3. Chapter 3: Screening, Recruitment and Enrollment

3.1 General Issues and Approach Related to Recruitment and Screening

The overall goal of ENRICHD is to recruit at least 3,000 patients over the three years of recruitment (10/15/96-10/14/99), or at least 125 patients each year for a total of at least 375 patients in each of the eight clinical centers. In order to ensure that the study will provide meaningful data on women and diverse racial/ethnic groups, the overall goal will be to recruit 50% women and 50% minorities.

Recruitment methods for ENRICHD will be implemented by eight clinical units in different parts of the country, each of which will be working in at least several hospitals. In addition to the ethnic and cultural diversity found among the eight clinical units, the variation in hospital procedures, practice conventions, clinical trial experience and conventions, and influence of managed care will be great. Hence, the general approaches to recruitment and the specific methods to be employed in each hospital will need to be adjusted to the variations found among hospitals, regions and ethnic and cultural groups. Despite the variations in approaches and methods found between clinical units and hospitals, the overall approach to recruitment, eligibility determination, baseline assessment and randomization is one of attempting to enroll eligible participants who are at increased risk for morbidity and mortality as quickly and efficiently as possible after an acute MI. This approach was adopted in an effort to begin treatment as quickly as possible in those participants assigned to treatment so that the benefits of treatment might be realized early after the MI, when patients are at the highest risk. It is important that every effort will be made to overcome barriers to enrollment and participation of eligible patients so that those who are the most ill or who might face other barriers to participation will not be excluded except in cases in which barriers to active participation cannot be overcome and so that the overall study’s recruitment goals are achieved.

3.1.1 General Issues Related to Recruitment and Screening

Despite the variations that will be inherent in the specific approaches and methods adopted by clinical units and within hospitals, there are a number of broad issues that require consideration for recruitment and screening for ENRICHD. Among these issues are the following:

I. enrolling patients as quickly and efficiently into ENRICHD, so that they might benefit from the psychosocial intervention during the period soon after having suffered an MI when they are at their greatest risk for mortality and re-infarction

Data suggest that patients who survive a myocardial infarction will suffer their highest risk for mortality within a relatively brief period (3-6 months) after the infarct. Data further suggest that patients with major depression are those who have the highest risk for mortality within three to six months after a myocardial infarction (Frazure-Smith, unpublished data). At the same time, while some benefits from psychosocial interventions, such as with depressed patients, can be seen soon after beginning therapy, skills changes associated with cognitive/behavioral interventions require some period of treatment to effect. Hence, ENRICHD investigators recognized the importance of
enrolling patients quickly so that those randomized to the psychosocial intervention might have sufficient exposure to the intervention to effect changes in their depression/low social support at the time when they are at greatest risk.

To accommodate concerns that participants are enrolled very early so that the intervention can then begin early in an effort to effect change in depression and social support, thereby reducing early mortality risk, ENRICHD has adopted a screening and recruitment plan that will allow enrollment of most patients in-hospital. However, patients in whom it is not possible to complete the baseline assessments in-hospital, may be randomized after completing baseline data collection during a post-discharge follow-up visit.

II. enrolling participants, particularly minority and low-SES participants, while they are still inpatients so that contact could be established between study personnel and these participants while they are still in the hospital in an effort to promote feeling “connected” and involved in the study and adherence and retention

Quick, inpatient enrollment would allow an opportunity for substantial contact between study personnel and participants and actually promote adherence and retention. This was thought to be particularly important for minorities, low-SES populations, and possibly even women.

III. balancing the desirability of enrolling participants quickly, while still ensuring that those who are enrolled have an adequate period and “behavioral run-in” to ensure high protocol adherence and retention

Clinical trials must often balance the desire to enroll participants quickly to meet recruitment goals while not enrolling participants so quickly that an adequate commitment from potential participants has not been obtained, resulting in participants who are less likely to be adherent and be retained. To ensure adequate motivation of potential participants to participate, common procedures often include multiple screening visits or “behavioral run-ins”. Patients who, in the Investigator’s judgment, may not have had adequate time in-hospital to make a solid commitment to participation, may be scheduled for a post-discharge follow-up visit to test compliance prior to randomization.

IV. ensuring that patients can be screened for eligibility both within the hospital as well as after discharge so that those who do not meet eligibility criteria upon initial screening but who meet criteria for depression and low social support soon after discharge would be eligible to participate

ENRICHD investigators recognized that some patients may have been depressed prior to their myocardial infarction, while some patients may become depressed in a reactive manner after their myocardial infarction has occurred. Hence, while some patients might meet duration criteria for major and minor depression while in the hospital for an acute myocardial infarction, others may not meet criteria for as much as two weeks after their hospitalization. After careful consideration, it was decided by ENRICHD investigators that recruitment and eligibility determination for ENRICHD
would allow patients who meet depression criteria either while in the hospital or within the first few weeks (i.e., up to 21 days after their infarct) after discharge to be eligible to participate.

Similar issues arose when examining social support. Since it is common for patients to experience increased social support from family and friends during a hospitalization only to experience a loss of support upon discharge, it was considered that some patients may meet criteria for social support/isolation while still hospitalized while others may not meet criteria until after discharge. Nonetheless, as with the depression criteria, it was thought that those patients who did not meet criteria until after discharge should still be eligible for participation and that screening methods should accommodate procedures to ensure screening both in the hospital and upon a post-discharge screening follow-up evaluation.

V. ensuring that the recruitment, screening, and eligibility determination in ENRICHD adopted methods to ensure that patients unlikely to meet eligibility for ENRICHD would be excluded from participation early so as to minimize staff time and expense as well as patient burden and facilitate maximizing efficiency

While it was thought to be important to enroll patients who meet depression and/or social support/isolation criteria while they were either an inpatient or within two weeks of discharge to accommodate patients who might not meet eligibility while an inpatient, it was also thought to be desirable to develop a screening algorithm that would not require follow-up of all patients after discharge but only those who are likely to meet study eligibility criteria upon follow-up.

