CHAPTER 9

RETENTION ACTIVITIES

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RETENTION ACTIVITIES

9.1. GENERAL INFORMATION

Retention will be a challenge in the LIFE study, as it is in all clinical trials. However, LIFE may present even greater challenges due to the compromised physical status of the participants. LIFE provides a variety of benefits in an effort to maximize the number of participants who complete all follow-up visits. These benefits include the interventions, medical monitoring, and financial incentives. Essential aspects of maximizing participation and promoting retention are: 1) carefully screening and assessing barriers to adherence and retention prior to randomization; 2) carefully monitoring adherence problems (which often predict retention problems), trying to identify these problems early before participants refuse further study contact; and 3) applying specific strategies to address these problems. The methods most likely to maximize retention will vary by individual and by clinic; therefore, each LIFE clinic must design an appropriate retention plan for its participants. General retention strategies and those to be applied in special situations are described in the sections that follow.

The center's behavioral psychologist should play an active role in training staff and investigators in adherence/retention problem identification, using motivational interviewing methods to promote adherence and retention, and developing and implementing drop-out recovery plans. Centers without a psychologist should designate the staff member with the most behavioral training and experience to assume these responsibilities. If the center does not have a psychologist, a consultation and referral relationship should be established with mental health professionals at the institution. These professionals can help develop retention plans and establish referral policies for participants who may need counseling or other psychological treatment.

9.2. GENERAL RETENTION STRATEGIES

LIFE retention will be facilitated by general strategies that include: facilitating access to the clinic, maximizing availability of staff, providing participants tangible support and emotional support, and providing appropriate information to participants, family members, and primary care providers.

9.2.1. Facilitate Access to Clinic

Maps and Signs:

The study site should be easy to find. Maps and good signage are essential.

- Maps often are available from sources within the institution or can be developed by LIFE staff. Detailed information such as elevator location, floor and room numbers is needed to guide participants to the specific area. Signage may be harder to acquire than maps because it often requires organizational sanction.

Physical Setting:

Although clinic and intervention areas should be separated to maintain masking of data collection staff to participants' group assignments, ideally both should be in convenient and attractive areas containing, as appropriate, a waiting area with receptionist/secretary, rooms that provide privacy for data collection or counseling, and offices for the staff.

- Participants should be escorted by staff and introduced to personnel in each area used for study activities. Escorting should continue until the participant volunteers can travel from one area to another independently.
- Bulletin boards, posters, and other materials can be used to provide information on LIFE to promote participants' allegiance to the study.

Transportation:

Convenience and cost of transportation are two factors that will affect study retention, particularly among lower-income participants and those who reside or work in areas in which public transportation is not well developed.

1. Convenience:

Location of and cost of parking garages or lots, distance from bus stops, perceptions of safety in gaining access to the building, as well as hassle associated with travel are factors that can affect appointment keeping and study retention.

- Information about public transportation stops and parking garages should be included on location maps discussed above.
- Safety considerations should be addressed. Do not assume that participants know what is risky versus safe behavior related to parking and walking in the area around the study site. When possible, have a

staff member accompany participants to parking or transportation areas.

- Concerns over travel during rush hour should be discussed with volunteers and used to guide the time visits are scheduled.

2. Cost:

   LIFE sites should develop a reimbursement policy for transportation expenses incurred by participants. Centers may elect to pay parking charges, etc., for all participants or to reimburse on an "as needed" basis. Mechanisms for reimbursement vary depending upon institutional policies and local resources.

   - Stamps to validate tickets or charge cards are common methods used to assign parking fees to study accounts.
   - Tokens for public transportation can be purchased in bulk and given to participants at each visit.
   - Charge accounts are available from taxicab and van services.
   - Many communities have volunteer transportation services, such as for senior citizens, which can be utilized at low or no cost to the study.

The marketing and social services departments at your institution are potential resources for information on transportation issues.

Changes in Access to Health Care:

Access to health care services is increasingly influenced by regulations, primarily rules associated with reimbursement plans.

- Participants recruited from HMO's and other managed care plans may perceive that a change in their plan influences their continued participation in the study. Changes in Medicare and Medicaid provisions also could affect retention of study participants.
- Some participants may lose health coverage while they are in the study.
- Changes in health care plans may mean a change in participants' primary care provider, introducing another factor that can influence retention. Monitoring of participant's access to primary health care services should continue throughout LIFE to alert staff to changes that may threaten study retention.

Be clear with participants what will be covered as a part of LIFE and what will not be. Participants should understand that they will need to maintain a primary care provider throughout the study.

9.2.2. Maximize Availability of Staff

It is critical that participants keep regularly scheduled appointments. Appointments serve many functions, one being monitoring of participants' progress. Individuals in the health education arm will be seen less frequently, and therefore may require the greatest encouragement to adhere to the appointment schedule.

Appointment Hours:

Study participants should be considered "customers". As volunteers, they cannot be expected to alter their schedules as they would to utilize health care services.

- The hours that staff is available for LIFE visits should be as flexible as possible to accommodate participants' schedules.
- Visits may need to be scheduled outside normal clinic hours such as in the evening or on Saturdays.

Availability Outside Of Business Hours:

Participants should be able to talk with staff at times other than study visits. This includes evenings and weekends.

- Study personnel who are familiar with the protocol should respond to calls.
- The on-call clinician must also be familiar with the protocol, or have a LIFE staff member on call to answer questions.

Staff Willingness to Spend Time with Participants:

The perception that members of the staff are willing to make extra efforts to accommodate participants' needs enhances retention. The amount and quality of time staff give participants may be as important as flexible schedules and access during non-business hours. This point is illustrated in a comment made by a participant to a study coordinator: "I like coming here because you listen to my stories."

Retention is enhanced when participants feel they are important and valued by the staff. This begins at the front door with friendly reception by staff and continues through the actions of staff over the duration of volunteers' participation in LIFE. Pleasant, kind, helpful, and attentive staff will facilitate bonding and retention in LIFE.

