CHAPTER 20

Outcome Events

Study Documents Referred to in this Chapter

- Outcome Events Questionnaire
- Outcome Event Tracking
- Other Health Related Events Questionnaire
- Adverse Event
- Adverse Event Evaluation
- Overnight Hospitalization
- Additional Outcomes Identification

CHAPTER 20
OUTCOME EVENTS

20.1 Ascertainment of Outcome Events (Overview)

In addition to reducing the primary LIFE Study endpoint, of major mobility disability, the study's physical activity intervention is also hypothesized to affect the frequency of serious fall injuries, combined cardiovascular events, and pulmonary disease events. Total death, combined with the primary endpoint is also a secondary outcome. Documents verifying the occurrence of these events are obtained by identifying and obtaining information on overnight hospitalizations, fall-related fractures, outpatient coronary and lower extremity revascularizations (including abdominal aortic aneurysm repair or rupture), other hospitalizations for lower extremity peripheral arterial disease, and deaths. This chapter describes the process and forms involved in identifying and classifying these events in a standardized and unbiased manner.

The hypotheses that relate to these outcomes are secondary and tertiary hypotheses:

- **Secondary:** Compared with SA, the PA program
  - Reduces the risk of serious fall injuries;
  - Reduces the risk of persistent major mobility disability and of the combined outcome of major mobility disability or death;

- **Tertiary:** Compared with SA, the PA program
  - Reduces the risk of hospital admissions for a combined set of pulmonary disorders, including, COPD/asthma, pneumonia, and bronchitis
  - Reduces the risk of combined cardiovascular events including:
    - Myocardial infarction (MI),
    - Angina requiring hospitalization,
    - Any stroke (ischemic or hemorrhagic),
    - Transitory ischemic attack (TIA) requiring hospitalization,
    - Hospitalization for carotid artery disease,
    - Hospitalization for congestive heart failure (CHF),
    - Hospitalization for peripheral artery disease (PAD) or outpatient revascularization for PAD,
    - Ruptured abdominal aortic aneurism (AAA), and
    - CVD death.

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 more frequent 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.

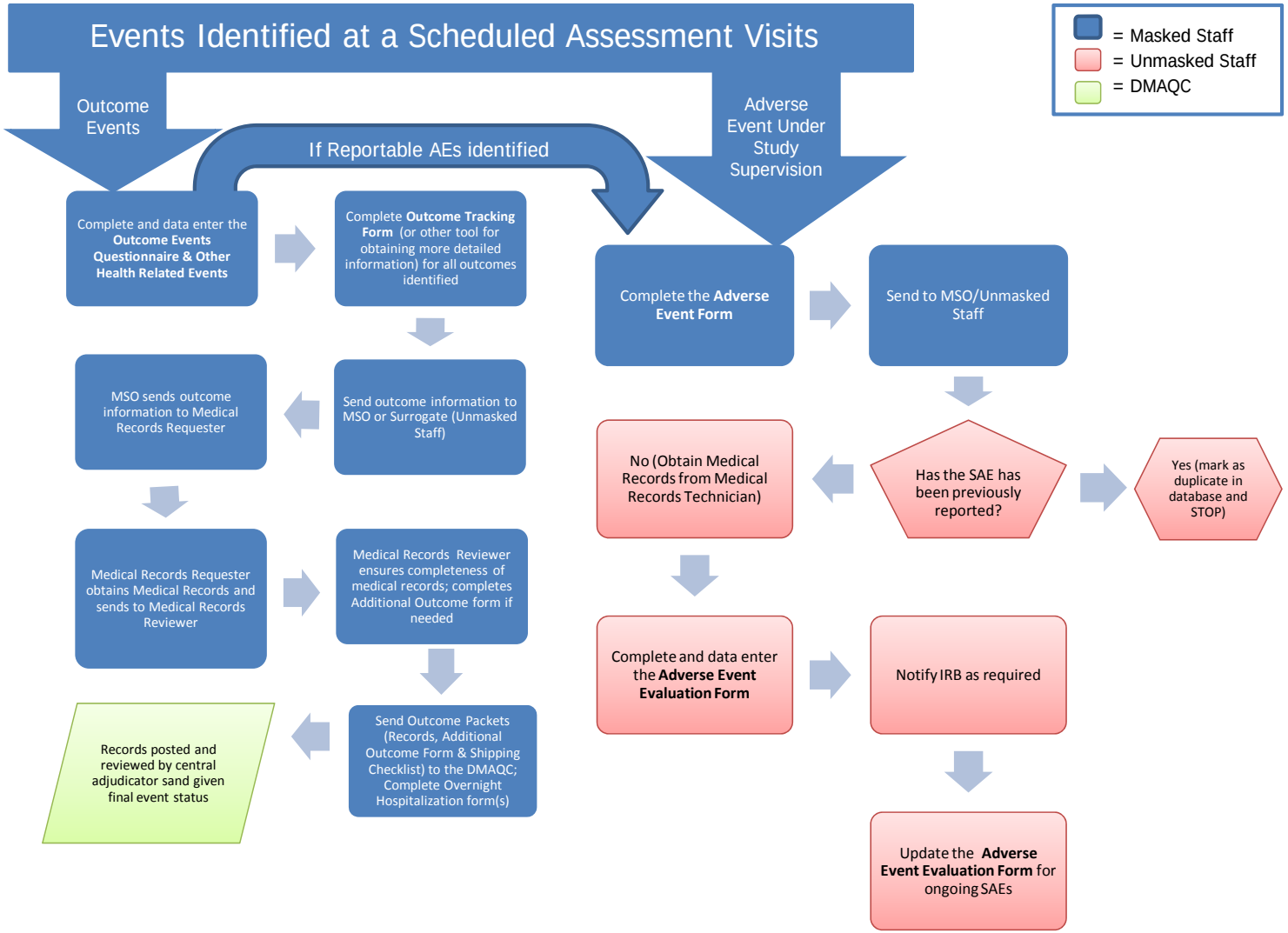
Therefore, relying on events reported to interventionists to judge the effect of the intervention is potentially biased, and could lead to the unfair appearance that the physical exercise intervention is associated with more events than it really is. To address this issue, the LIFE Study uses a dual system for dealing with Outcome Events:

First, a masked process for identifying and classifying potential study outcomes and adverse events in an unbiased fashion; and second, 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 semi-annual 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 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 six months. The interviews are intended to be done in-person, but may be done over the phone if the participant cannot return to the clinic and a home visit is not possible.

Figure 20.1 Process for Outcomes Collection



The interview process is based on the **Outcome Events** Questionnaire. This questionnaire specifically asks about health events that are study outcomes which require IRB notification. To ensure that ascertainment is complete for all tracked secondary and tertiary outcomes, ALL overnight hospitalizations will be investigated through the collection and review of medical records. When potential study outcomes are reported at the interview, the Outcome Event Tracking form (1 for each outcome reported) is available for study staff to use for collecting additional information (e.g. name of hospital, admission and discharge dates, etc.) that will facilitate obtaining medical records for the outcome adjudication process. This form is not required and is not data entered. Hence, sites may use an alternative form/mechanism to obtain the desired information. Following administration of the Outcome Events Questionnaire, assessors will administer the **Other Health Related Events Questionnaire.** This questionnaire specifically asks about various other health events that are not study outcomes but may require IRB notification. (See MOP Chapter 22 – Adverse Events for details on reporting adverse events).

In some cases, masked staff will become aware of adverse events that are outcomes through other avenues. In these cases, an **Adverse Event form** can be filled out directly. The study outcome will be captured at the next 6-month follow up visit. Please refer to MOP Chapter 22 – Adverse Events.

Unmasked staff who receive notification of an adverse event should fill out an **Adverse Event** form. Adverse events are entered into a separate database and will not be used to evaluate the efficacy of 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 Outcome Events Questionnaire should be completed with a proxy respondent on or before the next scheduled assessment. For example, if a participant dies during Month 10, the Outcome Events Questionnaire form should be completed by or before the target date for the Month 12 assessment.

20.1.2 Overview of Record Retrieval/Review Process

Upon completion of the follow-up visit, the **Outcome Events Questionnaire** and **Adverse Event** form should be entered into the data system. (See Chapter 22, Adverse Events for instructions on completing and data entering adverse event forms). For each possible study outcome, an outcome specific shipping checklist form and (if applicable) an Additional Outcome Identification form will be generated. The shipping checklist form will list all the items that must be collected from the medical records so that the study outcome can be adjudicated. The Additional Outcome Identification form will allow the site to indicate additional outcomes for other hospitalizations identified by the participant. The **Outcome Event Tracking forms** (or alternative site-specific forms)

should be forwarded, along with the associated shipping checklist forms, to the MSO (or unmasked nonintervention staff), who will serve as a “gatekeeper” for all medical records requests. This is necessary for two reasons: (1) to avoid duplication of medical record requests since all study outcomes are adverse events; (2) to maintain masking for the adverse events that are ascertained by interventionists and require collection of medical records.

