Human Subject Research Safety Monitoring FAQ's

1. **How does the NINDS policy differ from the NIH policy?**

   The NINDS policy is aligned with the NIH policy which includes all human subject research.

2. **Who determines whether my research protocol has greater than minimal risk?**

   Your IRB has primary responsibility for determination of the level of risk to study participants. When a decision is made to fund your grant, the Program Official (PO) will issue instructions to release funds if the research is clearly minimal risk, as defined in 45 CFR 46.102 (i) external link. If NINDS considers your research to be of greater than minimal risk, the PO may provide additional safety monitoring recommendations following review by an NINDS Medical Officer https://www.ninds.nih.gov/Funding/Apply-Funding/Application-Support-Library/NINDS-Guidelines-Data-and-Safety-Monitoring. If you disagree with the NINDS assessment, you may be asked for clarification or documentation of your IRB's determination of risk.

3. **Does this policy apply to all award mechanisms used by NINDS?**

   Yes, this policy applies to all NINDS-sponsored research that involves human subjects.

4. **What if the human subject aspect of my research begins after the first year of funding?**

   This policy only applies to human subject research. For example, if the human subject research portion of your study begins in year 3, then this policy must be followed prior to the initiation of human subject research activities starting in year 3. Other research activities that do not involve human subjects may proceed. Please refer to the terms and conditions of the award for further information.

5. **What should I do if there are changes in human subject research risk after award?**

   Any change in human subject research risk should be submitted to the NINDS PO for review prior to implementation.

6. **What should I include in my annual progress report (RPPR)?**

   The annual progress report (Type 5s) should summarize the implementation of the safety monitoring plan. Please include: 1). meeting dates, 2). A brief description of the outcome of the meetings, and 3). Investigator follow-up to any recommendations. Please refer to the terms and conditions of your award for additional reporting requirements.