

Clinical Study Reporting to NIDDK

Investigators should provide key information tracked as part of the data and safety monitoring plan in their annual progress report to NIDDK. It may be helpful to discuss annual reporting with the appropriate Program Director.

The grant annual progress report should include the purpose of the study and a brief review of the study design, including timeline and sample size.

In the progress report, the PI should summarize: 1) the tracking and review process used; 2) recruitment and retention over the reporting period; 3) any protocol deviations and remedial steps taken; and 4) any communications with the IRB.

The study's Safety Officer or DSMB should provide a summary for inclusion in the progress report, which includes: 1) summary of AEs and SAEs, including a brief discussion of any unanticipated and/or related events, and any steps taken to deal with these; and 2) statement regarding any loss of confidentiality that occurred, if applicable, and remedial steps taken. In the case of a study that does not have an external monitor, any adverse/unexpected events should be communicated by the Principal Investigator.