WOMEN'S INTERAGENCY HIV STUDY
SECTION 12: OUTCOMES ASCERTAINMENT PROTOCOL

A. GOALS

The goal of the Outcomes Ascertainment Protocol is to collect information from various sources in order to:

1. Confirm or specify the likelihood of diagnoses of self-reported conditions;
2. Verify the timing of events and death to assist in accurately determining temporal characteristics of HIV disease progression;
3. Assist in assessing the probable cause(s) of death; and
4. Collect documentation to aid in the adjudication of certain disease conditions of particular interest to WIHS investigators.

B. REPORTABLE OUTCOMES

The following outcomes will be verified and reported as part of this protocol:

1. Death
2. Malignancies
3. Tuberculosis
4. Hospitalizations (all overnight admissions and certain same-day hospitalizations)
5. Biopsies

C. ASCERTAINMENT TRIGGERS

This protocol is activated with the occurrence of any of the following:

1. PARTICIPANT SELF-REPORT

a. Events reported during semi-annual study visit:

At each follow-up visit, participants are administered the WIHS ***Follow-up Health History Questionnaire*** (F22HX), ***Biopsy Form*** (BX), and ***Hospitalization Form*** (HOSP), or the ***Abbreviated Visit Form*** (ABRV), which contains a series of questions regarding diagnosis of malignancies and TB, as well as information regarding hospitalizations and biopsies.

b. Events reported through interim contact with participants:

Participant reports diagnosis of an ascertainable event during interim contact with WIHS staff. Detailed procedures for collection of interim events are outlined in **MOO Section 17, Interim Events Protocol.**

2. REPORT THROUGH ACTIVE SURVEILLANCE

Reports from active surveillance include site-initiated searches of (1) the National Death Index; (2) local death registries; (3) local cancer registries; and (4) local tuberculosis registries. Procedures for registry matching are outlined in **MOO Section 20, Registry Matching Protocols.**

3. **REPORT THROUGH PASSIVE SURVEILLANCE**

   Any ascertainable event found upon review of participant medical or hospital records that was not previously reported. Procedures for collection and documentation of events identified through passive surveillance can be found in **MOO Section 17, Interim Events Protocol.**

D. CREATION OF AN ASCERTAINMENT TRACKING CHECKLIST (ATC)

Once an event is triggered, the Apollo data management system creates an Ascertainment Tracking Checklist (ATC).The purpose of the ***Ascertainment Tracking Checklist*** is to:

a. Collect information on when and where the reported event took place;

b. Assign a unique Event Tracking Number (ETN) to self-reported events;

c. Provide a means to track if the medical record(s) were obtained;

d. Indicate which events were confirmed;

e. Track within Apollo the completion of relevant forms and the submission of **redacted** and **de-identified** records.

Depending on how ascertainment of an event is triggered, ***ATC*** forms will be generated differently:

1. PARTICIPANT SELF-REPORT

Apollo will automatically generate an ATC with a unique Event Tracking Number (ETN) and SEQID for each self-reported event (diagnosis or procedure) captured via administration of the ***F22HX, HOSP, BX*** or the ***Abbreviated Visit*** form during a semi-annual visit or interim contact.

2. REPORT THROUGH ACTIVE SURVEILLANCE

<u>National Death Index (NDI)/Local Death Registries</u>

As per the Registry Match Protocol (Manual of Operations, Section 20), a ***Disenrollment Form (DENR)*** must be completed and entered into Apollo for every death discovered (through passive surveillance or registry match). Data entry of the DENR will cause an Ascertainment Tracking Checklist (ATC) to be generated.

<u>TB and Cancer Registries</u>

As per the Registry Match Protocol (Manual of Operations, Section 20), a ***Tuberculosis – Verified Case Report (TB)*** *or* ***Cancer Registry Case Report (CNCR)*** must be completed and entered into Apollo for every event that is discovered.

No Ascertainment Tracking Checklist (ATC) will be generated or completed to report TB or Cancer registry matches. Only a CORE form needs to be completed to report the event.

3. REPORT THROUGH PASSIVE SURVEILLANCE

Apollo will automatically generate an **ATC** with a unique Event Tracking Number (ETN) and SEQID for each event that is identified through passive surveillance. ATCs will be

generated upon the completion and data entry of following forms: ***DENR (for reported Deaths), HOSP (hospitalizations),*** and ***BX (biopsy).***

E. THE ASCERTAINMENT DASHBOARD

Following the creation of an ATC – the event will automatically be added to the **Apollo Ascertainment Dashboard,** which can be access using the Reports menu on the Apollo webpage (https://statepiaps8.jhsph.edu/apollo/studies/wihs/webroot/html/).

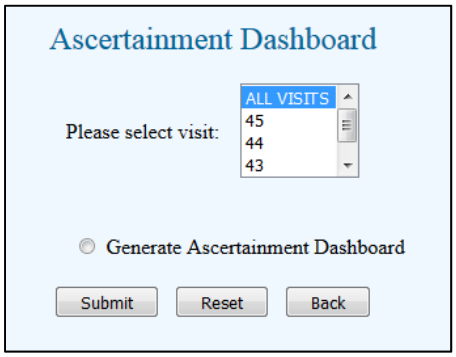
The purpose of the Ascertainment Dashboard is to provide an interactive tool that sites can use to:

- Track the completion status of ascertainment
- Access the ATC form to revise key variables (e.g., status of medical records request, institutions and provider name, event disposition etc.)
- Create or revise CORE forms
- Generate cover sheets for medical record packets
- Confirm receipt of medical records packets by WDMAC

1. ACCESSING THE ASCERTAINMENT DASHBOARD

The Ascertainment Dashboard can be modified to display all existing ascertainment events, or a specific visit. Staff should highlight the appropriate range of visits or the options for "ALL VISITS" and select the option "Generate Ascertainment Dashboard".

Figure 1. Ascertainment Dashboard Report Options



2. ASCERTAINMENT DASHBOARD DISPLAY

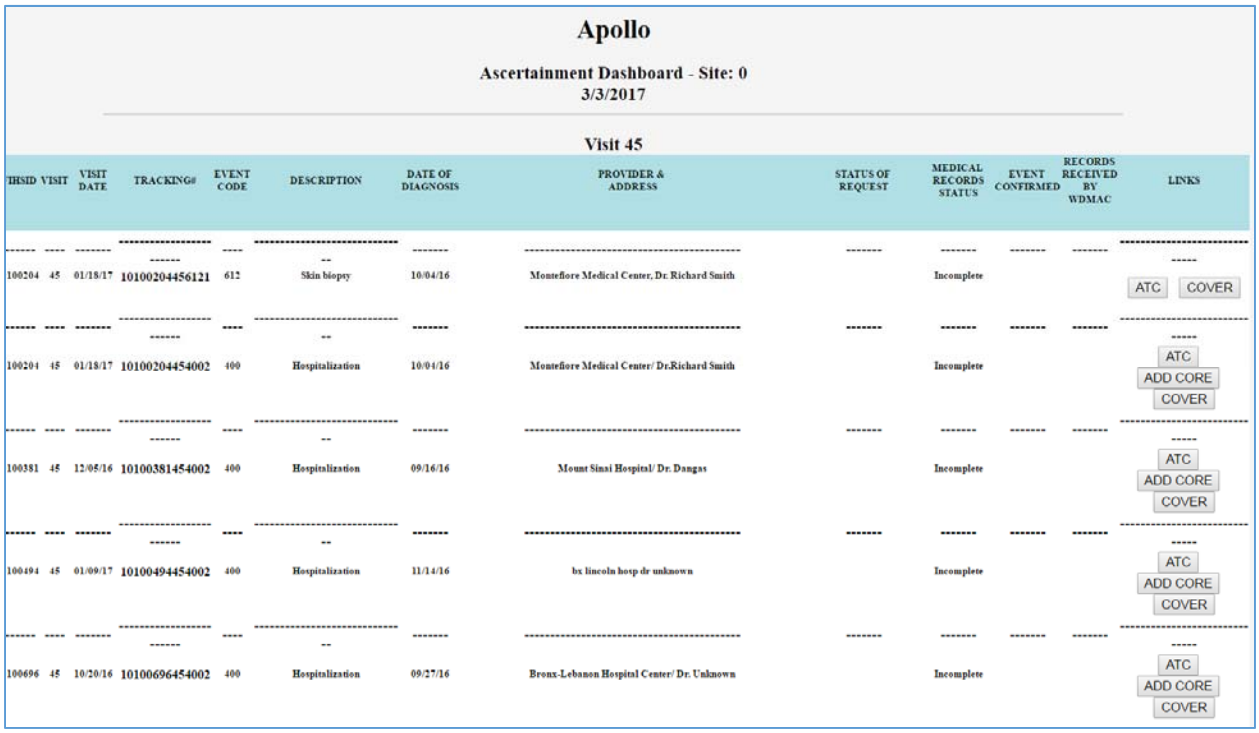
The Ascertainment Dashboard will generate a report that display events, organized by visit. Each row contains information regarding an individual event that is populated at different stages of the ascertainment process (**see Figure 2**).

