8. CHAPTER 8: Participant Safety and Confidentiality

8.1 Introduction

The psychosocial intervention will consist of individual and group cognitive-behavioral therapy for all participants, supplemented by antidepressant therapy, as needed. The active treatment phase will last approximately six months, with follow-up for one and one-half to four and one-half years. The experimental treatments for the ENRICHD study are not expected to pose any particular risk. Each participating investigator has primary responsibility for the individual participants under his/her care.

8.2 Protocol Review and Study Monitoring

An independent Data and Safety Monitoring Board (DSMB) will be appointed by NHLBI and charged with monitoring the progress of the study. The DSMB will review and approve the protocol prior to study initiation. During the study the DSMB will meet periodically to review study progress. These reviews will include evaluation of interim data as well as the monitoring of participant safety and the quality of all aspects of study operations.

Prior to study initiation, the study protocol will be reviewed and approved by each center's Institutional Review Board (IRB).

After enrollment, each individual Principal Investigator will monitor safety issues at his/her site continuously and report any problems to the Coordinating Center, which will inform the NHLBI Project Officer.

8.3 Exclusions

Persons with medical or psychological contraindications to the experimental treatment will not be eligible to be enrolled. Exclusions are detailed in Chapter 2.

8.4 Informed Consent

Informed consent will be obtained from each participant before they are enrolled in the study. The consent form will describe the potential risks and benefits of study participation as well as the responsibilities of the participants and the investigators.

8.5 Adverse Event Reporting and Discontinuation of Study Treatment

As treatment progresses and at all follow-up visits, possible adverse effects of the experimental treatment will be assessed. If participant assessment indicates an adverse reaction, the study investigator may, at his/her discretion and according to the psychosocial intervention design described in Chapter 5 of the ENRICHD Protocol, refer the participant for additional medical follow-up, additional individual therapy sessions, and/or assessment for psychopharmacological intervention. Depending on the situation, the change may be temporary or continue throughout the study term. In rare cases the experimental treatment may need to be discontinued, however the participant would continue to be followed.
8.6 Preliminary Primary Physician Notification Policy

Circumstances exist that require notification of physicians in the interest of patient welfare. Notification should occur when there is substantial potential for psychological morbidity associated with a patient’s psychological status. It is doubtful that notification will have a serious impact on the ENRICHD trial as a consequence of modifications in physicians’ behavior.

Preliminary Policy (not yet fully approved by the ENRICHD Steering Committee):

1. At the time of randomization, primary physicians will be notified that their patient is eligible for the study and the reason(s) for eligibility - social isolation, depression, or both.

2. If major depression is present at a subsequent assessment, the primary physician will be notified in writing on each occasion.

3. Primary physicians will be notified in writing and by phone if the patient’s condition poses a significant clinical risk at any point in the trial, i.e., serious suicidality as defined in the MOO.

4. The intake Consent Form will specify that primary physicians will be notified of their patients’ eligibility for randomization, the reason for being eligible, and that results of psychosocial evaluations might be communicated, if indicated.

5. A standard notification form will be developed and employed.

6. The Coordinating Center will be informed of notification events occurring after randomization.

8.7 Protection of Participant Privacy

Privacy in the context of this study includes confidentiality of data and personal information at the Clinical Center and in the handling and reporting of data by the Coordinating Center. It also includes discretion on the part of the clinical center staff and arrangements for physical privacy during interviews and examinations. Each Clinical Center will be responsible for ensuring physical privacy of participants and ensuring that data are stored in a secured area accessible only to ENRICHD staff. These provisions will be monitored during periodic site visits from the Coordinating Center.

8.8 Data Security and Confidentiality

The original paper data collection forms will be retained at the clinical centers. They should be stored using the confidentiality procedures provided for other medical records at the institution.

All data transferred to the Coordinating Center will be stored, processed, and analyzed within the Coordinating Center office suite. At the Coordinating Center, all access to office space containing data is controlled through manned reception areas. Visitors are screened by the receptionists and cannot move about without an escort. All office space is locked after working hours. Access to computer data files is controlled by passwords released only to those Coordinating Center personnel who use the files. In addition, critical data files are encrypted.
A backup of the database will be made daily to a second disk drive on the Coordinating Center local area network. Automatic magnetic tape backups of the database also will be made daily. Once a month, the current backup tape will be removed from the cycle and permanently archived at the Coordinating Center's off-site data storage facility.

Output mailed to clinical center staff will identify participants only by ID number.

No individually identifiable information will be distributed to clinical centers. When printed material containing confidential information is to be discarded, it is loaded, transported, and stored under supervision (using a chain of custody control process) until the material can be recycled into paper pulp.

All Coordinating Center staff are required to complete a confidentiality certification procedure upon employment. Policies regarding the confidential nature of the data collected, processed, and stored at the Coordinating Center, are explained to all personnel, who must then sign a "confidentiality certification," before being allowed access to confidential information. In addition to this initial training, the Coordinating Center reinforces the need for careful and confidential handling of data at staff meetings.