Outcomes
(Operations)

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Outcomes

Introduction

The Women's Health Initiative (WHI) Extension Study (ES) outcomes are diverse and complex. The aim of the ES is to continue to assess the relationship of particular interventions on a broad range of health and illness conditions in women including healthy aging. To ensure that the identified outcomes represent true disease states, detailed outcomes ascertainment procedures and diagnostic criteria for adjudication have been developed by study investigators. The standardized outcome procedures detailed below help ensure that the study outcomes are ascertained and adjudicated in an unbiased manner.

To enhance WHI's scientific value and support the overarching objective to study increased risk of Cardiovascular Disease (CVD) in older women of diverse race and ethnicity, Clinical Trial (CT) and Observational Study (OS) participants in the 2010-2020 ES were separated into two groups: the Medical Record Cohort (MRC) and the Self-Report Cohort (SRC). The MRC is comprised of all African American and Hispanic participants and all participants who were originally randomized to the Hormone Trial (HT). Outcomes reported by the MRC participant who consented to be in the ES will receive full ascertainment and adjudication as done in the WHI main study (1992-2005) and the 2005-2020 ES. For the SRC, only cancer outcomes will receive full ascertainment and adjudication, and all other outcomes reported by the SRC will be collected only by self-report.

The ES outcomes ascertainment and adjudication procedures are essentially the same as those used for the main WHI study, though limited to participants in the MRC, and to the SRC (cancer outcomes only). Outcomes ascertainment procedures performed by Field Center (FC) staff continues to include the identification, investigation, and documentation of potential outcomes.

A historical summary of the outcome process from 1993 - present is in *Table 10 – History of WHI Outcomes/Adjudication*.

8.1 Overview of Outcomes Process

Full outcomes ascertainment and adjudication will be conducted for the MRC and cancer only for the SRC. The initial self-reports and the details about these self-reports will be collected on *Form 33 – Medical History Update* for all participants so that these self-reported events may be documented and adjudicated in the future should funding become available. See the list of outcomes requiring adjudication in *Table 8.1 – WHI Extension Study Outcomes*.

MRC/SRC Designation and Outcomes Collection Type (OCT)

The WHI core model is based on a MRC or SRC designation and does not allow for easy integration of newly approved Ancillary Studies (AS). To create a more flexible model that allows AS outcomes ascertainment to fold seamlessly into the current FC workload, a new 'Outcomes Collection Type' classification is being used (in addition to MRC/SRC). The alpha classification (A, B, C, etc.) represents a specific group of outcomes/self-reports that FCs investigate based on WHI and ancillary study participation (see *Table 8 – Outcomes Collection Types*). The MRC/SRC WHIX designation is used throughout this section of the manual because this manual emphasizes core WHI work.

There are 11 sections in the Outcomes manual. *Sections 8.1-8.5* and *8.6-8.11* outline the outcomes process for the Outcomes Coordinators (OC) and Physician Adjudicators (PA), respectively.

The manual provides instructions and resources for FC staff and adjudicators to ensure systematic investigation and adjudication for WHI.

- *Section 8.2 – Identification of Outcomes, Section 8.3 – Investigation of Outcomes,* and *Section 8.4 – Documentation of Outcomes* describe how to process the initial identification of an outcome, investigate and obtain the required documents for each outcome, assemble the documentation into an adjudication case packet, and upload the case packet to the CCC for central adjudication.

- *Section 8.5 – Fatal Events in the MRC – Special Considerations* describes additional procedures and guidelines for follow-up of participant deaths, including contact with participant families.
- *Section 8.6 – Physician Adjudication* provides an overview of WHI adjudication procedures and steps the Physician Adjudicators must follow in reviewing documents related to a possible outcome.
- *Sections 8.7 – Fatal Events Adjudication, Section 8.8 – Cardiovascular Outcomes, Section 8.9 – Form 126 – Report of Venous Thromboembolic Disease, Section 8.10 – Fracture Outcomes Adjudication,* and *Section 8.11 – Form 130 – Report of Cancer Outcome* and describe in detail how to complete the specific outcomes forms and assign specific diagnoses.
- *Appendix A – Forms.* Includes *Forms 33* and other supplemental forms completed by participants and FC staff.
- *Appendix C* – Coding Reference, ICD 9-CM and ICD-10
- *Appendix D – Explanation of Medical Terms*: Medical terminology used in medical records documentation.

Table 8
Outcomes Ascertainment, Outcomes Collection Type (OCT)

WHI Outcomes	A	B	C	D	E	F	G	H
Formerly	MRC	SRC	MRC	SRC	SRC	SRC	MRC	MRC
Ancillary Study (s)	MRC African American, Hispanics, former HT	Self-Report Cohort (SRC)	AS355 COSMOS	AS355 COSMOS + WHISH overlap	AS510 WHISH HF	WHISH CMS Not in FFS Includes AS510	AS511 STAR in CMS FFS	AS511 STAR + COSMOS in CMS FFS
Outcomes	All Outcomes	Cancer	All Outcomes + Cancer Recurrence	All Outcomes Except: A-Fib Heart Valve, Hospital stays	Heart Failure & Cancer	All Outcomes Except: A-Fib Heart Valve, Hospital stays	All Outcomes	All Outcomes + Recurrence
Cardiovascular								
CHD	FC		FC	FC		**CCC**	FC	FC
CHD/MI death	FC		FC	FC		**CCC**	FC	FC
Myocardial Infarction (MI)	FC		FC	FC		**CCC**	FC	FC
CABG	FC		FC	FC		**CCC**	FC	FC
PTCA (PCI, stent)	FC		FC	FC		**CCC**	FC	FC
Stroke	FC		FC	FC		**CCC**	FC	FC
Heart Failure	FC		FC	FC	FC (RC)*	FC/**CCC****	FC	FC
Carotid artery disease	FC		FC	FC		**CCC**	FC	FC
Atrial Fibrillation (IP)							**CCC**	**CCC**
Atrial Fibrillation (OP)							**CCC**	**CCC**
PAD	FC		FC	FC		**CCC**	FC	FC
Heart valve	FC		FC				FC	FC
Aneurysm/dissection	FC		FC	FC		**CCC**	FC	FC
DVT	FC		FC	FC		**CCC**	FC	FC
Pulmonary Embolism	FC		FC	FC		**CCC**	FC	FC
Cancer								
Breast	FC	FC	FC	FC	FC	FC	FC	FC
Ovary	FC	FC	FC	FC	FC	FC	FC	FC
Endometrium	FC	FC	FC	FC	FC	FC	FC	FC
Colon/rectum	FC	FC	FC	FC	FC	FC	FC	FC
Other cancer	FC	FC	FC	FC	FC	FC	FC	FC
Recurrent cancers			FC	FC				FC
Fractures								
Hip fracture/upper leg	FC		FC	FC		**CCC**	FC	FC
Deaths (all)	FC		FC	FC		**CCC**	FC	FC
Hospital stay >/= 2 nights*	***							

Updated: 10/01/19 *Buffalo investigates Boston HF
**Heart Failure alone (FC). Heart Failure + any CVD outcome (CCC)
***MRC & targeted ancillary studies: Investigate 2-night hospital stays captured on the *Form 120H* as part of the death case

8.1.1 Definitions Used for WHI Extension Study Outcomes

Adjudication: The assignment of the final decision/diagnosis by a Physician Adjudicator or CCC Cancer Coder after reviewing the outcome documents contained in an adjudication case packet; recording the decision/diagnosis and details supporting the diagnosis on the appropriate outcomes form.

Adjudication case packet "case": Materials relevant to a specific outcome case. Each case packet includes a case ID cover sheet, *Investigation Documentation Summary* (*WHIX0988*), *Members Outcomes Status Report* (*WHIX1215*), relevant outcomes forms, and required medical records documentation pertaining to the specific outcome(s) being adjudicated.

Ascertainment: A three step process that includes the 1) initial identification of a possible outcome, 2) investigation of sources of supporting medical records, and 3) assembling of documentation for an adjudication case (AKA "case"). Ascertainment precedes adjudication of an outcome.

Closed outcome case: A WHIX database function in which further ascertainment and/or adjudication procedures are stopped or concluded, either because a final diagnosis has been assigned or it has been determined that no outcome occurred. A closed outcome is recorded in the database via assignment of a "close date" and corresponding "closure code" in the WHIX Outcomes Management Subsystem.

Discovery: A possible outcome or provider visit not self-reported by the participant on her *Form 33 – Medical History Update* but identified while reviewing medical records. Investigation of the unreported outcome or provider visit is appropriate if the discovered event was located in medical records the OC is authorized to review. Discovery does not apply to death. Investigate any report of death, no matter how it is discovered, including deaths identified through the Social Security Death Index (SSDI) or obituaries. A discovered event is investigated if it occurred on or after April 1, 2005 for any outcome except A-Fib, aortic aneurysm, and heart valve disease. These three outcomes were added during extension and are investigated only if discovered on or after October 1, 2010 thru May 2017 for Afib and through current for aneurysm and heart valve disease. Review specific ancillary study rules to determine if discoveries are eligible for investigation.

Documentation: The third step in ascertainment process; it is the assembly of required supporting medical records (obtained through investigation of a possible outcome) into an adjudication case packet. Documentation also includes tracking and reconciling the documents and packets through the WHIX database and/or manual tracking systems until the adjudication case is closed.

Emergency Room (ER) or Emergency Department (ED) visit: Visit or admission to a hospital ER/ED. This may or may not lead to a hospital admission. Several events (i.e., newly diagnosed hip fractures, deaths, cancers, coronary revascularizations, strokes, deep vein thrombosis [DVT] occurring or diagnosed solely at an ER visit [without subsequent hospitalization]) will be investigated, documented, and adjudicated as possible outcomes. Include ER/ED documentation in all adjudication case packets when the ER visit precedes a hospital admission or when a participant dies in the ED of a coronary event. See additional information under Hospitalization below.

Five primary cancers: The five primary WHI cancer outcomes sites: breast, colon, rectum, endometrium, and ovary.

Other cancers: This group of 'other cancers' includes all other cancer sites that are not one of the five primary cancer sites listed above.

Outcomes Collection Type (OCT): An alphabetical classification A-Z. Each letter represents a specific group of outcomes/self-reports to investigate based on WHI and ancillary study participation. ***Note:*** OCT A and OCT B = MRC and SRC, respectively.

HAH: Archived terminology. All Hispanic, African American, or HT participants who consented to the ES 2010. These participants are eligible to be in the 2015-2020 MRC if they consented in 2010-2011. This definition was changed to MRC super cohort.

Hospitalization: A hospitalization, for the 2010-2020 ES purposes, is defined as any overnight stay in an **acute** care hospital only for selected outcomes of interest and a two night stay for any other reason. Short stays, observation stays, and day surgeries may be referred to in medical records as outpatient visits, but for the ES study purposes, these stays are considered hospitalizations if they result in a hospital stay of two or more nights. Note that a stay of two nights or more in a rehabilitation facility (even if the participant is a direct transfer from an acute care hospital) is **not** considered a hospital stay and is not investigated in the 2010-2020 ES.

Note: Psychiatric admissions of one or more nights will not be investigated or adjudicated.

A hospital Emergency Room (ER) visit is not considered an admission *even if the date changes*.

- However, if any ER visit results in an overnight hospital admission, and meets the outcome definition of a one-night vs. two-night stay, adjudicate the outcome by requesting the appropriate ER medical records.
- Additionally, adjudicate an ER visit when the participant reports a revascularization procedure, or a DVT, stroke, hip fracture or cancer is diagnosed, or when the participant dies in the ER, regardless of length of stay.

Note: On June 6, 2018 the Steering Committee voted to stop investigation of stand-alone, 2 night hospital stays reported on a routine *Form 33* as a streamlining measure.

An overnight hospital admission and an overnight stay in an Emergency Room are not used interchangeably. If the participant is not actually admitted to the "acute care facility," (i.e., the hospital itself) it would not be considered a hospitalization. Forward questions about a particular institution's definition of an overnight hospital stay to the CCC OC liaison.