Once an "event" is triggered by an ATC, the **WIHSID, Visit Data, Event Code, Event Description and Date of Diagnosis** are automatically added to this report. As site staff complete the ATC checklist, other fields will be automatically updated including:

- **Status of Request:** Determined based on the questions to A11 on the ATC form which ask sites to identify the current status of the records request.

- **Medical Records Status:** Determined based on the completion of question A15 on the ATC form which asks staff to provide information on the specific types of medical records that were collected (e.g., progress notes vs. ECG report). (**NOTE:** Only for events reported in V44 onwards)
- **Event Confirmed:** Determined based on the questions to A14 on the ATC form which ask sites to determine whether the specific event can be confirmed (e.g., did a hospitalization take place, or did the participant have a cancer diagnosis)

Figure 2. Ascertainment Dashboard Report



Apollo

Ascertainment Dashboard - Site: 0
3/3/2017

Visit 45

IHSID	VISIT	VISIT DATE	TRACKING#	EVENT CODE	DESCRIPTION	DATE OF DIAGNOSIS	PROVIDER & ADDRESS	STATUS OF REQUEST	MEDICAL RECORDS STATUS	EVENT CONFIRMED	RECORDS RECEIVED BY WDMAC	LINKS
100204	45	01/18/17	10100204456121	612	Skin biopsy	10/04/16	Montefiore Medical Center, Dr. Richard Smith		Incomplete			ATC COVER
100204	45	01/18/17	10100204454002	400	Hospitalization	10/04/16	Montefiore Medical Center/ Dr.Richard Smith		Incomplete			ATC ADD CORE COVER
100381	45	12/05/16	10100381454002	400	Hospitalization	09/16/16	Mount Sinai Hospital/ Dr. Dangas		Incomplete			ATC ADD CORE COVER
100494	45	01/09/17	10100494454002	400	Hospitalization	11/14/16	bx lincoln hosp dr unknown		Incomplete			ATC ADD CORE COVER
100696	45	10/20/16	10100696454002	400	Hospitalization	09/27/16	Bronx-Lebanon Hospital Center/ Dr. Unknown		Incomplete			ATC ADD CORE COVER

3. ASCERTAINMENT DASHBOARD LINKS

The Ascertainment Dashboard offers convenient links on the rightmost column which take staff directly to the ascertainment related forms for a specific event (**see Figure 2)**.

ATC LINK

Selecting the ATC link will open the ATC form associated with the event. Sites can view the details in the ATC report or use the button at the bottom of the form to update values in the ATC (e.g., availability of specific types of medical records, confirmation of event).

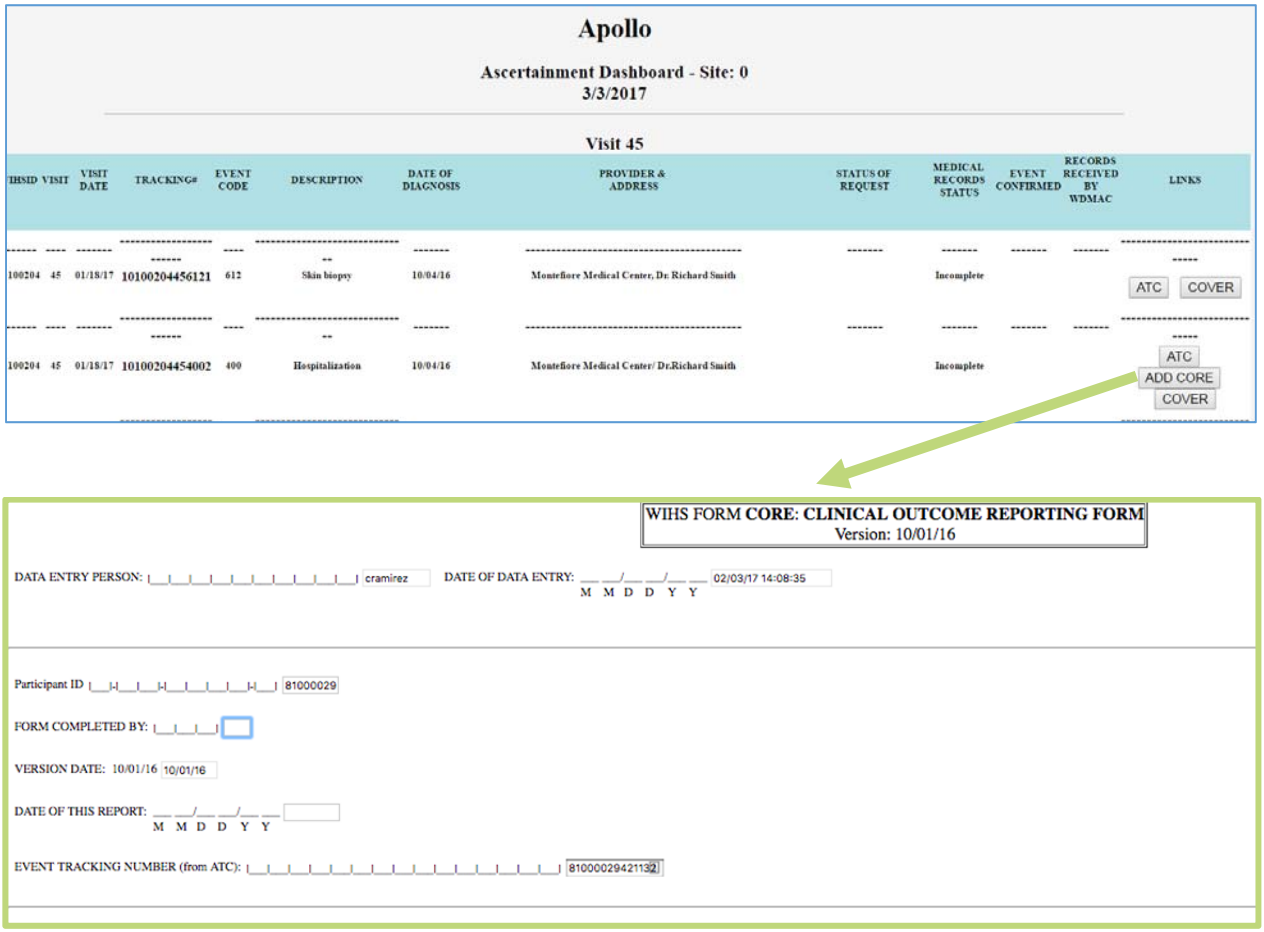
ADD CORE AND CORE LINKS

The Ascertainment Dashboard offers either a “ADD CORE” or “CORE” link for every event.

For events that do not have an existing CORE records, selecting the “ADD CORE” link will generate a new CORE form with pre-filled values for the following variables: WIHSID, and unique Event Tracking Number (ETN) (**see Figure 3**). Pre-filled fields will

also be generated for all sub-forms, including the ICD-10 sub-forms that capture clinical diagnoses associated with certain events.

