CHAPTER 20

Health Events

Study Documents Referred to in this Chapter

- Health Events Form
- Event Tracking Form
- Adverse Event Form
- Event Evaluation Form
- Medical Record Abstraction Form
- Vascular Events Form
- Final Report of Death Form
- Injurious Falls Form

CHAPTER 20

HEALTH EVENTS

20.1 Ascertainment of Health Events (Overview)

In addition to reducing the primary LIFE Study endpoint, the combination of walking disability and death, the study's test intervention is also hypothesized to affect the frequency of acute care hospital admissions, combined cardiovascular events, and injurious falls. Documents verifying the occurrence of these events are obtained by identifying and obtaining information on overnight hospitalizations, fall-related fractures, outpatient coronary revascularizations, and deaths. This chapter describes the process and forms involved in identifying and classifying these events in a standardized and unbiased manner.

In order to fairly evaluate these hypotheses, the process for identifying the targeted events must be both thorough and unbiased. Because the physical activity group's contact with study staff is so much more intense than the successful aging health education group's it is inevitable that more events will become known to staff involved in the physical activity intervention. Therefore, relying on events reported to interventionists to judge the effect of the intervention is potentially biased, and could lead to the unfair appearance that the physical exercise intervention is associated with more events than it really is. To address this issue, the LIFE Study uses a dual system for dealing with health events: a masked process for identifying and classifying potential study outcomes; and adverse events in an unbiased fashion; and an unmasked process for monitoring participants during the intervention. Adverse events detected by means of the masked and unmasked process require appropriate IRB and other regulatory reporting as described in Chapter 22. The masked system is based primarily on quarterly contacts with study participants and is carried out only by masked clinic assessment staff. The other process, based on adverse health event reports to unmasked study staff during the course of

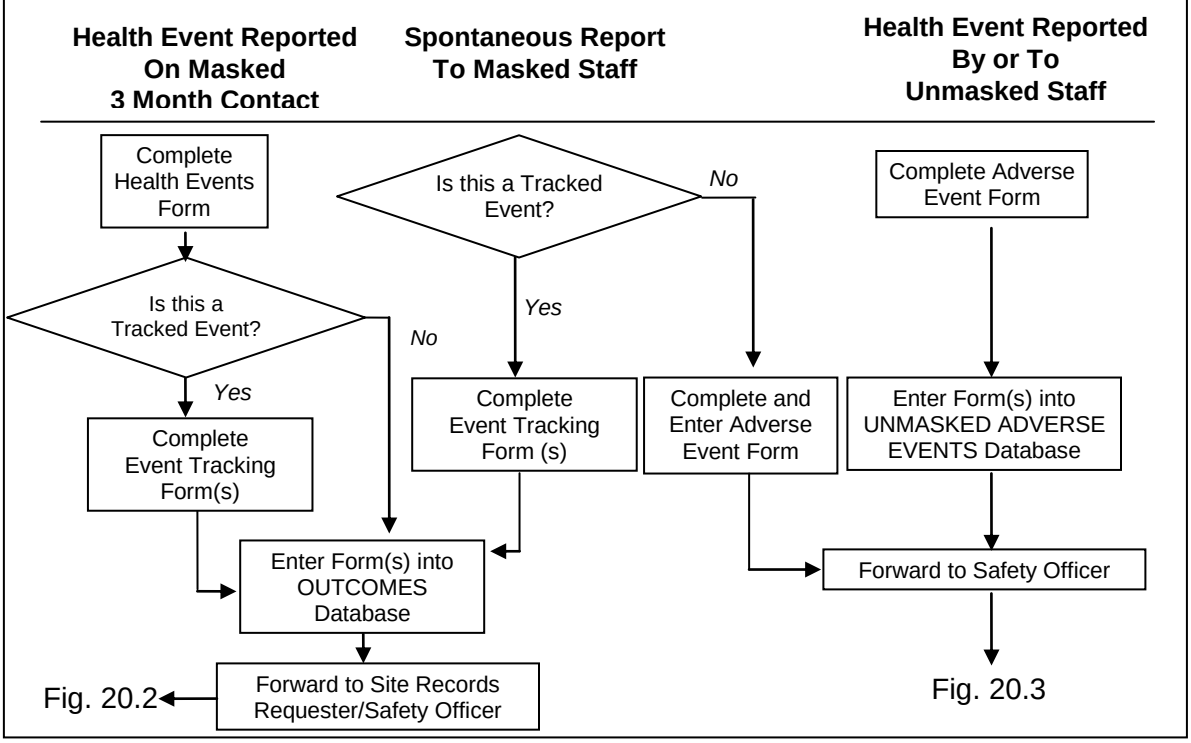
intervention contacts, contributes to the safety evaluation of the intervention, but (except for death) the information is not used to compare the two interventions.

20.1.1 Process Overview (Event Identification)

Figure 20.1 presents the initial event ascertainment processes contrasting the role of masked and unmasked staff. Masked study staff (i.e. staff unaware of participants' group assignments) interviews all participants every three months. The interviews at 3, 9 and 15 months are done by phone. The interviews at 6, 12 and 18 months are intended to be done in –person, but may be done over the phone.

The interview process is based on the **Health Events** Interview. This interview specifically asks about health events that are study outcomes, as well as various other health events that might qualify as adverse events requiring IRB notification. When potential study outcomes are reported at the interview, the study staff collects additional information using the **Event Tracking** form to obtain medical records for the outcome adjudication process. In some cases masked staff will become aware of health events through other avenues. In these cases, an **Event Tracking** can be filled out directly.

