Minimal Risk Compared to Greater than Minimal Risk

Federal regulations define 45 CFR 46.102 (j) *Minimal risk:* as 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 or during the performance of routine physical or psychological examinations or tests.

Greater than minimal risk is any study that does not meet the definition of minimal risk. Greater than minimal risk studies require adequate monitoring plans be in place to help minimize the risk and deal with situations should they arise.

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 nonresearch 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
• Observational research on Standard Treatment(s): Observational research on standard treatment(s) where the treatment(s) is (are) determined clinically and not assigned by research methodology (e.g. randomization)

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)