Figure 3. Creating a new CORE form using the "ADD CORE" link



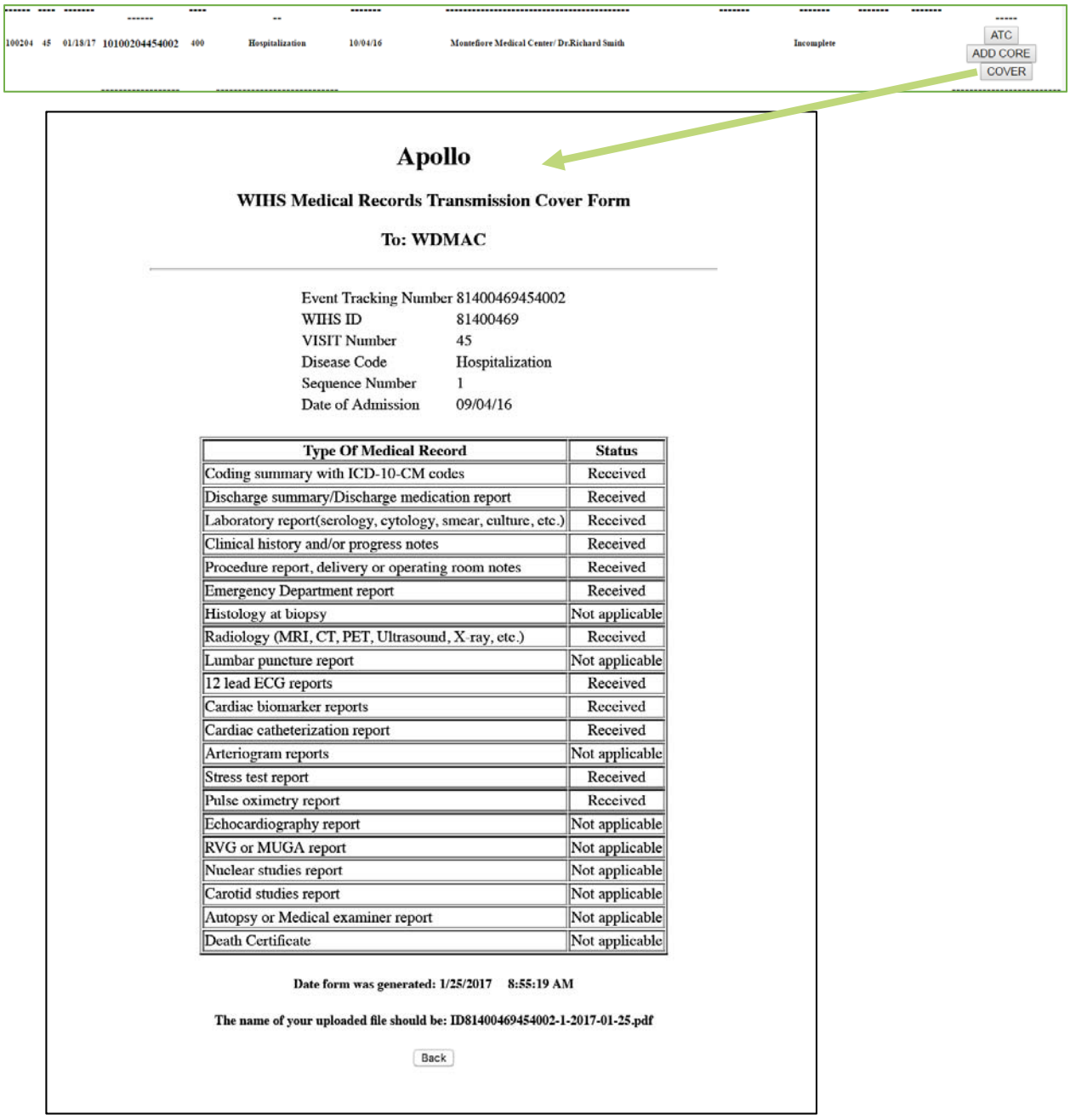
For events with existing CORE records, the "ADD CORE" link will not be available and only a "CORE" link will be visible. Selecting the CORE link will open the CORE form associated with the event. Sites can view the details in the form or use the button at the bottom of the form to update values.

For more information about completing a CORE form**, see Section H: Reporting Confirmed Clinical Outcomes.**

COVER LINKS

The Ascertainment Dashboard offers a "COVER" link for every event. Selecting this link will generate a WIHS medical records transmission cover form (see **Section I** for more information).

Figure 4. Generating a WIHS Medical Records Transmission Cover Form



NOTE: In order to optimize printing, or print to Adobe PDF, capabilities of the cover page report staff should select all text (CNTRL-A) and then choose either the “print” (CNTRL-P) or “save –as” option (CNTRL-S) on their computer.

F. OBTAINING MEDICAL RECORDS

In order for the Outcomes Ascertainment Protocol to be standardized and uniform across WIHS sites, all staff should follow the same guidelines for requesting and reviewing medical records to confirm events. Staff should request records since the last visit.

1. CONSENT FOR RELEASE OF MEDICAL RECORDS

In order to facilitate medical records requests, sites are encouraged to have participants sign records releases at each WIHS core visit. However, in the event that an up-to-date release is not available, WIHS clinic staff will mail the necessary forms to the participant's home with a self-addressed stamped envelope, including institution-specific releases if required.

In addition, the participant may be asked to complete institution-specific consent forms for those medical facilities that require them. Individual WIHS sites will develop a knowledge base over time on which local institutions require their own forms.

a. For deceased participants: If a medical record release form has not been signed by a participant who is now deceased, the staff should still try to obtain medical record release and review the medical records. Since there may be regional differences in guidelines regarding this issue, it is important that the staff member check with the site PI and/or PD to find out who would be authorized to provide such release. Sometimes the participant's next of kin may be allowed to give consent for release of medical records; or the participant may have signed an advance directive in which she authorized a specific person to be responsible for making medically-related decisions upon her death; or decision-making authority may have reverted to local convention (e.g., spouse).

b. For disenrolled or lost to follow-up participants without signed consent: If there is no medical record release form for a participant who is now disenrolled or has been lost to follow-up, the staff should work with the Interviewer and Project Director. Depending on the circumstances, it may still be possible to obtain a medical record release form from the participant.

2. OBTAINING INFORMATION

There are three methods of requesting medical records:

a. Requests via fax/mail

In most cases, WIHS staff will need to put the request for a medical record in writing. (See below for suggested strategies.)

Unobtainable records: A record should be requested at least three times during a six-month period before being considered unobtainable. In addition to three written requests, attempts should also be made to contact the Medical Record Department and/or to contact the participant's clinician by telephone to verify the event.

b. On-site abstraction

In some institutions, the Medical Record Department may not have the resources to photocopy and mail out records. Other institutions may require staff to do any abstraction on the premises of their institution. In such cases, it will be necessary to obtain permission to visit the institution to access the record for abstraction.

c. Medical records at WIHS clinic sites (without a written request)

Since some WIHS participants receive clinical care at the same institution at which they are enrolled in the WIHS, their medical records may be on-site and easily accessible or available with Electronic Medical Records (EMR) systems. If staff are able to obtain medical records in a timely manner by informal requests from members of the institution's staff, then they are encouraged to do so (assuming, of course, that the participant signed a medical release).