Figure 20.1 Outcomes/Events Process I
Initial Ascertainment of Health Event



Unmasked staff who receive notification of an adverse event, fill out an **Adverse Event** form. The events are entered into a separate database and will not be used to evaluate the intervention.

Inevitably the same events may be reported to both masked and unmasked individuals. This is to be expected. However, an unmasked staff person should never report an event to a masked staff member nor encourage a participant to call the assessment clinic to make such a report. Participants may be reminded that they will be asked about this event again at their next scheduled assessment.

For participants who have died since the last scheduled assessment, the Health Events form should be completed with a proxy respondent on or before the next scheduled assessment. For example, if a participant dies during Month 10, the Health Events form should be completed by or before the target date for the Month 12 assessment.

20.1.2 Overview of Record Retrieval/Abstraction Process

Once study outcomes are identified and the **Health Events** forms and associated **Event Tracking** forms are entered into the data system, forward the forms to the medical records requester. This person oversees the request for medical records required by the adjudication process. This person should be masked to assure that every the medical records of all participants are pursued with equal vigor. The person forwards copies of received medical records to the local records abstractor who must be masked.

20.1.3 Overview of the Adjudication Process

Medical records are forwarded by the medical records technician to the site's record abstractor. These records are then reviewed and abstracted onto study forms for each of the study outcomes. The pre-adjudicated results should be entered into the outcomes system. The completed abstraction forms along with supporting documentation will be copied (after removing identifying information) and sent to the Administrative Coordinating Center. The pertinent materials will subsequently be forwarded to the study's central adjudicator. If the adjudicator agrees with the initial review, a final adjudication status form will be entered into the outcomes system. If there is a disagreement, the nature of the disagreement along with the related documents will be discussed and reviewed by an adjudication committee after which a final event status will be assigned. The protocol for the hierarchical adjudication of major mobility disability is provided in Section 20.9.

Once adjudication of a health event has occurred, the relevant data entry forms will not be available for editing. The Health Event, Event Tracking, Medical Record Abstraction, Vascular Outcome, Injurious Falls and Fracture forms will only be available for view access by a site. Any request for editing must be made in writing to the LIFE DMAQC.

20.1.4 Health Events and Adverse Events Reporting

(Refer also to Chapter 22)

All health outcomes reported to the LIFE study are adverse events but not all adverse events are outcomes. The LIFE's outcomes process allows information to pass from the masked system of outcomes ascertainment to the unmasked medical safety and IRB reporting process. These processes are outlined by Figures 20.2 and 20.3. It is the medical safety officer's responsibility to determine whether events reported have already been reported to the IRB. In these cases, duplicate IRB reporting is not necessary.