Identification: The first step in the ascertainment process; the routine procedures through which the OC learns of a possible outcome, which is typically through participant completion of an annual *Form 33 – Medical History Update* or in the event of a participant's death, through some other interim report to FC staff by the participant's proxy (family, friend or health care provider). The initial notification of a participant's death may also come from other sources (e.g., CCC returned mail, newspaper obituaries).

Investigation: The second step in the ascertainment process; the process of locating provider (e.g., hospitals, clinics, physicians) information about a possible outcome, requesting and reconciling medical records that may support its diagnosis, and filing such documents in a participant's outcomes file.

Medical History Update Forms: *Form 33 – Medical History Update* is a self-administered mark sense form annually mailed by the CCC or collected by phone by FC staff with the participant. *Form 33* is an 8-page form. All 8 pages are to be completed.

Medical Record Cohort (MRC): All African American, Hispanic, or HT participants who have consented to the ES 2015-2020 in 2010-2011. This cohort will have full ascertainment and adjudication of outcomes.

Medical Record Super Cohort (MRC): Defined as MRC above, and includes those who did not consent to the Extension.

Outcomes file: A participant's file of outcomes-related documents. This file may include medical records documents that are not currently required for an open adjudication case packet, as well as copies of pending and closed adjudication case packets. Maintaining a hard-copy file is optional since an electronic record is scanned to the CCC and available upon request.

Outcomes forms: *Forms 121-132;* these outcomes-specific forms document confirmation of an outcome using pre-defined WHI ES criteria. Forms are completed by the PAs and cancer coders. Outcomes forms are located in *Sections 8.6 – 8.11*. A list of forms completed by FC staff and participants is located in *Appendix A - Forms*.

Outpatient visits: Any short stay, observation stay, clinic visit, or day surgery that does not involve an overnight stay. Only certain events (e.g., newly diagnosed stroke, hip fractures, cancers, cardiac revascularization procedures, DVT and death) occurring at an outpatient visit alone without hospitalization will be investigated, documented, and adjudicated as possible outcomes. If the selected outpatient visit results

in an overnight hospital stay, collect and include the outpatient documentation in the adjudication case packet. See *Table 8.1 – WHI 2015-2020 Extension Study Outcomes for MRC* for a complete list of outpatient visits requiring investigation.

Query: The formal request for additional medical records not originally included in the case packet. The document(s) is considered essential to review before adjudication is completed to ensure accurate adjudication. Either CCC staff or PA may initiate a query at any time.

Scanning: Electronic submission of outcomes cases from the FCs to the CCC. Outcomes cases are scanned in a standardized format and submitted electronically to the CCC for central adjudication.

Self-Report Cohort (SRC): Any participant who consents to the 2015-2020 ES who is not African American, Hispanic, or in the former HT, i.e., in the MRC. Ascertainment and adjudication will be limited to all cancer diagnoses (National Cancer Institute [NCI] funded). All other outcomes will be collected only by self-report unless additional funding becomes available.

Transfers: Any participant transfer that occurs during an episode of care (i.e., the participant is not discharged to home but is transported to another hospital) for definitive treatment. These separate visits are merged into a single adjudication. Participant transfers include:

- Between-hospital transfers (e.g., discharged from one hospital and admitted to another hospital on the same date). Complete a truncated *Form 125 – Summary of Hospital Diagnosis* for each hospitalization (and route case to all committees, as appropriate).
- Within-hospital transfers (e.g., transferred from the ICU to a step-down unit. Complete only one truncated *Form 125*).

  Note: Transfers from an acute care hospital to a rehabilitation floor or free standing facility are exempt from merging. Only the acute care hospital stay is adjudicated (see *Table 8.1 – WHI 2010-2020 Extension Study Outcomes for MRC).*

WHIX: The WHI database that provides the mechanism for collection and tracking of outcome cases through the ascertainment and adjudication process. It is used in conjunction with manual tracking to document the ascertainment process.

Table 8.1
WHI 2010-2020 Extension Study Outcomes for MRC & SRC Cancer
(As identified on *Form 33* or *Form 120* and *Form 120H)*

Outcomes Requiring Adjudication[3]

- **Coronary heart disease & other cardiovascular disease**[1]

Hospitalized one or more nights:

Acute myocardial infarction (MI)
Coronary artery bypass graft (CABG)
Heart failure (HF)
Peripheral arterial disease (PAD), symptomatic and/or requiring a procedure
Carotid artery disease (CAD) requiring a procedure or surgery
Heart valve disease/surgery
Aortic aneurysm/dissection
Pulmonary embolism (PE)

Hospitalization not required:

Coronary death
Coronary revascularization (PTCA, coronary stent, laser)
Deep venous thrombosis (DVT)

- **Cancers**[1,2]
- **Stroke**[1,3] (hospitalization not required)
- **Venous thromboembolic disease**[1,3] **(VTE)**

Hospitalization not required:

Primary Cancers:
Breast/Colon/Endometrium/Rectum/Ovary
Other Cancers[1,2] (excludes non-melanoma skin cancer; *includes* squamous cell carcinoma of internal organs, e.g., tongue, anus)

- Hip and Upper Leg Fractures[1]

Hospitalization not required:

- **MRC deaths**[1,3]

Self-reported outcomes collected on *Form 33* (Ver 13)

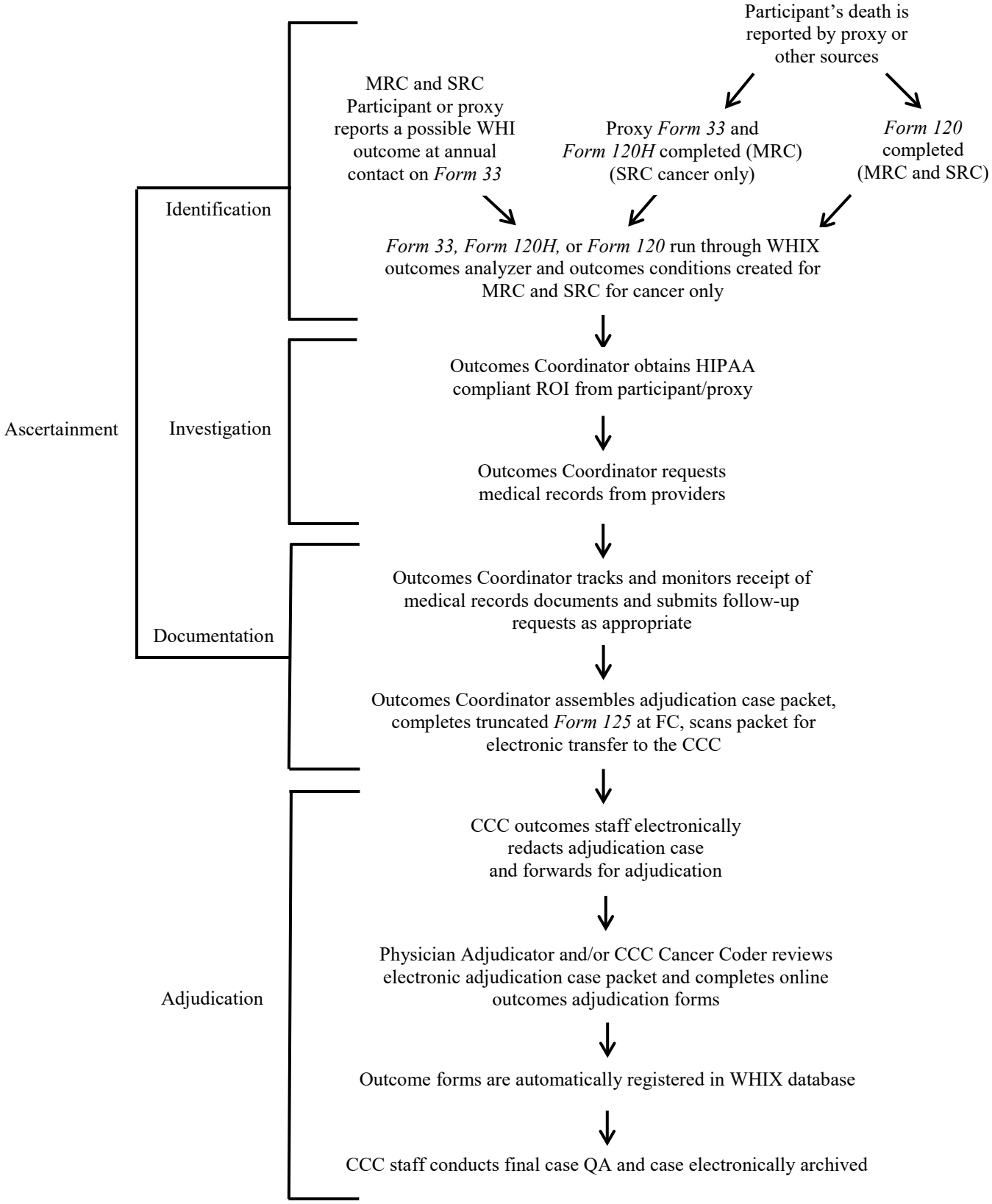
Diabetes mellitus requiring therapy
Other age-related outcomes:

- Osteoarthritis or arthritis associated with aging
- Macular degeneration associated with aging
- Moderate or severe memory problems (dementia, Alzheimer's)

Intestinal or colorectal polyps or adenomas
Angina pectoris
TIA
Parkinson's disease
COPD, emphysema, or chronic bronchitis

[1] Complete truncated *Form 125* if hospitalized one or more nights.
[2] All cancers are adjudicated for both the MRC and SRC.
[3] All are self-reported outcomes in SRC.

Figure 8.1
Outcomes Ascertainment and Adjudication Process



8.1.2 Field Center Outcomes Staff

Each FC will identify an Outcomes Coordinator (OC). This person is responsible for overseeing the activities of the outcomes team and the process of outcomes ascertainment, including:

- Identify medical events and have working knowledge of outcomes procedures.
- Collect *Form 33* by phone from participants who do not return forms by mail.
- Request medical records documentation from providers.
- Track documents that have been requested.
- Final assembly into adjudication case packets.
- Scan the case packet and forwarding the electronic case packets to the CCC.

The OC is the key FC staff involved in outcomes ascertainment, and other FC staff may assist in this effort. The OC contacts participants by phone or mail to obtain detailed self-report information about potential outcomes and thereby initiates the ascertainment process with the identification of potential outcomes. Investigation commences when the OC requests medical records documentation from the healthcare provider and prepares the documentation for the case packet. The OC is responsible for performing data entry as needed from *Form 33*, generating reports, conducting interviews to elaborate on self-report data, request documents, and prepare and track case packets for scanning.

8.1.3 Physician Adjudicators (PA)

The PA is responsible for review of assembled adjudication case packets and assigning the appropriate outcome diagnosis based on study defined criteria. See *Section 8.6 – Physician Adjudication* for more information on the PA's roles and responsibilities. See *Sections 8.7 – 8.9* for details of completing the outcomes forms.

An assembled case is assigned to one or more outcomes adjudication committees based on outcome type following a single-adjudicator review model. The five adjudication committees include:

- **Cardiovascular Disease (CVD):** The CVD committee is responsible for adjudicating myocardial infarction, CABG, HF, coronary revascularization, peripheral arterial disease, carotid artery disease, and venous thromboembolic disease. In addition, three new CV outcomes were added October 1, 2010 for this ES: atrial fibrillation (dropped May 2017), aortic aneurysm, and heart valve disease. The committee member completes *Form 121 – Report of Cardiovascular Outcome*, and/or *Form 126 – Report of Venous Thromboembolic Disease.* See *Section 8.8 – Cardiovascular Outcome*s for details.
- **Fatal Events:** The Fatal Events committee is a sub-group of the CVD committee. It's members are responsible for adjudication of all deaths and selected hospitalization to classify the underlying cause of death. The committee completes *Form 124 –Final Report of Death.* See *Section 8.7 – Fatal Events Adjudication* for details.
- **Stroke:** The Stroke committee is made up of neurologists who adjudicate and subclassify all strokes, completing *Form 132 – Report of Stroke Outcome* (see *Section 8.8 – Cardiovascular Outcomes*).
- **Fracture:** The Fracture committee adjudicates all hip and reviews upper leg fractures for a potential hip fracture. The committee completes *Form 123 – Report of Fracture Outcome* (see *Section 8.10 – Fracture Outcomes Adjudication*).
- **Cancer:** The CCC cancer coders adjudicate the five primary sites (breast, ovary, endometrium, colon, and rectum) and all other cancer sites completing *Form 130 – Report of Cancer Outcome* (see *Section 8.11 – Form 130 – Report of Cancer Outcomes)* using SEER (Surveillance, Epidemiology, and End Results) guidelines.

