

SOPP 8101.1 Appendix 2 Meeting Scheduling Memorandum Template

Our Reference: *tracking # (IND, BLA, CRMTS, PTS, etc.)*

Applications Division or Regulatory Management Staff name

Request received *date*

Requestor *Requestors name*
Requestor's affiliation

Meeting type (*pre-IND, End of Phase 2, etc.*) Meeting Schedule:

Date:

Time:

Location: *office building, conference room, exact address*

Tentative CBER attendees:

Please note that information package materials need to be submitted at least *2 weeks/Type A or 1 month/Type B or C* prior to the scheduled meeting date. Please submit ____ copies of the information package.

Due Date for receipt of meeting information package at *Division name*:

Please note that a productive meeting depends on the timely receipt of an adequate information package. Consequently CBER may cancel the meeting if the above conditions are not met. *For compliance with Pediatric Research Equity Act of 2003, the following should be inserted for appropriate meeting types: **Please be prepared to provide an update of your pediatric plan and timelines.***

If you have any questions, please contact *Point Of Contact* at *telephone number*.