Thus, the screening and recruitment methods were developed to accommodate follow-up of patients who are likely to become depressed or meet criteria for social support/isolation within two weeks of discharge. However, patients will only be eligible for follow-up if they meet one or both of the following criteria upon initial screening in the hospital (SV1): a) meeting the DISH criteria for minor or major depression and/or b) meeting the criteria for ESSI.

VI. incorporating appropriate methods to address gender and ethnic/cultural issues to ensure proportions of these sub-groups that will be adequate to meet overall study recruitment goals of 50% women and 50% minority representation

Clinical trials have identified barriers to participation for women and minorities. Hence, consideration was given to methods to facilitate and support women and minorities in overcoming barriers to participation. As discussed further below, central to the methods adopted in ENRICHD is the role of a Case Coordinator (CC) who will facilitate developing an adequate “infrastructure” for the patient and who will be trained to maintain personalized contact with participants and address logistical, belief and attitudinal issues that are likely to emerge among these individuals.

3.1.2 General Approach to Screening and Recruitment

Key to addressing the above issues in the approach to screening and recruitment for ENRICHD is ensuring an adequate “infrastructure” to facilitate the recruitment, screening, and later active
participation of all participants based on their individual needs. Particularly in a trial focusing on depressed and/or socially isolated post-MI patients, many of whom will have cardiac symptoms and be exposed to complex medical tests and medical and surgical treatments and many of whom will be minorities and women, it will be important to identify a cadre of health professionals who can assume responsibility for working with hospital staff, the patient’s physician(s), and study staff to enroll and retain patients. The Case Coordinator, a nurse with a coronary care or acute medical care background is best situated by training, experience and location to perform these activities.

Since patients will be enrolled soon after acute myocardial infarction from coronary care units or medical intensive care units, an effective liaison between the staffs of these units and the Case Coordinators will be essential. The Case Coordinators will be responsible for identifying potentially eligible patients, describing the study to them, gaining their informed consent to obtain information from the medical record, querying the primary physician to obtain critical information known only to the physician such as whether a bypass surgery is contemplated, and addressing the unique needs of individual participants. The Case Coordinator will ensure that a “relationship” is established with participants to address the individual needs of participants, particularly those often encountered by minorities and women as we describe more fully in Section 3.3 below.

3.2 Overview of Screening Visits and Study Eligibility

An overview of the screening visits is summarized in Figure 1 of Chapter 2. The following sections describe the sequence of screening, recruitment and baseline data collection visits by visit.

3.2.1 Pre-Screening (PS)

The Case Coordinator and individual hospital screening contacts will be responsible for approaching potentially eligible post-MI patients in participating hospitals for whom the patient’s physician has provided consent. Depending on local IRB and hospital requirements, chart pre-screening (PS) will occur either before or after obtaining patients’ consent to participate. In many cases, clarification of patients’ status will have to obtained from nursing staff and patients’ physicians during the prescreening to determine if particular patients are eligible.

3.2.2 Screening Visit 1 (SV1)

In cases in which patient consent is not required prior to chart review, informed consent will be obtained after chart review for eligible participants so that all patients will have provided informed consent prior to SV1. SV1 will consist of administration of the DISH Part A and the ESSI. For both the DISH Part A and ESSI, patients’ progression through screening will be determined by their classification according to these two instruments.

(For those sites in which screening with the DISH is not feasible, the BDI may be continued to be used as a screening tool under the original protocol (vers 5.0 criteria). However, note that for randomization into the study, depressed patients no longer need to have a BDI $\geq 10$ for entry.)
3.2.3 Screening Visit 2 (SV2)

Once a patient meets basic eligibility at screening either at initial screening (SV1) or re-screening after discharge (SV1a), they will qualify for eligibility determination with the DISH at SV2. SV2 can, at the discretion of the local site, occur immediately after eligibility determination at SV1 or SV1a or at a later visit but must occur within 21 days of patients’ myocardial infarctions. Screening at SV2 will consist of administration of the DISH and the BLESSED if determined to be warranted to gain further information concerning patients’ cognitive functioning. The DISH will be administered in this manner to all patients who qualify at SV1 or SV1a, even those who meet eligibility based on ESSI score. Patients who do not meet eligibility based on major or minor depression will be eligible for re-screening (SV2a) during a follow-up to SV2. Those patients who meet depression eligibility (i.e., have either major or minor depression according to modified DSM-IV criteria) and/or meet social support/isolation criteria and who meet all other eligibility criteria will proceed to baseline data collection at SV3.

3.2.4 Follow-up Screening Visit 2 (SV2a)

Those patients who have met criteria for screening at SV2, have not been found to meet criteria for major or minor depression, and have met criterion for social support/isolation will be eligible for re-screening to determine depression eligibility at SV2a. SV2a will be scheduled to correspond to a point that might be expected to allow patients to have had symptoms previously endorsed during DISH administration at SV2 for a period of two weeks but must be scheduled within 21 days after patients’ myocardial infarctions. Determination of major or minor depression during SV2a will be conducted by querying patients about the duration of symptoms endorsed during the previous DISH administration as a follow-up to the DISH. SV2a may be conducted either via phone or in-person visit at the discretion of the local clinic. Patients who do not have either major or minor depression according to DSM-IV criteria at SV2a will be ineligible to participate further. Patients who meet criteria for major or minor depression and all other eligibility criteria will proceed to SV3.

3.2.5 Screening Visit 3 (SV3)

Patients who meet eligibility criteria at SV2 will then be scheduled for a visit (SV3) during which additional baseline data will be collected. The measures to be collected at this visit are described in the baseline determination section of this MOO. SV3 can, at the discretion of the local site, occur immediately after eligibility determination at SV2 or at a later visit but must occur within 21 days of patients’ myocardial infarctions. However, every effort should be made to enroll patients as quickly as possible.

3.3 Specific Approaches/Methods to Recruitment

There are a number of specific approaches and methods to recruitment for ENRICHD that are anticipated to ensure active participation of physicians/hospitals, to promote receptivity of potential patients for ENRICHD, and to address particular logistical, belief and attitudinal issues common
among minorities that may affect participation. These approaches and methods are summarized below.