The adjudication process is fully electronic. Physician Adjudicators receive redacted electronic medical records and code adjudication forms online, including CCC coded cancers. Heart failure coded at University of North Carolina (UNC) is also fully electronic, including transmission of the outcomes data to the CCC.

8.1.4 Outcomes Adjudication Committee (OAC)

The Outcomes Adjudication Committee is an advisory committee whose role is to review protocol, policy, and procedures as they relate to outcomes and adjudication, and make recommendation to the Steering Committee (SC). The OAC is comprised of PAs, other ES investigators, an NHLBI and OC FC representative, and appropriate CCC staff. Adjudicators and staff are assigned to central adjudication subcommittees based on their professional expertise.

8.2 Identification of Outcomes

OCs may identify a potential outcome of interest through different mechanisms:

- Routine annual *Form 33 – Medical History Update*.
- Death reported by proxy (e.g., family, friend, health care provider) or other source (e.g., newspaper obituary and returned mail to the CCC).
- Discovery of a self-report or provider visit not reported on *Form 33*.

8.2.1 Outcomes Investigation

8.2.1.1 Outcomes Requiring Investigation and Adjudication

Outcomes to be investigated and adjudicated are listed in *Table 8.1 – WHI 2010-2020 Extension Study Outcomes for MRC*, under "Outcomes Requiring Adjudication". Full ascertainment and adjudication is limited to the MRC, with the exception of cancer which is investigated and adjudicated for participants in the MRC and SRC. For some outcomes, only the first occurrence of a particular outcome is adjudicated. Other outcomes require ongoing investigation and adjudication. On June 24, 2015 the subsequent condition rule was lifted for CVD and hip fracture events. No change was made for cancer investigations. This procedural change was implemented to support ancillary study investigations.

Outcomes investigation using standard WHI procurement and processing procedures for medical records retrieval will also be conducted for the WHI approved and funded Ancillary Studies (*Table 8.2* below). This may include collection of new outcomes and/or additional details relating to current outcomes, as defined by the aims of the Ancillary Study.

Table 8.2
WHI Approved and Funded Ancillary Studies

Ancillary Study Name	NHLBI Project Office Approval Date	IR File at Fred Hutch	IR File # 3467-EXT IRB Approval*	Location of Outcomes Investigation
AS370 – LILAC	2/28/12	IR#8239	5/19/14	Regional Centers**
AS355 – COSMOS	2/11/13	IR#9214	4/21/16	Regional Centers**
AS450 – WHISH	5/23/13	IR#8321	4/21/16	Regional Centers**
AS510 – WHISH 2 Prevent Heart Failure	2/4/15	IR#6462	9/21/16	Regional Centers**
AS511 – WHISH STAR	2/4/15	IR#8559	N/A	Centralized at the WHI-CCC

* Approval to add Ancillary Study scope of work at the Regional Centers to IR file #3467-EXT (IRB of record for the Regional Centers).
** Including Seattle/LaJolla at the WHI-CCC

8.2.1.2 Outcomes Identified Only by Self-Report on *Form 33 - Medical History Update*

Specific outcomes are identified by the participant's self-report alone on *Form 33 – Medical History Update* for the MRC. See the list of outcomes under the heading "Self-Reported outcomes collected on *Form 33* in *Table 8.1 – WHI 2010-2020 Extension Study Outcomes for MRC*. These self-reported outcomes do not require investigation, documentation, or adjudication.

8.2.1.3 Hospitalizations Not Tied to a WHI Outcome of Interest

On June 6, 2018 the Steering Committee (SC) approved the streamlining proposal to stop investigation, documentation and coding of hospital stays of 2 or more nights. This decision is limited to stand-alone hospitalizations not tied to a WHI outcome of interest or MRC death post-death proxy *Form 120H – Hospitalization Supplement* which do require investigation; this is an expansion of a prior decision to stop investigation of 1-night hospital stays.

8.2.2 Routine Administration of *Form 33 – Medical History Update*

Outcomes will primarily be identified through the routine administration of *Form 33 – Medical History Update. Form 33* collects information on those outcomes that do not require further ascertainment procedures (outcomes by self-report alone), as well as screens for those participants who have had a medical condition, event, or procedure that may require adjudication. A proxy (e.g., family, friend, or health care provider) may complete a *Form 33* for a participant who is unable to independently complete a *Form 33* and complete both a *Form 33* and *Form 120H* for deceased participants (see *Section 8.5 – Fatal Events*).

CCC mailing of *Form 33*: The CCC is responsible for mailing the *Form 33*s to all eligible participants as part of their annual contact (see *Section 7 – Follow-Up Contacts*). Participants typically complete *Form 33* as a self-administered form, although FCs will also choose to administer it as an interview if the participant is unable or unwilling to complete and return-mail the form, or if the participant has difficulty understanding or completing forms. Forms returned to the CCC are electronically imaged/scanned. Those collected by the FC are key-entered and archived at the FC.

***Form 33* Mailing Schedule**

Each participant receives at most 2 mailing attempts. The first attempt is mailed 2 months before her randomization/enrollment anniversary and a re-mail is attempted 3 months later, if there was no response to the first. All participants are eligible for a mailing except for the following participation levels, preferences and specific administrative flags set in WHIX. These include: annual check-in, no contact, or deceased; mail forms preference is unchecked, i.e., "no mail"; address is flagged as "undeliverable" at the timing of the mailing, or it has been less than 6 months since her last *Form 33* was completed.

Within a 12 month calendar year, a participant falls into the CCC mailing window for approximately 5 months and the FC follow-up window for 7 months (see WHIX report X2 Mail003 for the list of participants). If, during the 5 month CCC mailing window the participant does not meet the criteria for a mailing, she will not receive one. WHIX will continue to check her status each month until she is either eligible for a mailing or the CCC window closes and she falls to the FC for follow-up.

Given the large volume of mailings the CCC processes, preparation for a weekly mailing starts approximately 2 weeks in advance of the scheduled mail week. In 2017, the mailing schedule was reorganized by participant zip code and then grouped based on USPS distribution center creating a more efficient and cost-effective system.

Mail Assembly Week	FC Site & USPS Distribution Center
1	CT, DE, VT, ME, NH, MA, RI, NY, VA, DC, MD NJ, SC
2	NJ, VA, TN, SC, NC, GA, FL, AL, MS, OH, KS, LA, AR, TX,
3	PA, WV, KY, IN, OH, MI, WI, IA, SD, NE, IL, MN, ND, IL, MO, LA, AR, CA
4	MT, NE, OK, CO, NM, WY, UT, ID, WA, AZ, NV, CA, HI, OR, AK

Additional hospitalizations: If the participant or proxy indicates more hospitalizations/provider visits than are allotted on the *Form 33* or *Form 120H*, the participant is instructed to write the details for the additional hospitalizations under "Comments". The OC then manually creates the condition (if needed), provider visit(s), and adjudication and links the additional visits indicated on the form and investigates the possible outcomes as appropriate (see *Section 10 – Data Management* documentation for instructions on manually creating and linking conditions).

8.2.3 Edit or Update a Routine *Form 33*

If a participant or proxy informs the FC of a correction to her most recently completed *Form 33*, edit the form following the usual guidelines. The FC may also edit the *Form 33* based on hand written comments on the form. See *Section 10.6.2.2 – Edit Form 33 based on Form Comments*. If the *Form 33* has already been scanned at the CCC or key-entered at the FC, update the data in WHIX. *Form 33* may need to be re-analyzed following the form correction/edits. Do not record the updated information on a new *Form 33.*

8.2.4 Interim Reports of Possible Outcomes (Excludes Deaths)

An interim report of a possible outcome occurs when a participant contacts a FC to report a potential outcome between the administration of her routine annual *Form 33*. With the exception of a report of death and select ancillary studies, interim reports of outcomes are not collected in the ES. When the participant makes such a report, ask the participant to report the information at her next routine contact and make a reminder comments in WHIX. Reporting interim events at the next annual routine contact will help maintain a standard method of ascertaining potential outcomes. If the participant does not report the outcome at her next routine contact, do not provide any reminder prompts or investigate the outcome. Rather, wait and see if the outcome is picked up as a discovery or reported in the future by the participant.

8.2.5 Duplicate *Form 33*s

Some participants may respond to more than one mailing per year resulting in "duplicate" *Form 3*3s. For example, if the participant is late in responding to the first mailing, a second mailing may be sent and both forms are returned. WHIX is programmed to allow the CCC to scan any *Form 33* returned in the mail, even if one already exists in WHIX. This is also true for a key-entered form. A warning will appear to alert that a duplicate form is being entered.

Steps to reconcile duplicate forms:

If two forms provide identical information, regardless of analysis status, the FC can request the second form be deleted from WHIX by contacting the CCC Liaison. Before the form itself can be deleted, document request dates and any other information that has been entered into WHIX requires deletion.

If the first form has already been analyzed and the two forms provide different information, contact the CCC for specific instructions.

8.2.5.1 Interim Reports of Serious Adverse Experiences (SAEs)

There are no safety events to monitor or report in the 2010-2020 ES as there is no clinical intervention component. All health events are reported annually to the WHI Data and Safety Monitoring Board (DSMB).

8.2.6 Reports of Death

Participant deaths can be reported to FC staff by proxy (e.g., family, friend, health care provider) or other sources (e.g., CCC, FC, newspaper obituary). FCs use information from such reports to complete *Form 120 – Initial Report of Death*. Note that **all** information may not be available when *Form 120* is initially completed. *Form 120* is designed to take an "unknown" response if information is not currently available. Regardless of the amount of information gathered on the *Form 120*, data enter the available information as soon as possible. Key-entry of *Form 120* creates the death condition in WHIX for MRC only and registers the death for SRC participants. Entry of the *Form 120* also stops further participant mailings, and modifies other

WHIX reports accordingly. Complete a final (proxy) *Form 33* and *Form 120H* by contacting the participant's proxy for all MRC participants.

Note: Investigation of a 2 or more night hospital stay is required when reported on the *Form 120H* since it may be relevant to the death investigation and cause of death determination. Investigation of a SRC death is not required; however, the information recorded on *Form 120* is used to launch an NDI search. Recording accurate information, including state of death is important See *Section 8.7 – Fatal Events*.

Note for SRC: If the death is due to cancer or a cancer outcome is discovered while registering the SRC *Form 120*, complete a proxy *Form 33* and investigate the cancer but not the death. If a proxy *Form 33* cannot be obtained, the cancer condition can be created and linked to the *Form 120*, if the provider is known.

8.2.7 *Form 33* Processing Reports

After the CCC scans *Form 33,* various reports and screens are available in WHIX in which to view the results. These reports include:

- *X2_0983 - Outcome Analysis Results* - Provides a list of only those forms that need attention. For example, forms with info results or forms that still need to be analyzed. FCs can customize the output by using the available parameters by viewing all or only required, by OCT and Info Error Responsibility. "Months since analysis" defaults to 6 months but the data range can be expanded up to 48 months.
- The WHIX Analyzer Screen provides an option to customize the output by using the available parameters. See *Section 10.6.3 – Analyze Forms for Additional Information.*

There are many other outcomes reports available to track and monitor outcomes ascertainment and adjudication. Reports can be selected and printed from the WHIX Outcomes Subsystem menu; others may be distributed from the CCC or created by the OC via a CDE, or other tracking systems. Given the complexity of outcomes processing and expanded ancillary study participation, use of reports is essential and the CCC strongly endorses use of WHIX reports. Refer to *Section 10.7 – Queries and Reports* for the list of relevant reports, along with a brief description of the report and suggested interval for which to run them.