Facilitating Appointments:
There are a number of strategies that local clinics can pursue to facilitate participants in keeping their appointments, which include:

- Providing each volunteer with a LIFE calendar (monthly or quarterly) that indicates his or her appointment dates and specific information to prepare for an appointment. Individual centers may want to place the clinic's phone number on the calendar.
- Providing participants with wallet-sized appointment cards, which include the clinic phone number and "check-off" statements (fasting vs. non-fasting appointment, bring completed forms, bring medications, etc.) to help participants prepare for the next visit.
- Mailing written reminders or placing phone calls to the volunteers a week before the appointment. Staff members should take turns placing phone calls to volunteers. This will facilitate familiarity between staff and volunteers.
- Participant should also receive a phone reminder the day before their appointment.
- Using home or off-site visits. Based on the clinic specification and location, any staff member going off site should be escorted. Visits of this type should only occur during safe hours of the day as specified by clinic. If a volunteer is scheduled for an off-site visit for testing, it is suggested that an escort accompany the volunteer as well.

9.2.3. Provide Tangible Support

Tangible support includes those items that enhance voluntary participation in LIFE and minimize potential barriers to retention, fulfilling endpoint goals. These items include:

- Monetary incentives (given at assessment visits at the discretion of each site) as permitted by individual site's IRB.
- Reimbursement for parking
- Motivational/incentive items for achieving goals (items should have progressively greater value and require more effort to achieve).
- Referrals as needed for medical and mental health services.
- Social events once or twice a year for all participants to socialize with fellow participants and the staff. They should be offered to each study arm separately.
- Clinics may choose to use recruitment funds to reimburse participants for eldercare or transportation.

9.2.4. Provide Emotional Support

Participants feel supported when they perceive the study staff as caring and when they perceive themselves as full partners in the research process. The local clinic behavioral psychologist should lead efforts to provide participants with appropriate emotional support.

In general the following actions increase participant perceptions of support:

- Asking participants whether they prefer your using their last (e.g. Mr. Smith) or first name. Be sensitive to formal titles such as Dr. Smith. Once this information is known, write it down so that you and other staff members can be consistent and personal in your interactions with participants.
- Helping the participant feel the study environment is safe and comfortable.
- Engaging in general discussion with participants as opposed to "narrowly focused" on just activities within the clinic.
- Creating a relationship in which study goals are jointly established.
- Expressing interest in important aspects of a participant's personal LIFE.
- Asking about the participant's personal reactions to aspects of LIFE.
- Empathizing with and acknowledging what the participant has reported.
- Creatively conducting study procedures (when possible) in a manner that best meets the specific needs of the participant and family members.

9.2.5. Provide Feedback to Primary Care Providers

All LIFE participants should have an established source of medical care outside of LIFE staff.

LIFE is not intended to provide general medical management to the participants. However, communication with primary care providers may facilitate retention of participants in LIFE.

1. Participants will be given an information sheet that they can share with their primary care provider.
2. Relevant data from assessments will be provided to participants to share with their primary care providers. Standards of care or generally accepted guidelines for interpretation and/or interventions related to these parameters will also be provided.
3. LIFE staff will contact participants' primary care providers under other certain circumstances (e.g., if a participant's involvement in a LIFE intervention is discontinued for safety reasons or a situation requiring urgent medical follow-up is required.

9.2.6. Provide Feedback to Participants

LIFE participants should be given the results of relevant health data collected at study visits. If blood pressure exceeds alert values (see Safety Management – Chapter 21 for other alert levels and other details of safety aspects), a LIFE physician or other staff member will contact the participant and send a report to participants' primary care providers within one week.

The LIFE Study has developed a **Baseline Results Report** to be shared with the participants after their SV1 and SV2 visits. Result Reports will also be provided at follow- up visits. These reports are designed so that it can be personalized for each field center. A copy of the reports can be found at the end of this chapter, with the editable forms on the LIFE website under Study Tools. For SV1, the first 3 pages of the report should be provided to the participant at the end of their visit (blood pressure, height/weight/BMI, memory test). Details for completing the Blood Pressure and Memory Test forms are provided below. In addition, participants should be provided with a copy of their ECG. Staff should explain the results to them and answer any questions they may have. For SV2, the Lung Function and Ankle-Arm blood pressure results should be provided (pages 4 and 5 of the report). Information for examiners on how to complete those results reports are provided below. For the 6- and 18-month follow-up visits, weight, blood pressure and lung function reports should be provided and explained to the participant. For the 18-month follow-up visit, a copy of the ECG should also be provided. For the 24-month follow-up visit, the Memory Test reports should be provided and explained to the participant. For the 30-month follow-up visit, weight, blood pressure, lung function and Ankle-Arm blood pressure results should be shared with the participant. For the Close-out visit, the Ankle-Arm blood pressure results and a copy of the ECG should be shared if these procedures were performed. Again, staff should take time when reporting these results as they are a wonderful retention tool.

Participants will also receive a copy of their blood results. Field center Program Coordinators will designate a staff member (in most cases the Medical Safety Officer or Study Physician) to review the blood results and then send a copy to the participant via mail. These results should **NOT** be given to the participant through their Interventionist in order to maintain masking. The designated person will either send the Normal Blood Results Letter or the Out of Range/Medically Significant Results Letter or the Immediate Notification Letter. If any results are LIFE Study Alert Values, the study staff should contact the participant by phone, prior to mailing the report. If the values are just considered "Out of Range" based on Quest normative values, highlight the out of range values and mail the report. It is not necessary to contact the participant by phone.

Guidelines for the Blood Pressure Results Report:

The first page of the report provides blood pressure information. Below the participant's actual systolic and diastolic blood pressure results that will be written on the Results Report are listed three main categories of blood pressure results:

Normal: Less than 120/80 mm Hg
Prehypertension: 120-139/80/89 mm Hg
Hypertension: 140/90 mm Hg or higher

Also, based on the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure guidelines, there are five categories to check on the blood pressure portion of the Participant Results Report:

• If the participant's systolic blood pressure is normal, i.e., <120 systolic, and < 80 diastolic or prehypertension, 120-139 systolic, or 80-89 diastolic, check "Recheck blood pressure within 1 year" on the Participant Results Report.

• If the participant's systolic blood pressure is 140 to 159, or their diastolic blood pressure is 90-99, check the box on the Participant Results Report that says "Recheck blood pressure within 2 months." Suggest to the participant that they have their blood pressure rechecked within 2 months.

