

Appendix H – Ancillary Studies
WHI Life and Longevity after Cancer Study (LILAC)
Regional Center Manual of Operations

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Appendix H

WHI Life and Longevity after Cancer Study (LILAC) Regional Center Manual of Operations

1 LILAC Protocol and Study Overview

Introduction

The National Cancer Institute (NCI) has funded a cancer survivor cohort (CSC) ancillary study of Women's Health Initiative (WHI) participants to run from January 2013 through January 2018. The working moniker is the "Life and Longevity after Cancer" or LILAC study. The study will focus on 8 different types of cancer (see list in *Section 2.1 – LILAC Study Cancer Sites*).

The Project Director for the study is Lisa Johnson, Staff Scientist at Fred Hutchinson Cancer Research Center (FHCRC) in Seattle, WA. The Principle Investigators are Garnet Anderson at FHCRC, Bette Caan at Kaiser Permanent in San Francisco, and Electra Paskett at Ohio State University.

Overview

The overall goal of the LILAC study is to create a unique resource to support studies of cancer survival, survivorship and molecular epidemiology in the WHI. Specifically, the study aims to capture and collect cancer-related exposures and outcomes (treatment and recurrence) using administrative datasets. Additionally, the study will collect FFPE (Fixation in neutral-buffered formalin, paraffin embedded) tumor tissue for 5 of the 8 sites to enhance the WHI biorepository and further develop a strong research program in cancer survivorship by encouraging collaborators to take advantage of this resource.

Due to the large number of cancer types and the limited time-frame of the study, 8 cancer sites were selected for the LILAC study based on priorities to make data collection feasible for all cases. These parameters included sites where there were a sufficient number of cases within the WHI, an expected survival rate long enough to warrant studies of survivorship, potential to contribute to critical molecular epidemiology studies, and investigator interest. Further parameters have been set for specific sites and areas of data collection such as tumor tissue and targeted testing. LILAC is pursuing invasive cancers with the exception to in-situ melanoma collected for tumor tissue only.

Areas of data collection include the incident cancer, cancer outcomes, biospecimens, and quality of life. The WHI currently manages information containing diagnosis details for the incident cancer, death outcomes, blood and DNA, and general information for quality of life. LILAC seeks to capture treatment detail, recurrences and treatment effects, FFPE tumor tissue, and cancer-specific quality of life information.

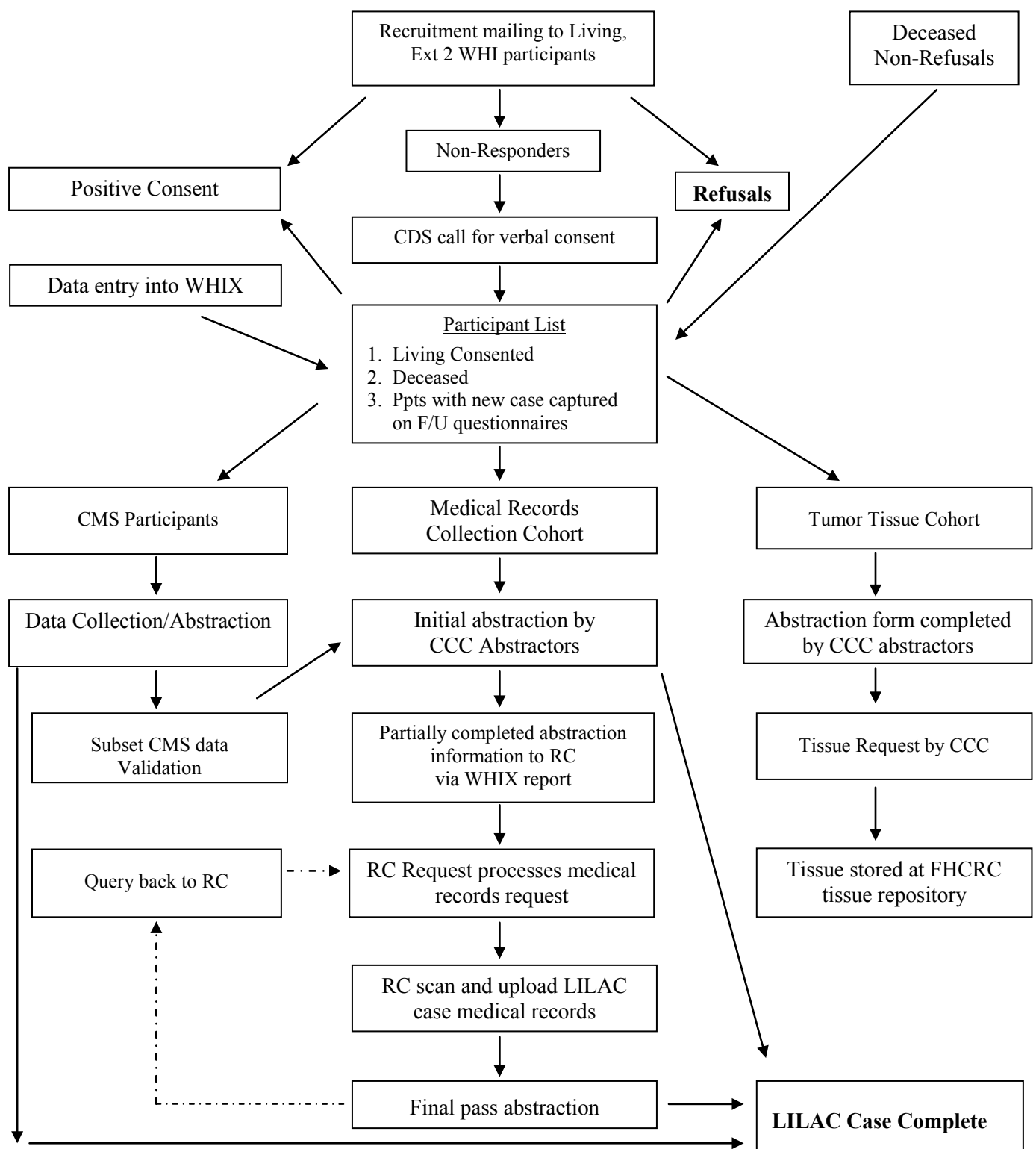
Medical records were collected and the documentation now exists at the Central Coordinating Center (CCC) at FHCRC for each reported primary cancer diagnosis of WHI participants. For all self-reported cancer outcomes, the WHI collects pathology reports (required), discharge summaries, and surgical reports from providers in order to characterize the cancer to Surveillance, Epidemiology, and End Results (SEER) standards, including tumor size, lymph node involvement, metastases, staging, laterality, and histology. For breast cancers, the receptor status for ER/PR and Her2Neu is also collected. The LILAC study will make use of this important information already collected.

For the LILAC-eligible women who are living, about 8,100, baseline questionnaires were mailed in the fall of 2013. Each participant who consented to the LILAC study will also receive an annual follow-up questionnaire. Tissue collection will be pursued for both living and deceased women, and the study expects to receive nearly 6,000 tissue samples. To document treatment and recurrence, the study will utilize a combination of Medicare and HMO data when available and pursue direct medical records abstraction when not. Some records will be pursued for validation of algorithms for treatment and recurrence.

Collection documents include the LILAC consent form, a LILAC-specific Release of Information (ROI), a participant questionnaire, site-specific abstraction forms, a tumor tissue collection form, medical records request reports, and a partial waiver of consent (for deceased participants whose cancer diagnosis makes them LILAC eligible). All materials used in the collection of records have been approved by the FHCRC's Institutional Review Board (IRB), which is the IRB of record for the WHI and the LILAC study.

Questionnaire development is managed by the LILAC affiliate at Ohio State University; the CCC handles the questionnaire operations (mailing, receipt of completed questionnaires, consents and ROIs, and storage of each). Tumor tissue collection, Medicare and HMO data collection, and initial abstraction of in-house WHI records will be conducted at the CCC. Cases requiring further investigation will be forwarded for medical records collection to the participating WHI Regional Centers. Final abstraction and subsequent data management and processing, as well as some investigation monitoring will also be conducted at the CCC. Other RC monitoring and distribution of payment is coordinated through the LILAC affiliate at Kaiser Permanente.

Diagram 1
LILAC Study Flow Diagram



1.1 Regional Center Procedures

Introduction

The AS370 RC manual includes instructions for RC staff responsible for ascertainment of cancer treatment and recurrence for the LILAC study. This manual is a supplement to the WHI Manual *Section 8 – Outcomes, 8.1-8.5* which documents ascertainment and adjudication procedures and *Section 10 – Data Management, 10.1-10.7* which provides instructions on use of the study database.

It is recommended RC staff review these sections in detail to become familiar with WHI ascertainment and data entry procedures prior to implementation of the LILAC study since many of the procedures outlined were adopted for use in the LILAC study. To eliminate redundancy, the focus of this manual is to define new or revised procedures unique to the LILAC study.

2 Medical Record Collection Overview

The goal of the RC ascertainment process is to identify, investigate, and obtain medical records documentation of cancer related treatment and recurrence for eight incident invasive cancer sites, previously centrally adjudicated in WHI.

2.1 LILAC Study Cancer Sites

- Breast
- Colon and Rectum
- Endometrium (corpus uteri)
- Leukemia
- Lung
- Lymphoma
- Melanoma
- Ovary (includes fallopian tube and primary peritoneum sites)

2.2 Definitions of LILAC Study Cancer Related Treatment and Outcomes

The following treatments and outcomes will be documented for the LILAC study.

Cancer treatment: The planned first course of therapy following the initial cancer diagnosis and staging. The time interval of the first course of therapy will vary by cancer site and a participant's comorbidities, but is often conducted between zero and 24 months after diagnosis and staging. **Collect records for the actual treatment (versus planned or recommended).** These records include exact start and stop dates (month/year), start date alone (month/year) or surgery dates for the following:

- Surgery, type
- Chemotherapy agents, other targeted therapy, and/or biologics, with start date only
- Radiation therapy, including total dosage (including boosts) and administration route/ type, with start and stop dates
- Combination chemotherapy and radiation therapy, if appropriate
- Endocrine-targeted (hormone) therapy (typically outside of the 0-24 month window, 0-5 years, occasionally 0-10 years), start and stop dates
- Molecular testing, site-specific results
- Site-specific treatment

Note: Exact dates (defined as month and year) of service are required. In the absence of exact dates, an estimated date can be submitted.