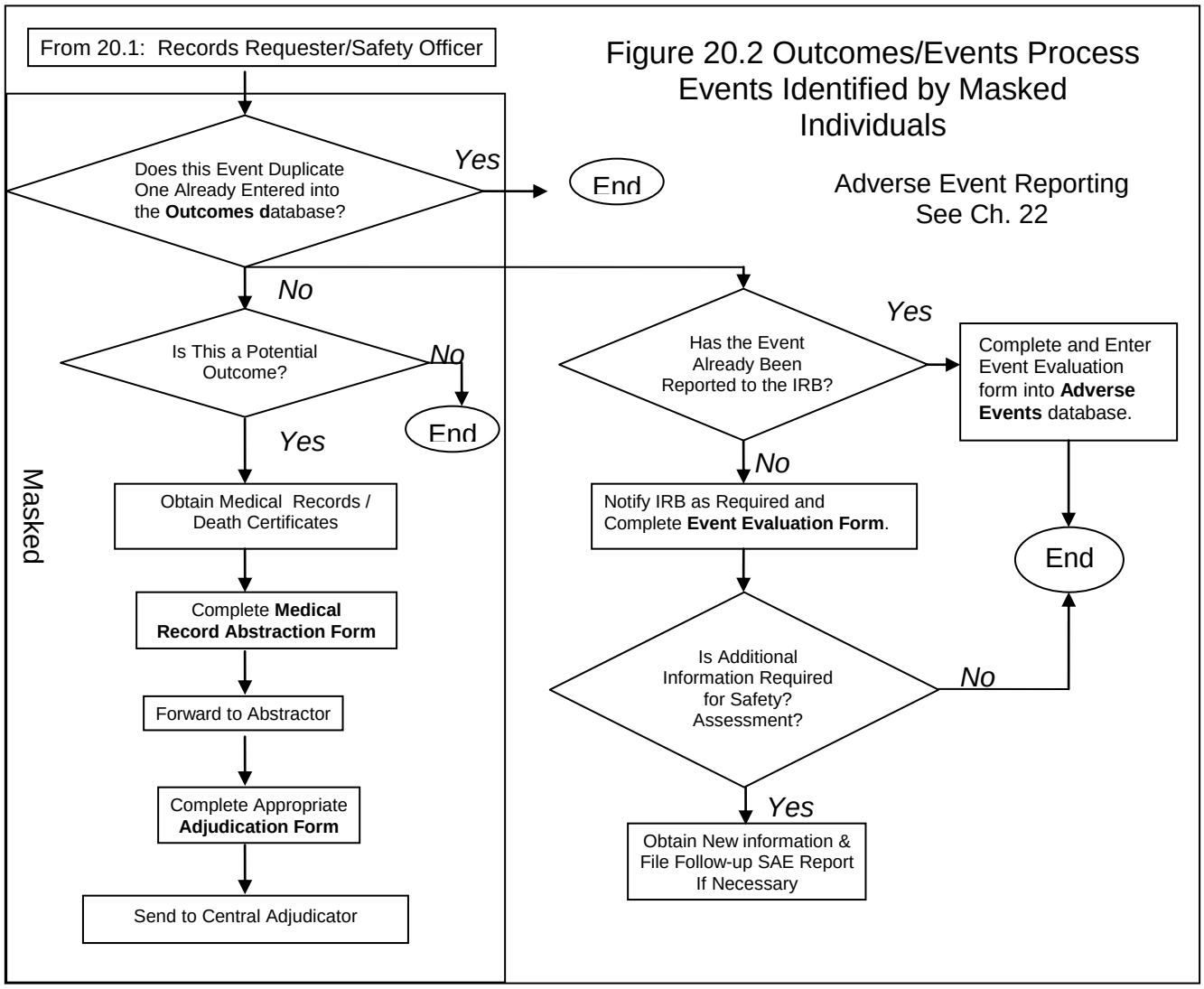


Figure 20.2 Outcomes/Events Process
Events Identified by Masked Individuals

Adverse Event Reporting
See Ch. 22

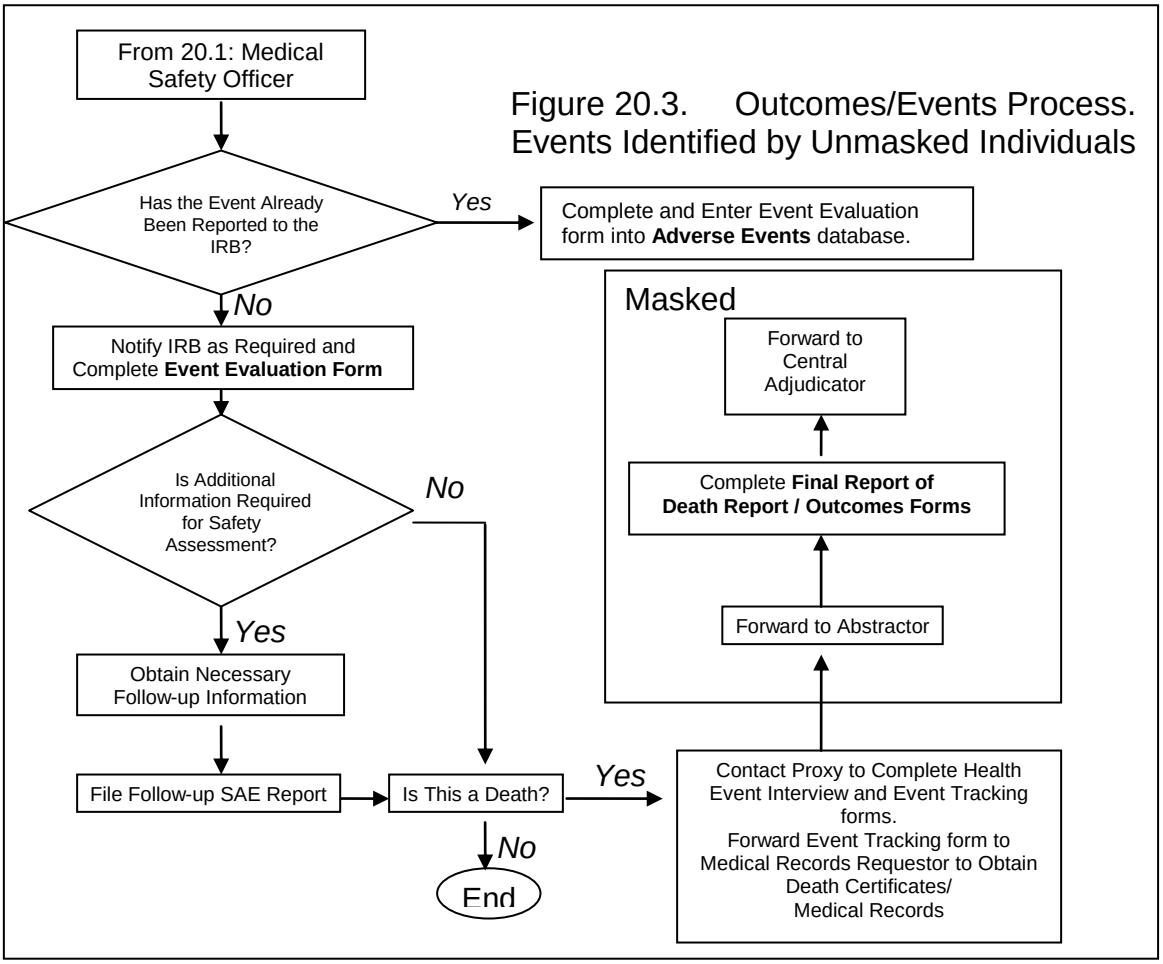


Figure 20.3. Outcomes/Events Process. Events Identified by Unmasked Individuals

20.2 Health Outcomes

The following events are LIFE outcomes and are tracked by the Health Events system.

