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Minimal Risk vs. Greater than Minimal Risk

Minimal Risk: Requires ongoing monitoring by the Principal Investigator (PI) and Institutional Review Board (IRB)

Minimal Risk to subjects means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests and that confidentiality is adequately protected. This category includes protocols that pose "no greater than minimal risk" according to federal regulations.

Examples of Minimal Risk are:

- Study poses no more risk than expected in daily life (e.g., blood draw, physical exam, routine psychological testing).
- Non-interventional studies (e.g., observational studies of behavior or nutrition).
- Survey/Questionnaire studies of a non-sensitive nature.
- Electrophysiological studies in healthy subjects or clinical populations (surface recordings such as EEG, ERP, MEG)
- Genomic studies
- Non-invasive imaging (e.g., MRI and fMRI) in healthy subjects or clinical populations to investigate basic mechanisms of brain function.
- Research involving the collection or meta-analysis of existing data, documents, records, pathological specimens, or diagnostic specimens to understand basic bio-behavioral processes.

Greater than Minimal Risk: Requires ongoing monitoring by the Principal Investigator and IRB and may also require monitoring by an Independent Safety Monitor or an independent Data and Safety Monitoring Board

Greater than Minimal Risk to subjects means that the probability and magnitude of harm or discomfort anticipated in the research risks are more than minimal risk, but not significantly greater. Studies that fall under this category will range in their probability of a moderate-severity event occurring as a result of study participation (and the level of safety monitoring will depend on that probability) but there are adequate surveillance and protections in place to identify adverse events promptly and to minimize harm.

Examples of Greater than Minimal Risk:
Some imaging studies (e.g. PET scan)

- Studies using transcranial magnetic stimulation

- Post-approval studies of FDA-approved drugs or devices (may require an independent safety monitor if the PI is blinded to randomization)

Monitored by an Independent Safety Monitor (in addition to the PI and IRB):

- Studies involving treatment delays or medication washouts or placebo controlled studies in clinical populations
- Subjects with serious mental illness in a treatment study (may require an independent DSMB)
- Some first-in-human or Phase I investigational intervention (may require an independent DSMB based on preclinical findings)

Monitored by an independent Data and Safety Monitoring Board (in addition to the PI and IRB):

- Phase II Investigational New Drug (IND)/Investigational Device Exemption (IDE) studies
- Phase III studies
- Some first-in-human or Phase I investigational intervention (may require an independent DSMB based on preclinical findings) (http://www.fda.gov/downloads/Drugs/Guidances/UCM078932.pdf)
- Multi-site clinical trial