3. STRATEGIES FOR FAX AND WRITTEN REQUESTS OF RECORDS

NOTE: Please remember to keep the nature of all requests confidential.

a. Prior to sending out request letters, contact the appropriate Medical Record Department to determine the following:

- Director/Manager's name, title, direct phone number and fax number for the request (if applicable).
- Correspondence clerk's contact information.
- Correct address (include building #, floor, etc.).
- The institution's normal turn-around time for sending the records after receipt of your request.
- Whether you need to supply additional or special release forms/information for diagnoses related to HIV/AIDS or psychiatric illnesses.
- Whether they will accept general parameters (e.g., Fall 1995) or only very specific admission and discharge dates (e.g., Sept. 16, 1995).
- Whether the institution's outpatient records are stored within the same department. If not, query further as to where and how to access these, if needed.
- Whether records are available as separate admissions, or are filed by patient including all procedures for an individual.

b. Create a written letter or memo page for a fax which includes:

- Importance of the request.
- Need for a timely response.
- Director/Manager's name.
- Patient's full name (include MAIDEN name), date of birth, Social Security Number (SSN) and signature.
- Demonstration of your willingness to facilitate their response; for example, you might consider including:
  i. your site's Federal Express (or other vendor's) authorization number;
  ii. a pre-addressed mailing label (multiple copies can usually be procured through the vendor);

iii. the name and telephone number of a contact person in case there are questions and/or problems (note, however, that a telephone call follow-up may result in disclosure of the nature of the request).

c. If you need to mail the request, ensure that it is in a large envelope since it will be more visible and less likely to be misplaced. Mark the envelope "CONFIDENTIAL." Don't forget to include the patient's authorization form (complete with DOB and SSN). The doctor's signature is usually required as additional authorization. The Principal Investigator at your site may opt to sign multiple forms or allow your co-signature. Alternatively, a rubber template of his/her signature can be made and used to stamp forms, as needed.

d. It is a nice gesture to follow up with a thank you phone call or letter once you have received the chart(s). Remember, you will likely be requesting more records from that facility in the future!

4. WHAT RECORDS TO REQUEST

Appendix A contains a list of what documentation should be requested for each ascertainable event requiring abstraction as part of the Outcomes Ascertainment Protocol. Site staff should base their request for documentation on this list. At a minimum, the **coding summary with ICD-10-CM codes** and the **discharge summary** are needed.

G. REVIEW OF MEDICAL RECORDS

In order to facilitate adjudication of clinical events, sites should attempt to collect and review all necessary records. For records that **are** obtained, the WIHS Outcomes Ascertainment Protocol requires using information from narrative sections of the record, such as the discharge summary, progress notes or consultation reports to determine clinical diagnoses. Any notations recorded by a physician, specialist, physician's assistant or nurse practitioner can be used. Nurse's notes, however, should not be used as a source of documentation for medical record abstraction.

1. HOSPITALIZATIONS

For all hospitalizations (including those related to CVD events), sites should make sure that the hospitalization occurred and that the required types of medical record documentation outlined in **Appendix A** (e.g., coding summary, clinical history/progress notes, laboratory report, etc.) are included. However, detailed review of the diagnosis itself is not necessary, and adjudication will be performed by the adjudication team.

2. BIOPSIES

Abstraction of biopsy events will involve reviewing diagnostic and/or laboratory results. Staff should always consider the final results (not the preliminary results) in making confirmation decisions. Depending upon the completeness of the record, staff will use either **primary** or **secondary** sources to determine if the biopsy can be confirmed.

a. Primary source document

Laboratory results or procedure reports are primary source documents. Use these sources instead of secondary sources whenever possible. Results obtained

from an institution's computerized files are also considered to be obtained from a primary source. For example, lab results obtained from a laboratory's main database are collected from a primary source.

b. Secondary source document

Information found in a discharge summary, progress note or consultation report is considered to be obtained from a secondary source when the medical provider has observed the primary source document that specifically references diagnostic test results and has "transcribed it" into his/her notes. As stated above, nurse's notes may not be included as secondary sources of information.

3. TB AND CANCER

Abstraction of TB and Cancer events will involve reviewing diagnostic and/or laboratory results. Staff should always consider the final results (not the preliminary results) in making confirmation decisions. Depending upon the completeness of the record, staff will use either **primary** or **secondary** sources to determine if an event is confirmed and, if so, the level of confidence in the diagnosis.

a. Primary source document

Laboratory results or procedure reports are primary source documents. Use these sources instead of secondary sources whenever possible. Results obtained from an institution's computerized files are also considered to be obtained from a primary source. For example, lab results obtained from a laboratory's main database are collected from a primary source.

b. Secondary source document

Information found in a discharge summary, progress note or consultation report is considered to be obtained from a secondary source when the medical provider has observed the primary source document that specifically references diagnostic test results and has "transcribed it" into his/her notes. As stated above, nurse's notes may not be included as secondary sources of information.

c. Other verification methods

If unable to obtain a copy of the participant's medical records, abstraction staff can attempt to verify a reported diagnosis via a phone call to the participant's clinician. While the level of confidence in a diagnosis confirmed in this manner won't be as high, it can be used as a last resort to confirm an event.

Site staff should review all medical records to determine whether the diagnosis can be confirmed using **Appendix B,** which contains the criteria needed to make a definitive or presumptive diagnosis.

4. DEATH

Deaths will be ascertained mainly via National Death Index – Plus matching. **However, sites should attempt to collect medical records related to the cause of death to help with the ascertainment of underlying conditions (e.g., myocardial infarction, stroke, heart failure, cancer).**

Abstraction of medical records related to fatal events will likely involve a combination of the methods outlined above. Depending on the circumstances surrounding a participant's death, sites may need to review hospitalization records or other types of source documents.

H. REPORTING CONFIRMED CLINICAL OUTCOMES

After review of medical records, site staff should complete the ***Clinical Outcomes Reporting Form (CORE).*** The ***CORE*** is used to report the clinical information for the following **confirmed** ascertainable events**:**

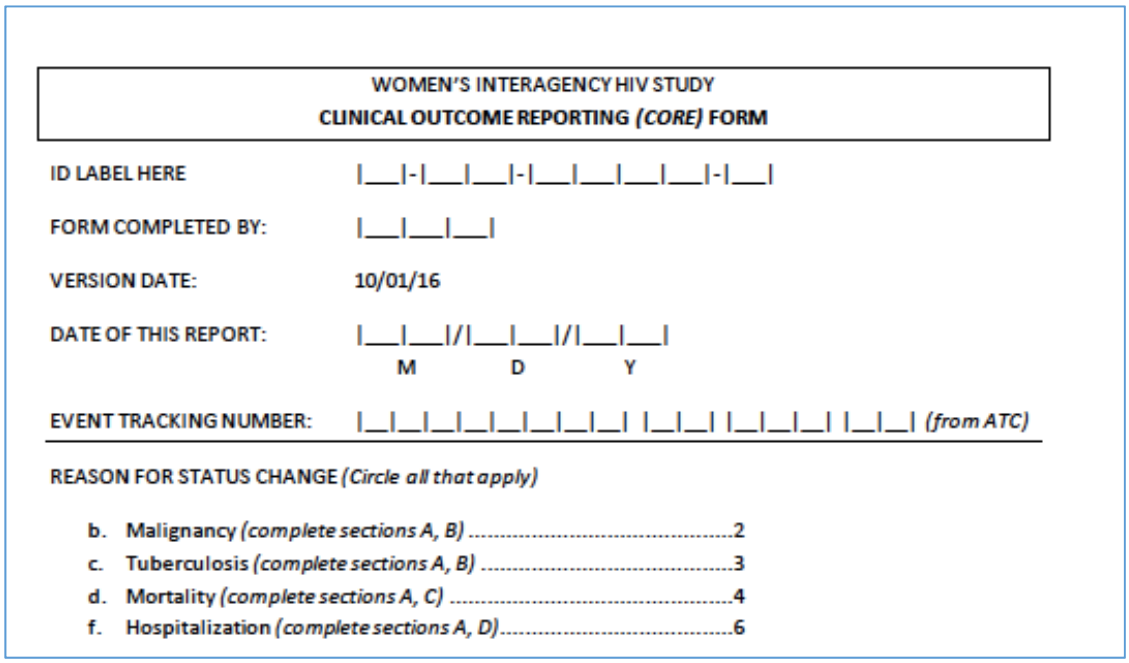
- Confirmed cancer diagnosis
- Confirmed active TB diagnosis
- Confirmed hospitalization (regardless of admission/discharge reasons)
- Confirmed death

NOTE: Biopsies are not considered "key clinical outcomes" and do not require the completion of a CORE form. Staff should attempt to confirm the biopsy event and follow the guidelines in Section H for redacting/uploading medical records.

1. SECTION A: ASCERTAINMENT DISPOSITION & SOURCE OF INFORMATION

The first section of the ***CORE Form*** will allow WIHS staff to indicate which outcomes are being reported (**see Figure 5**).