20.2.1 Acute Care and Nursing Home Admission and Length of Stay

Acute care hospitalization length of stay will be determined by reviewing medical records. Nursing home admission length of stay is assessed by means of self report to questionnaires assessed during follow-up visits and telephone interviews. Nursing home stays do not include stays in in-patient rehabilitation facilities.

20.2.2 Death

The confirmation and date of death are confirmed by death certificate. Cause is determined from hospital records and death certificate and coded into major categories of death.

20.2.3 Cardiovascular Disease Outcomes

Cardiovascular events include: acute myocardial infarction, stroke, hospitalization for heart failure, coronary artery bypass surgery, angioplasty, aortic aneurysm, carotid endarterectomy, peripheral arterial disease and cardiovascular death.

20.2.4 Fall-Related Fractures

Fall-related fractures are defined as those due to falls and do not include non-fall related fractures such as vertebral (i.e. compression) fractures, stress fractures, or fractures from excessive trauma (e.g. MVA or fall from height > 3 feet).

20.3 Masking

The integrity of the outcomes process depends upon the study staff involved in assessing study outcomes being unaware of the participants' group assignments. The masking process involves both staff and participant education and should start with the initial assessment visits.

Steps to Maintain Staff Masking at Randomization (Screening Visit 2):

- Inform participants that there are two sets of staff, a group of staff involved in the intervention and another set involved in repeating the tests and interviews done during the screening process.
- Instruct participants not to volunteer or discuss which group they are in unless specifically asked to do so.
- Tell participants that masked staff will remind them not to discuss the group assignment at every contact.

- Tell participants that more than one person might call during the course of the study to ask about certain health issues, and that sometimes the same questions may be repeated.

Steps to Maintain Masking During Follow-up Visits:

- Post signs in the assessment clinic reminding participants not to discuss group assignments.
- Verbally remind participants not to discuss group assignments at follow up visits.
- The script for the Health Events interview also has a reminder to the participant to not mention the group assignment.
- Whenever unmasked and masked study staff are together, remind the staff not to identify any participant by name or reveal a participant's group assignment.

20.3.1. Maintaining Masking during the Record Retrieval/Distribution Process

Medical records are required for outcomes determination but would not be routinely used during the safety/IRB process. Because of this, sites should keep the person charged with requesting medical records masked to study group. The medical record abstractor must also be masked.

In order to maintain the complete separation of masked and unmasked events, all health events and related information ascertained by masked individuals will be entered into a database that is maintained separately from the database into which adverse event information from unmasked individuals is reported. (See Data management chapter for details).

Final determination of whether a study outcome has been reached is made by the adjudicator. The adjudicator is masked and makes this final determination based only on information generated by masked study staff.

Table 20.1 Study Staff Roles and Responsibilities in the Maintaining Masking			
Person	**Masked Status**	**Role**	**Masking Responsibilities**
Outcomes Assessor	Masked	1. Ascertain Health Events 2. Enter Health Events and Tracking Form and Adverse Event Form into Outcomes Database. 3. If necessary, complete Adverse Event Form.	1. Remind participants not to reveal group assignment.
Interventionist	Unmasked	1. Report AEs via Adverse Event Form 2. Enter Form into AE system	1. Do not discuss participants with masked staff. 2. Do not encourage participants with AEs to report them to masked staff.
Records Requester	Masked	Request medical records as required for either AE assessment or Outcomes assessment.	Remove mentions of Intervention from medical records being forwarded to the assessor.
Abstractor/ Adjudicator	Masked	Abstract Medical Records onto Adjudication Forms	1. Provide feedback on the integrity of the process to the PI
Central Adjudicator	Masked	Verifies Outcomes Determinations Made at the Sites	1. Provide feedback on the integrity of the process to the PI

20.4 Quarterly Health Events Interview

20.4.1 Administration

The Health Event Interview is administered by masked staff members. The interview is administered every three months after randomization. The 3, 9 and 15 month interviews are to be done over the phone. The 6, 12, 18 month interviews can be done during scheduled clinic visits. If participants do not come to their scheduled assessment visit these interviews should be completed by phone. In some cases, the 15 month visit will be the close-out visit. When this happens, the interview can be administered in person.

The interview is to be completed within the windows for the given contact. The windows for the phone interviews are +/- two weeks, and for the clinic visits they are +/- 30 days.

The staff member administering the interview should not know the group assignment of the participant being interviewed. The script that introduces the questionnaire reminds the participant not to reveal his or her group assignment.

Preparation

Before administering the interview, the staff member should determine the last time the Health Event interview was administered. Typically, this will be 3 months earlier, but it may not be if a previous visit had been missed. This date is important because it provides a time reference for all the questions that are asked. For the 3 month interview, the date of the first screening visit should be used. Interviewers should not use phrases like, “Since the last time we talked, “ because this may confuse participants who do not distinguish between assessment and intervention staff.

Have a stack of **Event Tracking** forms available when administering this interview. For a number of the questions, additional information may be needed to help in the requesting of medical records. These additional questions are on the Event Tracking form. The Event Tracking form should be completed as soon as it becomes clear from the Health Event form that one is needed.

20.4.2 Proxy/Other Respondents

In some cases the participant may not be available for a given interview. In these situations attempt to administer the interview to the proxy identified by the participant. After contacting the proxy, explain who you are and why you are calling, and proceed to administer questions 1-16. Question 17 has to do with symptoms experienced by the participant and could not be reliably answered by a proxy. In some cases, information may be volunteered by contacts other than

the named proxy. In these cases mark “Other” as the source of information on the form.