Other treatments: Procedures, medications, or treatments found in medical records documentation but not tied to a specific document; no specific medical record requests will be made for these but include records as part of the case when any of the following are documented:

- Bisphosphonate medication use
- Ovarian ablation (breast cancer only)
- Breast reconstruction (breast cancer only)

Recurrence or Date Known to be Disease-Free

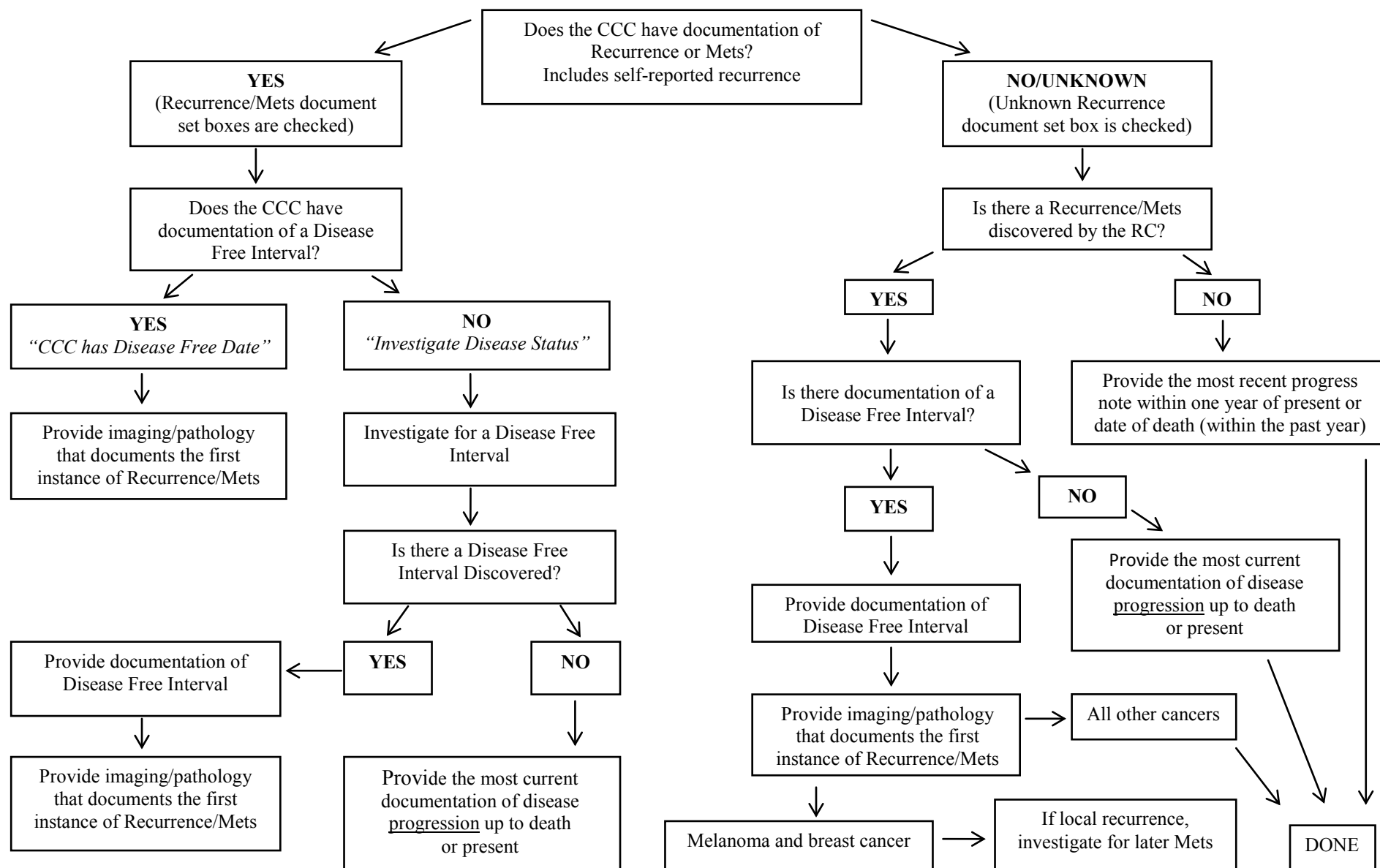
Cancer recurrence: A diagnosis made *after* the initial diagnosis and staging and after a documented disease free interval, not to include a diagnosis based on National Death Index (NDI) only. The LILAC study only codes recurrence or metastasis when there is documentation that there was a disease-free interval between initial diagnosis and a new diagnosis of invasive recurrence at either the local site or at a metastatic site. Recurrence is specific to the LILAC incident cancer site and therefore excludes an incident cancer diagnosed at a different site. The diagnosis date, histology and laterality of the invasive recurrence are collected; recurrence can be broken down into the following categories:

- Local recurrence: the diagnosis of an *invasive* cancer at the same site. This includes any new or recurrent invasive primaries of the incident site.
- Contralateral recurrence (paired sites): the diagnosis of an *invasive* cancer on the opposite side if the incident cancer site (breast, lung, and ovary).
- Regional or distant metastasis: the cancer is outside of, and attributed to, the incident cancer site.

Date known to be disease-free:

- When there is no documentation of a recurrence or metastasis, LILAC captures the time interval between the participant's incident cancer diagnosis and the absence of recurrence and/or metastasis documented in the most recent available medical records documentation.
- When there is a documented recurrence or metastasis after a documented disease free interval, LILAC codes the *first date* the participant is documented to be disease free.

Diagram 2
Recurrence Flow Diagram



*The majority of LILAC cases will follow the green pathway

3 Identification of Cancer Related Treatment and Outcomes

Cancer treatment and outcomes will be identified using a combination of participant self-reports from LILAC study baseline and annual questionnaires and information gathered from the initial abstraction process.

3.1 Form 340 - LILAC Study Baseline and Annual Follow-Up Questionnaire

LILAC consented study participants were asked to complete a baseline questionnaire to collect information related to one, and in a few instances more than one, of the eight targeted cancer sites. Participants were asked to self-report information about cancer treatment including surgery, chemotherapy, hormone, radiation, and biologic therapies, and complementary/alternative medicine, including type, start dates, and providers of these treatments; reports of new cancer events related to their incident cancer diagnosis; reports of longer-term disabling conditions or effects on quality-of-life that are common sequelae to many cancers or their treatments but not covered by WHI questionnaires (e.g., lymphedema, cardiotoxicity, nephrotoxicity, neurotoxicity) and questions on insurance coverage, income, employment status and access to care.

The CCC is responsible for contacting participants for incomplete or missing form responses on *Form 340 – LILAC Questionnaire* specific to Qx.1 – Chemotherapy, Qx.2 – Radiation treatment, Qx.3 – Hormone therapy, Qx. 4 – Other targeted treatment and/or Qx. 6 – Recurrence.

An annual questionnaire and ROI will be mailed to all living LILAC study participants who completed the baseline questionnaire. This form will assess traditional patient reported outcomes and will request updates from the woman on new cancer events and cancer treatments.

3.2 Case Abstraction

A two-phase, initial and final, abstraction procedure will be conducted as part of the study. Centrally trained abstractors will pull, review and abstract treatment and recurrence information from all cases available at the CCC, including the incident cancer case. The goal of initial abstraction is to document information already known about treatment and recurrence and to identify what is missing that requires RC follow up. A key part of this review is to identify health care providers, oncology clinics, or other treatment facilities from which medical records may be obtained. The initial review will serve as a launching point for RC investigation. Additional discussion about provider visits can be found in *Section 4.2 – Provider Visits*. Final abstraction begins when the RC scans the requested medical information or documents that medical records cannot be obtained to the CCC. Every case requires final abstraction even if no medical records are obtained. If the abstractor is able to fully code the case on first pass, the case will bypass RC investigation.

3.3 Investigation Algorithm

Participant reports on Form 340	Medical record abstractor documents	RC investigation?
No treatment	Yes treatment	Yes
Yes treatment	No treatment	Yes
No treatment	Unknown	Yes
Yes treatment	Yes treatment	No, unless specific details missing
No treatment	No treatment	No
No Form 340	Yes treatment	Yes
No Form 340	No treatment	No
No Form 340	Unknown	Yes

4 Investigation of Cancer Related Treatment and Outcomes

4.1 LILAC Document Sets

The RC is responsible for investigation of cancer related treatment and outcomes. Each LILAC treatment and outcome of interest has a corresponding medical records document set (See *Table 1– LILAC Documentation Sets*). The documents are listed in priority order, 1-4, with the ones most likely to have the needed information listed first (priority 1, 2, etc.). Unlike WHI, collection of all priority documents is not required. Any document that provides the needed treatment and recurrence information may be used, although treatment summaries are preferred over treatment flowsheets. Exceptions include the actual pathology report to document recurrence and molecular testing lab results that are tied to lab-defined normal ranges.

The LILAC document sets have some flexibility that are not available in WHI. For example, when both recurrence and metastasis status are unknown, the document sets are collapsed into one. In addition, the recurrence document set has two options, 1) known recurrence and 2) unknown recurrence. For a known recurrence, there is a self-report and/or medical record evidence of recurrence which supports an investigation and generation of a complete document set. For an unknown recurrence, the document set is truncated (History and Physical [H&P] and progress note, most recent available). This allows the RC to get a quick snapshot to determine if there is evidence of recurrence (in which case follow back is required after updating unknown to a known recurrence in the Dashboard) or no evidence of recurrence and disease free survival is documented.

In *Table 1 – LILAC Documentation Sets*, it is noted that many of the same document types are listed in multiple document sets. For example, a history and physical is listed in four different document sets but often with a different priority status within each set. In addition, two different progress notes, one for treatment and the other for recurrence (or to document disease free survival) are available:

- Treatment: Physician progress notes
- Recurrence: Physician progress notes

Having the same document listed in multiple document sets and two types of progress note options, allows for medical record requests to be made for distinct time periods thus streamlining the number of records requested and received. In general, it is recommended each document set remain intact and the RC refrain from deleting documents that appear to be duplicates.

Within each document set is an optional Miscellaneous (Misc.) document type numbered Misc. doc #1 to Misc. doc #5. The Misc. doc type may be useful for an abstractor looking for a specific document to complete abstraction or for a RC to add a document deemed useful but not listed in the document set. A text description is required when the Misc. document is selected. It is recommended to keep Misc. document descriptions brief so it displays on your request letter in its entirety.

Table 1
LILAC Documentation Sets

WHIX ID #	Documentation Required for LILAC Case	Radiation	Chemo	Endocrine (hormone therapy)	New/ Recurrence 1	Unknown Recurrence	Breast	Lung	CRC	Ovary	Endo	Melanoma
1	Discharge summary				x							
2	Outpatient report (need start and stop date for each prescribed drug)			x								
3	History & physical	4	4	3	x	2						
4	Consultations	2	2	1	3							
6	Radiation treatment summary (start/stop date/total dosage)	1										
7	Physician/Radiation progress notes	x										
17	Physician progress notes	3	3	2	4	1						
9	Chemotherapy progress notes		x									
10	Chemotherapy medication flow sheets (start dates/drug names)		1									
11	Operative/Procedure report (related to cancer)				1							
12	Radiology, nuclear imaging reports: CT, MRI, PET scans, bone scans				2							
13	Pathology lab reports, including bone marrow aspirates, biopsies, & addendums [all]				1							
14	Flow cytometry lab reports				x							
15	Cytology lab reports				x							
30	Miscellaneous document (s) #1											
31	Miscellaneous document (s) #2											
32	Miscellaneous document (s) #3											
33	Miscellaneous document (s) #4											
34	Miscellaneous document (s) #5											
35	Lung Cancer Molecular Tests: ALK tyrosine kinase inhibitors, EGFR/ERBB1/HER1, KRAS, BRAF, KIT							1				
36	Melanoma Molecular Tests: BRAF, c-KIT, KIT, NRAS, CDK4											1
37	Colorectal Cancer Molecular Tests: BRAF/V600E, KRAS, MSI, Oncotype Dx, CIMP, Tp53, PIK3CA, MMR								1			
38	Ovarian Cancer Molecular Tests: CA-125 (blood test found in labs)									1		
39	Endometrial Cancer Molecular Tests: Hormone Receptor Status: Estrogen & progesterone receptor assay										1	
40	Breast Cancer Molecular Tests: Biomarker/molecular testing (found in the pathology report), Mamma print, Oncotype Dx						1					
41	Lactate Dehydrogenase (LDH) [blood test]											x

4.2 Provider Visits

A critical step in the investigation process is the identification of health care providers from which to request medical records. Records will be obtained from in/outpatient facilities, physician's offices, radiation treatment centers, oncology clinics, etc., expanding to facilities not typically used in WHI. The process used to select these providers is briefly described in *Section 3.2 – Case Abstraction*. While the RC can rely on this provider information, staff has the option to update, edit, or add providers based on RC internal information (e.g., notes in member comments) and external investigations (phone calls, internet searches). Some examples of when to edit or add providers include:

- Confirmation that an MD has retired from medical practice
- Merged, closed, renamed, or relocated hospital
- RC notes regarding previously closed WHI adjudications not available to view at the CCC
- Noting a more current provider in WHIX
- Medical records received for LILAC document an additional or a more current provider from whom to request additional records

See *Section 8.2.1 – Review Provider Information* for instructions on how to edit provider visits

4.3 Release of Information (ROI) and Partial Waiver of Consent

There are three documents available for requesting medical records information, 1) the LILAC Authorization to Release Tumor Tissue and Medical Records 2) the Partial Waiver of Consent and 3) WHI ROI, if available.