8.3 Investigation of Outcomes

The investigation of a potential outcome involves locating relevant health care providers (e.g., hospitals, clinics, and physicians) and requesting medical records that may support a diagnosis/outcome of interest. Documents requested from a particular provider will depend on the outcome type and WHI component (MRC vs. SRC). See *Table 8.3 – Required Documents for Outcomes* for a list of the documents to request to complete the investigation of the outcome. The success of an outcome investigation (i.e., obtaining copies of required supporting documents) will depend on the expertise, resourcefulness, and communication skills of the FC OC. Institutional, local, and state regulations will also impact the ease with which the records are obtained.

8.3.1 Release of Information (ROI) Forms (Generic and Institution-Specific)

A release of information signed and dated by the participant is required in order to request medical records. The ROI is a stand-alone document *Form 330*. Hospital, state, and local Institutional Review Board (IRB) requirements differ with regard to obtaining medical records. Many hospitals will require that a current (e.g., signed within the last three to six months) ROI form, with an original participant signature, accompany any request for medical records. Some institutions will accept a blanket consent, acceptable for an indefinite or a fixed period of time. Others may require an institution-specific signed release.

If the FC is part of a non-profit organization or other special approvals (e.g., IRB) are obtained, the hospital may waive charges for the requested medical records.

8.3.1.1 Refusal to Sign a Release of Information Form

If a participant refuses to sign a current ROI form, medical records may not be requested. Contact participants refusing to sign a ROI and explain why the medical information is needed and the importance of outcome ascertainment to the study. Sometimes it may help to have a supervisor or PI make this contact (see *Section 9 – Retention*). Some participants may be willing to sign a ROI form that specifies the provider and/or medical documents being requested for a specific outcome.

The amount of time and effort spent trying to convince a reluctant participant to sign the ROI will depend on the type of event. If the participant continues to refuse to sign the release, note her refusal in the comments screen in WHIX.

Table 8.3
Required Documents for Outcomes Adjudication

☒ = Essential documents x = Recommended documents

			Cardiovascular Outcomes								
Scan Tab #	**WHIX #**	**Documentation Requirements for WHI Outcomes**	**MI**	**CABG/ Heart Revasc**	**HF**	**A-Fib**	**Heart Valve**	**Aorta**	**PAD**	**Stroke**	**Carotid**
1-Hospital Admin Sheet	1	Hospital Face Sheet	x	x	x	x	x	x	x	x	x
1-Hospital Admin Sheet	44	Physician Attestation; Coding Abstract	x	x	x	x	x	x	x	x	x
2-Discharge Summary	3	Discharge Summary (if unavailable, please send Progress Notes)[1]	☒	☒	☒	☒	☒	☒	☒	☒	☒
2-Discharge Summary	13	Outpatient/Short Stay Record[1] (includes outpatient visits)		x						x	
3-Physician Documents	2	History & Physical/Physical Exam	☒	☒	☒	☒	☒	☒	☒	☒	☒
3-Physician Documents	48	Emergency Room/Emergency Department report	x	x	☒	☒	x	x	x	x	x
3-Physician Documents	49	Physician Notes/Progress Notes (outpatient visits)		x						x	
4-Consultations	53	Neurology consult report								x	
5-ECGs	45	12-Lead ECG tracings, all days	☒	☒	☒	☒	x	x			
6-Labs	8	Cardiac Enzyme Reports (e.g., Troponin I, Troponin T, CKMB, CK or CPK), all days	☒	☒	☒	x	x	x			
6-Labs	74	Laboratory reports, all blood tests, all days (including BNP/pro-BNP, electrolytes, BUN, creatinine, CBC). ***Note:*** only BNP is an essential document	x	x	☒	x	x				
7-Imaging	4	Chest X-ray Report, all days	x		☒	x	x	x			
7-Imaging	12	Stress Test by treadmill ECG, echo or nuclear perfusion scintigraphy report	x	x	☒				x		
7-Imaging	16	Carotid Artery Angiography, Doppler flow study								☒	x
7-Imaging	22	Echocardiogram and Doppler (all reports of 2-D, transesophageal-TEE, or transthoracic-TTE)	x	x	☒	☒	☒	x		x	
7-Imaging	47	Nuclear Scans, e.g., thallium, Myoview®, sestamibi, RVG/MUGA	☒	☒	☒						
7-Imaging	64	Reports of Cardiac MRI/MR angiography	x	x	x	x	x				
7-Imaging	65	Reports of Cardiac CT Scan/CT angiography	x	x	x	x	x				
7-Imaging	67	Reports of Angiograms of head, neck or brain (MRA, CT, or catheter based)		x			x	x		☒	☒
7-Imaging	68	Reports of Angiograms of the lower extremities (MR, CT, or catheter-based angiography)						x	☒		
7-Imaging	70	Reports of Segmental Doppler assessment of the lower extremities						x	☒		
7-Imaging	71	Reports of Abdominal Ultrasound of aorta or other arteries						x	☒		
7-Imaging	72	Reports of Head/Brain CT Scans								☒	
7-Imaging	73	Reports of Head/Brain MRIs								☒	
7-Imaging	75	Reports of Angiography, CT/CT angiography; MRI/MR angiography						☒	☒		
8-Op and Procedures	9	Coronary Artery Bypass Graft (CABG)	☒	☒							
8-Op and Procedures	11	Percutaneous Coronary Intervention (PCI): PTCA; Coronary Stent/Artherectomy	☒	☒			x				
8-Op and Procedures	15	Operative or Procedure Report	x	☒	x		x			☒	☒
8-Op and Procedures	17	Cardiac Catheterization including coronary Angiograms and Arteriograms and Contrast Ventriculogram (LV)	☒	☒	☒	x	☒	x	☒		
8-Op and Procedures	24	Ankle brachial blood pressure ratio (ABI)						x	☒		
8-Op and Procedures	29	Lumbar Puncture Report								x	
8-Op and Procedures	66	Operative/Procedure reports (including Aortic Stent Graft)						☒	☒		
8-Op and Procedures	69	Operative/Procedure reports (including Angioplasty and/or stent of lower extremities)						x	☒		
9-Pathology	76	Pathology report from any valve surgical specimen(s)					x				

[1] A final progress note or hospital face sheet may be substituted for the final discharge summary for short stays or hospitalizations less than 48 hours.
[2] All cancers are adjudicated for both the MRC and SRC.

[3] Inpatient coronary death: Obtain ECGs, cardiac enzymes, and cardiac cath Shaded columns: Stopped investigation of Afib & stand-alone hospitalizations reported on routine *Form 33*.

Table 8.3 (continued)

Required Documents for Outcomes Adjudication

☒ = Essential documents x = Recommended documents

			Hip FX	Cancers[2]		Fatal Events[3]		Hospital	VTE	
Scan Tab #	**WHIX #**	**Documentation Requirements for WHI Outcomes**	**Hip Fracture**	**5 Main Cancers**	**Other Cancers**	**Inpatient Deaths**	**Out-patient Deaths**	**Hospital stay ≥ 2 nights**	**PE**	**DVT**
1-Hospital Admin Sheet	1	Hospital Face Sheet	x	x	x	x		x	x	x
1-Hospital Admin Sheet	44	Physician Attestation; Coding Abstract	x	x	x	x		x	x	x
2-Discharge Summary	3	Discharge Summary (if unavailable, please send Progress Notes) [1]	☒	☒	☒	☒		☒	☒	☒
2-Discharge Summary	13	Outpatient/Short Stay Record[1] (includes outpatient visits)	x	x	x	x	x			x
3-Physician Documents	2	History & Physical/Physical Exam	☒	☒	☒	☒		☒	☒	
3-Physician Documents	48	Emergency Room/Emergency Department report	x	x	x	x		x	x	x
3-Physician Documents	49	Physician Notes/Progress Notes (outpatient visits only)	x	x	x					x
4-Consultations	33	Consult (Oncology/Radiation Oncology)		x	x					
4-Consultations	43	Other Consults				x				
5-ECGs	45	12-Lead ECG tracings, all days				x				
6-Labs	8	Cardiac Enzyme Reports (e.g., Troponin I, Troponin T, CKMB, CK or CPK), all days				x				
6-Labs	74	Laboratory reports, all blood tests, all days (including BNP/pro-BNP, electrolytes, BUN, creatinine, CBC)				x				
7-Imaging	4	Chest X-ray Report, all days		x	x					
7-Imaging	20	Doppler flow study report							☒	☒
7-Imaging	22	Echocardiogram and Doppler (all reports of 2-D, transesophageal-TEE, or transthoracic-TTE)							x	
7-Imaging	25	Ventilation/Perfusion Lung Scan Report							☒	☒
7-Imaging	26	Pulmonary Angiogram							☒	☒
7-Imaging	27	CT Scan Report	☒	x	x	x				
7-Imaging	28	MRI Report	☒	x	x	x				
7-Imaging	30	Radiology and or bone scan reports/isotope or nuclear med bone scan	☒	x	x					
7-Imaging	75	Reports of Angiography, CT/CT angiography; MRI/MR angiography							x	
7-Imaging	77	Pulmonary embolus protocol CT scan of the lung							☒	☒
8-Op and Procedures	15	Operative or Procedure Report	x	☒	☒				☒	x
8-Op and Procedures	17	Cardiac Catheterization including coronary Angiograms and Arteriograms and Contrast Ventriculogram				x				
8-Op and Procedures	18	Venogram Report							x	x
9-Pathology	31	All Pathology Reports		☒	☒					
9-Pathology	32	Cytology Reports, all		x	x					
9-Pathology	35	ERA/PRA Hormone Receptor Lab Report, Her2/neu (Breast Cancer only)		☒						
10-Fatal Events	37	Death certificate				☒	☒			
10-Fatal Events	38	Autopsy or Medical Examiner/Coroner's Report				☒	☒			
10-Fatal Events	39	Emergency Medical Services (EMS) or Ambulance Report				x	x			
10-Fatal Events	51	WHI Form 120				☒	☒			

[1] A final progress note or hospital face sheet may be substituted for the final discharge summary for short stays or hospitalizations less than 48 hours.

[2] All cancers are adjudicated for both the MRC and SRC.

[3] Inpatient coronary death: Obtain ECGs, cardiac enzymes, and cardiac cath. Shaded columns: Stopped investigation of Afib and stand-alone hospitalizations, reported on routine *Form 33*.

8.3.2 First vs. Recurrent Events

Up until April 1, 2015, only the **first** confirmed occurrence (after randomization/enrollment into the WHI) of a **particular** outcome was adjudicated as an outcome of interest. This definition was revised due to the launch of several ancillary studies. Currently, all self-reports are investigated even if the outcome has been previously adjudicated/confirmed, the exception is cancer which is detailed below.

Cancer

- Investigate **newly diagnosed** cancers.
- All cancers for the MRC and SRC will be SEER coded. The NCI has provided funding for SRC cancers to be SEER coded in the 2015-2020 ES.
- A second primary breast cancer occurring in a woman who previously had a diagnosis of breast cancer will also require documentation and adjudication.
- A cancer of a new site for a participant who has previously had a cancer outcome will always require investigation and adjudication.
- With the exception of breast cancer, do not investigate a cancer relapse, recurrence, or metastasis for WHI core work except to confirm that it is not a primary cancer. Note that rules related to investigation of cancer recurrence will differ depending on OCT type.

WHIX1215 – Members Outcomes Status Report (*WHIX1215*) lists all previously adjudicated cases and those currently in-process for that participant. Outcomes confirmed in both WHI ES and ancillary studies are included on the report.