The MSO (or surrogate) will forward the relevant tracking information to the medical records requester. This person oversees the request for medical records required by the adjudication process. This person should be masked to ensure that medical records of all participants are pursued with equal vigor. The person forwards copies of the medical records received to the medical records reviewer who must also be masked. These records are then reviewed for completeness, copied (after removing identifying information) and sent to the DMAQC with the appropriate Outcome Records Shipping Checklists. Once the outcome packet has been shipped to DMAQC, the medical records reviewer should complete and data enter an Overnight Hospitalization form for each hospitalization identified in review of medical records. See Section 20.7.3 for more details on completing the Overnight Hospitalization form.

All individuals associated with collection, medical records review, and adjudication of outcomes must remain masked. Because there is potential for unmasking to occur through revealing the source (ex. an unmasked interventionist), procedures must be put in place to prevent outcomes staff and investigators from learning group assignment. As noted above, the MSO (or surrogate) should be designated as the gatekeeper of group assignment, allowing that person to transfer outcome information to masked staff without revealing source. Table 20.1 lists the specific elements of the Record Retrieval/Review Process, while Table 20.2 highlights the roles and responsibilities for maintaining masking in the transfer of outcome data.

Table 20.1. Elements of Record Retrieval/Review Process

Steps	**Procedures**
1	Outcome Events Questionnaire is completed by the masked assessor.
2	If needed, the Adverse Events Form and Outcome Tracking form (if the site prefers) are completed by the masked assessor.
3	Outcomes staff data enters the Outcome Events Questionnaire; the outcomes interface will assign an outcome identification number for each outcome reported by the participant and the relevant shipping checklist form(s) will be generated.
4	The outcomes packet, including the Outcome Tracking Forms (or alternate) and the shipping checklist forms, are sent to the MSO (or surrogate), who will forward the packet to the medical record requester.
5	The medical record requester retrieves the medical records and forwards them to the medical records reviewer.
6	The medical records reviewer ensures that all the needed medical records have been obtained. If additional outcomes are identified in review of medical records, the medical records reviewer also completes the Additional Outcome Identification form.

7	The medical records reviewer forwards de-identified medical records and outcome shipping checklist(s) to DMAQC for central adjudication.
8	The medical records reviewer completes and data enters the Overnight Hospitalization form for each hospitalization identified in review of the medical records.

20.1.3 Outcome 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 Study 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 20.1. 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.

20.2 Health Outcomes

The following events are LIFE outcomes and are tracked by the LIFE website through the use of the Outcome Management Tool (OMT). The OMT will register each outcome reported and will enable the sites and the DMAQC to track the outcomes as they move through the process of outcome reporting and adjudication.

Operational details are provided in Chapter 28 – Outcomes Adjudication.

- Death
- Serious Fall Injuries
- Pulmonary Disease Outcomes
- Cardiovascular Disease Outcomes

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 Outcome Events questionnaire 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 records reviewer must also be masked.

In order to maintain the complete separation of events reported by masked and unmasked staff, all Outcome 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 is reported. (See Data management chapter for details).

Final classification of a reported event as a study outcome is determined by the central adjudication committee. The central adjudicators are masked and make this final determination based only on information generated by masked study staff.

It is possible that a masked outcomes staff (medical records requestor/reviewer) may review a medical record that specifically states the randomization group of the participant, resulting in unmasking. For example, a participant may report a hip fracture, and when reviewing the medical record it may specify that the participant is in a trial and was randomized to a physical activity/exercise arm when the fall occurred. All reference to the randomization group must be obliterated in the same manner as other personal identifiers (see section 20.8.1). From that point forward, the staff who was unmasked may no longer complete any outcomes investigation or medical records review for that participant, and a second medical records requestor/reviewer should complete all work on subsequent cases for that subject.