The LILAC Authorization to Release Tumor Tissue and Medical Records (informally known as the Release of Information [ROI]) is a dual purpose document used by the CCC to request tumor tissue and by the RC to request medical records. A scanned copy of this signed authorization is available for the RC to view and print via the LILAC Visit Documents Screen in the Dashboard. To ensure all tissue specimens are routed to the CCC only, the CCC return address is listed on the authorization. The Medical Records Request Letter lists the RC address. If a provider mails medical records to the CCC based on the authorization address instead of the RC address listed on the medical record request, the CCC will immediately forward the records to the RC.

Note: A LILAC ROI template is available in SharePoint if a new ROI is required, e.g., the date signed is no longer valid. In addition, it is possible to use a WHI or institution-specific ROI previously signed by a WHI participant to request LILAC records. If an ROI has expired, the Regional Center is required to mail a blank ROI to the LILAC participant for an updated signature and date. It is at the discretion of the RC whether a LILAC or WHI ROI is sent based on if there is otherwise a need for a current WHI ROI for the participant.

The Partial Waiver of Consent is an IRB approved document that can be used to request medical records for deceased participants similar to the ROI used for participants who are alive. The waiver is listed as a permitted disclosure under the Code of Federal Regulations (CFR) privacy rules: Title 45, C.F.R. 46.116(d) and one has been approved for use by the LILAC study. A copy of the waiver and editable version of the WHI Waiver Cover Letter template are available to print from LILAC RC Operations tab, LILAC, in SharePoint.

To edit the cover letter template: Click edit document and select either Edit in Word or Edit in Word App to add participant-specific information:

- Participant name, date of birth and death (see the Member Data, Member Data Entry tab for dates)
- Provider name and address
- Outcomes Coordinator's name
- RC address, phone and FAX numbers

To save the edited cover letter, select “save as” and save the document to a local RC drive. RCs have the option of using the WHI or LILAC ROI. Experience and familiarity with provider ROI requirements will drive selection.

4.4 ROI and Partial Waiver of Consent Algorithm

Participant Status	LILAC ROI	WHI Extension 2 Consent (signed)	WHI ROI	Partial Waiver of Consent
Alive at study onset	X	X	X	
Deceased <i>after</i> study onset	X	X	X	X
Deceased after Extension 2 before study onset		X	X	X
Deceased prior to Extension 2 before study onset				X

4.5 Request for Medical Records Information

There are four study-approved request letters auto-generated based on selected treatment, recurrence and provider visit information: 1) treatment following the incident WHI cancer diagnosis 2) molecular testing only, 3) known cancer recurrence [including metastasis] and 4) recurrence or metastasis, status is unknown. The definition of treatment and recurrence are defined in *Section 2.2 – Definitions of LILAC Study Cancer Related Treatment and Outcomes*. Treatment and recurrence requests are generated on separate letters because often the time intervals differ. In some situations, RC staff may prefer to add “Unknown Recurrence” as a “Misc. Document” to a treatment request letter.

See *Section 8.2.2 – Review/Edit Provider Details* for instructions for reviewing, editing and printing the LILAC Medical Records Requests (LILAC0980).

4.5.1 Dates of Service

Each medical record request will include dates of service defined by the initial abstractor.

LILAC Abstractors use the following guidelines for determining ‘Start’/‘End’ dates and start dates alone:

- Treatment and molecular testing: Date of the initial cancer diagnosis, plus 25 months.
- Known hormone therapy use: Date of initial cancer diagnosis plus six years or best available.
- Recurrence, date known: Available date (suggest -2/+3 month window around available date).
- Recurrence, date unknown: Start date is based on documentation of known disease status in the incident WHI case and any subsequent case through most current date or date of death.
 - Participant alive: Date of incident cancer diagnosis to current date or best available.
 - Participant deceased: Date of incident cancer diagnosis to date of death.

4.6 Contacting LILAC Participants

When it is necessary to contact the LILAC participant for any reason, such as mailing a ROI, clarifying provider information, first review the participant’s member comments in WHIX. LILAC does not require contacting the NOK for deceased participants.

5 Documentation of Cancer Related Treatment and Outcomes

5.1 Definition of a LILAC Case

There is typically only one LILAC case for a WHI participant, unless the participant is one of the few who has multiple cancers (two different incident cancers diagnosed on the same date). Eligibility for LILAC

requires that the cancer of interest be the first adjudicated cancer of any type after WHI enrollment, and that a participant have no history of cancer before joining WHI. A LILAC case number and LILAC local adjudication number is automatically created. The LILAC local adjudication number is the next sequential number after the WHI local adjudication number. For example, if a participant has local case #'s 1, 2 and 3, the LILAC local adjudication will be #4.

All documentation for treatment and recurrence are investigated and collated into the single LILAC case then sent to the CCC for final abstraction/archival. A LILAC case is officially closed by the abstractor following final abstraction. Therefore, every case, even if the request for medical records yields no documentation, is sent to the CCC for final review and abstraction.

5.2 Review of Received Medical Record Documents

Upon receipt of medical records, compare demographic information in the medical records to LILAC participant data to ensure accuracy of the participant. Then compare medical records requested to those received and reconcile in the LILAC Dashboard.

At times, additional requests for medical records are required. LILAC is tracking the first three medical record requests, something that was not done in WHI. Strategies for requesting medical records can be reviewed in The WHI Manual, *Section 8.3.4 – Procedure for Requesting Medical Records Documentation*. If an additional request is needed, the dates in the 3rd request column will be updated. Refer to *Section 8.2.6* for requesting medical records details.

Additional medical records received after case was closed. If medical records are received after an incomplete case has been scanned and closed, email lilac@whi.org to re-open the case.

5.2.1 Rules for Medical Record Documentation

- **Chemotherapy** (other specialized treatments e.g., immunotherapy biologics)
 - LILAC codes start date and regimen.
 - If the RC obtains end date and regimen, RC is not required to re-request for start date
- **Radiation**
 - LILAC codes start date, end date and dosage.
 - If the RC obtains either start date or end date **and** dosage RC is not required to re-request for missing date

Radiation treatment is only collected for treatment to the primary tumor site. Exception: Lung cancer. Include radiation treatment to metastatic sites in addition to the primary tumor.
- **Hormone Treatment**
 - LILAC codes start and stop date for the duration of six years post-diagnosis
 - Investigate all hormone treatment prescribed during the six year interval
 - RC is not required to re-request for treatment dates past six years of diagnosis, however, if obtained, please submit.
- **Disease Status**
 - LILAC codes disease status within one year of death or present
 - When the most progress note does not mention the cancer disease status, but there is documentation of her being disease free within two years of the most recent note, submit **both** documents to support the most recent disease free date.

- **Recurrence/Metastasis**

LILAC codes the first instance of recurrence or metastasis after a documented disease free interval and then stops. Exceptions: breast cancer and melanoma; investigate disease status until there is one of the following: documented disease status until metastasis, death, or present.

5.3 Case Assembly

Organize the medical records chronologically oldest to newest by document type as much as possible.

Organize the case in the following order:

1. Case ID cover sheet with barcode
2. IDS
3. Medical records documentation assembled as described above under-case assembly

5.4 Preparation for Case Scanning

Completed cases will be scanned and uploaded to the CCC. The scanning procedures are identical to WHI, See the WHI Manual, *Section 8.4.7 – Scanning Procedures*, for complete scanning instructions including how to handle large case files, QC, and clean the scanner etc.

Note it is possible a previously scanned case may appear on an RC tracking report (for up to ten days, worst case scenario) until central case processing is complete. Cases are “burst” at the CCC over the weekend and then upload to the LILAC Dashboard on Tuesday morning. For example, a case scanned on a Monday will not have a status of “Needs Final Abstraction” until Tuesday of the following week. RCs will be notified if the scheduled day changes to help plan work flow.

5.5 Query for Additional Medical Records

Occasionally a document not received in the initial case packet, or a document with more complete information is needed to accurately complete case abstraction. In this instance, the central abstractor will initiate a query and ask the RC to re-request specific documents from a provider. RCs have 30 days to process a query.

Queries are generated and processed as follows:

- Abstractor includes a note in the CCC comments field detailing the query request
- Abstractor removes the scan date and the document status and any request dates for the needed documents; or adds a new, discovered, provider. These actions trip the Case Status to “Needs Query Doc Req”.
- The case will reappear on the LILAC 1213 Open Case report
- RC investigates for incomplete or missing documentation, following the same process as outlined for initial investigation, making three requests, reconciling returned documents and scanning the documents to the Dashboard.
- Print a new IDS
- RC rescans the original cover sheet, new IDS and the query document(s) (or documentation that the records do not exist). Do not re-scan the entire original case.
- RC enters the new scan date in the Dashboard

6 Fatal Events

When a LILAC staff member hears about a participant death, collect the following information, if possible:

- Participant name
- Date and Cause of Death, if known
- Contact name (i.e., who reported the death). Let the contact know that someone may be calling them back for additional information, if needed.

- Immediately forward to the RC Outcomes Coordinator (OC) of the responsible WHI RC, or send to the WHI email box if unsure.

Ideally, the WHI OC will complete a *Form 120 – Initial Notification of Death* and key enter the information into WHIX. Data entry of *Form 120* immediately changes the participant status from alive to deceased for the WHI and ancillary studies. In addition, key entry of the *Form 120* stops routine mailings and displays the participant on WHI reports for appropriate fatal event follow up. See the WHI Manual, *Section 8.5 – Fatal Events* for detailed instructions.

No proxy follow up is required for the LILAC study. Investigation of treatment and recurrence is conducted using either a previously signed LILAC ROI, the Partial Waiver of Consent, or in some instances, the WHI signed ROI, as described in *Section 4.3 – Release of Information (ROI) and Partial Waiver of Consent*.

7 Case Reimbursement

Purpose: Request services through the Regional Center Institution for obtaining medical records on behalf of the LILAC study.

- Each Regional Center (RC) will collect a specific number of LILAC cases spread over the course of the study for living and deceased women.
- Retrieval of very specific documents (defined by document sets)
- No abstraction is required
- Completion of abstraction will be documented in the WHIX Dashboard.

Reimbursement for Medical Record Retrieval

- RC will be reimbursed at \$130.00 per case closed prior to 1/31/16
- RC will be reimbursed at \$162.50 per case closed after 2/1/16
- RCs will be paid the full amount for every completed case. If the RC is unsuccessful at obtaining all of the requested documents, and can document retrieval attempts, RCs will be paid for the incomplete record.

If the RC is charged by a facility/hospital/provider for retrieval of the medical records, KPNC will pay for these costs, in addition to the case closure reimbursement. Most facilities do not charge fees for medical record requests.

Purchase order with Regional Center.

- Issuing purchase orders for these services
- Each institution will be set up in the Kaiser Permanente Northern California (KPNC) accounting system.
- Required documentation:
 - Signed and dated copy of each RC institution's W-9 form
 - A sample invoice
 - RC to submit invoice to 'Kaiser Permanente-Division of Research' via email to Adrienne.castillo@kp.org. Cc: DOR-AP@kp.org, and include a reference to the KPNC Project: WHI CSC LILAC and Project ID: RNG021474.
 - Include LILAC1005 (LILAC Invoice Report accessible in WHIX) for documentation of closed cases for the time interval.
- KPNC will initially pay the RC 50% of the annual funds based on their expected workload for Year 1 (i.e., $222 \times 0.5 \times \$130 = \$14,430$). Thereafter, KPNC will reimburse the RC semi-annually based on receipt of invoice and LILAC1005.

Sub contract with Regional Center:

- Execute sub contract for these services.
- Annual amendment to sub contract to cover each funded year.

- RC to submit monthly invoice to ‘Kaiser Permanente-Division of Research’ via email to Adrienne.castillo@kp.org with Cc: DOR-AP@kp.org, and include a reference to the KPNC Project: WHI CSC LILAC and Project ID: RNG021474. Include LILAC1005 (LILAC Invoice Report accessible in WHIX) for documentation of closed cases for the invoiced month.
- As needed, submit invoice(s) for additional fees for any facility charges that were assessed to Adrienne.castillo@kp.org.

7.1 Reimbursement for Medical Record Retrieval Fees

- Invoice(s) for Medical record retrieval fees should be submitted to Adrienne.Castillo@kp.org
- Invoice will be submitted to the KPNC procurement group for payment.
- Fees will be paid directly to facility.
- Records will be available to Regional Center following payment.

