UCLA Research Administration
Human Research Protection Program

Tip Sheet: Minimal Risk (updated July 7, 2020)

Definition of Minimal Risk (45 CFR 46.102)

"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*

- **of the general population *or***
- **during the performance of routine physical or psychological examinations or tests.**

Examples of Minimal Risk Studies*

Collection of blood samples from adults by venipuncture (with limits)
Prospective collection of mucosal and skin cells by buccal scraping or swabs
Collection of data through non-invasive means (excluding general anesthesia or sedation) routinely employed in clinical practice excluding x-rays or microwaves but including MRI, ECG, ultrasound.
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).
Collection of data from voice, video, digital, or image recordings made for research purposes
Research on individual or group characteristics or behavior

*That fall into one of the nine federally defined expedited categories.

Examples of Studies that Are *Not* Minimal Risk Studies*

Punch biopsies
An extra biopsy when others are already being taken for standard diagnostics
Blood draws from healthy nonpregnant women who weigh <110 lbs or more than 550 ml in an 8-week period or more than 2 times a week
Research on investigational devices or drugs
Classified research
Research in which the identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to their reputation or be stigmatizing to their group

Change history:
07/07/2020: Updated to reflect 2018 Revised Common Rule.