### 3.3.1 Approaches to Promote Active Participation of Physicians/Hospitals

A number of strategies will be adopted in ENRICHD to ensure that the providers and hospitals will be likely to support recruitment, adherence and active participation of patients. As discussed in Section 1.2, the role of the CC in developing personal relationships with the providers in the study hospitals, ensuring that the providers are appropriately engaged in recruitment generally and particularly in decisions that are being made concerning individual patients.

Additional approaches to promote the active participation of providers and hospitals are:

- **promoting articles, flyers and community talks to disseminate information to the broader community about the risks associated with depression and low social support and awareness of the project**

General awareness of the project within the broader community was thought to be important to generate support both from the professional community as well as from potential patients and their families.

- **gaining support for the project from relevant professional groups**

Support should be sought not only from cardiologists who may be treating patients at the time of enrollment but also from other professionals who may influence the cardiologists and the patients. Among these professional groups are: primary care physicians affiliated with referring hospitals who may have great influence over their patients; cardiac rehabilitation staff who may have substantial contact and influence with patients during their rehabilitation; and inpatient and outpatient nursing staffs who also may influence both patients as well as physicians. Support from these professional groups will be promoted by:

- **making personal contacts with the CC and/or local hospital nurse responsible for recruitment; discussions with attending physicians outside study practices**

- **making professional talks about the ENRICHD project objectives and protocol at the institutions Grand Rounds, Cath Conference, or Medical Staff meetings**

- **sending out a mailing such as a letter, announcing the project and asking for their support from Dr. Lenfant) and a letter from the Investigator at each center to all attending physicians describing ENRICHD.**

- **participating in inservice session for hospital personnel in all identified prescreening areas**

If outside physicians are familiar with the study, are assured that their patient will be used ONLY for the study and under no circumstances will he be accepted into your PI’s practice, you will have
success in gaining permission to approach many of these referred patients. Additionally, your physician will continue to receive referrals from these practices.

A courtesy, and helpful in gaining cooperation from outside practice physicians, is requesting their participation as Sub-investigators in ENRICHD, and listing them on the 1572.

While the active support of the professional community is seen as very important for ENRICHD, we recognize that a balance must be struck between ensuring that these professionals are supportive but not promoting their efforts to identify and manage depression and/or low social support to the extent that this would affect significantly their management of patients assigned to the usual care group. All of the investigative teams involved in ENRICHD are experienced in dealing with such issues, and we are confident that our efforts can strike an appropriate balance in this regard.

• involvement of HMOs as appropriate

For some sites, we recognize that the active support of HMOs will be important in our efforts to recruit participants. In other sites, given the rapid changes in managed care, the active support of newly-emerging HMOs may become more important over the proposed three years of recruitment for ENRICHD. All of the sites are aware of these issues and either already have solicited the support of HMOs or are prepared to do so when appropriate.

• educating the professional community through a HomePage on WWW.

• ENRICHD home page address is: www-bios.sph.unc.edu/escc

It is our experience that many members of the professional community have become avid purveyors of the WWW. Hence, the ENRICHD HomePage on the WWW. The home page is an effort to educate these providers about ENRICHD to promote their support of recruitment and retention efforts.

3.3.2 Approaches to Promote Receptivity of Potential Patients and Families
• community education to promote receptivity by potential participants and their families

As mentioned in 3.3.1., we anticipate active efforts to promote community education through multiple channels, using the media as well as talks within the community. Educating potential patients and families about the risk associated with depression and/or low social support may be important in promoting their receptivity to enrollment in ENRICHD. However, as with efforts within the professional community, care will need to be taken to ensure that concerns are not raised to the point that patients and families do not significantly alter their approach to seek care or self-manage depression and low social support for those patients assigned to usual care. Thus, we are sensitive to the needs to promote general education about ENRICHD but only in a relatively limited manner.
• developing tools and methods to ensure that potentially eligible post-MI patients and their patients can be educated quickly and efficiently

We recognize that much of the orientation and education of post-MI patients and their families concerning ENRICHD will need to occur while the patients are hospitalized since the community educational efforts to which they may have been exposed prior to the MI will be minimal. While patients and their families will need to be fully informed, we also recognize that hospitalization after a cardiac event is a busy period and little time may be available during the day to meet with patients and their families to inform them as well as to screen them. Hence, ENRICHD will develop brochures and a video tape in an effort to facilitate efficient education and orientation of patients and their families. We have had particular success with the use of video tapes and anticipate that this will be a very useful method for ENRICHD since most hospital rooms are now equipped with VCRs. We also anticipate that our recruitment and screening will largely need to occur during evening hours and plan our staffing patterns accordingly.

• incorporating motivational interviewing methods to promote patients to identify and clarify their own, personal reasons for participating in ENRICHD

Within the past few years, several of the ENRICHD investigators have had particular success in teaching recruitment staff to incorporate motivational interviewing methods into their discussions with patients. Motivational interviewing was originally developed by Miller and colleagues as a method of systematically identifying personal reasons for reducing alcohol consumption among problem drinkers (refs) but has more recently been applied in efforts to promote recruitment, adherence and retention within clinical trials. Thus, we will train the CCs and local hospital recruitment nurses to use motivational interviewing methods in an effort to promote recruitment and active participation.

• enlist support of health care providers (physicians and nurses) to lend credibility and provide potential patients with encouragement and support for participation

Physicians and nurses provide a highly credible source of information for most patients, particularly when they are hospitalized during an acute event. Consequently, there is great value in enlisting the support of health care providers in encouraging and supporting their patients to participate in ENRICHD. Health care providers should be enlisted in the recruitment process, encouraging them to mention ENRICHD to potentially eligible patients and to encourage patients to participate even before patients are approached by ENRICHD staff. For patients who seem reluctant to participate when they are approached, active efforts should be made to discuss the patient’s participation with his/her nurse and physician, and these health care providers should be enlisted in efforts to fully inform patients of the potential benefits of enrolling in the trial.