• If the participant's systolic blood pressure is 160 to 179, or their diastolic blood pressure is 100-109, check the box on the Participant Results Report that says "See your doctor within 1 month." Suggest to the participant that they see their doctor within one month.

If the participant's systolic blood pressure is 180 to 199, or their diastolic blood pressure is 110-119, check the box on the Participant Results Report that says "See your doctor in 1 week. Instruct the participant to contact their primary care provider within one week.

• If the participant's systolic blood pressure is ≥200, or their diastolic blood pressure is ≥ 110, check the box on the Participant Results Report that says "See your doctor immediately." If the participant gives their permission, you can contact their primary care provider immediately, or instruct the participant to contact their primary care provider immediately.

Anthropometric Results:

The results of the participants height (in centimeters and feet/inches) and weight (in kilograms and pounds) should be written on the results report. To calculate body mass index, find the participant's height along the horizontal axis on the left and move across that line to find their nearest body weight. The number at the

top of the column is the approximate BMI for that height/weight combination. Circle the closest number for the participant's reference.

Memory Test Results:

The results of the memory testing should be indicated as follows on the Baseline Results Report: Box 1 is checked for those with 3MSE values above established cut points. . If a person became ineligible for LIFE because of a 3MSE score below the established cut points, then Box 2 should be checked.

Lung Function Results:

The lung function results should be transcribed from the Spirometry data form to the Baseline Results Report. Box 1 should be checked when the lung function test was not performed or lung function could not be determined accurately. Box 2 should be checked when all values are within the Usual Normal Range, as per the results table. Box 3 should be checked when values fall below the Usual Normal Range.

Ankle-Arm Blood Pressure Results:

The ABI results should be entered in the results table for both the left and right leg. Results should then be checked as Normal, Borderline or Out of Range for each leg. Results are considered Normal when ABI levels are >1.0 and <1.30. Results are considered Borderline when results are between 0.90 and 1.0. Results are considered Out of Range when the Ankle-Arm ratio is <0.9 and >1.30.

9.2.7. Continue Using Motivational Enhancement Methods

The physical activity intervention section of this manual presents a number of counseling skills that are important to the motivation of participants in the LIFE study. These methods are useful for fostering continued adherence and active participation. Hence, efforts to sharpen staff and investigator motivational enhancement techniques should continue throughout the study.

9.3. THE LIFE NEWSLETTER

Each center is encouraged to produce a quarterly **site newsletter**, "News and Views" to share center news and to create a sense of community among participants. These site newsletters should be developed separately for each arm. In addition, on an annual basis, the newsletter will be used to share study-wide information with participants so that the National Scope of the study is underscored.

9.4. LIFE "Participant Handbook"

LIFE Participant Handbooks should be prepared for each treatment arm of the study. These binders make it easy for randomized study participants to save important materials, such as consent forms, lab results, fact sheets, booklets and other information they receive about the study. The manual should be presented to the participant following randomization and include:

1. Welcome letter to participants from Evan Hadley (NIA) printed on letterhead and provided to the clinics from the coordinating center.
2. Welcome letter from the site Principal Investigator.

Sites will tailor their binders to include additional information specific to their participants. Some suggestions on what the sites can include in the handbook are:

1. A list of materials to bring to clinic visits
2. Closest parking – cost of garage parking/availability of vouchers
3. Public transportation – location of closest bus stops, and commuter train stations
4. Eldercare availability
5. What to do if the weather is severe and volunteers cannot get to the hospital/clinic for an appointment
6. How volunteers are informed if the clinic is closed or if there is a program cancellation/change (due to severe weather), i.e.; radio, phone call

9.5. IDENTIFYING AND RESOLVING RETENTION PROBLEMS

Keys to success here include:

- Staff sensitivity to signs of problems, so they can be identified at the earliest possible moment, when intervention is easiest and most effective.
- Careful documentation of problems, allowing timely and complete communication among staff and with the participant to address the problem. Be mindful that all chart documentation should be conducted with the utmost professionalism, and all comments should be entered with the assumption that the individual participant may have access to all entries.
- Interventions designed to effectively resolve problems, especially efforts to maintain positive communication with participants who are having difficulty committing to a regular schedule of clinic visits.
- Active participation of the clinic behavioral psychologist in counseling case managers and meeting with participants.

These keys to success apply regardless of the stage participants have reached in LIFE or the level of difficulties. Efforts to address possible adherence and retention problems should be initiated during screening and baseline testing. Any signs of potential difficulty identified below as "red flags" should be taken seriously and fully discussed with potential participants and among the staff. Special attention should be paid to: problems scheduling screening visits, frequent rescheduling, difficulty establishing or maintaining phone contact, participant reservations about study burden, past problems in modifying behavior, complaints about clinic procedures, or serious reservations about randomization. Two additional points should be emphasized to potential participants prior to randomization.

- First, the critical need for follow-up visits even in the absence of protocol adherence should be made clear at this point and on a continuing basis. We need to make clear our governing paradox:

  > "We really, really want you to stick to your active LIFE program, but even if you decide you don't want to (or can't) right now, we really, really want you to stay in touch. We know there will be times when you may slip from your LIFE program. Everyone will do that, and it is to be expected. There are lots of things to do over a long period of time when you are a LIFE participant. Therefore, remember how important it is for the success of our study that you come to scheduled clinic visits no matter how you are doing with your study program."

- Second, given the critical importance of follow-up, the fact that study staff will make every effort (consistent with good sense and respect for the participant's privacy) to maintain contact during the trial should also be made clear. If the point is made early that we will try to maintain contact no matter what challenges are encountered, it should be easier to do, if required. Potential participants should be told that their continuing participation is so important, that LIFE staff will do all they can to maintain contact, including calling, writing, and trying to reach an identified contact person. It is often helpful to discuss with potential participants the specific strategies they would most like you to enlist if contact dwindles at any time during the study. Enlisting the participant's involvement in deciding the types and extent of contact strategies to be used should retention become an issue (e.g., contact at work, contact spouse, and enlist PCP in reinforcing importance of study), all may be a powerful factor in the participant's response to and acceptance of these efforts should they be necessitated during the trial.

