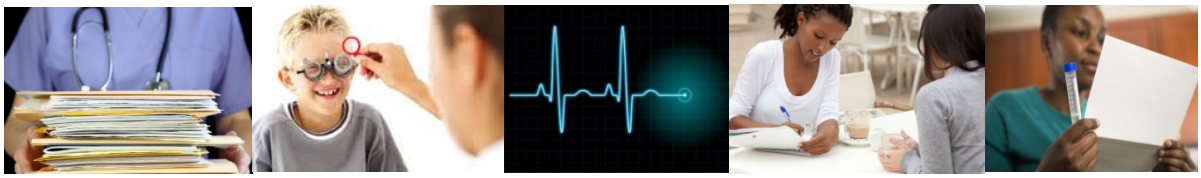
UCSF **Human Research Protection Program**

Tip Sheet: Minimal Risk

Definition of Minimal Risk (45 CFR 46.102(i) and 21 CFR 56.110)

"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 by venipuncture from adults and children (within limits)
Collection of data through non-invasive means (excluding studies that require general anesthesia or sedation for research purposes) routinely employed in clinical practice, including MRI (3 Tesla or under), ECG, ultrasound
Research involving materials (data, documents, records—including medical records--or biological specimens) that have been collected or will be collected solely for research purposes
Collection of data from voice, video, digital or image records made for research purposes
Research on individual or group characteristics or behavior (e.g., focus groups, surveys, interviews)
Mobile applications that only track information and do not directly inform care of the research subject

*In order for a study to be classified as and reviewed by the IRB as a minimal risk study using the expedited procedure, all of the study procedures must fall into one or more of the nine federally defined expedited review categories.

Examples of Studies that Are Not Minimal Risk Studies*

Punch biopsies
An extra biopsy when other biopsies are already being taken for standard diagnostics
X-rays, DEXA scans
MRIs when contrast media and/or sedation is used for research purposes
Research on investigational drugs or devices
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
Mobile medical applications that use health information to directly inform care of the research subject (e.g., applications that provide insulin dosing recommendations)