

POLICIES AND PROCEDURES

SECTION: Research and Compliance			NUMBER: CLN-30.00	
CHAPTER: Clinical Research Standard Operating Procedures	ISSUED: 7/28/2008	REV. A: 5/4/2009	REV. B 8/30/2010	REV. C:
TITLE: Administering Psychosocial Rating Scales			Page 1 of 2	

1. PURPOSE

To standardize the method of administering rating scales to research Study Participants (SPs).

2. SCOPE

Applies to Principal Investigator (PI) and, when delegated by the PI, additional Investigators, Study Coordinators (SCs), and other designated site personnel.

3. RESPONSIBILITIES

The PI is responsible for the training of the SC and other designated site personnel for the collection of study psychosocial rating scales.

4. BACKGROUND

Psychosocial rating scales must be administered to an SP by research personnel considered reliable in using that particular instrument. This individual may be the SC or an Investigator who possess these skills. The rater should be objective to avoid any bias in the SP's response.

5. PROCEDURE

- 5.1. Scales should be administered by the same individual throughout the course of the study in accordance with study protocol.
- 5.2. SPs completing self-report psychosocial rating scales should be given ample time to respond and should be provided with a clean surface to write on. Self-reported scales should be checked for completeness of response. Any change in response(s) should be initialed and dated by the SP.
- 5.3. SPs whose findings indicate a deterioration of the condition from baseline will be followed up by the PI and/or his/her designee.
- 5.4. For research purposes, SPs may choose not to complete portions of or entire questionnaires. This should be recorded in the source document.

6. TERMS & ABBREVIATIONS

PI Principal Investigator
SC Study Coordinator
SP Study Participant

7. REFERENCES

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None

8. ATTACHMENTS

None