3.3.3 Approaches to Address Particular Issues Among Minorities

ENRICHD will enroll 50% women and 50% minorities in the total sample. In order to achieve that objective, we plan to implement a number of recruitment strategies specifically designed to assist
women and minority patients in participating in the study. Since both these patient groups have often been under represented in previous clinical trials of the management of MI, we will use a set of generic recruitment strategies aimed at facilitating participation by both patient groups. The issues that we have identified and will address that are of particular importance for women, minority and low-SES participants can be categorized into logistical, belief and attitudinal issues. Important issues that will be addressed are further considered below.

- logistical issues such as transportation, child care, timing of visits, etc

As mentioned in Section 4.1.2, the role of the Case Coordinator will be critical in assisting intervention patients to meet individual needs. The Case Coordinators will be particularly sensitive to issues concerning transportation, meals, child care and other family obligations, timing of counseling sessions etc. In some cases, this will require liaison with social workers and other health professionals. In other cases, it will involve the Case Coordinator serving as an advocate for participants within the site activities to ensure that methods to overcome child care and session timing concerns are addressed at the local level.

- cultural diversity and sensitivity of staff

Recruitment efforts often suffer from a lack in diversity and sensitivity in study personnel, leading to poor recruitment results in certain subsets of patients. Obviously, this issue is not limited to female and minority patients, and may apply generally to the heterogeneous mix of patients that will be targeted for this trial. We will, therefore, endeavor to hire appropriate personnel aimed at maximizing the diversity of the staff. This will allow us to, where possible, match staff to patients in terms of gender and ethnicity. In addition, we will make sure that we have bilingual staff, particularly at the sites that plan to recruit Spanish-speaking patients.

In addition, we will require that all staff receive adequate training to ensure cultural sensitivity. Sensitivity on the part of the staff is not only important regarding the mixed gender and ethnicity composition of the study sample, but also regarding the age and specific psychosocial characteristics of the patients targeted in this trial. For example, given the recruitment objective of 50% women, we will likely enroll a substantial number of older and potentially quite frail patients, who might need special assistance during recruitment. Equally important is the fact that the ENRICHD trial is aimed at socially isolated and depressed patients, and we will therefore instruct recruitment staff regarding the nature of these conditions, and train them how to be sensitive to these conditions while trying to enroll them in the study. Severely depressed patients may form a particular challenge during recruitment, and recruitment staff will undergo special training to help them develop the skills to enroll these patients in adequate numbers.

- literacy and language issues

In a study which attempts to enroll bilingual people, mono-lingual non-English speaking people, and low-SES persons, literacy and language issues are extremely important. Populations for ENRICHD in which language is a concern is largely limited to Hispanic populations. While there is clearly
variation in language across different segments of the Hispanic population, diversity in our target recruitment population is sufficiently limited so as to make it possible to use a single translation of text material. Those centers recruiting non-English speaking participants will have sufficient recruitment, screening, clinical and intervention staff who are fluent in Spanish to address communication concerns. We will also ensure that appropriate text materials are used. Spanish language versions of all ENRICHD questionnaires are available.

Literacy is an issue that will likely be encountered by all of the ENRICHD centers. To address these issues, written materials to be provided to participants were developed at an 8th-grade reading level. However, we have also found that it is essential that appropriate options be available to participants for assistance in reading in completing assessment and intervention materials. For assessment materials, all of the ENRICHD centers have used procedures to ensure that clinic staff are available and ask participants whether they would like questionnaires and materials read to them. In our experience, asking in this manner in a straight-forward and non-judgmental manner is often sufficient to minimize the embarrassment of participants and awkwardness of the situation.

To address literacy concerns with materials that are sent home, we have often found that participants will have family members or friends who can assist in reading. Particularly for a study such as ENRICHD, focusing on the treatment of depressed and/or socially isolated persons, efforts to involve significant others in this manner might be seen as having therapeutic benefit in addition to ensuring that the content of materials can be conveyed. Any record keeping by participants assigned to the intervention can also adequately be dealt with by having significant others record the information or providing tape recorders for the recording of information. The Case Coordinator and therapists will work individually with patients to ensure that appropriate measures are being used to deal with any literacy issues.

- complex belief and attitudinal issues

Low-SES and minority participants often report beliefs and attitudes that serve as barriers to participation in trials such as ENRICHD. We have found it effective, nonetheless, to acknowledge these common beliefs and attitudes from the outset, thereby allowing open discussion between the staff member and the participant. Common among these belief and attitudinal barriers are: fear of large institutional settings; fear/distrust of "research" and/or academic institutions; concern/unfamiliarity with randomization methods; and concerns about treatment continuity of care and primary care. Training of therapists, Case Coordinatorss and other staff will ensure that ENRICHD project staff are familiar with these issues and prepared to openly discuss these matters with participants. Within the overall context of a supportive environment, open discussion in this manner is often sufficient to minimize these concerns.

Belief and attitude barriers to participation will also be addressed through soliciting the support and endorsement of key influentials who are women and who are minorities. Comments by these individuals will be incorporated in video and print materials to be used in ENRICHD.
3.4 Tracking Systems/Screening Logs to Monitor Recruitment

We have found accrual tracking systems to be essential for examining issues related to comparability of enrolled versus not enrolled patients and for conducting efficient recruitment. These data can be used to facilitate recruitment by allowing quick determinations to be made not only of recruitment progress but also to characterize rates at which participants are showing for visits, reasons for ineligibility, and recruitment methods that prompted participants to volunteer; these data can then be used to refine recruitment methods and procedures for a more efficient recruitment over time. In a study which seeks to recruit proportions of particular groups, such as in ENRICHD for the enrollment of women and minorities, adequate data are also useful for tailoring recruitment methods over time in an attempt to meet goals for these groups. Additionally, these data will be essential to our ability to describe individuals who were not eligible for randomization, characterizing their demographic characteristics and specific reasons for ineligibility, as well as individuals who choose not to participate. Hence, the Coordinating Center will develop an accrual tracking system, incorporating variables seen as useful by the Clinical Units. Variables that will be included are:

- overall yields by screening visits (consent, show and eligibility determination rates)
- responses and yields by recruitment method/hospitals
- key baseline socio-demographic and medical variables from those not randomized and those not willing to provide consent for screening

3.5 Identification of Potentially Eligible Participants

3.5.1 Potential Sources of Post MI Patients

Patients can be identified at a number of different locations, including: the hospital’s daily patient census, the Emergency Room, the Coronary Care Unit of Intensive Care Unit, the telemetry floors, the medical floors, the Cardiac Catheterization Lab or the Interventional Cardiac Cath Lab, and on Laboratory Printouts. It is extremely important to consider all units in your institution where you might locate possible ENRICHD patients, so that no post MI patient fail to be screened. The hospital census may identify patients with acute MIs; if so it is a good place to start screening, but if you only look there you may miss many potential patients. In many hospitals, ICUs and ERs keep logs of patients that would identify those with acute MIs. These lists should be used to identify additional patients to be screened. Patients referred in to a tertiary center from outside physicians may come into your institution after their MI, only for an angioplasty or other intervention. These patients would not be noted on your hospital census as MI patients. Other patients may initially be admitted to your institution with a diagnosis of unstable angina, or rule out MI, but go on later to rule in for MI. All areas listed above are units where you might locate post MI patients. Consider your own institution for additional areas to screen. By making contact with staff in these areas before ENRICHD begins, and providing inservice training about ENRICHD, you may receive patient referrals from them and will minimize the chances of missing potential patients. Another
approach to identifying potential ENRICHD patients is to make arrangements to receive your institution's laboratory printout of patients with abnormal biomarkers.

### 3.5.2 Personal Contacts Will Assist in the Identification of Post-MI Patients

Contacts from a variety of hospital areas can prove to be efficient sources of promising leads, such as:

a) The ER Head Nurse can provide you the ER admit sheet on a daily basis. The Head Nurses in the Cardiac Care Unit or other unit may do the same.

b) Floor Nurses can let you know which patient is still too ill to discuss the study, or whether a patient is incompetent.

c) Nursing staff can provide information on when the patient may be discharged, and what time of the day might be best to approach this patient.

Talk to anyone in your institution who may be of help in the identification and screening of MI patients. Making friendly contacts in all hospital areas identified can save you time because these people can provide data directly to you on patients currently in house post MI, or with a diagnosis that may become an MI. They may also provide information on patients admitted for a cardiac procedure, such as a PTCA. This can gain you needed information without time consuming and extensive leg work on your part.

### 3.5.3 Who Can Give You Permission To Approach Patients About ENRICHD?

This will vary by institution and situation, but may include: a) attending physicians; b) emergency room physicians; and/or c) private physicians from outside practices. Approaching patients that don’t “belong” to the physician you work for can cause multiple problems, unless you receive prior permission from that patient's referral physician. In large institutions with many referrals from outside general practice MDs, or internists, recruiting these patients without the knowledge and permission of their physician may be viewed in a hostile manner. In some cases the referring physician may be participating in another trial and plan to enroll that patient, once he/she is discharged from your institution. Your enrolling the patient in ENRICHD would often prevent that enrollment from happening, and result in animosity from the referral MD. Outside referral physicians are often very conscious that patients they refer to a specialist may continue to seek care from the specialist rather than returning to the referral physician for ongoing care. Both for reasons of common courtesy and for continued referrals from these physicians, it is important that the outside physician know about the ENRICHD protocol and give permission for his/her patients to be screened and approached about the study. Receiving blanket approval from attending physicians to approach their patients is suggested wherever feasible. This is more likely to occur if they know you will be sensitive to their lines of referral. When you screen patients from physicians who gave blanket approval (particularly those who do not regularly make rounds of their hospitalized patients), notify them (by mail) that the patient has been approached. This is not only a courtesy, but also a
way to help keep the patient in ENRICHD. If their physician knows the patient is in ENRICHD, and discusses the study in a positive way, the chance of dropout will be reduced.

### 3.5.4 Organization and Management of the Screening Process

The organization and management of the screening process will differ from site to site depending on the characteristics of the hospitals, the qualifications of the screening staff, and the preferences of investigators and staff. However, it is important to determine clearly who has responsibility for each step in the screening, eligibility determination, baseline data collection, and randomization process. Perhaps the best way to determine responsibilities by screening visits (SV0, SV1, SV1a, etc.), since these visits cluster comparable or compatible activities together. While it may be determined that a single individual has responsibility for more than one screening visit and that screening visits may occur sequentially without the patient even realizing that a new step in the screening process has been entered, alternatives to this approach are possible, depending on local circumstances, that break up the screening visits by time and by responsible staff member.

Variations in the screening process will also occur based on institution size and type, staff member’s work schedules and workloads, screening frequency desired, and availability of charts for screening. If your institution is a large tertiary center, with many admissions each day, and patients located in many areas, through prescreening make take a significant amount of time each day. At large centers, it may be necessary to have more than one person prescreening patients for ENRICHD to be certain that all MI patients in your institution are covered. This need will vary, dependent on the number of patients available for screening, and the Coordinator’s other responsibilities and work schedule. Obtaining medical records and auditing for inclusion/exclusion criteria on each identified MI patient may be a time consuming task. Chart auditing is an easy skill to teach; if Coordinator hours are at a premium, consider hiring a student part time to complete chart audits on identified post MI patients. At some large research centers, a Coordinator may be able to screen simultaneously for multiple trials with similar patients needs. At smaller hospitals, with fewer patients, one Coordinator screening on a daily (weekdays) basis should easily be able to prescreen every MI patient.