Figure 5. Event information, CORE Form



WOMEN'S INTERAGENCY HIV STUDY
CLINICAL OUTCOME REPORTING *(CORE)* FORM

ID LABEL HERE |___|-|___|___|-|___|___|___|___|-|___|

FORM COMPLETED BY: |___|___|___|

VERSION DATE: 10/01/16

DATE OF THIS REPORT: |___|___|/|___|___|/|___|___|
M D Y

EVENT TRACKING NUMBER: |__|__|__|__|__|__|__|__|__| |__|__| |__|__|__|__| |__|__| *(from ATC)*

REASON FOR STATUS CHANGE *(Circle all that apply)*

b. Malignancy *(complete sections A, B)* 2
c. Tuberculosis *(complete sections A, B)* 3
d. Mortality *(complete sections A, C)* 4
f. Hospitalization *(complete sections A, D)*.....6

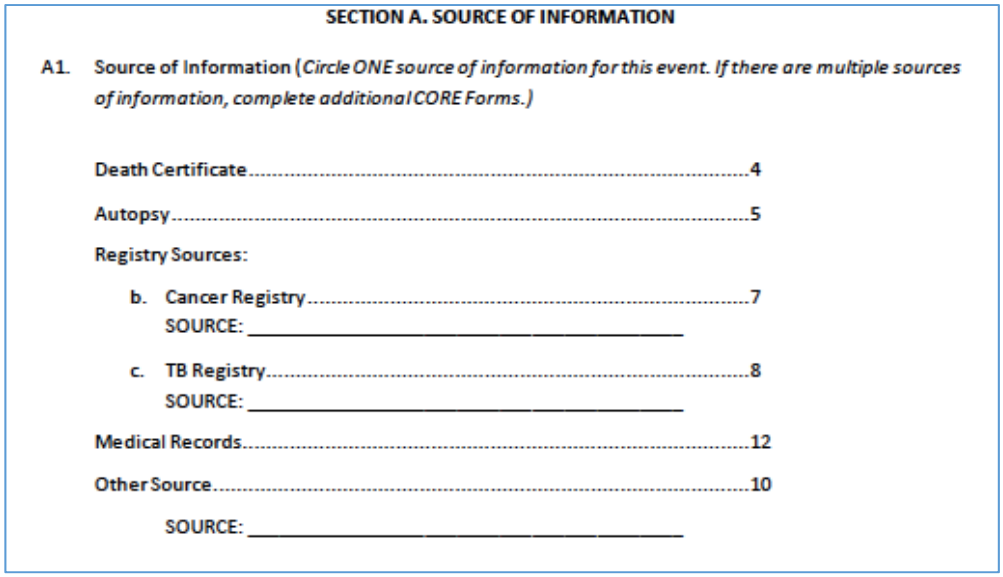
NOTE: There may be cases in which an "event" includes multiple ascertainable conditions, for example, a hospitalization during which a cancer was diagnosed. In these cases, all applicable ascertainable conditions should be indicated. If additional unique ascertainable events (e.g., events that are not related to the initial ascertainable event,

for example: a cancer diagnosis during a separate hospitalization from the one that was originally reported) are found during the abstraction of an event, additional CORE Forms should be completed. CORE Forms completed for ascertained events without an ATC should have the field "Event Tracking Number" left blank.

Since no ATC will be generated or completed, the event tracking number (ETN) will be left blank on CORE forms completed for TB, Cancer or AIDS registry matches.

Only one source of information (Section A) should be indicated for each ***CORE Form*** completed. If there are multiple sources of information for a particular event, additional ***CORE Forms*** should be completed for each source named. (**see Figure 6**).

Figure 6. Section A of CORE Form



SECTION A. SOURCE OF INFORMATION

A1. Source of Information (*Circle ONE source of information for this event. If there are multiple sources of information, complete additional CORE Forms.)*

Death Certificate.....4

Autopsy.....5

Registry Sources:

b. Cancer Registry.....7
SOURCE: _____

c. TB Registry.....8
SOURCE: _____

Medical Records.....12

Other Source.....10

SOURCE: _____

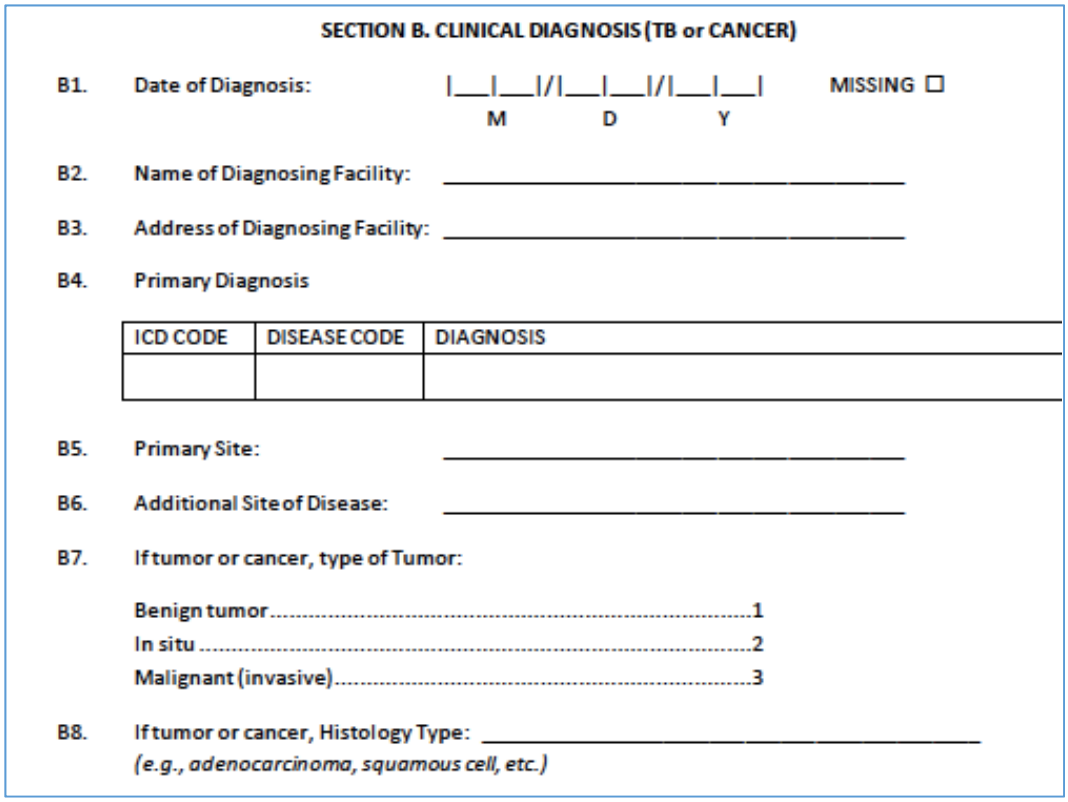
2. SECTION B: CLINICAL DIAGNOSIS (TB OR CANCER)

Sites should attempt to collect medical records for all TB and cancer diagnoses. Records should be reviewed carefully and, when possible, ***CORE Forms*** should be filled out with the pertinent ICD codes listed on the progress or coding summary notes (**see Figure 7**).

If medical records cannot be retrieved or ICD codes are unavailable, then staff should use the ICD-10 codes identified in the *WIHS Criteria for Clinical Diagnosis* (**Appendix B**).

NOTE: When ascertaining self-reported metastatic cancer, if the metastatic cancer is diagnosed and reported sometime after the primary cancer, review your records to ensure that the primary cancer was also confirmed. If both primary and metastatic cancers were reported at the same visit, an ATC will be generated for each. If both are confirmed, complete a CORE Form for each respective ATC. If only the primary cancer was reported, only one ATC will be generated. If you confirm the primary cancer and also find documentation of metastatic cancer, complete two CORE Forms with the same ETN as the ATC for the primary cancer.