Maintain the Masking

It is important that the person doing the interview be masked from the intervention status. The first part of the script states**,** “Now I would like to ask about important health events you may have had since [the last visit date]. You may have already told other LIFE staff about some of the events, but I would like to hear about them again. Also, for scientific reasons, please don’t tell me to which of the two LIFE groups you were assigned.” It is very important that the participant be deflected should he or she start to tell you about the group they might be in. Interrupt the participant and say remind them that for scientific reasons you are not allowed to know what group they’re in.

20.4.3 Completing the Form

Questions 1 & 2 refer the mode of administration and whether the respondent or proxy is the source of information. If participants have died between visits, still try to complete questions 1-15 of the interview with the proxy. These events are still important to capture and will contribute to the comparison between the two groups.

Questions 3-10 elicit information on discrete health events that are also study outcomes: fall-related fracture, heart problems, stroke, congestive heart failure, aortic aneurysm, peripheral artery disease, revascularization procedures and other injurious falls (Question 9). These events will only be classified as study outcomes after objective medical evidence substantiating their occurrence is found in medical records.

For each question ask whether the participant had an occurrence of the event since the last time the interview was administered. If they answer yes, complete the sub-questions requesting additional information. In each case, the form

instructs the interviewer when to complete an Event Tracking form. When a fracture is not fall-related, an Event Tracking form is not completed, but information should be provided regarding the site and type of the fracture. Excessive trauma includes an MVA and high falls, defined as falls from a height greater than 3 feet. Question 11 asks about same day surgery other than outpatient coronary revascularization. This is not a tracked outcome of the study, but may be an adverse event.

Question 12 asks about falls and whether any of these were injurious. Any falls mentioned here would include any fall leading to fracture reported in Question 3c.
Question 13 asks about nursing home or stays in long-term or extended care facilities. This would include stays in rehabilitation units after discharge from an acute care hospital.

The occurrence of hypertension is also a tracked study outcome. Question 14 asks about new diagnoses of hypertension over the reporting period.

Q15 asks about new diagnoses of cancer. While this is not a tracked study outcome it may be an adverse event. Cancer may have already been reported as a hospitalization on Questions 9. Record it here as well.

Q16 and Q17 ask about signs and symptoms related to expected adverse events that may occur during the study. Q16 specifically relates to problems so severe that a physician or other medical professional was consulted. Q17 asks about symptoms that may occur but not necessarily of a severity that it led to care-seeking behavior. When interviewing proxies it is not necessary to ask question 17 since a proxy is unlikely to be able to answer these questions reliably.

Completed forms should be data entered within one day of the interview and the Events Tracking forms should be forwarded to the medical records requester.

20.5 Event Tracking

All reports from participants or proxy's that might indicate that a tracked event has occurred are tracked by the study. The tracking process includes obtaining medical records and review by a study adjudicator.

20.5.1 Tracked Events

Tracked events are:

- Overnight hospitalizations
- Fall-Related Fractures
- Other Injurious Falls
- Outpatient Coronary Revascularizations
- Death

20.5.2 When to fill out an Event Tracking Form

An event tracking form should be filled out whenever a masked staff member receives information indicating that a participant has died or experienced any of the outcomes tracked by the LIFE Study (hospitalization, fall-related fracture, or outpatient cardiovascular revascularization), either as part of the Health Events Interview or by other means (such as a proxy calling the clinic, or the ascertainment of death during a scheduling attempt).

More than one Event Tracking form may be required during a given interview. For example, if a participant reported going to the ER because of a fall and at a later time reported being hospitalized overnight for congestive heart failure, two tracking forms should be filled out (one for each episode). However, if one event happens during the diagnosis and treatment of another event, only one event form needs to be completed For example, if during a hospitalization for a heart attack a participant falls and breaks a bone. Both diagnoses are part of one 'illness episode' and would be described in the single medical record. If a

participant was admitted to one acute care hospital, and directly transferred to another acute care hospital, only one Event Tracking form should be completed. Use the dates of the first hospitalization in the boxes, but write the information of the second hospitalization in the margin. If a subject visits and ER (not admitted) and is transferred/admitted to another hospital, complete one Event Tracking form because this is one illness episode. Enter the admission information for the overnight hospitalization with a notation about the ER visit.

20.5.3 Completing the Event Tracking Form

The Event Tracking form should not be completed for stays in rehab facilities, skilled nursing facilities, nursing homes, extended care facilities, or psychiatric hospitals. Only treatment in acute care facilities should be documented. All deaths should be documented regardless of location.

Question 1 asks for the participant's name.

Question 2 asks how the event was reported. For example, if the event was ascertained on during the Health Events interview, check the first box (a). If the event came to be noticed by another avenue (review of obituary pages, for example) box e. should be checked. In this case the source of information should be indicated.

Question 3 asks for the type of event. The sections of the form to be filled out depend upon the kind of event. The sections are: overnight hospitalizations for reasons other than fracture, fall-related fracture, outpatient coronary revascularizations, and death. There are additional questions for the respondent on this form, so it should be available while either interviewing the participant or the proxy.