In most cases, prescreening should be done each weekday. Without daily screening, patients may be located several days post MI, resulting in the patient being discharged before an approach for ENRICHD is possible. Hospital stays for uncomplicated AMI are becoming shorter and shorter. For this reason, it’s recommended that Friday prescreening be done in the afternoon, and Monday’s, in the early morning. To help determine the average amount of time uncomplicated patients will remain in your institution, and therefore their availability for screening, find out the procedures done on post MI, patients at your hospital. For example, in our institution cardiac catheterization is routine prior to patient discharge, but not in every institution. A catheterization may add another partial day to a patient’s hospital stay. Each patient is unique, but by determining standard practice patterns in your institution, you will get a feel for the amount of time available to find patients and screen them for study eligibility prior to their discharge. Ease of chart access for audits may vary by time of day and your institution’s practices. Determine an optimum time for review in your institution by questioning staff on the various units.
3.5.5 Organization of the chart review process

Prior to examining any charts or approaching any patients, permission should be obtained from the hospital administration, unit staff, and/or individual physicians according to local hospital procedures and policies and local IRB requirements. Note: IRB requirements may require patient informed consent prior to chart review. Also, IRB requirements or local procedures and policies may require physician approval before chart review. If either of these situations is the case, then consent and/or physician approval must be obtained before looking at any charts.

Screening of ENRICHD pilot study patients should then proceed as follows. Once patients are identified, determine which unit has the largest group of MI patients. Proceed with chart auditing on that unit first.

a) Obtain medical records on all identified MI patients located on the unit.

b) Organize the records by patient’s date of hospital admission.

c) Start audit with the record of the patient admitted first.

d) Begin audit by reviewing chart information easiest to locate with respect to inclusion / exclusion criteria; compare to determine if patient fits study criteria.

e) Look first at the admitting history and physical exam to determine underlying medical conditions.

f) If the first patient reviewed fits criteria, and is close to discharge, consider whether there will be time to approach the patient later, or whether he/she may be discharged imminently.

g) If time allows, continue reviewing charts until all MI patients on that unit have been prescreened for ENRICHD. Then approach the patient who seems closest to discharge first.

To avoid reviewing the entire record on patients who may not qualify, review first for concomitant medical conditions that may limit life expectancy or the patient’s ability to benefit from the study, or patients with known physical or mental limitations that might interfere with full study participation. Be sure to review MD narrative/progress notes for clues as to when the patient will be discharged. Better yet, ask the physician or the nurse caring for the patient.

3.5.6 Rescreening Promising Candidates

Keep a list of patients whose charts were screened who were excluded for conditions that might change prior to discharge. Examples of such exclusions include:

a. High values of lab safety parameters, or low values of cardiac enzymes

b. Patient too ill / unstable for current approach
c. Patient currently on prohibited medications

Plan to re-screen chart for changes in patient condition prior to discharge:

a. Note date of planned re-screen on patient list

b. Continue re-screening until patient is eligible or definitively ineligible for ENRICHD enrollment

3.6 Conducting the Screening and Baseline Interviews

3.6.1 Planning the Approach to the Patient

Once the patient is prescreened, and appears eligible for ENRICHD, plan carefully a time to approach him/her. Your visit needs to take place between the patient’s tests and procedures to get to them at a time they are not tired, and they can focus their attention on you.

Try to get a rough idea of the customary tests and procedures in your institution/community for post MI patients, and their usual sequence. With this knowledge, and careful attention to what stage the patient has reached, you can attempt to time your visit optimally.

a. Approach early in the hospitalization may be preferable; there is less chance of missing patient.

b. Each institution differs in timing of patient procedures; determine procedure schedule for particular patient.

c. Allow sufficient time to complete introduction, brief explanation, consent and interview in one visit.

d. Patients More Frequently Have Visitors Afternoons, Evenings and Weekends.

e. Late evening, after visitor hours, may be appropriate, as may late night or very early morning.

f. Day of discharge is the worst day for patient approach; patient is focused on leaving hospital.

3.6.2 Conducting the Initial Patient Contact

Smile and take it slowly; be empathetic and patient.

a. Introduce yourself; tell where you’re from and what you’re doing

b. Mention the patient’s doctor suggested (or approved) your contact

c. Ask if patient has a few minutes to talk to you. If patient is “too tired”, ask about a better time
Be courteous

a. If visitors are present, introduce yourself; say you’d like to talk to the patient
b. Don’t run visitors off; instead, ask when you can return, perhaps while visitors get a meal
c. Assure patient’s privacy

1) If staff are present in room, wait to get into personal information until they leave

2) Some hospital rooms are small and not private. Curtains provide only the appearance of privacy. Modulate your voice level appropriately.
d. Allow some time to get to know the patient. Take the time to let her talk to you awhile about what is on her mind before you begin talking about ENRICHD

3.6.3 Gaining Acceptance
A sample “Overview and Consent Script is provided in Appendix 4.1. This may be modified to meet local requirements and circumstances. General principals in obtaining consent include:

a. Be Positive About the Study: Your Attitude Counts
b. Briefly explain the study; save specifics for later

1) Emphasize all MI patients are being approached for this study which is being run nationally at many large medical centers

2) Use non-medical terminology and simple explanations whenever possible

3) Explain that earlier research suggests a post MI patient’s mood and his/her interactions with the people around him may effect his cardiac outcome

4. Identify the patients’ role in ENRICHD
c. Assure patient confidentiality of any information collected

1) Explain that the patients name will not be on any of the study materials, that patients are identified by study number and initials instead

2) Explain who has access to the information

− Patient must be told that others besides yourself will see the information, but they will be people connected with the study, or people who work auditing studies or for the FDA
d. Assure patient of lack of pain or discomfort in interview participation

e. Thank the patient for agreeing to participate

Make certain the patient understands that he/she was not specially singled out to participate in this study due to something he/she did or said, instead that **ALL** patients admitted to your institution with a heart attack are being considered for ENRICHD participation.

Talk honestly about the role the patient plays in research studies, and in ENRICHD. Explain honestly that although the patient may gain nothing from participation, information learned from his participation and that of the other patients may lead to improvements in the care of people having heart attacks in the future.

Make certain that patients understand that the information they give you on a questionnaire or in an interview is as confidential as their medical record. Some people other than yourself will see it, but the patient’s name will not be attached to the information in any way, even if information is written up about the study later.