8.3.3 Standard Hospital Medical Records

Medical record: The medical record from a hospital, outpatient facility, or doctor's office chronicles the health care condition, diagnosis, and workup. The OC and PA must understand the course of events from admission to discharge to generally reconstruct the hospitalization and outcome event(s).

The alphabetical list below is a summary of documentation that might be found in a medical chart and ultimately included in a case. Sometimes these records will be interspersed within the medical record instead of the corresponding section. Do not routinely add additional documentation to the document requests or adjudication case packets. Run *WHIX0980 – Request for Medical Records* for the outcome being investigated -- this report provides a comprehensive list of documents to request based on the participant's self-report. Or, select the appropriate medical documents from *Table 8.3 – Required Documents for Outcomes*.

Document sets have evolved over the course of the WHI, moving from general categories to specific document types, for example 'ultrasound' vs 'carotid ultrasound'. Both options are included in master document sets in case a person working in medical records department is more familiar with the general category and less familiar with a specific document type; or the naming convention used at the hospital relies on general terminology. The goal is to locate and only include the most specific document, the one that corresponds to an outcome of interest. Refer to *Appendix D-Explanation of Medical Terms* for definitions and terminology.

- **Admission History and Physical (H&P)** - Detailed description of symptoms leading to admission, condition of the patient on admission, medical history, review of systems (including vital signs), medications before and at admission, provisional diagnoses, and treatment plan. This is an essential document for all ES outcomes.

  If a complete physical examination has been performed within 30 days before admission, such as in a physician's office, a copy of that report may be the only H&P in the patient's hospital medical record, (provided there have been no changes or the changes have been recorded at the time of admission) and is suitable for the ES.

- **Ambulance Report or Emergency Room/Department Report** - Description of symptoms, initial treatment en route to hospital, vital signs, dates and times of symptoms, treatment, responses to treatment, and disposition. It often provides the initial lab work drawn on admission that serve as the baseline for repeat lab draws. This report is most useful for patients who were dead on arrival (DOA) at the hospital or for those who die in the ER before admission.

- **Consultations** - Neurology consultation reports are used to adjudicate strokes and Oncology consultation reports are needed for the five primary cancers. These will be found in a separate section of chart with typed or handwritten notes from the consulted medical or surgical specialists, in notes interspersed in the medical record, or in the progress notes. Include only those consultations that correspond to the outcomes under investigation. Exclude unnecessary consults, e.g., an infectious disease consultation.
- **Diagnostic or Radiology (including Nuclear Medicine) Procedures** - X-rays (chest or femur), stress tests, CT scans, magnetic resonance images (MRI), magnetic resonance angiographies (MRA), Electrocardiograms (ECGs), coronary angiographies (heart catheterizations), doppler flow studies, colonoscopies, bone scans, mammograms, and all other diagnostic procedures are often found in this section. These reports may also be interspersed in the medical record.
- **Discharge Summary** - Narrative summary of entire hospitalization, including the reason for hospitalization, significant findings, procedures performed, treatment(s) rendered, patient's condition on discharge, and any specific instructions given to the patient and/or family. The discharge summary (transfer summary) will be one of the most important documents for adjudicating ES outcomes. A written discharge summary is often not available for hospital stays less than 48 hours. A final progress note, discharge note, or the hospital face sheet may be substituted for the discharge summary for short-stays (i.e., events or procedures that require less than a 48-hour period of hospitalization); a death summary is often substituted for the discharge summary if the participant expires in the hospital.
- **ECGs (electrocardiograms)** - Twelve-lead ECG tracings performed during the hospitalization are often contained in a separate section of the chart and can be challenging to obtain, but may also be interspersed with other records, such as progress notes. Only 12-lead ECGs are required for cardiovascular outcomes, not the individual rhythm strips that might be found attached to daily progress notes or the summary report. The specific 12-lead ECGs are required for CHD outcomes (e.g., MI, coronary revascularization, and hospitalized/ED only death, if available). Request **all** ECG reports from each hospitalization, as the medical records department may not select the correct ECGs.
- **Face Sheet** - Demographic data; admission and discharge information (including dates and physicians, discharge diagnoses, procedures.
- **Laboratory Results** - Standard blood work (complete blood count [CBC]; electrolytes; blood urea nitrogen (BUN)/creatine) and other specimen analysis results, cardiac enzyme or Troponin results for MI. Brain natriuretic peptide (BNP) also known as B-type natriuretic peptide is a marker of cardiac insufficiency or HF. Laboratory results may be interspersed with other documents, however. It is not uncommon for cardiac enzymes to be recorded on a separate lab sheet. As a reference, include the institution's normal value/range for the given test as results and normal ranges vary between medical institutions. Contact the lab for normal ranges if none are provided and record this information for the lab report.
- **Operative Reports** - Surgical reports for CABG, PTCA, cancer resections or exploratory surgeries, tumor biopsies, colonoscopies, carotid endarterectomy, and other procedures are often found in this section.
- **Pathology Reports –** A report made by a pathologist who conducts the cytologic and tissue examinations and documents the summary of the findings. The descriptions include a gross description based on visual examination and microscopic description based on histologic examination. The final diagnosis by the pathologist is a determinate of the disease. Breast cancer estrogen and progesterone receptor reports (ER/PR), Her2/Neu reports are typically appended to the pathology results. Include pathology consultations often referred externally for a review of slides "ROS".

8.3.4 Request Medical Records Documentation

The WHIX outcomes management system automates the process of determining which documents (specific to a possible outcome type) need to be requested. The OC can print and mail or efax or email (secure email only) the document request to the identified providers (*Request for Medical Information Form - WHIX0980)*. Medical records departments are responsible for retrieving and returning the photocopied documents, efaxing or emailing or providing portal access to the FC.

Record abstraction/Electronic records: An alternative to mailing a request for medical records is having permission to go to the medical records department to collect and copy relevant portions of the medical chart or obtain electronically via a hospital computer link from which documents/reports can be printed. This method provides access to medical information not otherwise available to all OCs and may introduce the potential for a FC to over-report outcomes (ascertainment bias). To prevent over-reporting of events and ensure standardization of procedures among FCs, OCs must develop rigorous procurement procedures. Moreover, all OCs should be cognizant of procedures as outlined in *Section 8.2 – Identification of Outcomes* and *Section 8.3 – Investigation of Outcomes*).

Medical record requests, step instructions

1. Identify all appropriate conditions provider visits (document sources) in WHIX such as the hospital, physician's office, or other facility recorded on *Form 33 – Medical History Update*, *Form 120 – Initial Notification of Death* or *Form 120H – Hospitalization Supplement.*
2. For alive participants: Obtain a HIPAA (Health Insurance Portability and Accountability Act) compliant ROI signed and dated by the participant. ***Note:*** the participant may have signed/dated the ROI included in the *annual mailing*. A valid ROI is required before a request for medical records can be sent. This may not apply to a request for a death certificate from the local or state Vital Statistics Office. See *Section 8.5.2 – Identification of Fatal Event* for details on death investigation, including use of the Partial Waiver of Consent. FCs may use a previously signed WHI ROI.
3. Generate a *Request for Medical Information Form* (*WHIX0980*) from the WHIX outcomes management system for each provider visit. A list of required documents for each reported outcome will be generated for each provider. This report will also include the participant's name, participant ID number, date of birth, last four digits of social security number, approximate visit date, requesting FC, provider organization and identified outcome. For example, if a stroke is self-reported, the list of required documents (listed on WHIX0980) will include: Face Sheet, H&P, discharge summary Outpatient/short stay record, ED report, progress notes (outpatient only), neurology consultation operative or procedural reports, and reports of echocardiography, CT scan, lumbar puncture, MRI, MRA, and carotid studies.
4. For each request, include the WHIX *Request for Medical Information Form (WHIX0980)*, and a ROI form signed and dated by the participant. Mail, fax, efax, or email a request for all of the documents required for each identified outcome. See *Table 8.3 – Required Documents for Outcomes* for a summary.
5. Create (or pull) an outcomes file for each participant with an identified outcome and a tracking sheet. Information and documents from this file will be used to assemble the adjudication case packet. The adjudication case packet will contain the required subset of the participant outcomes file documents that are appropriate for the outcome being investigated.
6. Make every attempt to obtain the complete documentation needed for adjudication. See *Table 8.3 – Required Documents for Outcomes Adjudication* to determine if the case contains documents needed to meet minimum adjudication requirements. If some of the requested documents cannot be obtained after diligent effort (the OAC established a guideline of 4 attempts, at least one of which is a phone attempt), forward the case for adjudication. Record in WHIX the documents' absence in the *Visit Documents Screen* indicating the reason why records were not obtained. This text information is printed on reports and is available to the adjudicator reviewing the adjudication case. Documentation details prevent unnecessary queries and adjudication delays.
7. Receive requested documents:

   Upon receipt, match the documents to the document set as listed on WHIX 0980 and requested of a provider for a participant. Compare demographic data from medical records to study data to ensure accurate identification of participant.

   Clip together documents that will be required for adjudication of the outcome in the participant's outcomes file. These clipped documents will eventually form the adjudication case packet that will be organized in accordance with the assembly convention and scanned.

   Documents received post closure
   When additional medical records or the death certificate are received after the case has been closed, scanned and uploaded to the CCC, treat the records like a query. Notify the CCC, re-print the original

case ID cover sheet, scan records to the CCC and close the visit as a duplicate of the original case (Code 11).

8. Extraneous/Miscellaneous Documents

   On occasion, a hospital or provider may furnish the FC with documents not needed for a case. Hold these records in the participant's outcomes file and make them available to the PA, if requested. If the adjudicator requests these records, add them to the list of medical records received in the WHIX provider visit screen. If the records are not added to the case, these extraneous documents must be destroyed (e.g., shredded), once the case is closed. To avoid excessive accumulation of extraneous documents request only those records included in the approved documentation set. At no time should an OC request the entire medical record*. If an OC has a question about the appropriateness of a document, contact a CCC Liaison before discarding the document. On average, a hip fracture case averages 15 pages. The most complex admissions are typically less than 60 pages.

9. Upon assembly of the required medical records documentation and WHIX generated reports, upload the case to the CCC for adjudication. See *Section 8.4.7 – Regional Center Scanning*.

10. Monitoring Reports

    Use the WHIX outcomes management system to track which medical documents that have been requested from a provider, when the documents are received, and when follow-up requests need to be initiated (see *Section 10 - Data Management* for details). If the requested documents are not received within two to four weeks of the initial request, repeat the request, which may include an alternate form of communication, e.g., initial request was faxed, follow-up request by phone.

    As part of data monitoring, generate general reports of all participants for whom WHIX identified a possible ES outcome but no final documentation has been received. See *Section 10 - Data Management* for a complete list of outcome tracking and monitoring reports. The reports will allow the OC to verify the status of each identified outcome and assist with any pending document request.

8.3.5 Merge Adjudication Case Packets

In general, each hospital stay or other provider visit should be a separate adjudication case unless one of the following scenarios is present.

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* the NIH Program Office has Communicated the following:

As cited in the DHHS Implementing Regulations for the Privacy Act (Federal Register, Vol. 40, No. 196, page 47410, 10/08/75), "No record will be maintained by the Department unless it is relevant and necessary to accomplish a Department function required to be accomplished by statute or Executive Order." In other words, our Privacy Act records should only contain information relevant to the purpose for which the record was created.

Information documents added to a record may require reduction/modification/summarization, such that the document only contains information essential to the collection. Also, if review of a record indicates that non-relevant information/material is present; such information/material may be removed, as appropriate. This latter situation is not to be confused with purposeful action to alter a record, (e.g., to remove relevant documents or misrepresent research findings, etc.), which is illegal and subversive to the Privacy Act. The action of removing information not relevant to the record may be performed as part of any audit or periodic review activity. Those responsible for maintaining WHI records should, in accordance with the Privacy Act, make reasonable efforts to ensure that such records are accurate, complete, timely and relevant for agency purposes.