Strategies to optimize retention during the course of the study include:

- More frequent phone contact
- Face-to-face counseling with the group leader or team problem solving session
- Choose an alternate team member with strong participant rapport to contact the participant
- Consultation with behavioral psychologist or meeting between psychologist and participant
- Plan for intensified efforts for retention for major visits
- Optimize use of retention materials as response to a missed visit by mailing an incentive package (e.g., send a greeting card, calendar, or other material incentive).

9.5.1. Specific Retention Problems

Specific strategies identified are to be documented in the participant's clinic file. In addition to general strategies appropriate to all potential retention problems, LIFE staff should be aware of specific retention problems and ways to address them. These are discussed below.

9.5.1.1. Protocol Adherence Issues

Adherence problems (i.e., difficulty maintaining active participation in the interventions) should be noted, discussed among unblinded staff and investigators, and addressed as soon as possible, especially if the problem reflects a dramatic change from participants' prior behavior. Such changes should be considered a clear indication that the potential for retention problems has markedly increased. Adequate monitoring is possible only with a computer-based surveillance of all aspects of adherence. Programs will be provided by the coordinating center for this purpose.

Protocol Adherence Red Flags

Clinic staff and investigators should also be vigilant in order to identify early problems with adherence. Commonly, early indicators of adherence problems include the emergence of the following red flags:

- Missed visits
- Forms not returned
- Difficulty reaching participants by phone or failure to return calls
- Rescheduling twice or more for a visit
- Declining physical activity

Interventions for Protocol Adherence Problems

The staff member should try to "validate" the participant's feelings (e.g., "LIFE demands a lot from people, really more than many people can easily do. What part of the program is hardest for you right now? Perhaps I can help make it a little easier"). Similarly, the group leader is probably the best contact when participants need more attention or a repetition of information. Interventions to be considered in addressing identified red flags include:

- Provide opportunity to meet in any reasonable location or at any reasonable time which is convenient to participants
- Emphasize the positive; praise all successes
- Make sure that you are attending to participants' needs, emphasizing that success can mean different things to different people
- Emphasize general health issues and benefits from participation and follow-up
- Work out a "modified treatment plan" to maintain some degree of adherence and avoid retention problems, such as by simplifying efforts until desired behaviors are re-established, then gradually increase intensity or complexity to protocol goal
- Work to create and maintain best possible group leader/participant match
- Encourage the Principal Investigator and other investigators to hold regular sessions designed to help participants see the "big picture"
- Encourage Principal Investigator to call participants to offer encouragement
- Involve behavioral psychologist in retention efforts
- Maintain contact through newsletters and scheduled calls, mailed notes when indicated
- Offer extras, if acceptable to local IRBs, including birthday cards, incentives at each major visit, food for extended visits. These incentives should be used to underscore the bonding between staff and participants, not to replace that basic social connection
- Address all concerns about study interventions; involve the Principal Investigator, if appropriate
- Be prepared to explain how some questionnaires help achieve the study goal of preventing the loss of independence
- Encourage family participation in activities and meetings

9.5.1.2. Participant Behavioral Issues

Sometimes participants say or do things that indicate they are dissatisfied or discouraged with certain aspects of their LIFE experience. Staff and investigators should be alert for these signs and address participant concerns as quickly and effectively as possible. Since LIFE is based, in large part, upon a group intervention, comments of opposition or dissatisfaction may produce adverse effect on several participants if not addressed as soon as possible.

Participant Behavior Red Flags

Participant behaviors which suggest emerging adherence problems and are considered red flags include:

- Complaints about clinic visits
- Impatience during clinic visits
- "Distance" during clinic visits
- Lack of concern about non-adherence to protocol
- Expressed desire to stop the interventions in LIFE
- Complaints about burden of study (time required and questionnaires)
- Remarks or humor (about study issues) that the staff considers inappropriate

Interventions to Address Participant Behavioral Problems

For participants who feel ignored or taken for granted, the PI *may* be the best person to contact the participant. If the Principal Investigator does initiate contact, he/she should focus on emphasizing the importance of LIFE and of the participant to LIFE. Care should be taken to avoid "guilt tripping" participants or saying things that might be taken as manipulative. If the participant makes progress in adherence or attendance at appointments, the PI should re-contact the participant to express appreciation. Again, care is in order so as not to inadvertently come across as manipulative.

- Communicate caring and respect for participant in all actions.
- Acknowledge and discuss any concerns the participant communicates and address as appropriate. A follow-up phone call to discuss more fully or tell participants about what's being done to address their concerns can be helpful in facilitating adherence and minimizing risk of retention problems.
- Actively involve behavioral psychologist in efforts to resolve these problems.

Be open to discussing issues participant wants to talk about even when not related to LIFE.

9.5.1.3. Participant Medical Issues

In a study of predominately pre-frail older adults, medical issues involving participants and their families may make it difficult for some participants to keep scheduled LIFE appointments.

Participant Medical Red Flags

- Hospitalization
- Prolonged illness

Interventions for Participant Medical Problems

All efforts should be made to encourage participants struggling with medical problems that are not contraindications to exercise to remain active in LIFE; however, the intervention sections of this MOP include specific algorithms to follow with participants who develop an illness or are hospitalized. LIFE staff should consult with LIFE medical personnel about these issues, and, if appropriate, participants' medical providers should be contacted to follow up on the medical problems and/or to enlist participants' primary care physicians in emphasizing the importance of staying involved in LIFE.

9.5.1.4. Participant Psychosocial Issues

Some LIFE participants will experience psychosocial crises (including family problems or transitions, financial problems, and other challenging life events) during the course of the study. These events may produce major problems for retention, especially among participants whose coping resources are limited.

Participant Psychosocial Red Flags

- Specific complaints concerning lack of family support or active efforts by family members to sabotage participants' participation in LIFE
- Major family crisis, illness, or transition
- Major psychosocial problems

Interventions to Address Participant Psychosocial Problems

- Get your behavioral scientist's advice from the beginning
- The Program Coordinator, Principal Investigator, Group Leader, and Behavioral Scientist should collaborate with the participant to generate a plan for appropriate action.
- Take an open, inquiring attitude to find out what is going on for the participant
- Help participant find resources to cope with problems
- Encourage family support for participation in LIFE
- Help participant make contact with other participants for support and

facilitation of adherence

- Offer encouragement and support as well as more frequent contact if the participant wants that and time is available for the added contact.

