e(2))	Interaction (45CFR46.102.e(3))
• a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.	• 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.	• includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.	• includes communication or interpersonal contact between investigator and subject.

Types of Review/ IRB Determinations

Not research	Program evaluations; quality improvement/ quality assurance projects.
Research not involving human subjects (NHSR)	Research projects that are not about the person but may be about a process. May have people answering questions but not about thoughts, opinions, feelings, etc. Think Delphi process!
Exempt	Must meet specific categories. Exempt from federal regulations- NOT exempt from IRB review.
Expedited (Minimal Risk)	Does not mean faster. Must meet one or more of nine categories.
Greater than Minimal Risk	Fully convened review. Includes investigations drug and device studies and high risk social/behavioral research.

Levels of Review

Risk Level

- Risk determination involves the population being studied and the study procedures
- Level of risk will dictate the review category

Review Categories

- Exempt: Less than minimal risk to the subjects
- Expedited: Minimal risk to the subjects*
- Greater than Minimal Risk

*Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 CFR 46.102(i)].

Exempt Categories (46CFR46.104)

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.
2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording).
3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection.
4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens.
5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies.

**FAU does not engage in projects using broad consent as detailed in 45CFR46.104(7) and (8).*

Expedited Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required.
   b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. 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 survey, interview, oral history, focus groups.

Similar Categories

Exempt

- Category 2 or 3
- Category 4

Expedited

- Category 6 or 7 if involving minors or those with diminished decision-making capacity; if deception is used without prior disclosure; if information would but participant at risk.
- Category 5 if identifiers are maintained/ code link created

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