UCLA OHRPP
Office of the Human Research Protection Program

Tip Sheet: Minimal Risk (8/26/11)

Definition of Minimal Risk (45 CFR 46.102(i)

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 (w/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 nonresearch 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