8 RC Operations, LILAC Dashboard and Medical Record Collection

Sections 1-7, above, provide the background and rationale for the LILAC Study. *Sections 8 and 9* are the operational sections, providing detailed instructions on “how to” complete the LILAC scope of work. RCs are encouraged to contact the CCC LILAC Liaison with specific questions at lilac@whi.org.

8.1 The LILAC Dashboard Study Database

The Dashboard is the user interface to the WHI database (WHIX). It is used by RCs to request, receive, and track medical record requests; centrally used by the abstractors to key enter treatment and recurrence data; and to store the participant enrollment information, including consent status, and baseline/annual study forms. Essentially, all LILAC-specific tasks are completed in the Dashboard and tasks that impact WHI are completed in WHIX.

Communication between the WHI and LILAC OC (if different) is imperative to ensure critical information is communicated and updated correctly. Examples of tasks listed below impact WHI and LILAC but are only updated and or executed in WHIX:

- Key entry of *Form 120 – Initial Notification of Death*
- Printing participant study labels
- Updating RC site contact information (address, phone, FAX, OC)
- Changing passwords
- Updating the Member Data Entry screen (change in participant and proxy contact information)
- Reviewing member comments prior to calling the participant

It is recommended that important participant information be added to the member comments screen in WHIX and made available to everyone who is working with participants. This will ensure continuity between staff and studies.

The LILAC Dashboard toolbar buttons (Save, Close, Enter Query, Execute Query, etc.) and the function keys (such as F7 for Enter Query, F8 for Execute Query, F10 to save and Control/Page down) are the same. For staff unfamiliar with the function keys, use of the computer mouse and icons are now available.

Figure 1
LILAC Dashboard - Main Screen

The LILAC Study - Life and Longevity after Cancer

LILAC Case

Member Id	First Name	Last Name	WHI RC	Abstr Req'd	CMS	ROI	Tissue	Ramsey	Stanford	Recur	Incident Case	Dx Date	Adj #	CCC ID
18 10021	T		CCC-RC	Y	N	Y	N	N	N	N	Breast Cancer	07/21/00	7	13523

WHI Member Status: Full follow-up | mail: Y | Phone: Y | Dead: N | Death Date: | RC Responsible for Doc Requests: CCC-RC

Adj #	Case Status	Initial Abstractor	Assigned	Finished	Final Abstractor	Assigned	Finished	Payment	RC Closed	RC Use Only: Docs Scanned
9	Finished - needs Payment	Hicks, Joia	05/04/15	05/04/15	Hicks, Joia	05/02/16	05/02/16		N	04/21/16

CCC Comment: Per 340 ppt reports she had RAD Tx only. Please confirm.

RC Comment: Laura open case-after multiple attempts, including a phone call, unable to get more recent progress note past 2/2002-Kaite

[View Case Packet](#)

LILAC Visits

Visit	Prov Id	Provider Name	Start Date	End Date	Events	Amt Paid	Total Docs	Not Req	Not Rcvd	Comment	
1	90	1659 Group Health Central Hospital- Records	07/01/00	07/31/02	Chemo,Rad,Horm		19	0	0	UNK who her RAD & MED oncology	Edit Docs
2	90	1659 Group Health Central Hospital- Records	07/01/00		Recur-Unk		2	0	0		Edit Docs

[Create New Visit](#)

Deleted Visits

Visit	Provid	Deleted Provider Name	Start Date	End Date	Events	Comment	Deletion Date
3	90	1659 Group Health Central Hospital- Rec	01/01/12				01/27/16
4							04/21/16

LILAC Forms

Form	Ver	Date	Recur Case	Responses	PDF	
342	3	LILAC Breast Cancer Abstraction Form	05/02/06			
340	3	Lilac Baseline Questionnaire	11/22/13			
370	1	Lilac Annual Survey	03/06/15			

[Save](#) [Exit](#)

Status for Clinic Use:

Needs Provider Id
Needs Doc Request
Waiting for Docs
Needs Scanning
Needs Query Doc Req.
Waiting for Query Docs
Needs Query Docs Scanned
Scanned, not Received

Status for Abstractor Use:

Needs Initial Abstr
Init Abstr in Progress
Needs Final Abstr
Final Abstr in Progress
Finished – needs Payment
Finished

Click to view
visit details
(See Figure 2)

Click to create
a new visit

If F370 has a recurrence
investigation, the LILAC
Adj# of the recurrence
case appears here

Figure 2
LILAC Dashboard - Visit Details

Visit Details

Member ID: 11 10297 M Adj #: 4 Visit #: 5 Medical Record # (if avail.): Amt Paid for Records:

Treatment or Recurrence: ☐ Chemo ☐ Radiation ☒ Hormone Therapy ☐ Molecular Testing OR ☐ Known Recur OR ☐ Unknown Recur OR ☐ Metastasis

Start Date: 03/12/2011 End Date: 04/11/2013

Provider Information (For use on Medical Records Request Letter)

Provider ID: 86 1480 Select Edit Prov

Provider Name: Kovach, Mark MD

Address Line 1: 350 John Deere Rd

Address Line 2:

City: Moline State: IL Zip: 61265

Phone: (309) 743-6700 Fax:

Abstraction Form Provider Information (Optional)

For Abstraction Use Only:

Provider Name: Dr. Kovach (or F9 to copy details from another visit.)

Address Line 1:

Address Line 2:

City: State: Zip:

Phone: Fax:

Visit Comment: PCP as of 2010

Show Docs Save Exit

Click to view/request documents
(See Figure 3)

Figure 3
LILAC Dashboard – Request/Receive Documents

Click highlighted button to
run medical request letters

LILAC VISIT DOCUMENTS

Member ID	Visit	Visit Start	Visit End	Prov ID	Provider Name	Deceased	Breast Cancer
11 10297 M	5	03/12/11	04/11/13	86 1480	Kovach, Mark MD	N	

Lilac Visit Documents

Run Request Letter

First Request Second Request Third Request

Doc Set ID	Ver	Document Set Name	Request Priority	Doc #	Document Name	Request Date	Response Date	Request Date	Response Date	Request Date	Response Date	Document Status
3	2	Endocrine (hormone) Thera	1	4	Consult							
3	2	Endocrine (hormone) Thera	3	3	History & Physical							
3	2	Endocrine (hormone) Thera	2	2	Output report (All)							
3	2	Endocrine (hormone) Thera	8	8	Phys prog notes (most recent)							

Document Comment:

Provider Labels Download ROI Add Misc Doc(s) Save Exit

Run provider labels

View/Print ROI

Insert misc. doc(s)

Enter a description in
document comment
box

Figure 4
LILAC Dashboard – Medical Provider Screen

Medical Providers

Search For:

Use % as a wildcard e.g. %ospita% for hospital

(Double Click to select provider)

ID	Clinic	Name	Address	City	State	Zip Code
325	86	96th Medical Group Hosp.	Egla AFB	Fort Walton Beach	FL	32542
1097	86	Abbott Northwestern Hospital	800 E 28th St	Minneapolis	MN	55407-3799
54	86	Abbott Northwestern Med. Cen.	800 East 28th Street	Minneapolis	MN	55407
928	86	Accredited Dermatology Assoc.	2322 E Kimberly Rd	Davenport	IA	52807
186	86	Adair County Memorial Hospital	609 SE Kent Street	Greenfield	IA	50849
74	86	Advanced Foot & Ankle Clinic	2478 E. Euclid Ave.	Des Moines	IA	50317
721	86	Affinity Medical Group - Menasha	1550 Midway Place	Menasha	WI	54952
1094	86	Agrace HospiceCare		Madison	WI	
489	86	Akron General Med Ctr	400 Wabash Avenue	Akron	OH	44307
347	86	Alegent Mercy Hospital	P.O. Box 1C	Council Bluffs	IA	51502-3001

ID	Clinic	Name	Address	City	State	Zip Code
407	25	A. B. NORMAN	5340 51ST AVE N	MINNEAPOLIS	MN	55429-3612
509	56	A.C.T. Medical Group, S.C.	2473 McFarland Rd.	Rockford	IL	61107
17	25	ABBOTT-NORTHWESTERN HOSPITAL	800 EAST 28TH ST	MINNEAPOLIS	MN	55407
453	25	ABERDEEN HOSPITAL	NEW GLASGOW B 2H 356	NOVA SCOTIA		
308	56	Abbott Northwestern Hospital	800 E. 28th St.	Minneapolis	MN	55407
68	21	Academisch Ziekenhuis	Vrije Universiteit - afdeling neurologie	1007 MB Amsterdam		
23	21	Ackley Medical Center	416 Mitchell	Ackley	IA	50601
433	25	ACMC - REDWOOD FALLS	1100 E BROADWAY	REDWOOD FALLS	MN	56283
503	21	Adam, Diane MD	1100 6th	Coralville	IA	52241
335	11	Adams, John MD	1605 E Broadway	Columbia	MO	65201

Add New Provider Cancel

Click to add new provider details

Figure 5
LILAC Dashboard – New Provider Contact

Enter New Provider Contact Detail

Outcome Providers Maintenance Screen

Outcome Provider Organizations

Provider: Id:

Contact:

Address:

City: State: Zip:

Phone: Fax:

List of Values? ☒

Comment

Save Exit

After entering provider details,
click 'Save' then 'Exit'

After clicking 'Save' and 'Exit',
a new provider ID will be generated

The Dashboard tracks each step of the abstraction and ascertainment process in the LILAC case status block, Case Status field. *Table 2* summarizes operations by case status.

Table 2
Case Status

Order	LILAC Case Status	LILAC Case Status Description	Action	LILAC Dash Board Screen	LILLAC Reports
1	Needs Initial Abstr	Incident WHI cancer+ other CCC available cases need initial abstraction	CCC	LILAC Case	Cases to Assign Report (CCC)
2	Init Abstr in Progress	Initial abstraction, in progress	CCC	LILAC Case	Cases to Assign Report (CCC)
3	Needs Provider ID	Needs a Provider ID (create new, edit existing, or select from current provider list)	RC: Step 1	Visit details/Provider Information/Provider ID	1213-Open Cases Report
4	Needs Doc Request	Needs medical records document request	RC: Step 2	LILAC Visit Docs	Medical records request letters (4) and 1213-Open Case Report
5	Waiting for Docs	Waiting return of medical records documentation	RC: Step 3	LILAC Visit Docs	1213-Open Cases Report
6	Needs Scanning	Needs Scanning/uploading to CCC	RC: Step 4	LILAC Case	1213-Open Cases Report
7	Scanned, not Received	Scanned, not yet received at CCC	RC: Step 5	LILAC case	1213-Open Cases Report
8	Needs Final Abstr	Needs Final Abstraction	CCC	LILAC Case	Cases to Assign Report (CCC)
9	Final Abstr in Progress	Final Abstraction, in progress	CCC	LILAC Case	Cases to Assign Report (CCC)
10	Needs Query Doc Req.	Needs Query Document Request	RC: Step 6*	LILAC Visit Docs	1213-Open Cases Report
11	Waiting for Query Docs	Waiting return of query documents	RC: Step 7*	LILAC Visit Docs	1213-Open Cases Report
12	Needs Query Docs Scanned	Needs Query Docs Scanned/uploaded	RC: Step 8*	LILAC Case	1213-Open Cases Report
13	Scanned, not received	Closed and scanned, not yet uploaded to the CCC	CCC	LILAC Case	1213- Open Case Report
14	Finished - needs Payment	Case finished - needs Payment	KPNC	LILAC Case	1005 - Invoice Report
15	Finished	Finished (payment received)	KPNC	N/A	1005 - Invoice Report

*As needed

8.2 Regional Center Operation Instructions

The RC can use the LILAC Dashboard, *LILAC1213 – Open Cases Report*, or both to track and prioritize work.