Some participants might have psychosocial problems severe enough to interfere with active participation in the study. In this case LIFE staff should help the participant find help or treatment for the problems outside of the study. Staff should also help such participants modify their goals for study activity to maximize that activity consistent with limits imposed by the psychosocial problems. This modified involvement plan may promote a smooth return to full participation once the psychosocial or emotional issue is suitably resolved.

Participants who have psychological disorders (e.g., major depressive disorder, anxiety disorders, and substance abuse disorders) need treatment for these problems. The center psychologist should refer participants who may be suffering from such disorders for appropriate treatment. If the center does not have a psychologist on staff, other qualified staff should make the referral. All referrals should be documented.

9.5.1.5. Clinic Transition Issues

Over the course of the study, many things will change at LIFE centers, including staff, and even location. For some participants, these changes may threaten continued involvement in the study. LIFE staff should pay close attention to how individual participants respond to clinic changes and offer the support each participant needs to make a comfortable transition.

Clinic Transition Red Flags

- Reassignment to new group leader
- Reassignment to new clinic personnel for any procedure or test
- Less frequent interaction with staff
- Delays in timely progression of clinic visits

Interventions to Address Clinic Transition Problems

For participants who seem to be bothered by some aspect of the clinic organization or procedures, the Program Coordinator (PC) might be the best person to contact the participant. The PC is probably known to all participants, and should be able to communicate the “big picture” of the clinic.

- Let participant know in advance about changes at the clinic
- Introduce participant to new personnel

- Listen to and address any participant concerns
- Ensure privacy for all discussions, so participant feels secure comments are confidential

9.6. RETENTION MONITORING AND ASSISTANCE/ DROP-OUT RECOVERY

9.6.1. Recruitment, Adherence and Retention Committee

The Recruitment, Adherence and Retention Committee, (composed of Principal Investigators, Co-Investigators, Program Coordinators, and Recruitment Coordinators, the Administrative Coordinating Center, and the NIA), supports retention activities at LIFE clinics. The Recruitment Committee will meet on a regular basis via conference call.

9.6.1.1. General Information

The Recruitment Committee will monitor retention continuously and identify problems early in order to work with clinics to help them meet retention goals. Each clinic will have a representative on the Recruitment Committee who will maintain regular contact with the clinic PC and other appropriate clinic staff.

9.6.1.2. Retention Monitoring

LIFE data; including follow-up visit month contact forms, can be used to identify participants at risk for missing an annual outcomes visit. A participant is considered inactive when he or she misses an annual visit and does not complete a rescheduled visit within three months of the original annual visit date. When a participant is inactive, the clinic must document this on missed visit form. The study website will allow clinics to produce current reports on the semi-annual follow up visit month contacts and on semi-annual outcomes visit attendance at each clinic, including a listing of all participants with missed visits. Attendance at intervention sessions does not count towards a participant's activity status, though it might help identify participants at risk for becoming inactive. Only semi-annual outcome visits count in this regard.

The Recruitment Committee will monitor study-wide and clinic-specific retention reports.

9.6.1.3. Reports and Responses

Each clinic will have a recruitment coordinator. The coordinator will review the center's progress toward achieving its retention goals, discuss retention progress

and challenges with the clinic PC and other appropriate clinic staff, and serve as a resource for the center.

The Recruitment Committee will meet at regular intervals by conference call. It is anticipated that these will be at least once a month. The purposes of the conference calls will be to formalize reports to the Steering Committee and to begin the process of defining specific approaches to retention problems at the center, and/or study-wide level. Study-wide data regarding the number of participants who are missing contacts or are inactive will be reviewed, along with the reasons for these problems. These data will be compared among clinical centers, and if large differences are found, explanations for these differences will be sought. It will be the responsibility of each center to facilitate this review process by providing center-specific summaries of their retention activities, when requested. Problem-solving plans will be developed by the Recruitment Committee.

Each center will be kept abreast of study-wide and local retention progress based on web-based reports, retention summaries issued by the Administrative Coordinating Center, and the regular retention reports provided by the Recruitment Committee to the Steering Committee. These retention reports will reflect the progress of the study as a whole and allow clinics to measure how their efforts compare to others.

Strategies for solving retention problems will be a series of hierarchical responses. The stepped response is designed to address more serious and enduring retention problems with more aggressive assistance.

The following responses serve mainly as a process to approach retention problems; considerable flexibility will be required in the implementation of the responses. The actual response will be determined by the Recruitment Committee on a continuing basis, depending upon center-specific factors and study-wide retention progress. If a significant number of centers fail to meet retention goals, it may be necessary to reassess study-wide retention strategies and develop recommendations to enhance overall LIFE retention.

Level 1 Response: Recruitment Coordinator Consultation

If retention at a LIFE clinic falls below goal (95% of clinic visits completed), the recruitment coordinator will actively communicate with center staff to gather more information regarding possible problems, and steps planned to address these problems. This information will be communicated to the Recruitment Committee on the next conference call.

Level 2 Response: Written Response

If a site does not improve retention and approach or reach their goal within three months following a Level 1 response, the center will be asked to provide to the Recruitment Committee a written evaluation outlining the clinic's perception of the problem and planned approaches to improving retention. As part of this report, the Program Coordinator and Principal Investigator will each provide a brief written assessment and each will sign-off on the final document. This report will be reviewed on the next conference call of the Recruitment Committee.

Level 3 Response: Recruitment Committee Review

If retention goals are still not being met within three months of a Level 2 response, the center will be discussed in detail on the next conference call of the Recruitment Committee with the center recruitment coordinator serving as the discussant.

Level 4 Response

If a particular clinic still remains below the retention goal within three months after a Level 3 response, the Recruitment Committee will work with the coordinating center to be sure that appropriate site visitors are included in the next regularly-scheduled, study-wide site visit at the clinic. The Program Coordinator and Principal Investigator of the center will be required to participate in this process. Site-visitors will be identified by the Recruitment Committee and will be members of the LIFE study group. Following the site visit, the chair of the site visit will submit a written report and recommendations to the center and the Executive Committee. A written response by the center will be expected within one month following receipt of the report.