Figure 7. Clinical Diagnosis, Section B of CORE Form



SECTION B. CLINICAL DIAGNOSIS (TB or CANCER)

B1. Date of Diagnosis: |__|__|/|__|__|/|__|__| MISSING ☐
M D Y

B2. Name of Diagnosing Facility: _____

B3. Address of Diagnosing Facility: _____

B4. Primary Diagnosis

ICD CODE	DISEASE CODE	DIAGNOSIS

B5. Primary Site: _____

B6. Additional Site of Disease: _____

B7. If tumor or cancer, type of Tumor:

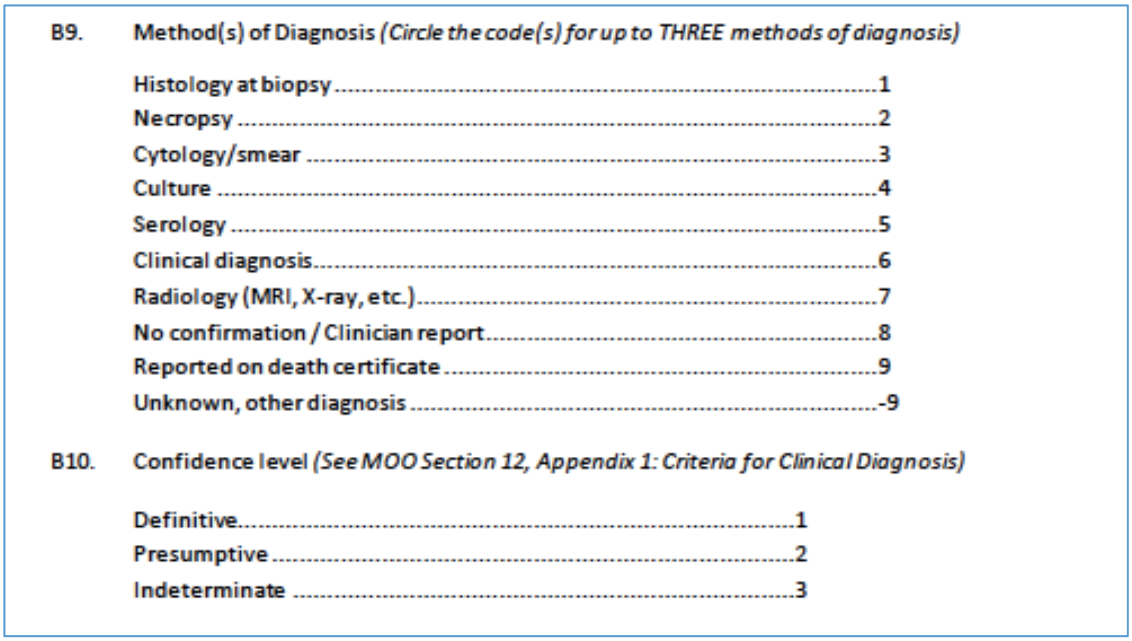
Benign tumor.....1
In situ.....2
Malignant (invasive).....3

B8. If tumor or cancer, Histology Type: _____
(e.g., adenocarcinoma, squamous cell, etc.)

When completing a ***CORE Form*** for an event confirmed through registry match, the method of diagnosis would be coded as "no confirmation/clinician report." The level of confidence in the diagnosis will therefore be "indeterminate" since there was no actual review of medical records by WIHS CORE Team members.

The level of confidence in the diagnosis (e.g., "presumptive" versus "definitive") is associated with the confirmation of an event. The criteria to be met for determination of the level of confidence are contained in the *WIHS Criteria for Clinical Diagnosis* (**Appendix B**). If the medical record reflects that the criteria outlined in the definitive column were met in making the diagnosis, the diagnosis would be considered "definitive." If the definitive standard was not met, the diagnosis may be made presumptively by meeting a lesser standard. The criteria for making a "presumptive" diagnosis are outlined in the presumptive column. When a diagnosis is confirmed solely through clinician report, registry match or death certificate review, the level of confidence in the diagnosis should be recorded as "indeterminate." (**see Figure 8**)

Figure 8. Method of Diagnosis & Confidence Level, Section B of CORE Form



B9. Method(s) of Diagnosis *(Circle the code(s) for up to THREE methods of diagnosis)*

Histology at biopsy	1
Necropsy	2
Cytology/smear	3
Culture	4
Serology	5
Clinical diagnosis	6
Radiology (MRI, X-ray, etc.)	7
No confirmation / Clinician report	8
Reported on death certificate	9
Unknown, other diagnosis	-9

B10. Confidence level *(See MOO Section 12, Appendix 1: Criteria for Clinical Diagnosis)*

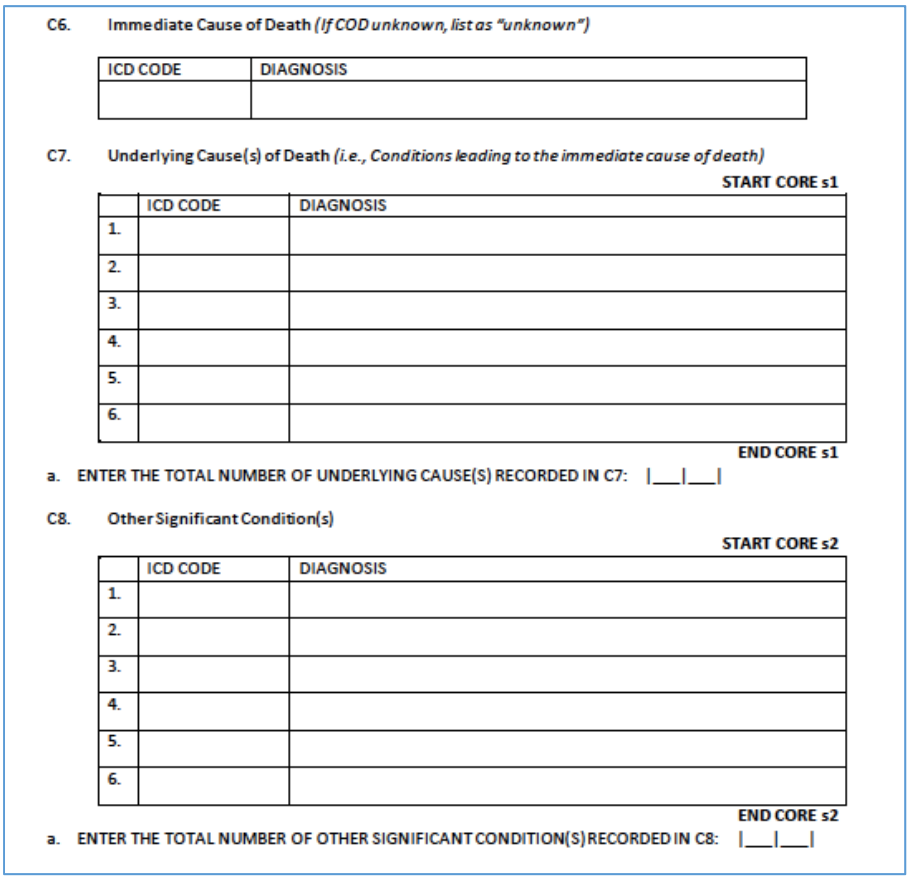
Definitive	1
Presumptive	2
Indeterminate	3

3. SECTION C: INFORMATION RELEVANT TO DEATH

When applicable, sites should attempt to collect medical records related to participant deaths. Records should be reviewed carefully and, when possible, ***CORE Forms*** should be filled out with the pertinent ICD codes listed on the autopsy report, discharge report, and/or coding summary notes (**see Figure 9).**

NOTE: Immediate and underlying causes of death should only be included in this section if they are explicitly outlined in the source document.

Figure 9. Cause of Death, Section C of CORE Form



C6. Immediate Cause of Death *(If COD unknown, list as "unknown")*

ICD CODE	DIAGNOSIS

C7. Underlying Cause(s) of Death *(i.e., Conditions leading to the immediate cause of death)*

START CORE s1

	ICD CODE	DIAGNOSIS
1.		
2.		
3.		
4.		
5.		
6.		

END CORE s1

a. ENTER THE TOTAL NUMBER OF UNDERLYING CAUSE(S) RECORDED IN C7: |___|___|

C8. Other Significant Condition(s)

START CORE s2

	ICD CODE	DIAGNOSIS
1.		
2.		
3.		
4.		
5.		
6.		