8.2.1 Review Provider Information

1. The abstractor has identified the providers self-reported from the *Form 340* and/or the incident case as well as other adjudications available and providers listed in WHIX. The RC selects, edits, or creates a new provider(s) based on the information provided to ensure requests for records are sent to a valid provider.
2. The RC is not required to request records from each provider listed if the documentation is obtained from another provider. Use the listed providers to determine the best location from where to request records.
3. RCs may delete a provider which is determined not to be needed. This provider can only be deleted when there are no request dates. Select the appropriate Provider Visit row and click on the red X. Deleted providers will appear in the deleted visits block in the Dashboard. RCs are to include a comment as to why a provider was deleted (ex. MD retired).
4. Provider ID needed: The best provider details the CCC abstractor is recorded on the right side of the *Visit Details* screen under *Abstraction Form Provider Information* with additional details recorded in the ‘Visit Comment’ box. RC staff will need to verify and/or research the contact information for a new provider, most likely by conducting an internet search.

When the provider information has been obtained

- Create a new provider ID by clicking **Select** under *Provider Information*,
- From the *Medical Providers Screen* click **Add New Provider** and enter the details
- Click **Save**, then **Exit**.

In these instances, RC has the option to delete providers where no medical records have been requested.

See *Figure 5 – New Provider Contact* for screen shot.

5. Edit Existing Provider (with a provider ID):
From the *LILAC Visits* block in the main LILAC dashboard, identify the provider then click **Edit**. On the left side of the *Visit Details* screen under *Provider Information*, click **Edit Provider**. Make any edits to the provider information in the *Outcome Providers Maintenance* screen, click **Save**, then **Exit**. See *Figure 5* for screen shot.
6. In 2015, WHI mailed a ‘Contact Update’ form to all WHI participants. It is possible the participant has returned this form, which could contain new provider information, since the LILAC case went through initial abstraction at the CCC. RC staff can view the ‘2015 Contact Update’ in the main WHIX Member Data Entry/Member Details screen. If the ‘2015 Contact Update’ button is greyed out, the form has not been returned. Otherwise, click the button to view her responses.

8.2.2 Review/Edit Provider Details

Before printing the LILAC0980 – Request for Medical Records, consider the following questions:

- Is a medical record # needed on the request?
- Does a phone or FAX number need modification?
- Does an additional treatment type need to be added?
- To modify, EDIT the provider information in the LILAC Visit Details screen, Save and Exit, before printing.

Dates of Service

Each provider visit needs both a ‘Start’ and ‘End’ date before printing the LILAC0980 – Request for Medical Records. LILAC Abstractors will complete these dates using available records, when possible, but in some instances, RCs may need to add or modify dates of service. For additional information about how

dates of service are determined, see *Section 2.2 – Definitions of LILAC Study Cancer Related Information Treatment and Outcomes*.

When the end date is left blank, it will default to the date the LILAC 0980 is being run.

When date of death is known, the abstractor may not use it as the end date, because they have a different date available and can reduce the date window for investigation.

Edit Dates of Service

To change dates of service, select the appropriate provider and EDIT the provider information in the LILAC Visit Details screen. Click Save, and Exit.

8.2.3 Review Medical Records Documents

Each LILAC treatment and outcome of interest has a corresponding medical records document set. Unlike WHI, collection of all priority documents is not required. Any document that provides the needed treatment and recurrence information may be used. (See *Table 1 – LILAC Documentation Sets*.)

Note: The Radiation Summary is considered the source document (gold standard). RCs are strongly encouraged to locate this document. In its absence, it is acceptable to substitute another document, such as a progress note. The RCs may truncate the document set for an individual case, for example entering a status of “Doc not Needed” for a document they have already received from another provider.

See *Volume 8, Section 8.3.4 – Procedures for Requesting Medical Records Documentation* of WHI Extension Manual when accessing records online.

8.2.4 Download ROI

Click the ‘**Download ROI**’ button in the LILAC Visit Documents screen. For additional information about medical releases see *Section 4.3 – Release of Information (ROI) and Partial Waiver of Consent*.

8.2.5 Printing Medical Record Request

The LILAC0980 – Request for Medical Records report prints a medical record request letter for a specific provider visit. The printed request letters will vary based on the reported event(s):

- Treatment type(s)
- Documented/known recurrence occurred
- Unknown if recurrence
- Metastasis

When records are requested for more than one type of treatment for a Provider visit (e.g., Radiation, Chemotherapy &/or other targeted therapy), the report lists the documents under the specific treatment heading (e.g., Radiation Documents, Chemotherapy &/or other targeted therapy Documents, etc.).

If records are requested for both treatment for the initial cancer and a recurrence, WHIX prints two separate request letters. Treatment and recurrence requests are generated on separate letters because often the time intervals differ. In some situations, RC staff may prefer to add “Unknown Recurrence” as a “Misc. Document”.

Print the *LILAC0980 – LILAC Medical Record Request* report from LILAC Visit Document screen.

First request

Click **First Request** then **Run Report** to generate the *Medical Record Request (LILAC0980)*. Requests can be submitted to a medical facility via FAX or mail. Contact the facility to determine their preferred method

of receiving record requests. If necessary, call the facility to confirm they have received/are working on the request, to clarify dates of service, or for confirmation the participant was treated at the facility.

Re-requesting medical records

When medical records are received at the RC, enter the appropriate response codes in the 'Document Status' column. If the document set is incomplete, leave the 'Document Status' column blank and click **Second Request** to generate the updated *Medical Records Request (LILAC0980)* then resubmit to the medical records department. Click the **Third Request** button to request any remaining records. RCs have the option to make more than 3 requests, to do this, update the request date in the Third Request column. A document status needs to be changed for at least 1 document or the "1st Request" button will remain displayed. RC staff can click "1st Request" again, but the new request date will replace the original request date. Multiple request dates can be documented in the "doc comment" box to show all request attempts by the RC. See *Section 8.2.6 – Required Attempts for Medical Records* for require attempts.

8.2.6 Required Attempts for Medical Records

If three request attempts fail to yield all records in the document set, enter the appropriate code indicating the document is not part of the case. The case can be closed/scanned after three attempts, including at least one phone contact, to obtain medical records from all credible providers entered by the abstractor and any providers discovered by the RC. See *Section 5.2 – Review of Received Medical Record Documents* for additional information.

LILAC is using a guideline of 3 requests per provider, with the caveat that the requests are made using a variety of communication modes (fax, phone, etc.) over a period of time (e.g., 2-3 months) to providers that are strong candidates for appropriate records. Administrative requests, e.g., to verify DOS or update DOB on a request letter as a request for records are not considered a formal request.

If a case is being closed without all required information, make a note in the visit comments field indicating the following:

- 1) Acknowledge what is missing
- 2) Document what was attempted to obtain the information
- 3) Document why it didn't work

8.2.7 Reconciling Medical Records

Upon receipt of the medical records, a document status code is required for each document requested. Mark the status code under the 'Document Status' Column in the LILAC Visit Documents screen. See table with codes below:

Table 3
Case Status Types

ID#	Document Description
1	Document Received
2	Document Not Needed
3	Document Does Not Exist
4	Release is Not Valid
5	Patient Not Found
6	Visit for Patient Not Found
7	Denied for Other Reason

When all documents for all provider visits in a LILAC case have a status code (received, document not needed, etc.), review and scan the case. If no records were requested for a provider, RCs have the option to delete this provider from the Dashboard. The only status code which can be entered without a request date is Code 2 –Document Not Needed.

8.2.8 Case Assembly

From the RUN menu in the in the LILAC Dashboard, print the following reports:

- LILAC0988-Investigation Documentation Summary (IDS).
- Case ID cover sheet (CASECVR)

Organize the case in the following order:

1. Case ID cover sheet with barcode
2. IDS
3. Medical records documentation assembled as described above under-case assembly

8.2.9 Scan LILAC Case and Enter Scan Date

Enter the scanned date (in the purple “RC Use Only Docs Scanned” box) in the LILAC Case block/LILAC Dashboard. The scanned date is equivalent to the WHIX ‘Case Closed Date’.

All cases must be scanned to the CCC even if no records were received. In the absence of medical records, include some form of documentation indicating the reason records were not received (e.g., received a provider letter stating medical records were destroyed).

8.2.10 Query Process

The central abstractor may initiate a query and ask the RC to re-request specific documents from a provider if a required document is missing and the RC did not provide a detailed explanation as to why the needed document was not included in the case.

The case will reappear on the *LILAC1213 - Open Cases* report with the status ‘Needs Query Doc Request’. Process the record request in the same manner as when collecting initial records, including **entering a new scan date**. See *Section 5.5 - Query for Additional Medical Records* for additional query information. Queries are due one month after they appear on your 1213 report.

8.2.11 Medical Records Applicable to Both WHI and LILAC Cases

It is possible WHI medical records may be received while investigating a LILAC case and vice versa. You may receive LILAC records when processing a WHI case, and vice versa. It is ideal to keep LILAC and WHI case records separate, i.e., scan LILAC only records, such as treatment records, with the LILAC case. This is to ensure RCs are paid for the LILAC case work and WHI cases are routed to the appropriate committees.

9 LILAC RC Reports

The RC-specific reports and printable items needed to identify cases and request medical records are located on the Dashboard, with the exception of the Participant labels which are only available from the WHIX menu.

9.1 Main LILAC REPORTS Menu

- LILAC1213 – Open Cases
- LILAC0977 – Outcome Condition Documents
- LILAC1001 Case Summary Report

- LILAC 0986 Cases to archive or destroy
- LILAC 1009 RC Caseload

Figure 6
Reports Menu



9.1.1 LILAC1213 - Open Cases Report

The *LILAC1213 – Open Cases* report provides a summary of all LILAC cases needing RC attention (e.g., providers needing an ID, document requests, query follow-up, etc.).

The report contains the following columns:

- Participant ID
- Participant Name (Last, First, MI)
- LILAC Adj. #
- Case Status ('current' status of LILAC case)
- Death (N/Y)
- Cancer site
- Provider Information:
 - Visit #
 - ID (Provider ID)
 - Name (Provider Name)
- Visit Status ('current' status of each Provider visit within a LILAC case)
- Latest Request (date records last requested)

Eight 'Case Status' show on the *LILAC1213 – Open LILAC Case* report that require RC action:

- Needs Provider ID
- Needs Doc Request
- Waiting for Docs
- Needs Scanning

- Scanned, not Received
- Needs Query Doc Request
- Waiting for Query Docs
- Needs Query Docs Scanned

Run the *LILAC1213 – Open LILAC Cases* report using any of the following options:

1. Ordered by: Participant ID, Participant Name, or Case Status
 - a. Case Status (LILAC case status, then participant ID)

The LILAC Case Status is based on the highest priority task required for ANY provider visit within the case. Example: A LILAC case has two provider visits; one provider needs a provider assigned, but the second provider has records requested and is now waiting for documents to return. In this example, the overall LILAC case has a status of 'Waiting for Docs'.

2. Filter by: Investigation Required, Ramsey cases only
 - a. RCs should run the 1213 using the 'Investigation Required' option. The 'Ramsey case only' filter was used by RCs working on specific group of breast cancer cases for the Ramsey group. Most RC have completed all of their Ramsey cases, making this filter unnecessary.
3. Cancer Type: Select a specific cancer site or run using the 'All cancer types' option (based on current study priorities).

Peritoneum and fallopian tube sites do not appear on the ovarian specific report. Their reports are run separately (or identified on the all-cancer site option) and coded on the Ovarian Abstraction form.

4. Docs Requested By: Select 'RC' as the default.

Run the *LILAC1213 – Open Cases* report using the 'Case Status' (or Participant ID) option. The report will prioritize the LILAC cases by the importance of task that needs to be done.

- Priority 1: actions to request medical records:
 - Needs Provider IDs
 - Note: All provider visits MUST have an ID assigned before documents can be requested.
 - Needs Doc Request
- Priority 2: actions to track and follow-up on medical record requests:
 - Waiting for Docs (may still have provider visits not yet initiated)
- Priority 3: actions to close and scan the case to the CCC:
 - Needs Scanning
 - Scanned, not Received
 - Note: When all documents for all provider visits have a status code (received, no doc, not needed, etc.), review and scan the case.
 - LILAC cases drop off the report when the CCC uploads the batched cases once a week. So, closed cases will not immediately disappear from the *LILAC1213 – Open Cases* report.