To prevent masked outcomes staff from being unblinded by a medical record, especially those who are also assessors, an unmasked staff member may pre-review the medical records for any reference to randomization group. The unmasked staff should obliterate any reference to group assignment, and then return the medical record to the outcomes staff for completion of document processing.

Table 20.2 Study Staff Roles and Responsibilities in Maintaining Masking			
Person	**Masked Status**	**Role**	**Masking Responsibilities**
Outcomes Assessor	Masked	1. Ascertain Outcome Events 2. Complete Adverse Event, if necessary. 3. Enter the Outcome Event Questionnaire and Adverse Event form into Outcomes Database. 4. Forward Outcome Tracking Forms (or alternate), the shipping checklist forms, and Adverse Event form to Medical Safety Officer (or surrogate).	Remind participants not to reveal group assignment.
Medical Safety Officer (or surrogate)	Unmasked	Forward Outcome Tracking Forms (or alternate) and the shipping checklist forms to masked Medical Records Requestor	
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 medical records reviewer.
Records Reviewer	Masked	Ensure completeness of medical records; ship records and documentation to DMAQC	Provide feedback on the integrity of the process to the PI
Central Adjudicators	Masked	Determine final outcomes adjudication status based on information provided through outcome interface	

20.4 Semi-annual Outcome Events Questionnaire

20.4.1 Administration

The Outcome Events Questionnaire is administered by masked staff members at each scheduled clinic visit. If participants do not come to their scheduled assessment visit, these interviews should be completed by phone or in the home. In some cases, the scheduled visits will correspond to the close-out visit. When this happens, the interview should be included at close-out.

The interview is to be completed within the windows for the given contact. The windows for the clinic visits 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 Outcome Events Questionnaire was administered. Typically, this will be 6 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 first 6-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.

The **Outcome Event Tracking** form is available for study staff to use for collecting additional information (e.g. name of hospital, admission and discharge dates, etc.) that will facilitate obtaining medical records for the outcome adjudication process. This form is not required and is not data entered. Hence, sites may use an alternative form/mechanism to obtain the desired information.

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 the questionnaire. 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.

Table 20.3 presents a detailed process for completing the Outcome Events Questionnaire and relative outcome forms at the semi-annual follow-up assessment visits.

Table 20.3 Process for Completing Outcome Events Questionnaire and Relative Outcome Forms

Col 1	Col 2	Col 3	Col 4	Col 5^
Steps	**Responsible?**	**Q11 – Other Hospitalization Identified**	**Q3-10 – Outcome Identified**	**AE Identified**
1	Masked Assessor	Obtain hospitalization info from participant (tracking info)	Obtain outcome info from participant (tracking info)	Complete the AE Form and data enter
2	Masked Assessor	Send collected info to MSO	Send collected info to MSO	Send copy of AE form to MSO
3	MSO	Forward tracking info to Records Requestor	Forward tracking info to Records Requestor	Receive email notification & copy of AE form. Confirms AE is not a duplicate Follows-up with participant regarding the AE and completes the Event Evaluation form. (If records are needed to ascertain relationship to the study, request medical records)
4	Records Requestor	Request medical records (limited list – see Table 20.4)	Look up assigned OID and request medical records by OID (using the Outcome Shipping Checklist – 1 per outcome identified)	Request medical records and forward copy of records back to MSO
5	Records Requestor	Remove mentions of intervention and forward medical records to Records Reviewer	Remove mentions of intervention from medical records, data enter Outcome Shipping Checklist, and forward medical records to Records Reviewer	
6	Records Reviewer	Review Records and complete the Additional Outcome Identification (aoid) Form (1 per hospitalization identified by the participant in Q11)	Review Records for additional outcomes not mentioned by participant	
7	Records Reviewer	<u>Was there any outcome identified in the records?</u> Yes – Data Enter Additional Outcome Identification form and Return to Records Requestor to obtain more specific outcome medical records (Step 4 Column 4) No – Data Enter Additional Outcome Identification form indicating no additional outcomes (Q4)	<u>Were any additional outcome identified?</u> Yes – Request an OID in OMT and Return to Records Requestor to obtain more specific outcome medical records (Step 4 Column 4) No – De-identify and label (with PID/acrostic) copies of medical records and send with Outcome Shipping Checklist to DMAQC, enter “shipped to DMAQC” date in outcome tracking interface	
8*	Records Reviewer	Overnight Hospitalization Form completed for all hospitalizations without outcomes (OID) associated and data enter	Complete Overnight Hospitalization form for hospitalizations with associated outcomes (OIDs) and data enter	

*not required to ship the Overnight Hospitalization form to the DMAQC, ^Column 5 – AEs Identified steps overlap with the steps in Columns 3 and 4.