9.6.2. Drop-out Recovery Program

Despite the staff's best efforts, some participants will not complete annual outcome visits and will be considered inactive. The goal of drop-out recovery is to reengage inactive participants and to keep them from formally withdrawing from the study. Each site should develop a drop-out recovery process under the guidance of the site's behavioral psychologist. The fundamental goals of drop-out recovery should be re-establishing contact and communication first, and then addressing adherence and active participation. Engaging participants in topics unrelated to LIFE can help. Maintaining even minimal contact with participants during periods when motivation to be active in LIFE is low makes it easier to reengage them in the study when stressors and barriers to participation lower. Efforts to contact inactive participants should be initiated by the staff member who has the best rapport with the individual participant.

Each clinic should involve the , PC, PI and intervention staff in devising a step-wise approach for drop out recovery. Specifically, sites should devise a

hierarchical list of efforts to re-engage inactive participants such as the following. Strategies should be implemented sequentially at intervals of 1-2 weeks.

- Telephone contact efforts by study coordinator (2-3). If no reply, a letter of concern from clinic with statements indicating "sorry we've missed you, hope you are well, want to help however possible to assist you in getting back in pursuit of your behavior change goals, please contact us at your earliest convenience, we can help…"
- Have the PI or PC call the participant's emergency contact to inquire about their health and your concerns.
- Final letter from clinic indicating desire to continue to follow participant for health monitoring. This letter may express a message of concern for their health, encouragement to re-contact at any time, support for their efforts, etc.

Some clinics may find that engaging a participant's PCP is an acceptable and effective means of maintaining contact with a certain participant, and may include this strategy in the above hierarchy.

APPENDIX A
LIFE Study Baseline Results Report

We would like to thank you for your participation in The LIFE Study. These tests were done for research purposes only and were not intended to diagnose any health problems. We encourage you to share them with your doctor. If you have any questions, please call Piera Kost at the LIFE clinic at: 412.624.2914.

Name:_____

Date of Clinic Visit:_____

Blood Pressure: _____ _____ _____ **/** _____ _____ _____ **mm HG**

Normal:	Less than 120 / 80 mm Hg
Prehypertenison:	120-139 / 80-89 mm Hg
Hypertension:	140 / 90 mm Hg or higher

Based on your blood pressure taken today, the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure recommends that you:

- ☐ Have your blood pressure rechecked within 1 year
- ☐ Have your blood pressure rechecked within 2 months
- ☐ See your doctor about your blood pressure within 1 month
- ☐ See your doctor about your blood pressure within 1 week
- ☐ See your doctor about your blood pressure immediately

If you have any specific questions about your blood pressure, please talk with your doctor.

Height: _____ **cm** _____ **feet** _____ **inches**

Weight: _____ _____ **kg** _____ _____ _____ **pounds**

Body Mass Index: Body mass index (BMI) is a measure of body fat based on height and weight that applies to both adult men and women. The left column lists height. Move across to a given weight (in pounds). The number at the top of the column is the BMI at that height and weight. Pounds have been rounded off.

BMI less than 25 is normal; 25.0 to 29.9 is overweight; 30 or greater is obese. BMI may **overestimate** body fat in athletes and others who have a muscular build. It may **underestimate** body fat in older persons and others who have lost muscle mass.

BMI	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
Height (ft, in)	Body Weight (pounds)																
4'10''	91	96	100	105	110	115	119	124	129	134	138	143	148	153	158	162	167
4' 11"	94	99	104	109	114	119	124	128	133	138	143	148	153	158	163	168	173
5' 0"	97	102	107	112	118	123	128	133	138	143	148	153	158	163	168	174	179
5' 1"	100	106	111	116	122	127	132	137	143	148	153	158	164	169	174	180	185
5' 2"	104	109	115	120	126	131	136	142	147	153	158	164	169	175	180	186	191
5' 3'	107	113	118	124	130	135	141	146	152	158	163	169	175	180	186	191	197
5' 4'	110	116	122	128	134	140	145	151	157	163	169	174	180	186	192	197	204
5' 5"	114	120	126	132	138	144	150	156	162	168	174	180	186	192	198	204	210
5' 6"	118	124	130	136	142	148	155	161	167	173	179	186	192	198	204	210	216
5' 7"	121	127	134	140	146	153	159	166	172	178	185	191	198	204	211	217	223
5' 8"	125	131	138	144	151	158	164	171	177	184	190	197	203	210	216	223	230
5' 9"	128	135	142	149	155	162	169	176	182	189	196	203	209	216	223	230	236
5' 10"	132	139	146	153	160	167	174	181	188	195	202	209	216	222	229	236	243
5' 11"	136	143	150	157	165	172	179	186	193	200	208	215	222	229	236	243	250
6' 0"	140	147	154	162	169	177	184	191	199	206	213	221	228	235	242	250	258
6' 1"	144	151	159	166	174	182	189	197	204	212	219	227	235	242	250	257	265
6' 2"	148	155	163	171	179	186	194	202	210	218	225	233	241	249	256	264	272
6' 3"	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	279
6' 4"	156	164	172	180	189	197	205	213	221	230	238	246	254	263	271	279	287

Memory Test Results

The LIFE Study is testing memory in order to better understand ways to prevent memory loss in older adults. The information on memory function collected as part of LIFE is also for research purposes and cannot be used to make a diagnosis. Therefore, even if your results now or in the future were outside expected ranges, only your doctor can determine whether further testing would be of benefit to you.

Your results from the memory portion of The LIFE Study indicate that at present your memory is:

☐ Within the acceptable range for your age and requiring no further clinical evaluation.

☐ Possibly below normal. Further discussion with your physician is recommended and only from such a discussion can you know whether you would benefit from additional memory testing.

If you have any questions about this report, please call XXXXXXX at The LIFE Study clinic at (phone number).

Lung Function Results

Lung Function Test	Your Value	Usual Normal Range
FEV_6* total amount of air you blew out of your lungs	_____ % of Predicted	70% and greater
FEV_1: amount of air you were able to blow out in the first second	_____ % of Predicted	70% and greater
FEV_1/FEV_6* ratio of the other two volumes	_____	60% and greater (men) 65% and greater (women)

* Information for your doctor: FEV_6 is a valid approximation of FVC

☐ The lung function test was not performed or lung function could not be determined accurately.

☐ Your values are within the normal range or above; your lung function is normal.