If a LILAC Adjudicator needs additional information for the case, the case will reappear on the *LILAC1213 – Open Cases* report for RC follow-up with the status 'Needs Query Doc Request'. It is the responsibility of the RC to run the *LILAC1213 – Open Cases* report to identify new queries.

- Priority 4: actions to identify and follow-up on case queries.
 - Needs Query Docs
 - Waiting for Query Docs
 - Needs Query Docs Scanned

Note: If a LILAC case has more than one Provider visit and both visits have a Visit Status of ‘Waiting for Docs’ or ‘Waiting for Query Docs’, the dates in the ‘Latest Request’ column are used to order the Provider visits oldest to newest.

9.1.2 LILAC0977 - Outcome Condition Documents Report

Displays the document sets for cancer specific treatment and recurrence.

9.1.3 LILAC0986 - Cases to Archive or Destroy

Displays cases eligible for archive or shredding. A case will display 90 days post abstraction.

9.1.4 LILAC1009 - RC Caseload

Displays RC workload by cancer site

9.2 LILAC Dashboard RUN Menu Reports

The following reports are run for open cases from the LILAC dashboard RUN menu:

- *LILAC0988 – Investigation Documentation Summary (IDS)*
- Case Coversheet

Figure 7
LILAC Dashboard – Run Menu

9.2.1 LILAC0988 – IDS (Investigation Documentation Summary)

Summarizes the provider visit and document details for all provider visit attached to each case. Print and place on top of the LILAC case before scanning.

9.2.2 Outcomes Case ID Cover Sheet with QR Code

The Outcomes Case ID Cover Sheet is the case-specific report attached to each completed case before it is scanned. The report includes the QR code required for scanning. The instructions for scanning and uploading LILAC cases to the CCC are identical to WHI and can be found in section 8.4.7 – Regional Center Scanning .of the WHI Manual

See Outcomes *Section 8.4.3 – Preparing and Electronically Routing the Adjudication Case Packet to the CCC* for detailed scanning instructions.

9.3 LILAC Dashboard Reports

The following reports are located and printed directly from the LILAC Dashboard:

- LILAC0980 – Request for Medical Records Letters (4 options)
- Signed Participant ROI

Provider labels are available if an RC wishes to use them, but they are not required.

See *Figure 6 – Reports Menu* for report locations.

9.3.1 LILAC0980 – Request for Medical Records

The *LILAC0980 – Request for Medical Records* report prints a medical record request letter for a specific provider visit.

The printed request letters will vary based on the reported event(s):

- Treatment type(s)
- Documented/known that recurrence occurred
- Unknown if recurrence occurred
- Metastasis

When a participant reports more than one type of treatment for a Provider visit (e.g., Radiation, Chemotherapy &/or other targeted therapy), the report lists the documents under the specific treatment heading (e.g., Radiation Documents, Chemotherapy &/or other targeted therapy Documents, etc.).

If a participant reports both treatment for the initial cancer and a recurrence, WHIX prints two separate request letters. Recurrence and treatment have different dates of service and document sets.

To print the *LILAC0980 – LILAC Medical Record Request* report, each Provider visit needs both a ‘Start’ and ‘End’ date. LILAC Abstractors will complete these dates using available records when possible, but in some instances, RCs may need to enter or modify dates of service. There will be instances when the end date is blank, in which case the current date will print on the report in lieu of an end date in calendar format. See *Section 4.5.1* for definitions of dates of service.

Before printing a *LILAC0980 – LILAC Medical Record Request*, consider the following questions:

- Are there any documents that do not need to be requested (e.g., Discharge Summary because the visit is outpatient)?
 - If yes, EDIT the ‘Document Status’ in the LILAC Visit Documents screen before printing.
- Is the Medical Record # needed on the request?
- Does an additional treatment type need to be added?
- Do dates of service need to be modified?
- Does the phone or fax # need to be modified?
 - If yes to any of the four questions above, EDIT the provider in the LILAC Visit Details screen before printing.

9.3.2 Participant-Specific ROI

9.3.3 Provider Labels

9.4 Table of Reports

Table 4
Table of Reports

Report Number/Name	Report Purpose	Report Run Location
LILAC1213 – Open Cases	Displays a summary of all open LILAC cases requiring RC follow-up, e.g., initial medical records requests. Report can be ordered by participant ID, name or one of the eight case statuses: – needs Provider ID – needs Doc Request – waiting for docs – needs scanning – needs query doc request – waiting for query docs – needs query docs scanned – scanned, not received Case status is the recommended sort option, ordering tasks chronologically with the lowest status of any provider visit listed first. If > visit within a case and the case status is identical, the report will further sort by the oldest records request.	LILAC Reports menu
LILAC0980 – Request for Medical Records	Medical records request letters, specific to treatment and recurrence/metastases, respectively.	LILAC Dashboard, Documents Screen
LILAC0977 – Outcome Condition Documents	Displays the document sets for cancer specific treatment and recurrence.	LILAC Reports menu
LILAC0988 – IDS	(Investigation Documentation Summary) Summarizes the provider visit and document details attached to each case.	LILAC Dashboard Run menu
LILAC1001 – Case Summary	Displays summary of work load and case progress by each RC	LILAC Reports menu
LILAC 1005 – Invoice Report	Displays summary of closed cases waiting for payment	LILAC Reports menu
LILAC 0986 – Cases to destroy or archive	Displays cases eligible to for shred or archive.	LILAC Reports menu
LILAC 1009 –RC Caseload	Displays RC workload by cancer site	LILAC Reports menu

Other Printable Forms	Purpose	Print Location
ROI	To send hard copy of participant-signed ROI to providers	LILAC Dashboard, Documents Screen
Participant Labels	For identification and mailings	WHIX
Provider Labels	For mailings	Link in LILAC Dashboard, Documents Screen
Run Case Cover Sheet	The scanning case ID cover sheet added to the case prior to scanning	LILAC Dashboard Run menu

9.5 Other LILAC Resources Located on SharePoint

- Fact Sheet and Study Population
- Consent, Invitation Letter, and Baseline Questionnaire
- Organization Chart
- Blank LILAC ROI
- Medical Records Request Letters (4 templates)
- Delineation of approximate number of LILAC cases per Regional Center
- Custom Data Extract (CDE)
- Partial Waiver of Consent
- Cover letter for institute specific ROI
- Abstraction Forms - by cancer site
- Continuation Review Report (CRR)
- RC call minutes
- RC call audio recordings (starting 9/16)

APPENDICES

Appendix A: Bisphosphonates/Bone Loss Medications Reference List

Generic Name	Trade Name
bevacizumab	Avastin
etidronate	Didronel
clodronate	Bonefos
clodronate	Loron
tiludronate	Skelid
pamidronate	APD
pamidronate	Aredia
neridronate	Nerixia
olpadronate	
alendronate	Fosamax
ibandronate	Boniva
zoledronate	Aclasta
zoledronate	Zometa
Denosumab	Prolia
Denosumab	Xgeva
exemestane	Aromasin
exemestane	
fluoxymesterone	Halotestin
fluoxymesterone	Fluoxymes
fluoxymesterone	Fluoxymesterone

Appendix B: Endocrine-Targeted (Hormone Therapy) Reference List

Generic Name	Trade Name
tamoxifen	Tecnotax
tamoxifen	Nolvadex
tamoxifen	Tamone
tamoxifen	Tamox
tamoxifen	
raloxifene	
raloxifene	Evista
anastrozole	Anastrozole
anastrozole	Arimidex
megestrol acetate	Megestrol Acetate
megestrol acetate	Megace
goserlin	
goserlin	Zoladex
leuprolide	Leuprolide
leuprolide	Lupron
aminoglutethimide	Aminoglutethimide
aminoglutethimide	Cytadren
toremifene	
toremifene	Fareston
letrozole	
letrozole	Femara
diethylstilbestrol	
diethylstilbestrol	DES
fulvestrant	Faslodex
fulvestrant	
exemestane	Aromasin
exemestane	
fluoxymesterone	Halotestin
fluoxymesterone	Fluoxymes
fluoxymesterone	

Appendix C: Chemotherapy and Other Biologics Reference List

Generic Name	Trade Name
Mechlorethamine	Mustargen
Mechlorethamine	Nitrogen mustard
Mechlorethamine	Mustine
Mechlorethamine	Mechlorethamine HCl
Mechlorethamine	
Melphalan	Alkeran
Melphalan	Megace Alkeran
Melphalan	L-PAM
Melphalan	L-Sarcolysin
Melphalan	Phenylamine mustard
Melphalan	
Cyclophosphamide	Cytosan
Cyclophosphamide	Neosar
Cyclophosphamide	
Ifosfamide	Ifex
Ifosfamide	
Chlorambucil	Leukeran
Chlorambucil	
Thiotepa	Thioplex
Thiotepa	TESPA
Thiotepa	Thiophosphoamide
Thiotepa	TSPA
Thiotepa	
Altretamine	Hexalen
Altretamine	Hexamethylmelamine
Altretamine	HMM
Altretamine	
Busulfan	Busulfex
Busulfan	Myleran
Busulfan	
Procarbazine	Matulane
Procarbazine	
Dacarbazine	DTIC-Dome
Dacarbazine	DTIC
Dacarbazine	DIC
Dacarbazine	Imidazole Carboxamide

Generic Name	Trade Name
Dacarbazine	
Temozolomide	Temodar
Temozolomide	
Carmustine	BiCNU
Carmustine	BCNU
Carmustine	
Lomustine	CEENU
Lomustine	CCNU
Lomustine	
Streptozocin	Zanosar
Streptozocin	
Cisplatin	Platinol
Cisplatin	Platinol-AQ
Cisplatin	CDDP
Cisplatin	
Carboplatin	Paraplatin
Carboplatin	
Oxaliplatin	Eloxatin
Oxaliplatin	
5 -FU	Adrucil
5 -FU	Fluorouracil
5 -FU	5-fluorouracil
5 -FU	
Floxuridine	FUDR
Floxuridine	
Cytarabine	Cytosar-U
Cytarabine	Ara-C
Cytarabine	Arabinosylcytosine
Cytarabine	
Capecitabine	Xeloda
Capecitabine	
Gemcitabine	Gemzar
Gemcitabine	
Methotrexate	Rheumatrex
Methotrexate	Trexall
Methotrexate	Amethopterin
Methotrexate	Methotrexate sodium
Methotrexate	MTX

Generic Name	Trade Name
Methotrexate	
6-Mercaptopurine	Purinethol
6-Mercaptopurine	6-MP
6-Mercaptopurine	
Thioguanine	6-Thioguanine
Thioguanine	6-TG
Thioguanine	2-Amino-6-Mercaptopurine
Thioguanine	
Cladribine	Leustatin
Cladribine	2-CdA
Cladribine	2-Chlorodeoxyadenosine
Cladribine	
Fludarabine	Fludara
Fludarabine	
Pentostatin	Nipent
Pentostatin	
Doxorubicin	Adriamycin
Doxorubicin	Rubex
Doxorubicin	
Daunomycin	Cerubidine
Daunomycin	Daunorubicin hydrochloride
Daunomycin	Rubidomycin hydrochloride
Daunomycin	
Mitoxantrone	Novantrone
Mitoxantrone	DHAD
Mitoxantrone	
Idamycin	Idamycin PFS
Idamycin	
Epirubicin	Ellence
Epirubicin	
Doxorubicin	Doxil
Dactinomycin	Cosmegen
Dactinomycin	Actinomycin-D
Dactinomycin	
Mitomycin	Mutamycin
Mitomycin	Mitomycin-C
Mitomycin	MTC
Mitomycin	

