EXPEDITED CATEGORIES IN NEW COMMON RULE

All Pepperdine University human subjects research projects must undergo review and approval by an IRB prior to initiation of research activities. There are 3 categories of review (exempt, expedited, and full board) defined by the Federal Regulations for Protection of Human Research Subjects (45 CFR 46).

Expedited reviews are

- Usually conducted by two reviewers,
- Involve no more than minimal risk to participants,
- Does not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing; unless reasonable and appropriate protection will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal,
- Not involving prisoners as participants.

Expedited research falls under one or several federally-defined categories. The regulations at 45 CFR 46.110 contain provisions that permit the use of expedited review procedures for human subjects research that is both minimal risk and where the research procedures are limited to one of the Expedited Review Categories published by OHRP in the Federal Register. The nine categories are:

1. Clinical studies of drugs and medical devices only when certain conditions are met.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture when certain conditions are met.

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 nonresearch 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 group, program evaluation, human factors evaluation, or quality assurance methodologies.**

8. **Continuing review of research previously approved by the convened IRB as follows**:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; **or**

(b) where no subjects have been enrolled and no additional risks have been identified; **or**

(c) where the remaining research activities are limited to data analysis.

9. **Continuing review of research, not conducted under an investigational new drug application or investigational device exemption** where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.