☐ Your values are below the usual range; your lung function is somewhat below normal. About 5% of healthy people have values just below the normal range. We suggest you share this information with your doctor.

If you have any questions about this report, please call Piera Kost at The LIFE Study clinic at (phone number).

Ankle-Arm Blood Pressure Results

Peripheral arterial disease is a blockage of the arteries in the legs that can show up as a reduced systolic blood pressure in the legs. During your visit, the systolic blood pressure of the arms and ankles were measured. The results of the ratio between your ankle systolic blood pressure and your arm systolic blood pressure on both sides are shown in the table below. Normal results are ankle/arm ratios greater than 0.9 and less than 1.30. Your results were:

Blood Flow Measurement Results

	Ankle/ Arm Ratio	Normal	Borderline	Out of Range
Left				
Right				

A blockage in the legs, usually due to atherosclerosis, frequently means there could be atherosclerosis in other parts of the body, including the heart and brain. This test was done for research purposes only and was not intended to diagnose any health problems. However, we encourage you to share these results with your doctor.

If you have any questions about this report, please call XXXXXX at The LIFE Study clinic at (phone number).

Appendix B

6 Month Follow-Up Results Report

We would like to thank you for your continued participation in The LIFE Study. These tests were done for research purposes only and were not intended to diagnose any health problems. We encourage you to share them with your doctor. If you have any questions, please call _____ at the LIFE clinic at: XXX-XXX-XXXX.

Name: _____

Date of Clinic Visit: _____

Weight: _____ _____ **kg** _____ _____ _____ **pounds**

Blood Pressure: _____ _____ _____ **/** _____ _____ _____ **mm HG**

Normal:	Less than 120 / 80 mm Hg
Prehypertenison:	120-139 / 80-89 mm Hg
Hypertension:	140 / 90 mm Hg or higher

Based on your blood pressure taken today, the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure recommends that you:

- ☐ Have your blood pressure rechecked within 1 year
- ☐ Have your blood pressure rechecked within 2 months
- ☐ See your doctor about your blood pressure within 1 month
- ☐ See your doctor about your blood pressure within 1 week
- ☐ See your doctor about your blood pressure immediately

If you have any specific questions about your blood pressure, please talk with your doctor.

Lung Function Results

Lung Function Test	**2.1.1** Your Value	2.1.2 **2.1.3** Usual Normal Range
FEV_6* total amount of air you blew out of your lungs	_____ % of Predicted	70% and greater
FEV_1: amount of air you were able to blow out in the first second	_____ % of Predicted	70% and greater
FEV_1/FEV_6* ratio of the other two volumes	_____	60% and greater (men) 65% and greater (women)

* Information for your doctor: FEV_6 is a valid approximation of FVC

☐ The lung function test was not performed or lung function could not be determined accurately.

☐ Your values are within the normal range or above; your lung function is normal.

☐ Your values are below the usual range; your lung function is somewhat below normal. About 5% of healthy people have values just below the normal range. We suggest you share this information with your doctor.

If you have any questions about this report, please call _____ at The LIFE Study clinic at XXX-XXX-XXXX.

Appendix C

LIFE Study 18 month Follow- up Results Report

We would like to thank you for your participation in The LIFE Study. These tests were done for research purposes only and were not intended to diagnose any health problems. We encourage you to share them with your doctor. If you have any questions, please call XXXX at the LIFE clinic at: XXX-XXX-XXXX.

Name: _____

Date of Clinic Visit: _____

Blood Pressure: _____ _____ _____ **/** _____ _____ _____ **mm HG**

Normal:	Less than 120 / 80 mm Hg
Prehypertenison:	120-139 / 80-89 mm Hg
Hypertension:	140 / 90 mm Hg or higher

Based on your blood pressure taken today, the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure recommends that you:

- ☐ Have your blood pressure rechecked within 1 year
- ☐ Have your blood pressure rechecked within 2 months
- ☐ See your doctor about your blood pressure within 1 month
- ☐ See your doctor about your blood pressure within 1 week
- ☐ See your doctor about your blood pressure immediately

If you have any specific questions about your blood pressure, please talk with your doctor.

Weight: _____ _____ **kg** _____ _____ _____ **pounds**

Lung Function Results

Lung Function Test	2.1.4 Your Value	2.1.5 2.1.6 Usual Normal Range
FEV_6* total amount of air you blew out of your lungs	_____ % of Predicted	70% and greater
FEV_1: amount of air you were able to blow out in the first second	_____ % of Predicted	70% and greater
FEV_1/FEV_6* ratio of the other two volumes	_____	60% and greater (men) 65% and greater (women)

* Information for your doctor: FEV_6 is a valid approximation of FVC

☐ The Lung Function test was not performed or lung function could not be determined accurately.

☐ Your values are within the normal range or above, your lung function is normal.

☐ Your values are below the usual range, your lung function is somewhat below normal. About 5% of healthy people have values just below the normal range. We suggest you share this information with your doctor.

If you have any questions about this report, please call XXXXXX at The LIFE Study clinic at XXX-XXX-XXXX.

Appendix D

LIFE Study 24 month Follow- up Results Report

We would like to thank you for your participation in The LIFE Study. These tests were done for research purposes only and were not intended to diagnose any health problems. We encourage you to share them with your doctor. If you have any questions, please call XXXX at the LIFE clinic at: XXX-XXX-XXXX.

Name: _____

Date of Clinic Visit: _____

Memory Test Results

The LIFE Study is testing memory in order to better understand ways to prevent memory loss in older adults. The information on memory function collected as part of LIFE is also for research purposes and cannot be used to make a diagnosis. Therefore, even if your results now or in the future were outside expected ranges, only your doctor can determine whether further testing would be of benefit to you.

Your results from the memory portion of The LIFE Study indicate that at present your memory is:

- ☐ Within the acceptable range for your age and requiring no further clinical evaluation.
- ☐ Possibly below normal. Further discussion with your physician is recommended and only from such a discussion can you know whether you would benefit from additional memory testing.

If you have any questions about this report, please call XXXXX at The LIFE Study clinic at XXX-XXX-XXXX.