END CORE s2

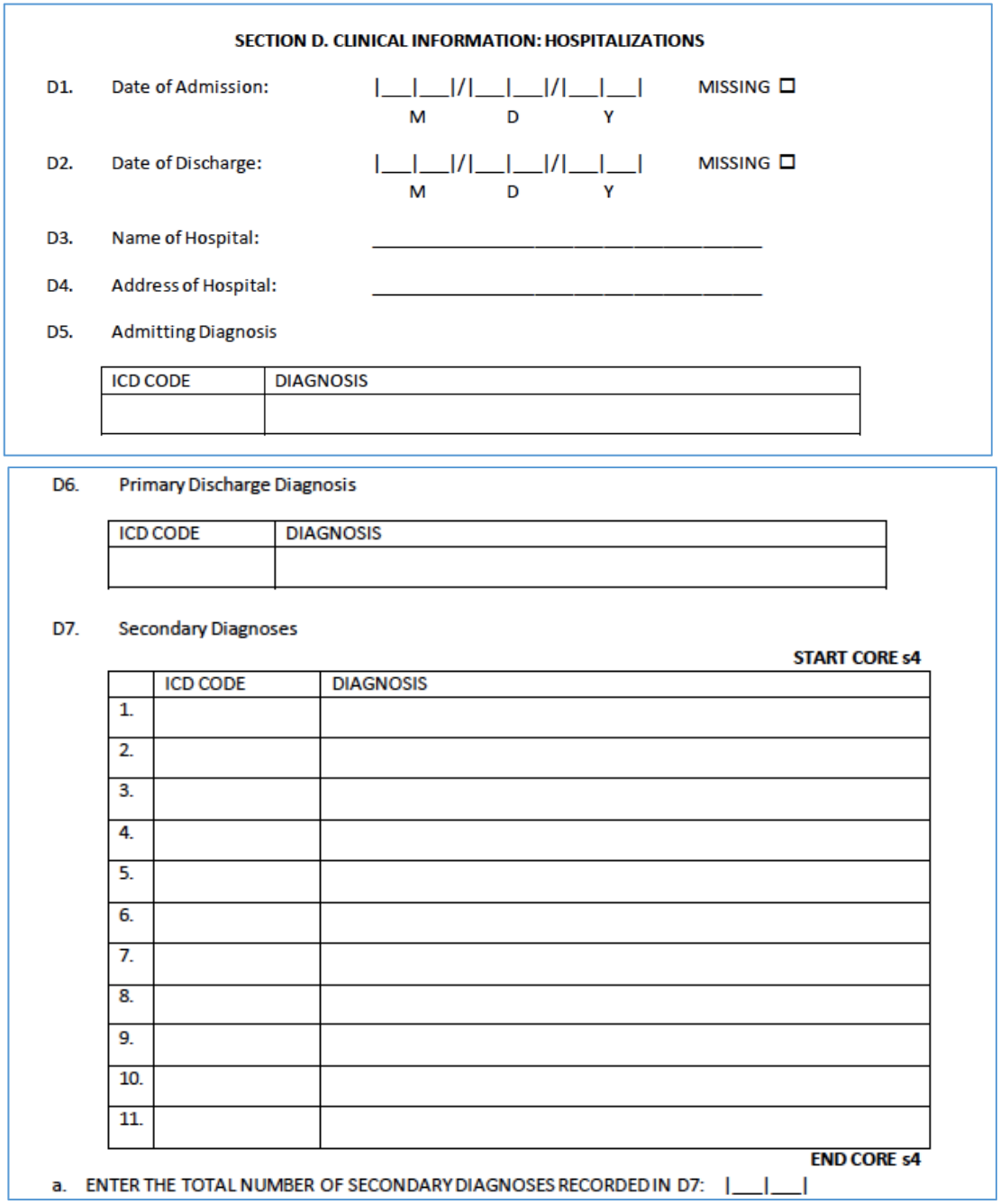
a. ENTER THE TOTAL NUMBER OF OTHER SIGNIFICANT CONDITION(S) RECORDED IN C8: |___|___|

4. SECTION D: INFORMATION RELEVANT TO HOSPITALIZATIONS

Hospitalization records should be reviewed carefully and ***CORE Forms*** should be filled out with the pertinent ICD codes listed on the relevant reports and coding summary notes (**see Figure 10).**

Special care should be taken to indicate the admitting diagnosis, primary discharge diagnosis and any secondary diagnoses (***CORE Questions D5-D7)*.** For Question D5 (primary discharge diagnosis), if the admitting diagnosis is not available from the coding summary, then use the first diagnosis listed instead.

Figure 10. Clinical Information, Section D of CORE Form



SECTION D. CLINICAL INFORMATION: HOSPITALIZATIONS

D1. Date of Admission: |___|___|/|___|___|/|___|___| MISSING ☐
M D Y

D2. Date of Discharge: |___|___|/|___|___|/|___|___| MISSING ☐
M D Y

D3. Name of Hospital: _____

D4. Address of Hospital: _____

D5. Admitting Diagnosis

ICD CODE	DIAGNOSIS

D6. Primary Discharge Diagnosis

ICD CODE	DIAGNOSIS

D7. Secondary Diagnoses

START CORE s4

	ICD CODE	DIAGNOSIS
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		

END CORE s4

a. ENTER THE TOTAL NUMBER OF SECONDARY DIAGNOSES RECORDED IN D7: |___|___|

I. REDACTION & UPLOAD OF MEDICAL RECORDS

Once the CORE form is complete, the corresponding medical records will be assembled, redacted, and uploaded to WDMAC's secure server via the WDMAC Ascertainment FTP System. For this purpose, each site is assigned a username and a password to access the secure FTP site. Sites who do not have this information can contact JHSPH.wdmac@jhu.edu for this information.

Assembly and redaction of medical record packets

Sites should prepare the pertinent medical records as a single packet for upload through the following process:

1. **Check completeness of medical record types for specific clinical events according to the table in Appendix A (e.g., acute MI, stroke, heart failure, coronary artery disease procedures, peripheral artery disease procedures), and if incomplete, follow up with the provider to complete the record.**

   As previously noted, if the hospitalization event is not associated with a clinical event of interest (e.g., acute MI, stroke, heart failure), then only a minimal set of medical records types are absolutely required: coding summary, discharge summary.

2. **Sequence medical record types into the order shown in Appendix A for subsequent event adjudication.**

   The coding summary (required for all hospitalization events) should be the first medical record item in the packet.

   Duplicate parts of medical records can be excluded from the packets, as well as extraneous records not required as shown in Appendix A.

3. **Redact/de-identify records**

   All medical records will be redacted at the local WIHS clinic site, with the following potential identifiers redacted:

   - Name
     Social security number
     Home address
     Email address
     Phone and fax numbers
     Medical record number
   - Account number
   - Health plan beneficiary number

   Redaction can occur one of two ways:

   A. Electronic redaction

   Specialized software may also be used to redact the records electronically**.** We recommend either Adobe Acrobat Pro or ABBYY FineReader 12. See **Appendix C** for redaction instructions specific to each software.

   NOTE: If specialized software is used, then the redaction will occur after the medical record is scanned in (**Step 6**).

   B. Manual redaction

   If manual redaction is used, all of the above identified must be crossed out with a **thick black permanent marker** and/or **stamped with an "identify theft protection" stamp** designed to obscure underlying text. This must occur on all pages of the medical records.

4. **Print out "WIHS Medical Records Transmission Cover Form" and add as first page of medical record packet**

   This is a cover form to the medical record packet containing the participant's WIHSID, visit number, and Event Tracking Number (ETN).

   It can be accessed in the Ascertainment Dashboard, and is customized for each specific reported event (see **Section E**: Ascertainment Dashboard for detailed instructions).

   Please be certain that the date of admission and the status for the types of medical records are completed. If they are not completed, they should be entered on the associated CORE form.

5. **Scan in the medical record as a single PDF file, using the filename as shown on the WIHS Medical Records Transmission Cover Form**.