There should only be one form filled out for each illness episode. However, it may occur that there are multiple outcomes that occur during the course of one

hospitalization. In this case the event should be tracked according to the reason for hospitalization but the fact that other events have occurred should be noted on the face of the Event Tracking form.
The more information that is collected on this form the easier it will be to obtain the relevant medical records. Thus, participants should be encouraged to provide as many relevant details of the hospitalization as possible. Staff should do their best to obtain accurate dates of treatment by asking subjects to find billing or other documentation with definitive dates and names of facilities.

Section I asks about overnight hospitalizations other than those involving fracture. Section II asks about all fall-related fractures. The outcomes process requires radiographic evidence to substantiate the occurrence of a fracture. Therefore, it is important to document whether x-rays were obtained in a doctor's office, clinic or emergency room. Section III asks about outpatient coronary revascularizations. Revascularizations performed as part of a hospitalization are tracked in section I. Note, diagnostic catheterization procedures are not tracked. However, in some cases a diagnositic catheterization may become combined with a revascularization. Section IV asks about death, both in and out of hospital. If a death occurs during a hospitalization, document it in Section IV, not in Section I.

20.6 Obtaining Medical Records

All subjects will be asked to sign a HIPAA-compliant medical records release authorization giving permission to the hospital to provide the LIFE study with copies of the requested documents. A HIPAA compliant release must, by Federal mandate, contain the following components:

- The subject's name and identifying information (date of birth and social security number, if provided).
- A description of the information to be disclosed (dates of treatment and the specific list of documents requests)

- The name of the group to which the information is being disclosed (the LIFE study at the University of _____)
- The reason for the disclosure (Research purposes only)
- An expiration date (date range of the study duration)
- A statement indicating that the individual may revoke the authorization in writing
- A statement about the ability or inability of the covered entity (hospital) to condition treatment, payment, enrollment or eligibility for benefits on the authorization
- A statement that there is potential for the Personal Health Information (PHI) to be redisclosed by the recipient.
- The signature of the subject and date, or if the authorization is signed by a proxy, a description of the representative's authority to act for the individual.

A sample HIPAA compliant authorization is included in the appendix. Based on the required content of a HIPAA compliant release, it is a free standing document that contains all the information required to send to a hospital for a record. The document should also include the name and phone number of the LIFE study medical record requestor, for the hospital to contact for more information, and the mailing address where the hospital should mail the records.

The following are the documents that should be requested for the specific study outcomes. Not all documents will be available for each outcome. Each chart should be reviewed upon receipt for completeness, and follow up of missing documents should be done in a timely manner to ensure thorough retrieval of relevant information. For short stay admissions and/or hospitalizations less than 48 hours, progress notes may be substituted if discharge summaries are not available. In certain cases additional information will be required to determine whether an outcome has occurred. Additional records can be obtained as necessary.

Myocardial Infarction, congestive heart failure, inpatient coronary artery bypass surgery or angioplasty, cardiovascular death:

- Face Sheet/Physician Attestation with ICD Codes
- Discharge summary
- Admission History and Physical Exam
- Operative/Procedure Report
- Cardiac Catheterization Report
- All ECG Tracings
- Lab Reports
- All Radiology Reports
- Stress Test /Thallium scan Report
- Echocardiography Report

Stroke, carotid endarterectomy:

- Face Sheet /Physician Attestation with ICD codes
- Discharge summary
- Admission history and physical exam
- Neurology consult
- Operative Report
- Echocardiography report
- Carotid doppler/duplex scan report
- Carotid angiography report
- CT head/MRI brain report

Peripheral arterial disease/Aortic aneurysm:

- Face Sheet/Physician Attestation with ICD codes
- Discharge summary
- Admission history and physical exam
- Operative report
- Lower extremity/abdominal doppler/ultrasound

- Lower extremity/abdominal angiography

Outpatient Coronary Revascularizations:

- Outpatient Summary/Progress Notes
- Operative/Procedure Report
- Cardiac Catheterization Report
- All ECG Tracings
- Lab Reports
- All Radiology Reports
- Stress Test /Thallium scan Report

Inpatient Fractures:

- Face Sheet/Physician Attestation with ICD codes
- Discharge summary
- Admission history and physical exam
- Radiology reports

Outpatient Fractures:

- Radiology reports

All Deaths:

- Non-certified death certificate
- Autopsy (if done)

Copies of non-certified death certificates should be obtained locally within the restrictions and guidelines of your state.

All other Overnight Hospitalizations

- Face Sheet/Physician Attestation with ICD codes
- Discharge summary
- Admission history and physical exam

Medical records should be requested within 48 hours of receipt by the medical records reviewer of the Events Tracking Form, unless the event is recent (discharge or death less than 1 month ago). Records requested within less than 1 month from discharge or death will unlikely be complete due to delays in dictation and transcription. Hold all requests for at least one month after the discharge/death date before requesting them.

It is important to monitor when records have been requested and when records have been received in the event tracking system. Medical records forwarded to the adjudicator should be examined for references to the intervention and these should be removed.

20.7 Abstraction of Medical Records and Event Classification

All medical records to be used in outcomes documentation should be forwarded to the local physician adjudicator for review and abstraction. Once local adjudication is complete, the sterilized medical records along with copies of the associated abstraction forms should be mailed to the LIFE Clinical Coordinating Center for forwarding to the study's central adjudicator.

20.7.1. Medical Record Abstraction Form

The medical records abstraction form is based on the initial review of the medical records retrieved as part of the outcomes documentation process. The putative date of occurrence of all outcomes should be entered onto this form along with the any ICD9 diagnosis or procedure codes attested to on the medical record and the admission and discharge dates of the any overnight hospitalizations.