20.4.3 Completing the Outcome Events Questionnaire

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 1-14 of the interview with the proxy. These events are still important to capture and will contribute to the comparison between the two groups.

Questions 3-13 elicit information on discrete outcome events that are also study outcomes: death, fall-related fracture, symptomatic coronary artery disease, stroke, congestive heart failure, abdominal aortic aneurysm, peripheral artery disease, pulmonary disease, cancer, and other conditions that required hospitalization (Question 13). These events will only be classified as study outcomes after objective medical evidence substantiating their occurrence is found in medical records.

When a fracture is not fall-related (Question 4), information should be provided regarding the cause of the fracture. Excessive trauma includes an MVA and high falls, defined as falls from a height greater than 3 feet.

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 what relative outcome forms and adverse event forms require completion.

Question 9 asks about procedures to improve blood flow to the legs. Include surgery, angioplasty, stent placement or thombolysis for peripheral arterial disease for this question. Include inpatient and outpatient procedures.

Question 14 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 completed Outcome Events Questionnaire should be entered under the appropriate follow-up visit where the form was administered.

20.5 Outcome Event Tracking

All reports from participants or proxies that might indicate that a study outcome has occurred are tracked by the study.

To ensure that ascertainment is complete for all tracked secondary and tertiary outcomes, ALL overnight hospitalizations will be investigated through the collection and review of medical records. **An overnight hospitalization requires an admission to the hospital.** Even if it spans two days, e.g. 9 pm on one day to 9 am the next day, a visit to an emergency department is not considered an overnight hospitalization if it does not result in a hospital admission. For billing purposes, some hospital admissions may be classified as “hospital outpatient” or “observation care”. These should be considered as overnight hospitalizations, as long as the discharge date is different from the admission date.

20.5.1 Tracked Events

Tracked events are:

- Fall-related fractures and other serious fall injuries
- Cardiovascular disease hospitalizations or deaths .
- Outpatient coronary or lower extremity revascularizations
- Pulmonary disease hospitalizations or deaths
- Fall-Related Fractures and other serious fall injuries
- Death

20.5.2 When to Complete an Outcome Event Tracking Form

An Outcome Event Tracking form (or alternate site-specific form) can be filled out whenever a masked staff member receives information indicating that a participant has died or experienced any of the study outcomes tracked by the LIFE Study (cardiovascular or pulmonary hospitalizations, serious fall-related fractures or injuries, or outpatient cardiovascular or lower extremity revascularization) either as part of the interview using the Outcome Events Questionnaire or by other means (such as a proxy calling the clinic, or the ascertainment of death during a scheduling attempt).

An Outcome Event Tracking form should be completed for each outcome reported during the outcome events interview. For example, if a participant reported going to the ER because of a fall and reports being hospitalized overnight for congestive heart failure on a different occasion, two tracking forms can be filled out (one for each episode). However, if one event happens during the diagnosis and treatment of another event, only one event form can 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 Outcome 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 an ER (not admitted) and is transferred/admitted to another hospital, complete one Outcome Event Tracking form because this is one illness episode. Record the admission information for the overnight hospitalization with a notation about the ER visit.

20.5.3 Completing the Outcome Event Tracking Form

The Outcome 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 Outcome 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 a fracture, fall-related fracture, outpatient coronary revascularization, outpatient lower extremity 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.

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 for reasons other than a 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 that diagnostic catheterization procedures are not tracked. However, in some cases a diagnostic catheterization may become combined with a revascularization or an overnight hospitalization.

Section IV asks about outpatient lower extremity revascularization.
Section V asks about death, both in and out of hospital. If a death occurs during a hospitalization, document it in Section V, 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. At the discretion of the site, the form may be left undated to facilitate subsequent use in accordance with individual hospital requirements.

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/records that should be requested for the each outcome identified. Not all documents/records will be needed for every 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. The Outcomes Interface and the relevant Outcome Event Shipping Checklist also provides a mechanism to ensure a complete packet of outcome records.

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.

If possible additional outcomes are identified by a central adjudicator, the DMAQC will notify the site about any additional medical records that are required.