Merge Rules by Specific Outcomes Types

- **Cardiovascular.** Other than participant transfer procedures defined under "Transfers" in *Section 8.1.1 – Definitions Used for WHI Extension Study Outcomes*, each cardiovascular hospitalization stands alone as one adjudication.
- **Hip Fracture.** An outpatient (OP) X-ray confirms a hip fracture and the participant is subsequently hospitalized for treatment of the fracture. WHIX will automatically merge the visits into a single adjudication case.
- **Cancer.** If more than one cancer provider visit is entered on *Form 33*, WHIX will automatically merge them into a single adjudication case. In the event that two separate cancers are reported on a *Form 33*, the provider visits will need to be unmerged to separate adjudication cases.
- **Hospitalized deaths:** Merge the death case (death certificate and WHI *Form 120 – Initial Notification of Death*) with the hospitalization.

Note: Merging rules apply to a single outcome of interest. If there is more than one outcome condition in a case (the case is to be reviewed by more than one committee), ensure that both conditions are displayed on the MOSR and the appropriate medical records exist for each condition listed.

8.4 Documentation of Outcomes

Each outcome has specific documents that must be collected and reviewed (if available) to adjudicate that outcome. See *Table 8.3 – Required Documents for Outcomes Adjudication* for detailed documentation requirements for specific 2015-2020 ES outcome types.

8.4.1 Essential (Required) Documents by Outcomes Type

Every attempt should be made to obtain the documentation needed for an adjudication. If some of the requested documents cannot be obtained after diligent effort (the Outcomes Adjudication Committee [OAC] established a goal of four attempts), their absence should not delay the submission of the other information for adjudication. Note the absence of these documents in the WHIX outcomes subsystem with the reason why the records were not obtained. For each outcome, there are some "essential" documents and these medical records are more important than others. Again, these medical records may not be available because the test or procedure was not completed, but knowing what these documents are can assist with the decision to forward the case for adjudication or continue to request records. For all inpatient outcomes, the H&P and discharge summary are essential documents, though often not available for hospital stays of less than 48 hours. See *Table 8.3 – Required Documents for Outcomes Adjudication* for a list of the essential documents for a specific outcome type.

Table 8.4
WHIX Outcomes Closure Codes

Closure Code:		Meaning and Guidelines for Use
9	Extension case forwarded to CCC.	Case linked to at least one defined self-report outcome and eligible for adjudication. For death adjudications without medical records, use *Form 120 – Initial Notification of Death* as the record source if no other medical records or death certificate are available. WHIX requires that one medical record be present for an adjudication with Code 9 status. All MRC deaths require adjudication.
10	Not adjudicated, not forwarded to the CCC.	All conditions linked to visits in this case do not meet investigation criteria. Staff must include comments indicating why the case was not forwarded.
11	Duplicate visit, not forwarded to the CCC.	All visits in this case are flagged as duplicates. Use this code for an adjudication (or provider visit) determined to be a duplicate of a previously adjudicated visit from the main WHI or ES (e.g., participant self-reports identical information on a subsequent *Form 33*). Obtaining medical records to confirm the duplicate visit is not required (see *Section 10.6.12.2 – Close a "Non-WHI Extension Outcome"* for instructions on how to process a duplicate visit.)
12	Cannot get documentation for visit, not forwarded to the CCC.	The FC is unable to locate the provider or unable to obtain documents from provider. Typically reserved for non-death outcomes that are greater than one year old (see *Section 8.4.2 – Closing Problem Adjudication Case Packets (Excludes Death)*.
13	Cannot get ROI, not forwarded to the CCC.	The FC is unable to obtain a ROI from participant, next of kin (NOK) or family due to refusal or non-response. Typically reserved for non-death outcomes that are greater than one year old (see *Section 8.4.2 – Closing Problem Adjudication Case Packets (Excludes Death)*.
14	Administrative problems (details in comments), not forwarded to the CCC.	Reserved for CCC use only.

Note: WHIX requires that a comment be key-entered for all codes >9.

8.4.2 Close Problem Adjudication Case Packets (Excludes Death)

A problem case is defined as:

- A non-death case that is greater than one year old (the annual date is based on the contact date of *Form 33* analysis in the WHIX database); and/or
- The OC has exhausted all possible sources of medical records documentation/information (e.g., multiple medical records requests were made and records were not obtained; the outcome occurred out of the country and provider information is not available; unable to investigate the outcome because the participant or proxy refuses to sign the ROI).

If a problem adjudication case packet meets the above requirements, the FC staff and/or CCC may close the case using the appropriate outcomes closure code (see *Table 8.4 – WHIX Outcomes Closure Codes*).

8.4.3 Prepare and Electronically Route the Adjudication Case Packet to the CCC

When all required documents are received, assemble them for adjudication and complete the following steps in preparation for electronic scanning (see *Section 8.4.7* for scanning procedures).

Print the following reports (required): Case ID Cover Sheet for Scanning (CASECVR) from the *Outcomes Reports* screen in WHIX, Local Investigation Documentation Summary (IDS) - WHIX0988, and the Member Outcomes Status Report (MOSR) - WHIX1215. The Case ID Cover Sheet is case-specific and is always the first page of the case. Each Case ID Cover Sheet includes a case-specific barcode. This barcode corresponds to the WHIX participant Member ID and adjudication number.

Organize the case in the following order:

Case ID cover sheet

File Local Outcomes Forms behind the Local Forms Separator page. This separator page barcode is not participant or case-specific (i.e., it only identifies Local Forms to be filed in this section). The Local Forms section includes the following: Local IDS - WHIX0988, and MOSR - WHIX1215, *Form 125*.

File the medical records behind appropriate Medical Records Separator pages (barcodes also not case-specific). Use only the separator pages/dividers for which records are received.

All medical records for the case go in scanning order, behind the respective numbered Medical Records separator Pages. See *Table 8.5* for the correct scanning order.

Note: For multiple hospital admissions organize all medical records within each Medical Records Separator page/divider section by document type, in date order, earliest to latest. The exception is progress notes or lab reports that are printed by the medical provider in run-on format. The most recent progress note or lab results display results newest to oldest, and no re-ordering is required.

In the adjudication screen, enter the appropriate closure code. Upon review of the medical records documentation, assign and key-enter a closure code in WHIX. See *Table 8.4 – WHIX Outcomes Closure Codes*.

Keep a copy of the case at the FC until the case appears on *cases to archive or destroy* X2-0986. It is recommended the case be archived as originally scanned, including separator pages until notified it is OK to shred. Keeping the separator pages in place could make it easier to rescan a case if there is a query or a request to rescan.

See *Section 8.4.7* for scanning procedures.

8.4.4 CCC Routing of Adjudication Case Packets to Physician Adjudicator

Upon receipt at the CCC, the CCC outcomes staff performs redaction on the electronic file. Once redacted, the case is forwarded to the appropriate committee for adjudication. The CCC will notify the FC via query of any additional materials are required to complete the case packet.

When the PA submits the online forms, the case is automatically closed and entered into the database (if there are no required actions), or CCC staff reviews the case for additional actions needed, such as:

- Address case comments and questions
- Submit a query to the FC for additional documents
- Submit the case for full committee review
- Forward the case to another committee
- Enter ICD-10 death codes

8.4.4.1 Outcomes Coordinators

- Complete and scan query records to the CCC within 30 days.
- Please note: It is possible that missing documentation requested may be located in another adjudication packet at your RC.
    - Review participant's pending and closed adjudications before requesting documents from medical records.
    - If the document is in another case packet, scan and upload the original documentation to the CCC following the scanning instructions listed below.
- If a Provider visit already exists in WHIX:
    - Insert each document received, along with the date received, in the "Provider Visits" screen of the WHIX outcomes subsystem.
    - Record Member ID on each page of the documentation you scan to the CCC.
    - Scan all completed query records into the CCC. Only scan the following documents for complete queries:
        1) Case ID cover sheet
        2) Copy of Query Report – "CCC0980 – WHIX Central Adjudication Case Query"
        3) Completed Query Medical Records
           ***Note*:** No need to include the Medical Record divider sheets between different document types, only the completed query records.
- If a NEW Provider Visit is needed in WHIX:
    - Create a new provider and adjudication number and link it to the condition being queried.
    - Request query documents and indicate in the new case in WHIX when they are received.
    - Close the new adjudication with a Code 10 and indicate in the Comments Box in the adjudication screen "This is a query for Adj X".
    - Scan the Case ID Cover Sheet for the original adjudication (not the case closed with a Code 10), a copy of the Query Report "CCC0980 – WHIX Central Adjudication Case Query," and the completed query medical records.
      Note: No need to include the Medical Record divider sheets between different document types, only the completed query records.
- If unable to obtain documents, please make a note on the Query Report (CCC0980) and scan it with the Case ID Cover Sheet.
- Contact your Outcomes Liaison if you have any questions.

8.4.5 FC Responsibilities Post-Adjudication

The FC Outcomes staff ensures that the completed outcomes file is filed at the FC for future reference and extraneous records are shredded. Retaining the outcomes file for future reference is optional.

RC staff also responds to any queries for additional information or records as needed.

8.4.6 Central Monitoring of FC Ascertainment and Centralized Adjudication

The CCC, OAC and Performance Monitoring Committee (PMC) will work with the FC to monitor FC performance via centralized WHIX reports of outcomes-related data to support and make recommendations for performance enhancement as needed.

8.4.7 Field Center Scanning

8.4.7.1 Scanning Procedures

The case is ready to scan once in scanning order.

1. On the PC desktop double-click on the "Kodak Capture Desktop Software" icon.
2. The "Batch Manager" window will appear.
3. Click "New".
4. Next, the "new Batch" window will appear. Click "OK".

5. Gently load the assembled case **face down and upside down** into the scanner. (***Note:*** For *extra-large case files* please see additional information below in **Box 1**.)

Box 1
Large Case Files

- If a case contains **more than approximately 45 pages**, first divide the case in half (or into smaller, workable stacks)
- Load the first half of the oversized case into the scanner.
- Click the GREEN ARROW icon in the top left corner of the screen to start.
- Load the second half of the case into the scanner.
- Click the GREEN ARROW icon again to complete scanning the second half of an oversized case. (This will keep all pages for the same case together in one file.)

6. Check to make sure "WHI Scan Page Setup" is selected, then click the GREEN ARROW icon in the top left corner of the screen to start the initial scan job. It may take a moment, the GREEN ARROW turns to a RED SQUARE, and the case will feed automatically into the scanner.
7. Carefully watch all pages as they pass through the scanner to ensure they feed properly and stay in order. It is important to stay at the scanner while the entire case scans.
8. Once scanning is complete for a case, remove all case documents from the scanner tray and place them back in the case folder.
9. If scanning only a single case, continue to the "Quality Control" instructions. If scanning **multiple cases please see instructions below.**

Scanning Multiple Cases:

10. To scan additional cases in the same scanning session, load the next case into the scanner.
11. Click the "New Document" icon on the left-hand toolbar. (The icon is a yellow folder with a little red star on it). **DO NOT click the GREEN ARROW icon**. To ensure the second case is scanned as a separate case it must be identified as a New Document.
12. The next case will feed automatically.
13. Repeat steps 10-12 until all cases have been scanned. Then continue to "Quality Control" instructions.

8.4.7.2 Quality Control (QC)

Quality Control (QC) is necessary to ensure all records were properly scanned and that corrections were made to the file (insert or delete pages) before converting it to a "read-only" file. **All changes must be made during QC, prior to Outputting the batch.**

1. Click on the "First Document" icon on the left-had toolbar (the icon is 1 of 4 yellow folders with a blue arrow. To check, hover the mouse over it until it reads "First Document").
2. Click on the first page (Case ID Cover Sheet) so that the RED SQUARE highlights the page.
3. Check that the Case ID Cover Sheet corresponds to the case.
   Optional: Click the mouse on the ZOOM IN MAGNIFYING GLASS icon on the top toolbar. Click the icon as many times as needed to magnify the case. If correct, click the ZOOM OUT MAGNIFYING GLASS icon until restored to original size.
4. **Check that each page of the case was scanned properly.** (See **Box 2** below for instructions on how to *delete, insert,* and *rotate pages*.)
5. If **multiple cases** have been scanned in one session, click the "Next Document" icon on the left-hand toolbar (icon is another yellow file folder with blue arrow) to view the next case.
6. Follow steps 2-4 and carefully check each case scanned.
7. If you notice vertical lines on the scanned pages which are not on the original paper, it's an indication the scanner needs cleaning (see *Section 8.4.7.6 – Clean Scanner*).

