

## **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.