Table 20.4 Medical Records Required for Outcome Ascertainment

Medical Records Required for LIFE Central Adjudication (if available)	Outpatient Fracture (office note can be used in lieu of radiology report)	Inpatient Fracture or other fall injuries	Myocardial Infarction (MI), Angina, Chest Pain	Congestive Heart Failure (CHF)	Inpatient or outpatient CABG/PTCA/Coronary Revascularization	Stroke	Carotid Endarterectomy	Inpatient Peripheral Arterial Disease (PAD)	Inpatient/outpatient lower extremity revascularization	Hospitalized Abdominal Aortic Aneurysm Rupture or repair	COPD, asthma, pneumonia, bronchitis	Overnight Hospitalizations for other conditions	Death*
Face Sheet/Physician Attestation with ICD codes		X	X	X	X	X	X	X	X	X	X	X	
Discharge Summary (or Progress Notes if DS not available)		X	X	X	X	X	X	X	X	X	X	X	
Admission History and Physical Exam		X	X	X	X	X	X	X	X	X	X	X	
Operative/Procedure Report		X	X	X	X	X	X	X	X	X	X		
Cardiac Catheterization Report			X	X	X								
All ECG Tracings			X	X	X								
Lab Reports		X	X	X	X						X		
All Radiology Reports	X	X	X	X	X						X		
Stress Test/Thallium scan Report			X	X	X								
Echocardiography Report			X	X	X	X	X						
Neurology Consult						X	X						
Carotid Doppler/Duplex Scan Report						X	X						
Carotid Angiography Report						X	X						
CT head/MRI brain Report		X				X	X						
Lower extremity/abdominal Doppler/ultrasound								X	X	X			
Lower extremity/abdominal angiography								X	X	X			
Pulmonary Function Test Report											X		
Chest CT Scan Report											X		
Non-certified death certificate													X
Autopsy (if done)													X

*For deaths that occur out of the hospital, please include the hospital discharge summary and history and physical for the hospitalization that occurred immediately prior to the death. For deaths that occurred in the hospital, please include appropriate records associated with the hospital diagnosis.

Medical records should be requested within 48 hours of receipt of the Outcome Tracking forms (or alternate) and the shipping checklist forms, 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 be unlikely to 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 outcome event tracking system. Medical records forwarded to the local abstractor should be examined for references to the LIFE study intervention and these should be removed (see Section 20.3.1).

20.7 Review of Medical Records and Event Classification

All medical records to be used in outcomes documentation should be forwarded to the local medical records reviewer to ensure completeness. The medical records reviewer should complete an Overnight Hospitalization form for each hospitalization reported by the participant or proxy (see Section 20.7.3). The medical records reviewer should also carefully review all medical records to determine if there is reference to an earlier hospitalization or other study outcome that was not previously reported by the study participant or proxy. If the medical records were obtained based on participant report of a hospitalization (Q11 on the Outcome Events Questionnaire) then complete the Additional Outcome Identification form (see Section 20.7.1). If the medical records were obtained based on other information (or in another way) and if they reveal additional outcomes, the medical records reviewer will request a Manual OID in the OMT and return the information to the Medical Records Requestor to obtain more specific outcome medical records. This method of ascertainment can be duplicated across all sites so no bias will be introduced.

For each outcome identified, the de-identified medical records and related shipping checklist should be mailed to the DMAQC for central adjudication.

20.7.1 Additional Outcome Identification Form

Complete the Additional Outcome Identification form in the following case:

1. If the participant (or proxy) answers ‘Yes’ to Question 13 (other overnight hospitalizations) on the Outcomes Events Questionnaire.

Items 1-3 – Enter the hospital admission and discharge dates for the hospitalization(s) or the event or procedure date, if the participant was not hospitalized. If the additional outcome that was identified is a procedure during a hospitalization we expect that the hospitalization admission and discharge dates will be entered, not the date of the procedure.
Item 4 – Indicate whether any additional outcomes were identified in the chart review. If additional outcomes were identified, check ‘Yes’ and go to Question 5. If there were no additional outcomes identified, check ‘No’ and end the form.

Question 5 – Record who identified the additional outcomes.

Note: This form should only be completed in response to the participant answering "Yes" to Q13 on the Outcome Events Questionnaire, therefore, 'Participant' should always be marked.