Appendix E

LIFE Study 30 month Follow- up Results Report

We would like to thank you for your participation in The LIFE Study. These tests were done for research purposes only and were not intended to diagnose any health problems. We encourage you to share them with your doctor. If you have any questions, please call XXXX at the LIFE clinic at: XXX-XXX-XXXX.

Name: _____

Date of Clinic Visit: _____

Blood Pressure: _____ _____ _____ **/** _____ _____ _____ **mm HG**

Normal:	Less than 120 / 80 mm Hg
Prehypertenison:	120-139 / 80-89 mm Hg
Hypertension:	140 / 90 mm Hg or higher

Based on your blood pressure taken today, the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure recommends that you:

- ☐ Have your blood pressure rechecked within 1 year
- ☐ Have your blood pressure rechecked within 2 months
- ☐ See your doctor about your blood pressure within 1 month
- ☐ See your doctor about your blood pressure within 1 week
- ☐ See your doctor about your blood pressure immediately

If you have any specific questions about your blood pressure, please talk with your doctor.

Weight: _____ _____ **kg** _____ _____ _____ **pounds**

Ankle-Arm Blood Pressure Results

Peripheral arterial disease is a blockage of the arteries in the legs that can show up as a reduced systolic blood pressure in the legs. During your visit, the systolic blood pressure of the arms and ankles were measured. The results of the ratio between your ankle systolic blood pressure and your arm systolic blood pressure on both sides are shown in the table below. Normal results are ankle/arm ratios greater than 0.9 and less than 1.30. Your results were:

Blood Flow Measurement Results

	Ankle/ Arm Ratio	Normal	Borderline	Out of Range
Left				
Right				

A blockage in the legs, usually due to atherosclerosis, frequently means there could be atherosclerosis in other parts of the body, including the heart and brain. This test was done for research purposes only and was not intended to diagnose any health problems. However, we encourage you to share these results with your doctor.

If you have any questions about this report, please call XXXXX at The LIFE Study clinic at XXX-XXX-XXXX.

Lung Function Results

Lung Function Test	**2.1.7** Your Value	2.1.8 **2.1.9** Usual Normal Range
FEV_6* total amount of air you blew out of your lungs	_____ % of Predicted	70% and greater
FEV_1: amount of air you were able to blow out in the first second	_____ % of Predicted	70% and greater
FEV_1/FEV_6* ratio of the other two volumes	_____	60% and greater (men) 65% and greater (women)

* Information for your doctor: FEV_6 is a valid approximation of FVC

☐ The lung function test was not performed or lung function could not be determined accurately.

☐ Your values are within the normal range or above; your lung function is normal.

☐ Your values are below the usual range; your lung function is somewhat below normal. About 5% of healthy people have values just below the normal range.

If you have any questions about this report, please call XXXX at The LIFE Study clinic at XXX.XXXX.

Appendix F

LIFE Study Closeout Results Report

We would like to thank you for your participation in The LIFE Study. These tests were done for research purposes only and were not intended to diagnose any health problems. We encourage you to share them with your doctor. If you have any questions, please call XXXX at the LIFE clinic at: XXX-XXX-XXXX.

Name: _____

Date of Clinic Visit: _____

Ankle-Arm Blood Pressure Results

Peripheral arterial disease is a blockage of the arteries in the legs that can show up as a reduced systolic blood pressure in the legs. During your visit, the systolic blood pressure of the arms and ankles were measured. The results of the ratio between your ankle systolic blood pressure and your arm systolic blood pressure on both sides are shown in the table below. Normal results are ankle/arm ratios greater than 0.9 and less than 1.30. Your results were:

Blood Flow Measurement Results

	Ankle/ Arm Ratio	Normal	Borderline	Out of Range
Left				
Right				

A blockage in the legs, usually due to atherosclerosis, frequently means there could be atherosclerosis in other parts of the body, including the heart and brain. This test was done for research purposes only and was not intended to diagnose any health problems. However, we encourage you to share these results with your doctor.

If you have any questions about this report, please call XXXXX at The LIFE Study clinic at XXX-XXX-XXXX.

Appendix G
Letter for Normal Blood results

Date _____

Dear _____,

Thank you for participating in The LIFE Study. Enclosed are the results from your blood sample analysis.

These results will be used to describe the health status of our participants in this study. These tests are not intended to replace any test that your doctor may order for a specific reason, but do provide important information about your health. We have enclosed a copy of your results for you to share with your doctor.

Your participation in this study represents an important, valuable contribution. Please call me at XXX.XXX.XXXX if you have any questions about this report. Again, we appreciate your commitment to The LIFE Study.

Sincerely,

XXXXXX
The LIFE Study
Medical Safety Officer

Enc. Blood Analysis

Letter for blood results with out of range values

Date _____

Dear _____,

Thank you for participating in The LIFE Study. Enclosed are the results from your blood sample analysis.

The laboratory report shows that at least one of your blood results is considered out of the normal range. We have highlighted each out of range value on the enclosed laboratory report. We ask that you share these results with your doctor so that additional follow-up and/or evaluation can be decided by your personal medical care provider. We have enclosed two highlighted copies so that you can keep one and give one to your doctor.

These results will be used to describe the health status of our participants in this study. These tests are not intended to replace any test that your doctor may order for a specific reason, but do provide important information about your health.

Your participation in this study represents an important, valuable contribution. Please call me at XXX.XXX.XXXX if you have any questions about this report. Again, we appreciate your commitment to The LIFE Study.

Sincerely,

XXXX
The LIFE Study
Medical Safety Officer

Letter for immediate notification

Date _____

Dear _____,

Thank you for participating in The LIFE Study. Enclosed are the results from your blood sample analysis. These results will be used to describe the health status of our participants in this study. These tests are not intended to replace any test that your doctor may order for a specific reason, but do provide important information about your health.

At least one of your blood test results may be medically significant. This is a follow up to the phone call you should have already received from us to discuss this finding and to ask your permission to pass the information directly on to your physician. The decision about what to do based on this information should be made by your personal medical care provider based on his/her knowledge of your condition. We have enclosed two copies so that you can keep one and give one to your doctor.

Your participation in this study represents an important, valuable contribution. Please call us at xxx-xxx-xxxx if you have any questions about this report. Again, we appreciate your commitment to The LIFE Study.

Sincerely,

The LIFE Study
Study physician