Quality Assurance Activities for C3D from Outside Sites

Quality Assurance Activities for C3D from Outside Sites When CCR Is the Coordinating Center

SOP #:	**Next Review Date: 07/2010**
Version #: 1	**Review Interval Period: Biennial**
Approved Version #: 1 Date: 07/2008	**Policy Reference:**

Purpose: To define Quality Assurance activities for C3D for outside sites when CCR is the Coordinating Center

STEP 1: Data Entry at Participating Site

1. Data will be entered by identified Data Entry personnel at remote sites.

STEP 2: Remote Quality Control at Outside Site

1. Data will be ***Verified***by personnel independent of Data Entry staff at remote sites.
    - **Note:** *Participating sites may not have the same research team structure as the CCR. A non-Research Nurse team member may verify the data*.

STEP 3: Quality Assurance Checks by CCR Study Coordinator

1. Data entered in C3D by outside sites should be reviewed by CCR Study Coordinator.
2. CCR Study Coordinator should review data in C3D to ensure data is being entered by each site per the timeline outlined in the protocol.
3. CCR Study Coordinator should review the data for missing data, or the incorrect use of CRFs.
4. CCR Study Coordinator should contact the sites with any data issues.

STEP 4: Monitoring Activities at Outside Site

1. Protocol monitoring will be conducted per the protocol.
    - See CCR SOP #MI-5 Multi-Institutional Monitoring Visit

STEP 5: Data Clarification Routing

1. Monitors will use the Approval functionality to track monitoring activities.
2. Monitor will be able to create Manual Discrepancies to be resolved by the Site Study Coordinator/DM.