Many patients are concerned about additional pain or discomfort; assure the patient that this interview is “talking only”, no discomfort. In fairness to the patient, they need to know that if they qualify and go on to full study participation, they will have blood drawn at a later date.

### 3.6.4 Approaching Patients who can’t be interviewed in-hospital

General principles with patients who have been discharged include:

a. Initial face to face contact while the patient is hospitalized is preferable to a telephone introduction

b. If patient’s remaining time in the hospital is very short, make your introduction brief

c. State that you’d like to call the patient when he settles in at home to talk with him further

d. Mention the conversation will concern the patient’s mood after his heart attack

   2. Tell the patient his doctor either suggested or OK’ed your contacting the patient

d. Request permission to telephone in a day or two; ask what time is best

e. Make phone call as scheduled; follow guidance provided for in hospital approach
3.6.5 General Issues in Interviewing Patients

There are a number of general issues to which interviewers must adhere in interviewing patients. These include the following:

- Sensitivity to patient burden. Consent must be obtained from patients’ physicians before approaching patients to participate in the pilot study. Patients who are too ill, easily fatigued, or who would be overly burdened by participation will not be approached for recruitment. The screening and baseline measures (for patients who participate in completing the baseline measures) will be administered at separate times, rather than in one session, in order to avoid patient fatigue. Interviewers must be sensitive to signs of fatigue or other indications that patients are uncomfortable, such as yawning, difficulty concentrating, agitation, etc. If interviewers note signs of fatigue or discomfort, they will discontinue or postpone the assessment should it become onerous to patients. At the first signs of fatigue or discomfort, interviewers will discuss with patients the option of interrupting or terminating the assessment. In addition, when beginning each measure, interviewers will check with patients to make sure that they wish to continue.

- Literacy/data collection method. Some of the data collection for the pilot requires that it be collected in an interview format, while some of it can either be completed by self-administered questionnaire or by interview depending on patient preference. Although not the only factor that will determine patient preference for interview format, literacy will be one of these factors for at least some patients. While some individuals are comfortable in admitting that they are low in literacy, this is uncomfortable for many patients. It is essential to be sensitive to these, as well as other, potential patient concerns. The best manner in which to handle issues of patient preference is typically to ask all patients for their preference, such as by asking them: “I have some questionnaires which you can complete either on your own, or I can read them to you if you like; what would you prefer?”

- Confidentiality of information. All information obtained from chart review, discussions with patients’ physicians or other medical care staff, and from the patients themselves is confidential. Procedures have been developed centrally to ensure the confidentiality of information, such as ensuring that patient information is not identified with patient names and that analyses are conducted and reported by group rather than by individual patient. However, each site will also develop and enact procedures to ensure the confidentiality of information. This will be particularly challenging with interview information that is collected from patients. Interviewers must ensure that confidentiality is not violated in the collection of information as a result of family members, other patients, or non-ENRICHD staff being able to hear or see patients’ responses. The methods to do this will vary from setting to setting but will require either conducting the interviews in patients’ rooms when no one other than ENRICHD staff are present and no one can over-hear the interview (e.g., the door must be closed) or in another room in which confidentiality can be assured.

- Presence of family members or friends. There are concerns about confidentiality from conducting interviews with family or friends present, and this is to be avoided. However,
some patients may state a preference for having family members or friends present during the interview and hence may waive their right to confidentiality of their data from these persons. Even in these cases, though, it is best to conduct the interviews in private, because the patient may feel more freely answer questions truthfully in private than in the presence of family or friends. Hence, even when patients express a preference for others to be present, it is best to discourage this by saying something such as: “We have found that it is best to conduct these interviews in private. The interview won’t take long, and perhaps your [family or friend] can excuse us for this time. Alternatively, I can return at another time so that we can complete the interview.”

- **Completion of self-administered questionnaires.** Some of the questionnaires can be completed by patients if they so desire. However, even when patients are completing the questionnaires on their own, interviewers should remain in the room with the patient for two reasons: 1) to answer any questions that might arise; and 2) to ensure that no one comes into the room and attempts to assist patients in completing the questionnaires. We are interested in patients’ responses to the questionnaires, not responses that may be influenced by others. Hence, interviewers should remain in the room at all times when patients are completing questionnaires.

- **Detection of patients at suicidal risk.** Since the psychodiagnostic interview addresses diagnosis of depression and suicidal risk, issues concerning how detection of these conditions must be addressed. These issues are addressed more thoroughly in DISH Manual (see appendix). However, protocols for determining how the detection of depression and low social support are to be handled at each hospital must be determined and followed and is the responsibility of each clinical unit.

- **Benefits to patients.** ENRICHD has great potential for determining the benefit of psychosocial treatment of depressed and/or socially isolated post-MI patients on the development of new MIs and deaths. In addition, the information gained from the study will also be of direct benefit to the participants. If patients are found to be depressed via the diagnostic interview, this information will be provided to their primary care physician so that appropriate referrals can be made for treatment. Since depression is not an uncommon phenomenon during the post-MI period, yet is rarely if ever routinely assessed in post-MI patients, timely diagnosis and referral represent a direct benefit for these patients which may not be realized under typical hospital procedures.

### 3.7 Eligibility Determination and Randomization

#### 3.7.1 Eligibility Determination

For each eligible patient screened, the following procedures should be followed prior to calling the ENRICHD Coordinating Center to randomize the patient:
• Enter the patient information on the ENRICHD administrative form - Screening Log (SLA)

• Complete the Medical Eligibility form (MEA)

• Complete Social Support Inventory screen scoring (ESSI)

• Complete the DISH (see detailed instructions in Appendix; Appendix 4.2 contains a sample script for introducing the DISH)

• Complete the Randomization Worksheet (RAN)

If the patient meets all medical inclusion and exclusion criteria, proceed with randomization into the ENRICHD study, and meets DSM IV criteria for major depression, or meets the low social support criterion score.

If the patient meets all medical inclusion and exclusion criteria, but the decision is made not to randomize the patient into the ENRICHD study at this time because of failure to reach a threshold score on the psychosocial screen, re-evaluate the patient within 2 weeks for a change in symptoms of depression or low social support.

