Table 2: RISK DESCRIPTION/RISK ASSIGNMENT

Many factors influence the risk assignment and must be taken into consideration when assigning a risk category to the study. These factors include study design (interventions/procedures, multi-site vs. single site, blinding, size of study, length of participation, etc.), risk-to-benefit ratio, potential for invasion of privacy/breach of confidentiality, potential for psychological impact of protocol, participant population (i.e. "vulnerable" population), social implications, experience of research team, potential for conflicts of interest, etc. The level/intensity of safety monitoring will be determined by the level of risk. Only the term "minimal risk" is specifically defined by federal regulations. The "Low," "Moderate," and "High" risk definitions below are definitions intended to break down "greater than minimal risk" into categories from which guidance for monitoring can be made. The examples cited after each level of risk category below are to be used as a *general guide* (this is guidance, not IRB policy) to assist in making the risk assignment for your study.

Risk Classification **Description/ Examples**	**Monitoring guidance**
☐ **No Greater than Minimal Risk**	
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 (45 CFR 46.102i). - Examples: Physical exam, blood sampling, exercise testing in healthy adults.	May be monitored by PI only or PI and study staff on a scheduled basis.
☐ **Greater than Minimal Risk: Low**	
Involves a minor increase over minimal risk. Increased probability of a low-severity event that is reversible (i.e. muscle/joint soreness); likelihood of serious harm is very rare (such as anaphylaxis from routine allergy skin testing of common aeroallergins). - Examples: Studies of normal volunteers using well-described low-risk procedures.	- Scheduled monitoring by PI and staff. - Team meetings to discuss AEs and protocol issues. - Independent reviewer may be considered if there is potential for conflict of interest.
☐ **Greater than Minimal Risk: Moderate**	
Risks are greater than low/minimal, but not considered high; they are reasonable in relation to anticipated benefits to participants and the importance of the knowledge that may reasonably be expected to result. Likelihood of serious harm is rare. Includes otherwise low risk interventions in populations at risk for serious clinical events based on underlying disease or low risk interventions in potentially vulnerable populations. - Examples: A study using a drug with moderate side effect profile for an indicated use; studies with previously documented human safety data indicating reasonably acceptable risks; muscle biopsies; insulin clamps; endoscopies; genetic testing and storage/distribution of samples (including identifiers or codes); questionnaires (unless anonymous) requesting sensitive information.	- PI and staff monitor study on on-going basis. - A Safety Monitor or Data Monitoring Committee may be utilized to review adverse events. - A Data Safety Monitoring Board (DSMB) *may* be utilized, especially with large multi-site blinded studies.
☐ **Greater than Minimal Risk: High**	
Interventions with potential for high incidence of adverse events from the interventions/procedures or underlying condition of enrolled participant. Increased probability for the occurrence of a study-related event that is serious and prolonged or permanent, or there is significant uncertainty about the nature or likelihood of adverse events. - Examples: Study intervention or procedure with known substantial risks; study with high risk of serious adverse events based on underlying disease; studies involving drugs or devices with little available safety data in humans; gene therapy studies.	- Frequent monitoring by PI/study staff (on-going). - Often necessitates an outside (sponsor or independent) monitor or monitoring committee. - Often utilizes an independent DSMB.