Tool Summary Sheet

|  |  |
| --- | --- |
| Tool: | Individual Randomized Trial Accrual and Safety Updates Independent Monitoring Meeting Report Form |
| Purpose: | MS Word template to be used as a starting point for a brief accrual and safety update since the previous DSMB report. The Interim Report is to be prepared every 4 months after scheduled DSMB meetings for the trial have taken place. |
| Audience/User: | Statisticians and Principal Investigators responsible for preparation of DSMB reports |
| Details: | This template includes a proposed structure for a DSMB report as well as draft language and other guidance  Delete this Tool Summary Sheet from Interim Report prior to submission |

**DSMB Interim Report Date:**

**Previous DSMB Report Date:**

# Executive Summary of trial status

{Provide a brief summary of trial status and timeline since the previous DSMB Report.}

# Enrollment and Participation Status Updates

{Describe enrollment and study participation status, for progress **since the previous DSMB Report**. Provide a summary table (see example below). Provide enrollment statistics by site if the study involves multiple sites.}

Number of anticipated sites:

Number of sites enrolling participants:

Date participant enrollment began:

**Table #. Subject Enrollment and Participation Status for All Subjects,**

**since the previous DSMB Report on Date XXXX**

| **Type – N (%)** | **Site A**  Cumulative (# since last report) | **Site B**  Cumulative (# since last report) | **Site C**  Cumulative (# since last report) | **Total**  Cumulative (# since last report) |
| --- | --- | --- | --- | --- |
| Pre-Screened |  |  |  |  |
| Consented and Screened |  |  |  |  |
| Eligible |  |  |  |  |
| Randomized |  |  |  |  |
| Completed the Intervention |  |  |  |  |
| Completed the Follow-up Visits |  |  |  |  |
| Prematurely Discontinued |  |  |  |  |

# Safety Status Updates

{Summarize all serious adverse events (SAEs) that have occurred **since the previous DSMB report.** Extensive listings may be placed in the Appendix.

Sample Table:}

**Table #. Summary of All Serious Adverse Events for Consented Subjects,**

**since the previous DSMB Report on Date XXXX**

| **Topics -- N (%)** | **Site A**  Cumulative (# since last report) | **Site B**  Cumulative (# since last report) | **Site C**  Cumulative (# since last report) | **Total**  Cumulative (# since last report) |
| --- | --- | --- | --- | --- |
| **Number of SAEs reported** |  |  |  |  |
| **Number of Subjects with SAEs [1]** |  |  |  |  |

**[1] Subjects who experience one or more SAEs are counted only once.**