Box 2
Delete, Insert and Rotate Pages

How to <u>DELETE</u> blank or unwanted pages picked up by the scanner:

- Click the mouse once on the selected page to delete (it will highlight with a RED box).
- Click the mouse on the GARBAGE CAN ICON ON THE TOP TOOLBAR.

Note: To delete multiple blank pages visible on the screen at one time, hold "Control" on the keyboard while clicking the mouse on all unwanted pages. Then click on the GARBAGE CAN icon on the top toolbar to delete all selected pages.

How to <u>INSERT</u> pages skipped by the scanner:

- Click the mouse once on the page that comes AFTER the page that was missed (the page parameter is highlighted in RED)
- Insert the skipped document in front of this highlighted page.
- Click on the "Insert pages" icon on the left-hand toolbar (the icon is 2 sets of pages with a green arrow between them.)
- The system allows a few moments to feed the skipped page into the scanner face down and upside down.
- Check the screen to ensure the page was inserted correctly into the scanned document.

How to <u>ROTATE</u> a horizontal page so it is readable (e.g., MOSR or ECG tracing):

- Right-click on the page to rotate.
- Scroll down and select "Rotate" from the drop-down menu.
- Select the direction to rotate the document. (Automatically saved.)

8.4.7.3 Output Scanned Cases

Output the scanned cases once QC is complete for all cases scanned. ***Note:*** When cases are output they are converted to **<u>read-only</u>** files, and **<u>no additional changes can be made</u>**.

1. Click the CHECKERED FLAG icon entitled "Output Batch" on the left-hand toolbar to output the cases. (It takes a moment to respond.)
2. Minimize the Kodak Capture software.

8.4.7.4 Upload Scanned Cases to the CCC

It is the responsibility of each FC to manually upload scanned files into WHIX so they can be accessed by the CCC for Central Adjudication. Routine scanning cases to the CCC maintains a steady work flow for the CCC staff and central adjudicators.

1. Go to https://www.whi.org/data, and login with username and password.
2. From the Menu, select "Upload case files"
3. Click on the "Start upload process now" link. This will launch a job that uploads a copy of each new scanned case file on the FC PC to the CCC and also moves a copy to the FC "archived" directory.

   Note: This procedure will only work if you are using the WHI PC at your FC that is connected to the scanner. Also note that these are very large files, so the job can take quite a while to run.

4. When you run the script it will ask two questions:
   - Do you want to run or save this file? Choose **Run**.
   - The publisher could not be verified. Are you sure you want to run this software? Choose **Run**.

5. The job will launch in a DOS window that displays information about what it is doing.
   - Please let it run until you see confirmation that your files have uploaded, then press ENTER to finish the process and close the window.

Note: If for some reason the program reports that one or more of the files failed to upload, try running the job again.

8.4.7.5 View and Rename Scanned Files

1. To view copies of uploaded scanned files open Windows Explorer.
2. Click on the C Drive.
3. Click on the "Batches" folder.
4. Open the "Archived" sub-folder to view files that have been uploaded to the CCC.
5. To view a file, right-click on the filename, select "Open With", and select "Irfanview" from the list. (This is a reader that allows viewing, but not modifying the file.)
6. Click the LIGHT GREEN ARROWS on the top toolbar to scroll through the pages of the file.
7. While in the "Archive" folder, re-name uploaded files to the Member ID (including check digit and adjudication #), or another identifier, e.g., Participant name.
8. Click once on the filename. Click again so that the name highlights, and rename the file.

8.4.7.6 Clean Scanner

It is recommended that FCs routinely clean the scanner glass and rollers using a non-abrasive towelette such as Staticide Wipes. This is to ensure the scanner operates as efficiently as possible.

8.5 Fatal Events

The identification, investigation, and documentation of fatal events can occur routinely through returned mail or non-routinely through communication by relatives, friends, etc. Follow-up on fatal events requires sensitive and resourceful communication and investigative strategies. Although any staff member may identify a participant's death, the OC is usually responsible for the investigation and documentation. This section provides guidelines for ascertainment of fatal events and communication with participants' survivors.

For SRC, only a *Form 120* is completed and entered in WHIX, no further investigation is required for a death. For an overview of the flow, refer to *Figure 8.2 – Fatal Event Flow Diagram*.

8.5.1 Death Certificate

Copies of death certificates are required for MRC to confirm a cause and date of death. Other documents may be required, such as autopsy report or medical records from a personal physician, or State Board of Health death certificate registry. If conflicting information is obtained regarding the exact date of death, use the information from the most reliable source (with hospital records or death certificates considered more reliable than word of mouth from family or physician). A certified copy of the death certificate is not required, an informational copy with cause of death listed is adequate. Some states require an agreement be in place for ascertainment of death certificates.

8.5.2 Identification of Fatal Event

Methods of Identification: FC staff may become aware of a participant's death in a variety of ways, including but not limited to the following:

- Follow-up of participants lost-to-contact. For example, web based searches to locate lost participants.
- Family members, friends, or the Post Office in response to the routine annual mailings (e.g., forwarded mail or returned mail marked "addressee deceased").
- Health care providers (e.g., medical records departments, clinics) from whom outcomes documentation has been requested to investigate earlier outcomes.
- A proxy, such as health care professional, family member, or friend, who is aware of a woman's participation in the ES and the need to provide such information to the FC.
- Obituaries or articles in local newspapers or other publications.
- CCC National Death Index search. Special procedures apply. See *Section 8.5.5 – National Death Index (NDI)*).

Initial Notification, Packet of Materials: News of a participant death can occur at any time and can be communicated to any staff member. Having a packet of materials readily available can reduce staff anxiety and assist with efficient yet respectful collection of information surrounding the participant's death. The packet may include the following:

- A sympathy card signed and sent on behalf of the FC.
- *Form 120 – Initial Notification of Death*.
- Proxy *Form 33 – Medical History Update*
- Proxy *Form 120H* to capture hospitalizations of one or more nights
- Release of Information (ROI) or proxy ROI
- A check list to ensure that all relevant documents are collected and promptly routed to both the OC and data entry staff for data entry.

Procedures Upon Notification of Death: Upon receipt of a report of death, FC staff:

- Send a sympathy card(s) to the next of kin and/or proxy as soon as possible. The card(s) can serve as a prelude to a longer contact, at an appropriate time, during which the *Form 33* and *Form 120H* is completed or the appropriate person is mailed the forms to complete on their own.
- Complete *Form 120 – Initial Notification of Death.* (MRC and SRC) FC staff use information obtained from the proxy or other source to complete *Form 120*. Not all information may be available when completing the *Form 120*, however, collect, record, and data enter as much information as possible. This form flags the participant as deceased in WHIX and stops all mailings thus preventing the participant from appearing on follow-up reports.

  If the initial notice is obtained at the CCC, CCC staff initiates the *Form 120*, including only the encounter information (contact date, completed by, contact type, and Q.2 - Source of Notification), then key-enters this limited information into WHIX to capture the participant death. Following key-entry, the partially completed *Form 120* is forwarded to the FC via the weekly mailing. The FC OC (or designee) is responsible for completing the *Form 120*, Questions 3-7, key-entry of the information in WHIX, and initiating the death investigation. See *Section 10.6.12.1 – Complete Data Collection for Fatal Events* for additional information on completion of *Form 120*.
- **Collect a Release of Information (ROI)** signed by the participant's next-of-kin. Occasionally, some providers accept an earlier medical release signed by the participant. ***Note:*** Some institutions require permission from the executor of the participant's estate. If there was no executor appointed before the participant's death, the hospital might require proof that the person signing is next-of-kin. Consider asking the NOK for a copy of the executor paperwork.
- **Collect a Death Certificate (DC):** Issued by the County or State Office of Vital Records, a death certificate (non-certified copy) includes information pertinent to the MRC death investigation. The DC includes date, time, cause and location of death (inpatient, hospice, residence, etc.). Knowing the cause and location of death will help with investigations and procurement of medical records. A next of kin is recorded on the DC and may be contacted to complete a proxy *Form 33* and *Form 120H* and although rare, a box can be checked to indicate that an autopsy was conducted. If this is checked, request the autopsy report.
- **Partial Waiver of Consent for Deceased Participants:** In January 2014 the FHCRC IRB approved study-wide use of a Partial Waiver of Consent for deceased participants. This waiver can substitute for the proxy ROI typically obtained from the deceased participant's next-of-kin (NOK) to procure medical records and a death certificate. Examples of when the waiver can be used include:
  - Proxy/NOK cannot be located
  - Proxy/NOK does not return signed ROI
  - Proxy/NOK is deceased
  - Required legal documentation is unavailable and required by an institution, e.g., a letter of Testamentary, Executor of the Estate
  - If the Executor paperwork is not available, the FC may combine a copy of the Partial Waiver of Consent with a previously signed ROI or the extension consent. Email the CCC doc request (docrequest@whi.org).

Use of the waiver is limited to obtaining medical records for deceased participants to adjudicate WHI outcomes. Because the Partial Waiver approval date does not change, it is recommended that the FC append the first page of the annual IRB approved Continuing Review Report (CRR) to the Waiver prior to submitting a request for medical records. This documentation is found on the WHI SharePoint website.

Note: Use of this waiver use does not replace collection of the final *Form 33* and *Form 120H* from the NOK if one is willing to complete these forms. It provides an option for using either the waiver and/or the proxy ROI to obtain records, depending on which approach is more likely to be successful.

- **Complete Proxy *Form 33* and *Form 120H***: For the MRC, a final *Form 33* and *Form 120H is* completed by a proxy to identify any other outcomes or hospital stays not yet reported or investigated (i.e., those outcomes ascertained only by "self-report" and those that require further investigation). A staff person who is sensitive with good communication is the ideal person to speak with the proxy and may decide, based on this initial contact, to defer completion of this form until an appropriate amount of time (e.g., 1-3 months) has passed since the death. Refer to *WHIX1225 – Unresolved Death Report* to identify deceased MRC participants missing a *Proxy 33* and *Form 120H*. SRC participants needing a proxy *Form 33* only because of a cancer do not display on this report.

  For SRC only, complete a proxy *Form 33* if the cause of death is determined to be due to a new cancer or a new cancer is reported at the time of death. Contact the CCC for instructions on how to process the *Form 33*. The cancer requires investigation and adjudication and the fatal event does not. No action is required if the cause of death is a recurrent cancer previously confirmed. For SRC deaths a *Form 120H* is not required.

8.5.3 Investigation

The investigation of fatal events can be challenging and requires:

- Knowledge of the documentation priorities for processing death outcomes.
- Ability to communicate appropriately with health care professionals, family members, and friends.
- Familiarity with local legal systems and requirements for obtaining death certificates and autopsy reports.

WHIX analysis of the *Form 120* will identify a documentation set for MRC inpatient and outpatient provider visits. If the location (inpatient or outpatient) of death is unknown and the provider visit is flagged as "other" in WHIX, a complete documentation set is not generated. Once the location of death is confirmed, update the visit status of "other" to generate the appropriate documentation set (see *Section 10 – WHIX Database Procedures for Fatal Events*).

