

Quarterly Progress Report

A quarterly report is required during the start-up and recruitment and enrollment of participants stages of a multisite clinical research project that exceeds \$1M direct cost in any given funding period. The NINDS may request this report for complex multisite studies in which funding does not exceed \$1M, this will be decided on a case-by-case basis. The first report should be delivered to the Program Director 120 days after the notice of grant award reflecting the first 90 days of the grant award period. After enrollment of all participants has been completed, and there are no concerns by the NINDS with follow-up, retention of participants, or other issues have not been identified, the NINDS and the PI may agree upon semi-annual reports. All attempts will be made to have this (quarterly/semi-annual) report coincide with reporting to the DSMB or other oversight committee reports (whenever possible).

In addition to a summary of the study status, issues/problems, resolutions to those issues, suggested solutions, and future plans over the next 90 days, there should be an updated table showing site specific and overall study recruitment, enrollment, follow-up, loss to follow-up, drop-outs, and completers (an example of this table is at the end of this document, the PI and Program Director should agree upon an acceptable table prior to the first due date). A graph showing cumulative enrollment plotted against target enrollment should be updated in each report (an example is at the end of this document).

Outline of Quarterly Summary

Study Status: This should be a short 2-3 paragraph summary of the overall study status and should reflect broad statements that will be described in greater detail in the subsequent sections.

Issues/Problems: This section should describe any overall or site specific study issues, including but not limited to the initiation of the study, IRB issues, drug mfg or distribution issues, personnel, training, close-out, competing studies, staff turnover, etc.

Resolutions: Describe any resolutions to the issues and problems that were listed above.

Suggested Solutions: For those issues and problems that have not been resolved, please provide suggested solutions or things that have been tried to resolve these issues.

Future Plans: Please list your future plans over the next 90 days and any issues or problems you foresee.

Study Status – *Study Name Here*

XYZ Study Cumulative Enrollment

