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Tip Sheet: Minimal Risk

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

Minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in *daily life*. Risks can include but are not limited to:

1. Physical risks such as bodily contact or administration of a substance, etc.
2. Psychological / Emotional risks such as feeling uncomfortable or upset
3. Social risks such as economic impacts, loss of status, employability, or reputation
4. Legal risks such as arrest, subpoena, or recording without consent

In order for IRB to review and classify a study as 'minimal risk' and use the expedited procedure, all of the study procedures must fall into one or more of the federally defined expedited review categories.




Examples of Minimal Risk Studies

Research on group characteristics or behavior where individuals cannot be identified
Collecting data through non-invasive means (i.e., pre-existing data already obtained)
Research involving materials (e.g., data, documents, records—including medical records--or biological specimens) that have been collected or will be collected solely for research purposes
Collecting voice, video, digital or image records made for research purposes, with prior consent
Collecting blood specimens for research purposes using techniques consistent with routine clinical practice to minimize pain and risk of infection and within the following limits for volume: (a) from non-pregnant adults who weigh at least 50 kg, the amounts should not exceed 550 ml in an 8-week period; or (b) from children and other adults, the amount of blood should not exceed of 150 ml or 3 ml per kg in an 8-week period
Applications that only track information and do not directly inform care of the research subject
Research involving Electroencephalogram (EEG), Electrocardiogram (ECG or EKG) or MRI (3 Tesla and under) other medical devices and/or tests used as part of research study

Examples of Non-Minimal Risk Studies

Punch biopsies, or extra biopsies when other biopsies are already being taken
X-rays or MRIs when contrast media and/or sedation is used
Surveys asking for personal or sensitive information where participants can be identified
Research on investigational drugs or devices
Research in which the identification of the subjects 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)