If an overnight stay in an acute care facility is followed by a direct transfer to a rehab/SNF unit within the same facility, only include the date range for the acute care portion of the hospitalization on the Medical Abstraction Form. Only the

records for the acute care component of the stay should be attached, UNLESS the discharge summary and/or other support documents from the rehab/SNF admission provide more detailed information about the acute care stay to aid in review of the record. Do not include the dates from the rehab/SNF stay as part of the acute care hospitalization.

If a participant is admitted to an acute care hospital, and is subsequently transferred to a rehab/SNF unit but returns to the acute care unit, create separate adjudication packets for each acute care hospitalization (separate Medical Record Abstraction forms). The rehab/SNF records may be attached to assist in providing chronology and details of the transfers, but the dates of the rehab/SNF admissions should not be included on the Medical Record Abstraction form."

After reviewing the medical record, and none of the primary endpoints have occurred (vascular, fall/fracture, death), indicate the primary diagnosis for the event in the 'None of the Above' field."

20.7.2. Final Report of Death

The Final Report of Death should be completed for all deaths, both in and out of hospital.

1. Enter the date of death as reported on the death certificate.
2. After review of all associated medical record, death certificate and other documentation, enter the underlying and immediate causes of death. Do not transcribe the information from the death certificate unless you are in full agreement that these causes are accurate. Enter any contributory causes, if present.
3. Classify the underlying cause of death as:
    (01) Cancer including primary site in text field
    (02) Accident/Injury related to a fall

(03) Accident/injury related to a non-fall related accident, suicide, or other injury. Indicate in the text field the specific information.

(04) Cardiovascular disease – Coronary Heart Disease (CHD)

a. Indicate the basis on which the CHD death was diagnosed.

b. Indicate the subclassification of the CHD death.

c. Indicate the time frame from onset of symptoms to CHS death.

(05) Cardiovascular disease – Cerebrovascular Disease

Indicate if the stroke death was due to an acute stroke or the late effects of a prior stroke, indicating the date of the prior stroke.

(06) Cardiovascular disease – Pulmonary Embolism

Indicate if the underlying cause of death was a pulmonary embolism.

(07) Cardiovascular disease – Other Cardiovascular Disease

Includes deaths from valvular heart disease, endocarditis, aortic aneurysms, other peripheral arterial disease, and any other cardiovascular causes not described in causes 04-06.

(09) "Other" cause of Death, known – Indicate if death was from a cause not already described above but known.

(10) "Other" cause of Death, unknown – Indicate if death was from a cause of death not known.

4. Indicate if an autopsy was completed based on the death certificate and information from the medical record.

5. Complete Medical Records Abstraction.

6. Complete Outcome forms as indicated on Medical Record Abstraction. (Vascular Outcomes or Injurious Fall and Fracture)

20.7.3. Fall-Related Fracture or Injury

The Injurious Fall and or Fracture form should be completed for all inpatient and outpatient falls that lead to a fracture or other significant injury, as defined on the first page of this form.

1. Indicate if the outcome was an injurious fall based on the criteria for fracture in question 3, or by the other criteria as listed.
2. Indicate the date of the fall.
3.a -c. Indicate if a fracture resulted from the fall. If there was a fracture, complete section b for the fracture site. Multiple fractures may be documented on the same form. Do not document old fractures. For all fractures, indicate how the fracture was confirmed.
4. Indicate if an overnight hospitalization resulted from the fall or fracture.

20.7.4. Vascular Events

The Vascular Outcome form should be completed for all inpatient myocardial infarction, resuscitated cardiac arrest, congestive heart failure, coronary revascularizations, peripheral arterial disease including abdominal aortic aneurysm and claudication, stroke, and carotid endarterectomy or revascularization. The subject must stay overnight in the hospital with the exception of the coronary revascularization. Enter the date of the admission to the hospital.

I. For acute myocardial infarction, indicate if the subject experienced chest pain. Review the cardiac enzymes and indicate if the results based on the lab normals for that facility. Review the ECG tracings and classify the changes. Indicate if the MI was procedure-related, and the type of procedure.

II. Indicate if there was a resuscitated cardiac arrest during the hospitalization.

III. Indicate the presence of acute congestive heart failure based on the criteria of physician diagnosis and treatment. Review the chest x-rays for pulmonary edema and/or congestion. Review the echocardiogram or MUGA for ventricular dysfunction. Indicate if the CHF was procedure-related, and the type of procedure. Indicate all the conditions present related to or causing the CHF.

IV. Indicate if the subject underwent a CABG or PTCA during the hospitalization (including outpatient).

V. Indicate if the subject had symptomatic peripheral arterial disease including of the abdominal aorta or lower extremities. Review the ultrasound, angiography,

stress test, surgical reports to determine the criteria for diagnosis. Indicate if the PAD was procedure-related, and the type of procedure.

VI. Indicate the presence of an acute stroke based on the symptoms. Review the brain imaging studies and indicate any findings of an acute stroke. Classify the type and subtype of acute stroke. Indicate if the stroke was procedure-related, and the type of procedure.