Question 6 – Indicate the other study outcomes that were not already reported on the Outcome Events Questionnaire.

Multiple additional outcomes can be identified on this form if they were within the same hospitalization. NOTE: Additional Outcome Identification (AOID) forms are generated only for the number of "other hospitalizations" identified in Q13 on the Outcome Events Questionnaire. To data enter these forms(s) after review of medical records the site will need to go to the visit link associated with the original report of the hospitalization (under the participant visit page in the LIFE Study database).

20.7.2 Manual Outcome Identification Request

Complete a Manual Outcome Identification (OID) Request in the following case:

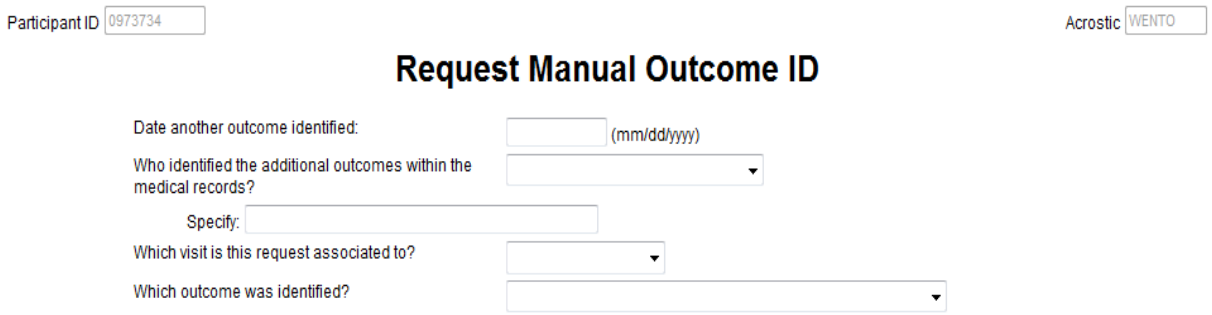
1. If, after review of medical records, additional outcomes are identified within the same hospitalization for the outcome reported on the Outcome Events Questionnaire.

Items 1 – Enter the date the medical records were reviewed and the additional outcome identified.

Item 2 – Indicate who identified the additional outcome. Note: Site Outcome Technician refers to the Outcomes staff at the site.

Item 3 – Indicate which visit this outcome is associated with.

Item 4 – Indicate the additional outcome identified. Only 1 additional outcome can be identified. To obtain additional OIDs submit additional Manual Outcome Identification Requests.



20.7.3 Overnight Hospitalization

The Overnight Hospitalization form is completed for EVERY hospitalization identified during the outcome process. It is expected that each hospitalization reported on the Outcome Event Questionnaire or any additional hospitalizations identified during review of medical records will be documented on this form. This form should be completed after collection of medical records and submission of records to the DMAQC to ensure that all associated OIDs are recorded. If no outcomes were identified in hospital records (especially those collected in response to Q13 on the Outcome Events Questionnaire) the Overnight Hospitalization form must still be completed.

Note: **An overnight hospitalization requires an admission to the hospital.** Even if it spans two days, e.g. 9 pm on one day to 9 am the next day, a visit to an emergency department is not considered an overnight hospitalization if it does not result in a hospital admission. For billing purposes, some hospital admissions may be classified as "hospital outpatient" or "observation care". These should be considered as overnight hospitalizations, as long as the discharge date is different from the admission date.

Items 1-2 – Enter the hospital admission and discharge dates
Item 3 – Indicate if any study outcomes were identified with the hospitalization.
Item 4 – If the study outcomes were associated with the hospitalization, list the associated OIDs.
Item 5 – List the ICD-9 diagnosis and procedures codes for the attested to in the medical records.
Item 6 – If ICD-9 codes are not available, record the first 10 discharge diagnoses in the order they are listed on the hospital record face sheet.

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 Overnight Hospitalization 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 the dates of the rehab/SNF admissions should not be included on the Overnight Hospitalization form. Complete separate Overnight Hospitalization forms for the two hospitalizations.

However, if a new, more recent event (AFTER the reported hospitalization) is identified, for example by searching electronic medical records, do NOT collect that record. Wait until the next regular ascertainment point for that participant to report the new event. If the participant does not report it, do not collect it. Since not all sites will have the same method of ascertainment in this manner, bias would be introduced.