Generic Name	Trade Name
Bleomycin	Blenoxane
Bleomycin	
Paclitaxel	Taxol
Paclitaxel	Onxal
Paclitaxel	
Docetaxel	Taxotere
Docetaxel	
Paclitaxel	Abraxane
Vincristine	Oncovin
Vincristine	Vincasar Pfs
Vincristine	Vincristine Sulfate
Vincristine	LCR
Vincristine	VCR
Vincristine	
Vinblastine	Alkaban-AQ
Vinblastine	Velban
Vinblastine	Vinblastine Sulfate
Vinblastine	Vincaleukoblastine
Vinblastine	VLB
Vinblastine	
Vinorelbine	Navelbine
Vinorelbine	
Etoposide	Toposar
Etoposide	Vepesid
Etoposide	Etopophos
Etoposide	VP-16
Etoposide	Etoposide phosphate
Etoposide	
teniposide	Vumon
teniposide	VM-26
teniposide	
Irinotecan	Camptosar
Irinotecan	Camptothecin-11
Irinotecan	CPT-11
Irinotecan	
Topotecan	Hycamtin
Topotecan	

Appendix D: Glossary of Terms

TERMS	EXPLANATION	LOCATION IN MEDICAL RECORDS
Ablation	A treatment that destroys very small tumors.	Operative
Adenocarcinoma	Cancer arising in adenomatous (glandular) tissue.	
Adjuvant Treatment	Treatment that follows primary treatment. Usually given after surgery where all detectable disease has been removed but where there remains a statistical risk of relapse due to occult disease. Adjuvant therapy may include chemotherapy, radiation therapy, hormone therapy, targeted therapy, or biological therapy.	Consultation
ALK testing	To identify the ALK (anaplastic lymphoma kinase, also known as tyrosine kinase receptor) gene in tumor samples.	
Aromatase Inhibitor (AI)	Aromatase Inhibitors -- These drugs, known as <u>AIs</u> , block the body's means of making estrogen via the enzyme aromatase. These drugs are now considered to be first-line endocrine therapy for metastatic estrogen-receptor positive breast cancer in post-menopausal women. They are also considered to be first-line adjuvant therapy for "curable" estrogen-receptor positive breast cancer in women who are beyond menopause. In both these scenarios, AIs are more effective than SERMs.	
Ascites	Abnormal buildup of fluid in the belly area (abdomen) or pelvis.	
Axillary	Body area under the armpit	
BSO	As seen in medical records this indicates a Bilateral Oophorectomy	
Benign Neoplasm/ Benign Tumor	A non-cancerous growth.	Pathology
Biopsy	A medical procedure to remove a small amount of tissue or fluid to determine the presence or extent of disease.	
Bisphosphates	A class of drugs that prevent the loss of bone mass, used to treat osteoporosis and similar diseases.	
Brachytherapy	Also called interstitial radiation. Involves placing radioactive objects in or near to where the tumor was located. Brachytherapy may also be given to boost EBRT for those women who had a lumpectomy.	Consultation
Bronchial carcinoma	Lung cancer.	
Cancer Registry	A cancer reporting system for the centralized collection of information on all cancers diagnosed within a geographic region or hospital. Information on cancer is collected using standardized methods and recording forms. This information is entered into a computerized database which is maintained on an ongoing basis and updated as reports of new cases of cancer are received. The best known set of cancer registries in the United States is the SEER system (See SEER).	
Carcinoma	Cancer of epithelial cell origin. Most cancers diagnosed in the U.S. are carcinomas.	
Carcinoma in Situ	A localized cancer that has not grown beyond the layer of tissue in which it originated, i.e. which has not extended into the surrounding tissue. In situ cancers are usually small and well-differentiated, and are usually cured by surgical removal.	Pathology
Chemotherapy	Generally given in cycles of treatment days followed by days of rest. The cycles vary in length dependent on drugs given. Cycles are generally 14, 21, or 28 days long. It is given orally as a pill or intravenously into a vein with a needle. Chemotherapy is given as a single agent or as a combination of drugs called a chemotherapy regimen which increases the odds that more cancer cells will be eradicated.	

TERMS	EXPLANATION	LOCATION IN MEDICAL RECORDS
Codons	3 nucleoids that make up amino acids in gene cells. Codons are contained in the exons.	
Colectomy	Operation to removal the colon (large bowel) or a segment of it. Commonly done in people with colon cancer.	Operative
Colonoscopy	A procedure in which the inside surface of the colon (large bowel) is examined using a colonoscope . Colonoscope is a flexible hollow tube that is inserted into the colon via the rectum. It uses fiberoptic technology to allow direct visualization of the inside of the bowel without an operation. Sigmoidoscopy is a more limited form of colonoscopy in which only the sigmoid colon (the segment of colon closest to the rectum) is analyzed.	Procedure/ Operative
Colostomy	Opening of the colon onto the abdominal wall, formed by means of surgery. The colon discharges its contents through a stoma (opening in the abdominal wall) into a colostomy pouch. This procedure is sometimes done in patients with cancer of the colon or rectum if it is not possible to reconnect the two ends of the bowel after removing the tumor.	Operative
Concurrent Chemoradiation	Chemotherapy given at the same time as radiation therapy.	
Contralateral	On the other side of the body/organ than the symptom or disease.	
Core Needle Biopsy	Hollow needle is used to withdraw small cylinders (or cores) of tissue from the abnormal area. The needle is put in 3 to 6 times to get the samples, or cores, which is more likely to provide better results because more tissue is taken.	Operative
CT (computed tomography)	A test that combines many x-rays to make pictures of the inside of the body.	
Cytology Report	Report on characteristics of a specimen of cells. The cells are stained and examined under a microscope to look for changes in cell appearance suggestive of cancer. Special stains are sometimes used to detect tumor markers.	Lab or pathology
Cytostatic	Cytostatic refers to a cellular component or medicine that inhibits cell growth.	
Debulking procedure	An operation to reduce the size of a cancerous tumor. This is done to relieve symptoms and/or slow the progression of the disease, in cases where complete removal of the tumor is not feasible.	Operative
DIEP Flap	Blood vessels, skin, and fat from the lower abdomen used in breast reconstruction	Operative
Ductal carcinoma	A type of breast cancer that arises in the milk-carrying ducts of the breast.	
EBRT	External beam radiation therapy	Consultation
EGFR testing	To identify the epidermal growth factor receptor in cells.	Lab or pathology
Endocrine Therapy	i.e. hormone therapy; Treatment that adds, blocks, or removes hormones.	
Endometrial aspiration	Removal of tissue lining the uterus using a suction device that is inserted into the uterus via the vagina and opening in the cervix. The tissue is then submitted for histology (tissue analysis). This is usually done to screen for endometrial cancer.	Procedure/ Operative
Endometrial biopsy	See Endometrial aspiration.	
Endometriosis	Benign overgrowth of endometrial (uterine lining) tissue outside of the uterus. Occurs predominantly in premenopausal women. Should not be confused with endometrial carcinoma.	

TERMS	EXPLANATION	LOCATION IN MEDICAL RECORDS
Estrogen Receptor Assay (ERA)	A test done in women with breast cancer to see if the tumor cells have estrogen receptors. Tumor cells with estrogen receptors are called estrogen receptor positive (ER positive) . The results of this test are considered when planning treatment. Women with ER positive tumors are sometimes treated with an anti-estrogen drug called Tamoxifen in order to reduce the risk of tumor recurrence.	Lab or pathology
Exfoliative Cytology	Specimen of loose cell scrapings taken for pathology, usually to check for cancerous changes. Cells may be obtained from a number of different sites, depending on what type of cancer is suspected, e.g. bronchial brushings to look for lung cancer, Pap smear to look for cervical cancer.	Pathology
Exons	The coding parts of gene cells.	
External Beam Radiation (EBRT)	Delivers radiation from a machine outside the body.	Consultation
Extracorporeal Circulation Technique (ECC)	A procedure using apparatus outside the body in which blood is taken from a patient's circulation to have a process applied to it before it is returned to the circulation.	
Fine Needle Aspiration (FNA)	A medical procedure to remove either fluid from a cyst or a small group of cells from a tumor.	Operative
Flap Procedure	Tissue taken from one area of the body and used in another area.	Operative
Flow Cytometry	Flow cytometric DNA analysis of tumor cells provides information on both the nuclear DNA content (DNA ploidy), which is often abnormal in primary tumor cells, and the percent in the S-phase (S-phase fraction, SPF), which is a measure of the proliferative rate of a growing cell population.	Pathology
Gene test	A gene test looks at 21 genes to give a score of high, intermediate, or low risk for recurrence. A low recurrence score below 18 means one can safely skip chemotherapy but still must take hormone therapy. A high recurrence score means that chemotherapy should be taken with hormone therapy. A decision should be based on a number of factors, including age and person preferences.	Lab
Gluteal Free Flap	Superior GAP—skin and fat removed from upper buttock; Septocutaneous GAP— skin and fat removed from between the gluteus medius and maximus muscles; and Inferior GAP—skin and fat removed from lower buttock	Operative
Grade	A term used to describe how malignant the cancer cells are and how closely the cancer cells look like normal cells. Higgrade tumors are very malignant and are generally associated with a poor prognosis, while low-grade tumors are less malignant and are generally associated with a better chance of cure.	Pathology
Her2neu	Is a <u>protein</u> that in humans is encoded by the <i>ERBB2</i> <u>gene</u> . HER2 is a member of the <u>epidermal growth factor receptor</u> (EGFR/ErbB) family. <u>Amplification</u> or over-expression of this gene has been shown to play an important role in the development and progression of certain aggressive types of <u>breast cancer</u> . In recent years the protein has become an important <u>biomarker</u> and target of therapy for approx. 30% of <u>breast cancer</u> patients	Lab or pathology
Histology	The characteristics of a tissue biopsy specimen at a microscopic level. This is similar to cytology, except that intact tissue is examined rather than loose cells. Histology is generally superior to cytology for diagnosing and characterizing cancer.	Pathology
Hodgkin's Disease	A cancer of the white blood cells, a type of lymphoma. (See Lymphoma).	

TERMS	EXPLANATION	LOCATION IN MEDICAL RECORDS
Hormone Receptor	See Estrogen Receptor Assay and Progesterone Receptor Assay .	Lab or pathology
Hysterectomy	Surgical removal of the uterus, usually done through an incision in the abdominal wall. However some hysterectomies are done vaginally, which requires a shorter hospital stay, and is sometimes done as a day surgery.	Operative
IHC Testing	Immunohistochemistry—A test of cancer cells to find specific cell traits involved in abnormal cell growth.	Lab or pathology
Incisional biopsy	A medical procedure to preserve the histologic architecture of the tissue cell while removing a sample of tissue for microscopic evaluation.	
Invasive/invasion	Tumor that extends locally beyond the layer of tissue in which it originated. Indicates more advanced disease than the non-invasive counterpart.	
IORF	Intraoperative radiation therapy	Operative
Intrathecal chemo	refers to something introduced into or occurring in the space under the arachnoid membrane of the brain or spinal cord ; the 3 licensed agents are methotrexate, cytarabine, and hydrocortisone	
Isolated Limb Perfusion	Considered (for LILAC purposes) a “local” therapy. This treatment consists of isolating the limb from systemic circulation wherein a limb perfusion is performed with a cytostatic drug for 60 minutes with extracorporeal circulation technique (ECC).	
KRAS testing	To identify if cells have the K-RAS protein.	Lab or pathology
Latissimus Dorsi Flap	The large, flat muscle of the back posterior to the arm, beginning near the armpit.	Operative
Leukemia	Cancer of the white blood cells. There are several different types e.g. chronic myeloid leukemia, acute lymphoblastic leukemia.	
LDCT (low dose computed tomography)	A test that uses little amounts of radiation to make pictures of the insides of the body.	
LHRH	Luteinizing hormone-releasing hormone (see Ovarian Ablation).	
Lobe	A clearly seen division in the lungs.	
Lobectomy	The removal of an entire lobe of the lung.	Operative
Lobular carcinoma	A type of breast cancer that arises in the lobules (glandular tissue) of the breast.	
Lumpectomy	A colloquial term used to describe the removal of a breast cancer (or other type of breast lump) without removing the whole breast.	Operative
Lymph node dissection	All groups of disease-fighting cells are removed from a cluster.	
Lymph node sampling	One group of disease-fighting cells is removed from a cluster.	
Lymphadenectomy	Surgery to remove lymph nodes.	Operative
Lymphoma	Cancer of the lymph nodes. There are two major types of lymphoma: Hodgkin’s disease or Hodgkin’s lymphoma , and non-Hodgkin’s lymphoma .	
Malignancy	Cancer.	
Malignant	Cancerous.	
MammaPrint	A 70-gene panel developed for patients under age 55 who had lymph node negative breast cancers. MammaPrint categorizes tumors as either high or low risk. This panel is marketed by Agendia and is for use in breast cancer status irrespective of ER status. The panel traditionally used rapidly frozen tissue but there is also a room temperature, molecular fixative available for use within 60 minutes of obtaining fresh tissue samples.	Lab