Append the 'Last Relevant Case', the one that will be most informative and ideally assist with determining the cause of death. When a death case is closed with code 9, the 'Last Relevant Case' window immediately pops up after the closure code is entered. The window displays all prior cases sent forward, with the condition and date listed. Click on and assign the appropriate Last Relevant Case (LRC) or choose "No relevant case" (*see below if you have more than one LRC to attach). A confirmation window will appear, click Yes to confirm your selection and the window will close. The ID# of the LRC you assigned will be displayed in the 'Last Relevant Case' field on the adjudication screen. If you have <u>not yet</u> saved the case on the adjudication screen, you can change your LRC selection by clicking "Edit" next to the "Last Relevant Case" field and repeat steps above.

If you assigned a Last Relevant Case, place the 'Tab 12-Last Relevant Case' page as the last page of the case packet. WHIX will electronically attach the LRC you assigned to the closed case (you no longer need to manually attach the LRC). Use of Tab 12 will help the adjudicators differentiate between the case needing review vs. the one included as a reference.

*If you have more than one LRC to attach, you will need to manually place the other case(s) behind the Tab 12 page. WHIX can only electronically attach ONE LRC so any other LRC's will need to be manually attached and scanned in with the case (like old process). You only need to use <u>ONE</u> "Tab 12 page-LRC" page regardless of how many LRC's you are attaching.

8.5.3.1 Communication

Communications with individuals who have knowledge of or documents about a participant's death require FC staff members:

- Be sensitive to and comfortable with possible emotional responses and coping mechanisms and the need to address ES priorities as well as respond to these issues (e.g., by sending sympathy or condolence cards, listening to individual concerns and providing empathy). Although staff are required to try and obtain information needed to secure appropriate medical records and medical history update information, staff are not required to conduct in-depth interviews with next-of-kin for descriptive information about events, signs, and symptoms leading up to the death. Refer to *Section 7 – Follow-up Contacts* for further information on appropriate communication considerations.
- Have basic understanding of medical conditions and terminology.
- Have ability to prioritize 2015-2020 ES requirements for information (e.g., in rare circumstances, a participant's vital status—alive or dead—is all the information that can be confirmed).

8.5.3.2 When to Close a Challenging Death Case

In instances when it is clear no records can be requested (for example, a Partial Waiver of Consent is not accepted, NOK are deceased and/or the ROI is invalid, etc.), enter *Code 9 – Sent to CCC* in WHIX, and transmit the case to the CCC with, at minimum, a *Form 120 – Initial Notification of Death*. Clearly document the steps taken to obtain relevant medical records and justification for why the case was closed with incomplete documentation. This will ensure the case is included in a NDI search, if applicable.

Documents Received Post Closure

When additional medical records or the death certificate are received after the case has been closed, notify the CCC, scan and upload to the CCC, treat the records like a query. Re-print the original case ID cover sheet, scan record and close the visit as a duplicate of the original case (Code 11).

8.5.3.3 Participants with a Status of No-Contact

There can be no mail or phone contacts or attempts to collect data for participants from the NOK or proxy when a participant's follow-up status is no contact. In most instances a death certificate can be requested from the State Vital Statistics Office or NDI.

8.5.4 Report: WHIX1225 – Unresolved Death Report

WHIX1225 – Unresolved Death Report is the only report designed to track all tasks surrounding the participant death; it is recommended this report be run monthly. This report excludes NDI discovered deaths but includes annual check-in and no follow-up no follow-up participants; the report tracks the following:

- Member ID and name
- Outcomes Collection Type (OCT) designation and responsible group (FC vs. CCC)
- Duplicate entry of *Form 120* and/or *Form 124*
- *Form 120* (linked death condition)
  - Follow-up status
  - *Form 120* contact date
  - Number of days elapsed since *Form 120 contact*
  - Date of death

- MRC open death and closed adjudications missing a proxy *Form 33* and *Form 120H*
- Pending proxy *Form 33s* and *Form 120H* will drop off of the report one year after the death case is closed (death closed date)

This report does not display for SRC participants who needs a proxy *Form 33* because of a self-report of cancer.

8.5.5 National Death Index (NDI)

During the ES, the CCC will annually make application to the National Center for Health Statistic's NDI. NDI is a centralized database containing death certificate information from across the nation. A data file of ES participants identified as lost-to-follow-up, known deceased, and known to be alive is submitted and will provide vital status information on ES participants as well as cause of death classification.

Upon completion of the NDI search, the CCC updates a participant's vital status to deceased and enters the corresponding ICD-10 cause of death code into WHIX.

The NDI application states that the FCs are not allowed to do follow-back investigations with Next-of-Kin and/or health care providers when the report of death is not previously known to WHI. In this instance, the FC should not initiate any further contact with the participant's family or physician. The CCC has revised WHIX database reports to exclude the deceased participants' information. Relevant outcome reports now exclude participants who have NDI indicated as the source of death status. Additionally, the CCC has updated the FC reports with a comment advising staff not to follow back for additional information. Follow-back with the family and health care providers is allowable only if the FC knew about the death prior to NDI matching.

Figure 8.2
Fatal Events Flow Diagram

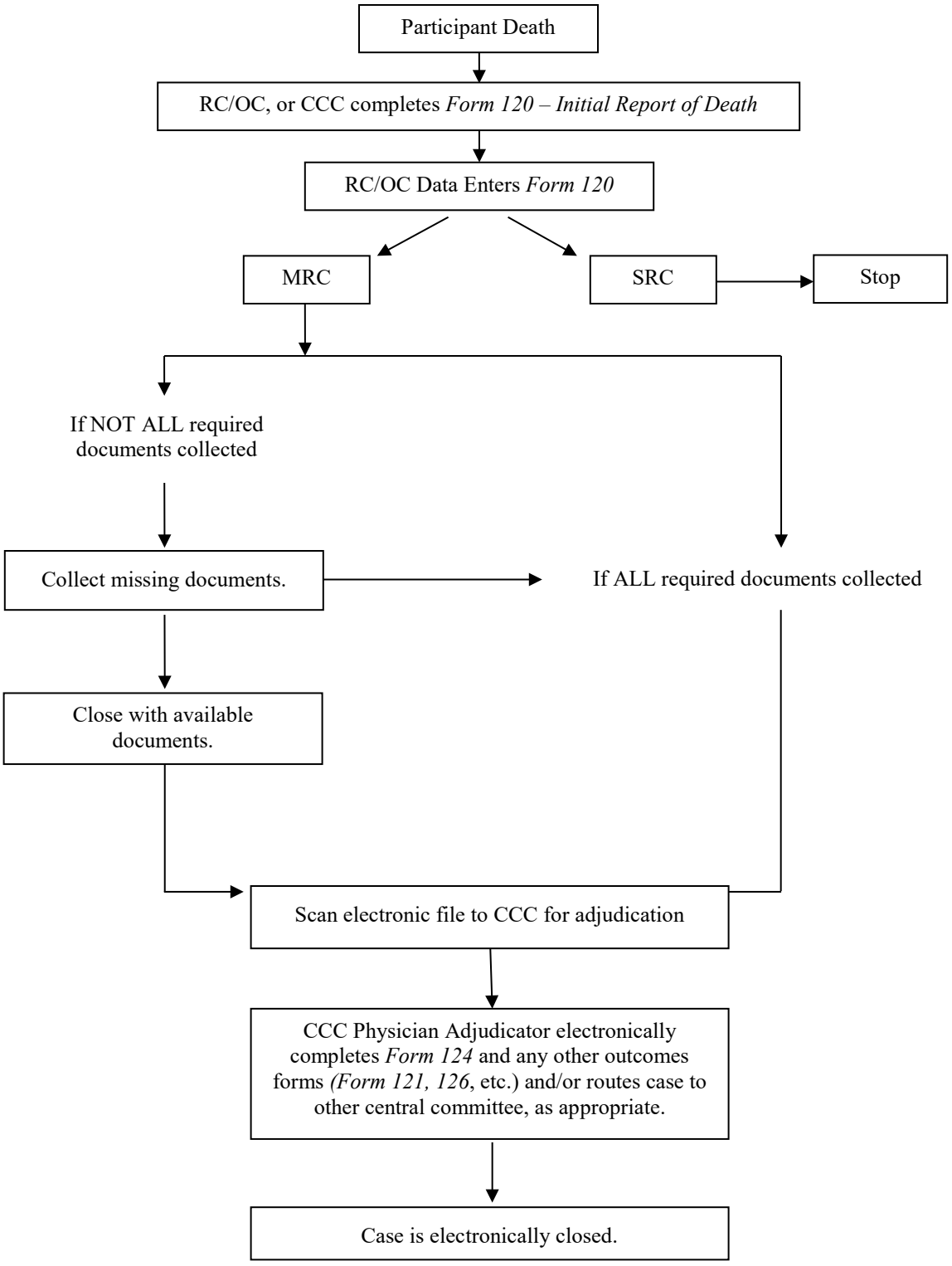

Table 8.5
Scanning Documentation Order by Separator Page

1 – Hospital Admin Documents
1 – Hospital Face Sheet – ICD9/10-CM Codes
44 – Physician Attestation; Coding Abstract

2- Discharge Summary
3 – Discharge Summary (if unavailable, please send Progress Notes)
13 – Outpatient/Short Stay Record

3 – Physician Documents
2 – History and Physical/Physical Exam
48 – Emergency Room/Emergency Department report
49 – Physician Notes/Progress Notes

4 – Consultations
33 – Consult (Oncology/Radiology)
43 – Other Consults
53 – Neurology consult report

5 – ECGs
45 – 12-Lead ECG tracings, all days

6 – Labs
9 – Cardiac Enzyme Reports (e.g., Troponin I, Troponin T, CKMG, CK or CPK), all days
60 – Lab: Brain B-type natriuretic peptide (BNP), pro-BNP
61 – Lab: Blood urea nitrogen (BUN), creatinine
62 – Complete blood count (CBC)
63 – Lab: Electrolyte Reports

7 – Imaging
4 – Chest X-ray Report all days
12 – Stress Test by treadmill ECG echo or nuclear perfusion scintigraphy report
16 – Carotid Artery Angiography, Doppler flow study
20 – Doppler flow study report
22 – Echocardiogram and Doppler (all reports of 2-D, transesophageal-TEE, or transthoracic-TTE)
25 – Ventilation/Perfusion Lung Scan Report
26 – Pulmonary Angiogram
27 – CT Scan Report
28 – MRI Report
30 – Radiology and/or bone scan reports/isotope or nuclear med bone scan
47 – Nuclear Scans, e.g., thallium, Myoview®, sestamibi, RVG/MUGA
64 – Reports of cardiac MRI/MR angiography
65 – Reports of Cardiac CT scan /CT angiography
67 – Reports of angiograms of head, neck or bran (MRA, CT, or catheter based)
68 – Reports of angiograms of the lower extremities (MR, CT, or catheter-based angiography)

7 – Imaging (continued)
70 – Reports of Segmental Doppler assessment of the lower extremities
71 – Reports of Abdominal Ultrasound of aorta or other arteries
72 – Reports of Head/Brain CT scans
73 – Reports of head/brain MRIs

8 – Op and Procedures
9 – Coronary Artery Bypass Graft (CABG)
11 – Percutaneous Coronary Intervention (PCI): PTCA; Coronary Stent/Artherectomy
15 – Operative or Procedure Report
17 – Cardiac catheterization including coronary angiograms and arteriograms and contract ventriculogram
18 – Venogram report
24 – Ankle Brachial blood pressure ratio (ABI)
29 – Lumbar puncture report
66 – Operative/Procedure reports (including Aortic Stent Graft)
69 – Operative/Procedure reports (including angioplasty and /or stent of lower extremities)

9 – Pathology
31 – All pathology reports
32 – Cytology reports, all
35 – ERA/PRA Hormone Receptor Lab report, Her2Neu (Breast cancer only)

10 – Fatal Events
37 – Death certificate
38 – Autopsy or Medical Examiner/Coroner's report
39 – Emergency Medical Services (EMS) or ambulance report
51 – WHI *Form 120*

11 – Miscellaneous
99 – Miscellaneous document, specify
– Death cases: Append the last relevant case "For reference only"

12 – Fatal Events Reference Case