20.8 Preparing the Outcome Adjudication Packet

20.8.1 Sterilizing the Medical Records

HIPAA regulations require all documentation to be 'sterilized' in order to maintain confidentiality of subjects, prior to those records being shared with any entity outside the study clinic. This involves the removal of all personal identifiers. Every page of a medical record will have personal identifiers, and these must be masked. The preferable method is to use china markers or grease pencils. Use of other types of pens, despite being black ink, still permits reading of the letters when the paper is held up to a light. The following are a list of the identifiers that must be sterilized from all records:

- Participant names, addresses, phone numbers and emails
- Next of kin/other family/power of attorney names, addresses, phone numbers and emails
- Social security numbers, insurance numbers, Medicare numbers and medical record numbers
- Day and month of birth (but not year)

Do NOT sterilize dates within the medical record related to specific tests or treatment including lab tests, and do not sterilize dates of admission and discharge. It is important to be able to link dates of various tests and events within the chart to put together a temporal sequence of the illness episode.

20.8.2 Shipping Outcome Packets

After collection of all required medical records the relevant Outcome Event Shipping Checklist should be data entered. De-identified copies (see Section 20.8.1) of the records should be sent with the relevant Outcome Event Shipping Checklist to the DMAQC within 60 days of notification.

When medical records are sent to the DMAQC a LIFE participant ID label should be placed on each document, preferably on each page (PID and acrostic written is okay on subsequent pages). Also, obscure any reference to the LIFE study intervention.

When shipping outcome records to the DMAQC it is likely that records for one hospitalization will be used for documentation of multiple outcomes/OIDs. In these cases it is permissible to send one copy of the hospitalization records and attach multiple Outcome Records Shipping Checklists as a collection of outcomes.

Once received, the DMAQC project manager (PM) will verify receipt of the outcome records in the outcome interface by for each outcome/OID. If site sends a collection of outcomes (one hospitalization, multiple outcomes) the records for each OID will be verified in the outcome interface.

After verification the medical records will be scanned and an electronic 'outcome packet' for each OID will be created and posted in the outcome interface linked to the appropriate outcome report form and shipping checklist by OID. If multiple outcomes are

included in one collection, the entire collection will be posted as the electronic ‘outcome packet’ for each outcome reported within the collection.

APPENDIX A:
(EXAMPLE for LIFE study: UF 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 Aging and Geriatric Research at the University of Florida, 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:

> 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.

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 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

APPENDIX B
(Example for LIFE Study: Pittsburgh Site)

Study ID Number: _____

Authorization to Release Protected Health Information for Research

Participant Name _____ Date of Birth _____

Social Security/Medical Record Number: _____

I authorize _____ to release information from the record of_____
Hospital/Provider Participant

to the **Lifestyle Interventions and Independence for Elders (LIFE)** in the (Site Name/Department). The reason for this request is that I am a participant in this research study. These records are for **research purposes only**, and are not being used for patient care. I authorize a photocopy or facsimile of this authorization to be acceptable and valid. I authorize this release to be valid for the duration of the study (***2010-2015***). I understand that I may revoke this authorization in writing at any time by providing a request to the study. I understand that once this information is disclosed, it may be redisclosed by the recipient and the information may not be protected by federal privacy laws or regulations. My request to release these records to LIFE will have no impact on the releasing facility's provision of care to me.

The records to be released are for the treatment dates: __ __/__ __/__ __to __ __/__ __/__ __ for a diagnosis of _____.

___ Face Sheet/Attestation with ICD codes

___ Admitting History & Physical Exam

___ Emergency Room Report

___ Laboratory Reports

___ Echocardiography Reports

___ Cardiac Catheterization Reports

___ Carotid Duplex/Angiography Reports

___ Abdominal Ultrasound/Angiography Reports

___ Pathology Report

___Other _____

___ Discharge/Death Summary

___ Consult (specify_____)

___ Operative Reports

___ Radiology Reports

___ Stress Test Reports

___ ECG tracings

___ Lower Extremity Duplex/Angiography

___ Pulmonary Function Testing

___ Behavioral Health/Drug/Alcohol or HIV

_____ _____
Participant/ Representative Signature Date Witness Date

_____
Relationship to participant, if representative

Health Information Department: Mail records to:
Site name and address

Records may be faxed to xxx.xxx.xxxx. Please call the LIFE Events Coordinator at xxx.xxx.xxxx with any questions about this request.