**NIMH CREST Site Initiation Visit (SIV) Sample Agenda**

**Tool Summary** (*Remove Tool Summary before finalizing and distributing the document)*

***Purpose:*** *This is a sample agenda for a CREST SIV*

***Audience/User:*** *Site Monitors, Principal Investigators, and study team members who participate in SIVs*

**NIMH CREST Site Initiation Visit Sample Agenda**

**Day 1**

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| Time | Activity |
| 8:45 am | Meet at PI site |
| 9:00 – 10:30am | Introductory meeting with study team  Overview of NIMH activities on site  NIMH Good Clinical Practices Presentation  *Required: PIs, Co-Is/raters directly involved in evaluating study participants, and primary study coordinators. Recommended: all study staff* |
| 10:30am-12:00pm | Tours of study facilities (e.g. MRI center, pharmacy, PI’s lab space, subject data storage area, physical exam rooms, etc.) |
| 12:00-12:30pm | Lunch |
| 12:30pm-4:00pm | NIMH Monitor review of regulatory binder |

**Day 2**

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| Time | Activity |
| 9:00am – 9:30am | Electronic Data Capture (EDC) system demo by study team |
| 9:30 – 11:00am | NIMH Monitor review of the EDC (e.g. does system capture protocol-required data points?) |
| 11:00 – 12:30pm | Additional meetings with subsets of study personnel (e.g. clinical raters, data coordinating center, IRB representatives, etc. (as requested by institution or CREST monitor)) |
| 12:30 – 1:00pm | Lunch |
| 1:00 – 2:00pm | NIMH Monitor review of regulatory binder |
| 2:00 –3:00pm | NIMH Monitor meeting with study regulatory coordinator to obtain any missing regulatory documents |
| 3:00 – 4:00pm | Wrap-up meeting with PI and primary study coordinator |