Expedited Review

Research Compliance Office

Stanford University

Expedited Review

- Minimal risk
- Expedited categories (45 CFR 46.110 HHS, 21 CFR 56.110 FDA)
- Review conducted by IRB chair or designee
- Criteria for IRB approval still apply
- Informed consent requirements or waiver criteria still apply
- No continuing review
  - Excluding FDA or DOJ regulated
  - CIRM funded stem cell research

Categories 1 and 2

1. Clinical studies of drugs or devices when an IND or IDE is not required, or if device is cleared/approved for marketing and being used according to labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, non-pregnant adults who weight >110 pounds where the amount drawn is:

- <500 ml/8 week period and collection occurs at most 2 times/week,

or from adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected

- at most 50 ml or 3 ml/kg/8 week period, and the frequency with at most 2 times/week.

Categories 3 and 4

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. Where medical devices are employed, they must be cleared/approved for marketing.

Categories 5, 6, and 7

5. Research involving materials (data, documents, records, or specimens) that have been, 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 or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Category 8 - Continuing Review

8. Continuing review of research previously approved by the convened IRB where:

- Research is permanently closed to enrollment, all subjects have completed all research-related interventions, and study remains active only for long-term follow-up, **or**;
- No subjects have been enrolled at the site and neither PD nor IRB at site has identified any additional risks from any site or any other relevant source, **or**;
- Remaining research activities are limited to data analysis.

Category 9 - Continuing Review

9. Continuing review of research, not included under an IND or IDE where categories (2) through (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.

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Reviewer Actions

- Approve
- Request additional information
- Refer for review at convened meeting

Questions?

http://researchcompliance.stanford.edu