Interim Report Template

[NAME] DSMB meeting [Date]

Pre-meeting summary report

General overview
Brief overview of the highlights from the reporting period.

Description of Study Progress
Include a detailed description of the study progress in the last year. Suggestions of things to include are:
- If an interim analysis is scheduled, summary of outcome data by treatment group.
- Summary of publications/finding since the last DSMB meeting.
- Any major scientific, protocol related, or safety updates since the last DSMB.
- Summary of the data completeness (e.g., percentage of missing data).
- Assessment of participant adherence to the treatment regimen, overall and by treatment group (e.g., drug accountability report).
- Study milestones reached.
- Any concerning SAE/AE trend here, especially if the DSMB brought it up as a concern previously.

Adverse events
Include summary of cumulative rates of AEs, overall and by treatment group (if known).

List of AEs by treatment group and/or body system should be attached (coded AE log).

Serious Adverse Events
XX SAEs have been reported to the IRB since the beginning of enrollment, XX in the last year.

SAEs in the last year:
List of individual SAEs, including PI’s determination of relatedness.

State if changes/no changes were made to the protocol and consent in response to adverse events.

Problem Reporting: Protocol deviations, unanticipated problems (UPs), and/or non-compliance
XX protocol deviations have been reported to the IRB since the beginning of enrollment, XX in the last year. (Specify how many UPs and non-compliances, if any)

Problems in the last year:
List of protocol deviations, unanticipated problems (UPs), and non-compliance.
Amendments

XX protocol amendments have been approved by the IRB for this study (Amendments X-XXX). XX new amendments have occurred in the last year.

Amendments in the last year:
Summary of protocol amendments since the last DSMB review

Recruitment and Enrollment
Things to include in this section
- Summary of accrual, overall and by study site, compared to accrual targets.
- Summary of baseline characteristics, overall and by treatment group.
- Summary and status of study participants, overall and by treatment group (e.g., proportion of subjects on- and off-study, on- and off-treatment, including screening failures, withdrawals and drop-outs).

Accrual progress

XX participants have been enrolled into the X and XX cohorts. X were enrolled in cohort X. XX were enrolled into cohort XX.

Gender breakdown: XX females, XX males.

Racial/Ethnic breakdown: X American Indian/Alaska Native, X Asian, X Native Hawaiian or Other Pacific Islander, X Black or African American, X White, X more than one race, X Unknown or Not Reported (also state number of Hispanic/Latino).

Address any racial/ethnic disparities. Address accrual issues, if any.

Withdrawals

XX patients have withdrawn from the study; XX treated, X in baseline, etc. XX were withdrawn by the PI. Of the XX withdrawals, X are from Cohort X, XX are from Cohort XX. X withdrawals occurred in the last year. Discuss any trends in withdrawals here (for example, if 5/10 withdrawals withdrew due to AE post-treatment).

Previously:
Summary of withdrawals by each group and stage of the study, including reason for withdraw.

New in the last year:
Summary of withdrawals by each group and stage of the study, including reason for withdraw.