TERMS	EXPLANATION	LOCATION IN MEDICAL RECORDS
Mammogram	A special type of x-ray of the breasts used to detect breast cancer in its early stages when it is still too small to be felt as a lump.	Radiology
Mastectomy	Removal of the breast. Removal of the breast alone is sometimes called a simple mastectomy . A more extensive operation in which the underlying pectoralis major muscle and all the lymph nodes in the armpit are removed, as well as the breast, is known as a radical mastectomy . This is sometimes done in cases where the breast cancer tumor is large and locally-invasive at the time of diagnosis. A more limited procedure in which only a part of the breast is removed (usually one quadrant) is known as a partial mastectomy . This is sometimes done for in situ breast cancer.	Operative
Mediastinal nodes	Groups of disease-fighting cells in the middle of the chest.	
Mediastinoscopy	Use of a thin tool inserted above the breastbone to do work in the middle of the chest.	
Medical Oncologist	A physician who specializes in all types of cancer.	
Melanoma	A cancer that arises from melanocytes, the cells in the skin that produce brown pigment. Although most melanomas occur on the skin (most commonly on the leg, foot, or the face), melanomas are generally not called skin cancer. However so as to make the distinction between melanomas and other cancers that occur on the skin clear, other skin cancers are sometimes referred to as “non-melanoma skin cancer”. This distinction is important because melanomas often metastasize to other sites can be fatal, whereas non-melanoma skin cancers rarely metastasize and are rarely fatal.	
Menopause	The end of menstrual periods which can be natural, medical, or surgical means.	
Metastases (Mets.)	Satellite cancer tumors occurring at a site in distant to the site of origin, i.e. not directly contiguous to the primary tumor.	
Microinvasion	A microscopic evaluation by a pathologist and refers to tumor invasion of 0.1 cm or less in greatest dimension. Oftentimes you will see the TNM staging as Tmic. Microinvasion is documented either in the final diagnosis or the microscopic section of the pathology report.	
Molecular Profile	An individual’s genetic profile. Serves as a prognostic indicator of risk recurrence and chemotherapy benefit. Recurrence risk score is reported as low or high. Note: typically not located in the original pathology report. Located in cases < 5 years old.	Lab or pathology
MRI (magnetic resonance imaging)	A test that uses radio waves and powerful magnets to see the shape and function of body parts.	
Neoadjuvant treatment	Treatment given as a first step to shrink a tumor before the primary treatment, which is usually surgery. Examples of neoadjuvant therapy include chemotherapy, radiation therapy, and hormone therapy. It is a type of induction therapy.	Consultation
Neoplasm	Synonym for a tumor. Literally means “new growth”. This term may be applied to benign tumors as well as cancers.	
NOS	Not otherwise specified	

Omentectomy	Refers to the surgical removal of the omentum, a relatively simple procedure with no major side effects, that is performed in cases where there may be spread of cancerous tissue into the omentum. Examples for this are ovarian cancer and advanced or aggressive endometrial cancer as well as intestinal cancer. The procedure is generally done as an add-on when the primary lesion is removed.	
Oncology Consult	Consult by a physician who is specialized in the clinical management of people with cancer.	Consultation
Oophorectomy	Removal of the ovary. “Bilateral oophorectomy” means removal of both ovaries. If the fallopian tube is removed with the ovary, the procedure is sometimes called salpingo-oophorectomy.	Operative
Oncotype DX	Sometimes known as the 21-gene assay. It was designed for use in ER positive tumors. The test is run on formalin fixed, paraffin-embedded tissue. Oncotype results are reported as a Recurrence Score (RS), where a higher RS is associated with a worse prognosis, which refers to the likelihood of recurrence without treatment. Also, a higher RS is associated with a higher probability of response to chemotherapy. Endorsed by American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN). Developed by Genomic Health laboratory.	Lab
Osteoporosis	A disease that causes thinning, weakened bones.	
Ovarian Ablation	Removal of the ovaries that stops most estrogen from being made. This procedure can be done by surgery, radiotherapy, or by drugs that block estrogen production. LHRH (luteinizing hormone-releasing hormone) block estrogen production by the ovaries by stopping LHRH from being made in the brain.	
Palliative Therapy	Treatment given to relieve the symptoms and reduce the suffering caused by cancer and other life-threatening diseases. Palliative cancer therapies are given together with other cancer treatments, from the time of diagnosis, through treatment, survivorship, recurrent or advanced disease, and at the end of life.	
Papillary	A descriptive term applied to tumors (benign or cancerous) that have multiple finger-like protrusions when examined under the microscope.	
Partial Breast Irradiation	Radiation to the lumpectomy site.	
Pathology	The branch of medicine that deals with the laboratory examination of samples of body tissue for diagnostic purposes.	
Pathologic Stage	Stage of cancer assigned by a pathologist based on surgical samples.	Pathology
Pelvic Exenteration	Also called pelvic evisceration, this is a radical surgical treatment that removes all organs from a person's pelvic cavity . The urinary bladder , urethra , rectum , and anus are removed. The procedure leaves the person with a permanent colostomy and urinary diversion . In women, the vagina , cervix , uterus , fallopian tubes , ovaries , and in some cases the vulva are removed. This procedure is performed for many types of cancer including genitourinary and colorectal cancers.	
PET (positron emission tomography)	A test that uses radioactive material to see the shape and function of body parts.	
Pleural effusion biopsy	Removal of a sample for testing of the excess fluid between the two layers of tissue lining of the lungs.	
Pneumonectomy	Surgical removal of the entire lung.	
Poorly-differentiated	Tumor that differs markedly from non-cancerous tissue. Generally a sign of high-grade malignancy, associated with a poor prognosis.	Pathology
Postmenopausal	The state of no menstrual periods for at least 12 months.	

Primary treatment	The main treatment for cancer.	Operative
Primary Cancer Site	The site where the cancer tumor originated. This may occasionally differ from the site where the cancer was first detected. With poorly-differentiated tumors it is sometimes not possible to determine the primary site.	
Progesterone Receptor Assay (PRA)	A test done in women with breast cancer to see if the tumor cells have progesterone receptors. Tumor cells with progesterone receptors are called progesterone receptor positive (PR positive) . This assay is usually done at the same time as an estrogen receptor assay. The results of this test are considered when planning treatment.	Lab
Prognosis	A term used to describe the likelihood of progression of cancer or other medical conditions. A cancer with a poor prognosis is usually fatal, while a cancer with a good prognosis is usually curable.	
Quadrantectomy	This procedure removes one-fourth of the breast and removes more breast tissue than the lumpectomy.	Operative
Radiation Oncologist	A physician who specializes in the treatment of cancer with radiation.	
Radioisotopes	Also known as radionuclide or radioactive isotopes: atoms with an unstable nucleus used in cancer treatment.	
Receptor status	Cells have receptors on their surface and in their cytoplasm and nucleus. Hormones bind to receptors, and this causes changes in the cell. Breast cancer cells may or may not have many different types of receptors, the three most important being estrogen receptor (ER), progesterone receptor (PR), and HER2/neu. Cells with these receptors are positive (+), without, negative (-). Cells with none of these receptors are called triple negative.	Lab or pathology
Recurrent (cancer)	A cancer may be designated as recurrent, meaning that it appeared again after being in remission or after all visible tumor has been eliminated. Can be local or distant.	
Regimen	First-line regimen is the first round of chemotherapy; second-line regimen is the second.	
SEER	Surveillance, Epidemiology, and End Results: SEER collects incidence and follow-up data in designated areas in the United States for the purpose of identifying and monitoring trends in cancer incidence and survival.	
Segmentectomy	Surgical removal of a large part of a lobe.	Operative
Sentinel Lymph Node	The first group of disease-fighting cells to which cancer cells spread after leaving the first tumor. Dye injected by the surgeon allows the discovery of this first lymph node.	
Sequential Chemoradiation	Chemotherapy followed by radiation therapy.	
Stage	The process of determining how much cancer is in the body and where it is located. Staging prior to surgery is called clinical staging and staging by surgery is known as pathological staging. The stage, along with other aspects, assists in making appropriate treatment choices.	
Stereotactic biopsy	Also known as stereotactic core biopsy. A medical procedure that uses a computer and imaging performed in at least two planes to a target lesion so a small sample of the tumor can accurately be removed. This is often done to biopsy suspicious microcalcifications (tiny calcium deposits) when no mass can be felt or seen on ultrasound.	
Subcutaneous Mastectomy	Removal of breast tissue, but the nipple-areola complex is preserved. This is a breast-conserving surgery.	Operative
Systemic Therapy	Drugs are used to treat cancer cells that may have spread beyond the breast, which include chemotherapy, hormone therapy, and targeted therapy in either pill or IV form.	
TAH	Total Abdominal Hysterectomy	

Tamoxifen	Tamoxifen Citrate Tablets USP, a nonsteroidal antiestrogen, is for oral administration. It is from a class of drugs called: Selective Estrogen Receptor Modulators. It is the endocrine therapy of choice for premenopausal women and is the class of drugs known as <u>selective estrogen receptor modulators (SERMs)</u> , which are taken orally. Probably the best known of these is <u>Nolvadex (tamoxifen)</u> . SERMs work by blocking estrogen in breast tissue; but in other parts of the body this effect can produce side effects similar to those who are in the menopausal transition, such as vaginal dryness, excessive sweating, sleeplessness and hot flashes.	
Targeted Therapy	A treatment that affects only the cancer cells and not the normal cells. An example of this therapy is the drug Trastuzumab.	
Thoracic surgeon	A doctor who is an expert in surgery within the chest.	
Tissue block	Tissue is imbedded in paraffin to keep it viable. This is called a 'block'. The block is put on a 'cassette' for storage and/or transport. The terms 'blocks' and 'cassettes' may be used interchangeably on the pathology report.	
TMG/TUG flap	(Transverse Myocutaneous/Upper Gracilis) Tissue taken from the gracilis muscle on the superior inner thigh for breast reconstruction.	Operative
TNM	A staging system for cancer. The T describes of extent of the cancer in the primary site; the N specifies the extent of the cancer in the lymph nodes, and the M tells if the cancer has spread to distant organs.	
TRAM flap	(Transverse Rectus Abdominis Myocutaneous) Tissue taken from the transverse abdominal muscle for breast reconstruction.	Operative
Trastuzumab/ Herceptin	Trastuzumab (<u>INN</u> ; trade names Herclon, Herceptin) is a <u>monoclonal antibody</u> that interferes with the <u>HER2/neu receptor</u> . Its main use is to treat certain breast cancers. The HER receptors are proteins that are embedded in the cell membrane and communicate molecular signals from outside the cell (molecules called <u>EGFs</u>) to inside the cell, and turn genes on and off. The HER proteins stimulate cell proliferation. In some cancers, notably certain types of breast cancer, HER2 is over-expressed, and causes cancer cells to reproduce uncontrollably.	
Tylectomy	Removal of the entire breast lump with some normal breast tissue. Also known as a lumpectomy.	Operative
VATS	Video-assisted thoracic surgery, a newer method for lung surgery, often preferred over thoracotomy for a small nodule. A video from the camera is shown on a computer so that the surgeon can see the organs. Use of thin tools inserted between the ribs to do work in the chest.	Operative
VEGF Testing	To identify Vascular Endothelial Growth Factor protein receptors in cells.	Lab or pathology
Wedge Resection	A wedge of tissue is excised from the breast.	Operative
XRT	Radiation Therapy	Clinical Notes