3.7.2 Randomization Procedures

Complete the following procedures to randomize an ENRICHD patient:

1. With the completed Randomization Worksheet in hand, place a telephone call to the data coordinating center, 1-800-472-2595. The ENRICHD coordinating center Telephone Randomization System (TRS) will prompt you for your user ID and Personal Identification Number (PIN) to verify that you are an authorized user.

2. Next, information from the Randomization Worksheet will be used to answer a series of qualifying questions. The TRS computer will prompt you for the patient ID, BDI, and ESSI scores and the DIS, and Dysthymia scores from the DISH.

3. After confirming that the patient meets either the depression or low social support criteria, TRS will provide the patient's treatment assignment and randomization ID number. TS will also FAX the randomization information for the patient to your ENRICHD field center case manager office for confirmation.

4. Record the treatment assignment and treatment number on the randomization form worksheet.

5. Appendix 4.3 contains a sample script for informing the patient about their treatment assignment.

6. Once the phone call is completed, schedule the appointment with the ENRICHD therapist for patients assigned to the intervention group. For the usual care patients, take this opportunity to
schedule the first follow-up visit 6 months from today (within a visit scheduling window of 3 weeks).
Appendix 3.1. Sample Overview and Consent Script.

"Hello Mr./Mrs. Jones. How are you feeling? (How are you doing? How are things going for you?) I'm Jane Doe from the _______ Department. I work with a group of doctors who are studying new ways to help people recover from a heart attack and I would like to describe this study to you. Dr. _______ has agreed for me to talk to you about this.

(This statement can and should be made stronger when true, e.g., Your doctor knows about this program and believes that it would be a good opportunity for you).

"The project I am about to describe is a research study funded by the National Institutes of Health in Washington, D.C. It involves identifying people who have just had a heart attack who may be having problems with feeling down or depressed or feeling stressed, or who might not be getting as much support from other people in their lives.

The scientists who have put this new program together have spent many years interviewing heart patients. They have found that prolonged sadness or depression or feeling isolated (apart from) from others are common problems for heart patients that make it more difficult (harder) for them to recover.

I would like to ask you some questions that will help me decide if this program fits you. If the program might help you, I would like to then do a longer interview. If after the interview it appears that (looks like, seems like) you might be depressed (be feeling down or sad) or that you might need more social support, then I will invite you to be in our study. There is no cost for your participation in this study.

Do you have any questions at this point?

(Pay attention to the subject's non-verbal behavior which may give you some information as to their interest. Some people will be ready to go over the consent at this point, others may be backing out.)
"If you would like to take part in this project, there is a 50-50 chance that you could receive the new program to help you with these difficulties (problems). Even if you aren't assigned to receive the new treatment, we will want to check in with you every six months to see how you are doing. You will be free to seek treatment on your own if you wish. In either case, your medical care and any other treatments will continue under the direction of your usual doctor (internist, cardiologist, clinic doctor, etc.). Can I answer some questions for you?

Let's go over the consent form together."
Appendix 3.2. Sample Script for Introducing the DISH.

"Now I would like to ask you some questions about how you have been feeling and how your mood has been. Some of the questions may seem a little unusual or may not apply to you, but they are all about attitudes and feelings that patients may experience. Answering these questions should take less than an hour. While we would like you to answer each question to the best of your ability, you are free to choose not to answer any question or questions that you do not want to answer. Do you have any questions at this point?

(Note: It is best to remind patients that they can refuse to answer any questions the first time that the problem occurs. Sometimes telling them this gives them enough reassurance to go ahead and answer. We often explain the importance of, or reasons for, asking questions when we get to that point. How to help patients with this will be covered in the interview training.)
Appendix 3.3. Sample Randomization Information Script.

"Mr./Mrs. Jones. Hello. I am from the ENRICHD PROJECT (etc.). (Personalize call here, e.g., How are you doing, etc.) I have had a chance to call the Coordinating Center to get your group assignment. You have been randomized to the __________ group.

"This means (usual care) that you will continue to be treated by your doctor over the course of the study and will receive phone calls from the project staff about every six months. You will be asked to come to the clinic at 6 and 12 months from now, and then every year for the next ____ years for a short visit to discuss your recovery. Your blood pressure and weight will be measured, and you will be asked to complete a few questionnaires by interview. Your continued participation in the project is very important to the project. You will help ensure that we are able to obtain the best information we can about patients' recovery from a heart attack. Do you have any questions?"

"This means (intervention) that you will be followed by the staff of the ENRICHD program, and will be receiving individual counseling by a counselor over the next few weeks, and you will then graduate to a group program where you will be able to share experiences with other patients who have had a heart attack and have similar concerns as you do. You may be prescribed anti-depressant medication if
you are very depressed or don't improve with this counseling. These counseling sessions may last up to six months. You will also be telephoned by the ENRICHD staff and will be asked to come to the clinic for a short visit every six months. You will be asked about your recovery, your blood pressure and weight will be measured, and you will be asked to complete a few questionnaires by interview. Your continued participation in the project is very important and will help ensure that we are able to obtain the best information we can about patients' recovery from a heart attack. Do you have any questions?"
Appendix 3.4. Educational Component Script.

"Mr./Mrs. Jones as part of the ENRICHD Program I want to provide you with some important information about your recovery now that you have had a heart attack. The (American Heart Association) has developed a program for people like yourself to help you with some of the adjustments you need to make in your lifestyle. These changes include such things as modifying your eating habits to lower your cholesterol, beginning a regular program of exercise based on what your doctor says is safe for you, and quitting smoking if you smoked prior to coming into the hospital. This workbook is yours to keep--to read and to review over the next few weeks. It has answers to many of the questions that you may have once you get home and back to work. The workbook gives you factual information and also contains some self-assessments that let you test how well you are doing. Most of the important information you need to know is presented in the first part of each section of the workbook. We hope you will take the time to read each section and use the information to give you ideas to help you make changes in your lifestyle. You may also want to share this workbook with other family members who are interested in your recovery."