VII. Indicate if the subject underwent a carotid endarterectomy or other revascularization during the hospitalization.

VII. Indicate if the subject died at the end of the hospitalization.

20.8 Events Adjudication

After local completion, copies of all relevant medical records and completed adjudication forms should be forwarded along with an Event Tracking form should be forwarded to the administrative coordinating center. Before sending the medical records, personal identifying information should be removed or obscured, and any reference to the intervention should be removed or obscured. The central adjudicator will review the records and local adjudication forms. If the central adjudicator concurs, this fact will be noted on the Adjudication website.. If there are questions, the relevant outcomes committee will discuss the final resolution of the case.

20.9 Hierarchical Adjudication of Major Mobility Disability Outcome

Definite: ANY of the Following

(1) PRIMARY
Unable to complete 400-meter walk in 15 minutes

(2) ALTERNATIVE (IN HOME OR CLINIC)
Unable to walk 4 meters without assistance of another person or mobility aid (e.g. cane, walker) OR Unable to complete 4-meter walk test in 10 seconds or less, i.e. gait speed less than 0.4 meter/sec

(3) ALTERNATIVE (TELEPHONE OR IN HOME)

(a) Self report of inability to walk across a room (12 ft) without the assistance of another person

Operationally, this criterion is met based on an affirmative response to one or more of the following 2 questions:

(i) respondent answers "unable to do" when asked, "During the past month, how much difficulty have you had walking across a small room because of your health?"

(ii) respondent answers "Yes" to "Do you usually receive help from another person when you walk across a small room";

OR

(b) Proxy report of inability to walk across a room (12 ft) without the assistance of another person or mobility aid (e.g. cane, walker)

Operationally, this criterion is met based on an affirmative response to the following question:

(i) proxy answers "Yes" to "Does (participant) usually receive help from another person when he/she walks across a small room";

(4) ALTERNATIVE (MEDICAL RECORD)
Documentation of inability to walk across a room (12 ft) without the assistance of another person or mobility aid (e.g. cane, walker); example of descriptors include: bed-bound or wheelchair-bound, obtunded or moribund, etc.

Possible: Meets Criterion for #1 OR #2

(We will also Evaluate Results for #1 AND #2)

(1) SURROGATE QUESTIONS: PARTICIPANT
Answers Yes to Q1 and No to Q2 and Q3

1. Because of a health or physical problem, do you have any difficulty walking a distance of one mile, that is about 8 to 12 blocks?
2. Could you walk up and down every aisle in a grocery store without sitting down to rest or leaning on a cart?
3. Do you think you could walk a quarter of a mile now without sitting down to rest?

(2) SURROGATE QUESTIONS: PROXY
Answers No to Q1 and Q2

1. In the past two weeks, has the participant done any walking outside the home? This would include walking in your neighborhood or in other parts of the city/town, walking in the mall or at the gym?

2. Could the participant walk the entire length of an indoor shopping mall without sitting down to rest?

APPENDIX A:
(EXAMPLE for LIFE study: WFU site)

Authorization for Release of Medical Records

Name: _____
Last First Middle/Maiden

Social Security Number: _____ **Date of Birth**: _____

Request for Release of Information: I request and authorize my health care provider _____ ***(insert name and address of the institution from which you are requesting medical records)*** to release my medical records (as described below) to the _____ ***(insert study name)*** investigators and their study staff. The purpose for this authorization is to allow my medical records to be used in the _____ study, an Institutional Review Board (IRB) approved research study being conducted by the Department of Public Health Sciences at Wake Forest University Health Sciences, of which I am a participant. My records should be sent to the attention of _____ ***(insert name and address of the individual who should receive the information)*** for use in conducting the research study.

Medical Records To Be Disclosed: This authorization permits _____ ***(insert name of provider/institution from which you are requesting medical records)*** to disclose the following medical records: ***(check one)***

- ❑ All of my medical records that the provider has in his or her possession, including information relating to any medical history, mental or physical condition, and any treatment received by me. This information may include medical information related to treatment of alcohol, substance abuse, HIV/AIDS, and/or psychiatric care or psychological assessments, if applicable.
- ❑ All of my health information described above except for the following: ***(list information that is not needed by study personnel)***

  _____
- ❑ Only the following records or types of health information: _____ ***(insert dates of treatment, types of treatment, or other designation)***

Limits of this Authorization: I understand that my medical records/health information will be used and shared with others to carry out this research study and as required by law. I understand that while every effort will be made to protect this information, absolute privacy and confidentiality cannot be guaranteed. I further understand that if the person or entity receiving this information is not covered by federal privacy regulations, the information may be redisclosed and will no longer be protected by these regulations.

Term of this Authorization: This authorization will remain in effect until the end of the _____ study and I will not be able to obtain my research records until then.

Refusal to sign/Right to Revocation: I understand that I may refuse to sign this Authorization for any reason but that such refusal will affect my eligibility to participate in this research study. In addition, I may change my mind and revoke (e.g., withdrawal or cancel) this authorization at any time by writing the Principal Investigator of the study. This letter can be sent to _____***(Insert name and address of PI here)***. However, I understand that even if I revoke this authorization, my health information and medical records already obtained by the _____ study may still be used and shared as necessary to maintain the integrity of the research study.

Questions: I may contact the Principal Investigator named above for answers to my questions about the privacy of my health information. He/she can be reached at _____ ***(insert the telephone number of the PI here)***.

_____ _____

Signature Date

If the participant is unable to sign this Authorization, I am the Legally Authorized Representative and have the authority to sign this form.

_____ _____

Name Legal Relationship Date