   The format for the file name uses the following format:

   ID[ETN]-[Seq Num]-[Date of cover form generation in YYYY-MM-DD].pdf

   For example, the filename for the medical record packet above is:

   ID10102537454002-1-2017-01-24.pdf

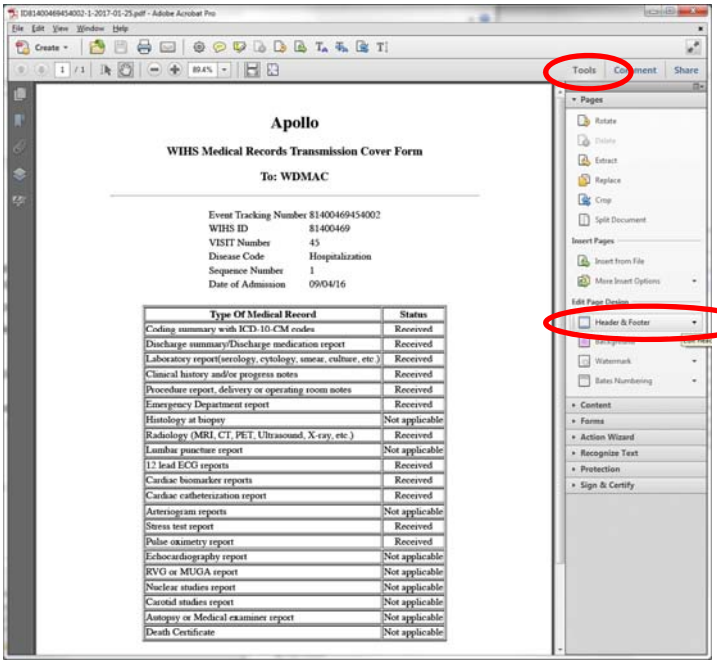
   Note that PDF files should be stored on a secure local computer or server on which it is acceptable by the site's own policies for identifiers to be saved.

6. **Redact identifiers** as in Step 3, if electronic redaction is chosen.

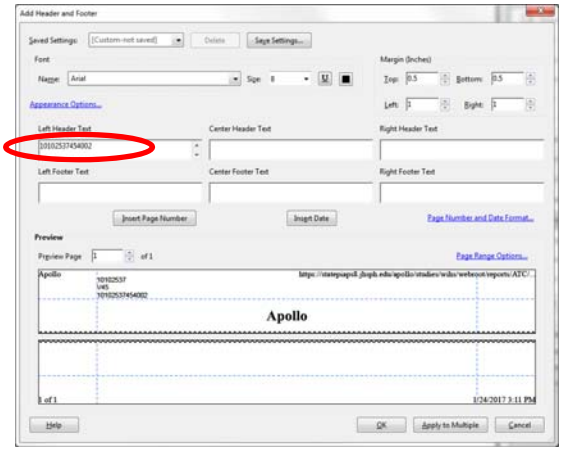
7. **Add header to the medical record packet PDF with WIHSID, visit number, and Event Tracking Number (ETN).**

   This may be done using Adobe Acrobat Pro:

   - Click on the Tools Bar on the upper right hand part of window
   - Select Pages | Edit Page Design: Header & Footer | Add Header & Footer



- Click on the Left Header Text box (see below), and type in:
    - WIHSID [press return]
    - Visit Number [press return]
    - Event Tracking Number [press return]



- Click OK

At this point, every page of the PDF will now have the WIHS ID, Visit Number, and ETN in the header.

8. **Double-check that all identifiers have been properly redacted.**

   Sites may choose to have a second staff member review the record, as a further check that all identifiers have been removed.

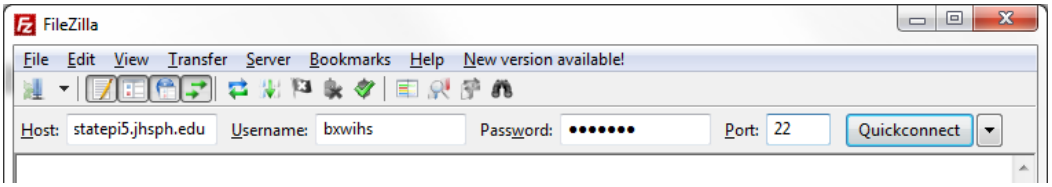
Uploading of medical record packets and next steps

1. **Upload the file to the WDMAC secure FTP site.**

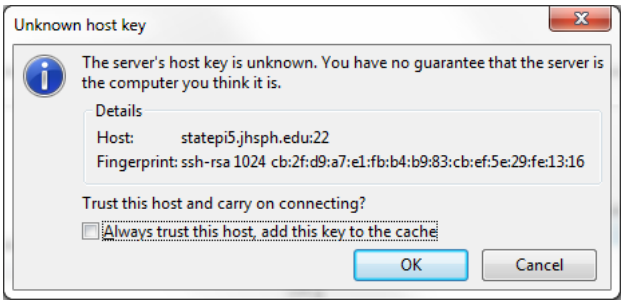
   Using FTP client software such as "SSH Secure File Transfer" or "FileZilla FTP Client", securely log in to WDMAC's FTP server using the username and password assigned to your site, in order to access the secure FTP site. Use the host name and port as below:

   Host name: **statepi5.jhsph.edu**
   Port: **22**

   In FileZilla, the information is entered as below:

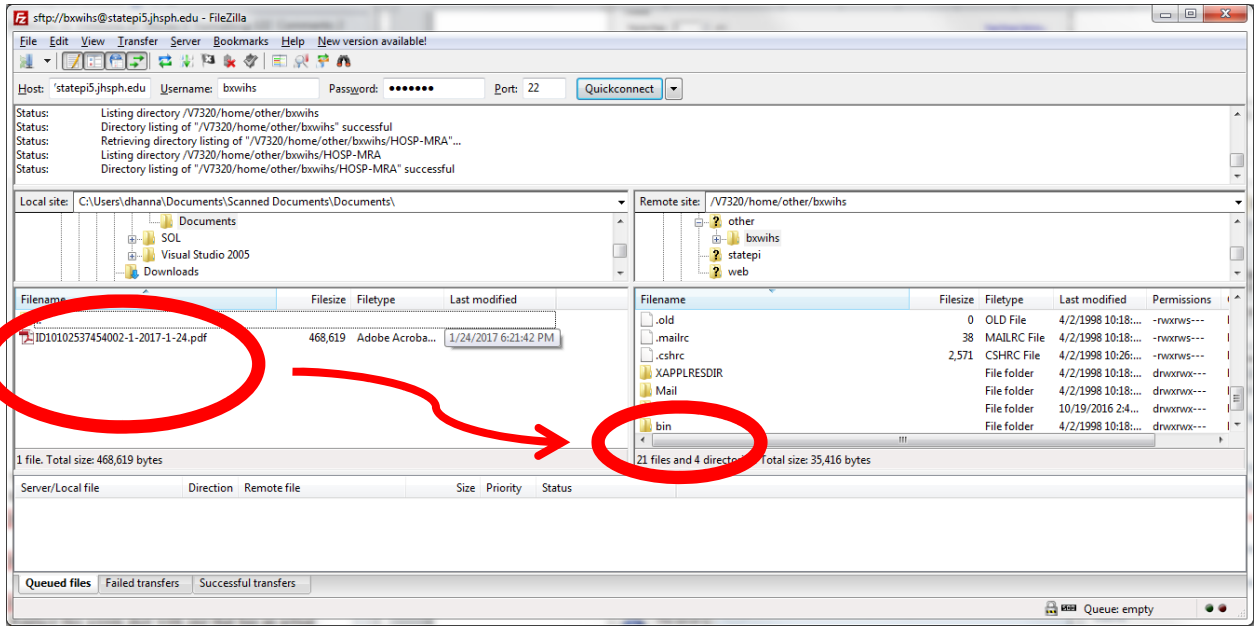


NOTE: The first time that you log in, you may see the below message.



If you get this message, click the box next to the text, "Always trust this host…" and then click OK.

After log-in is successful, this should bring up a list of directories and files on the computer you are using in the left pane, as well as a list of directories on WDMAC's server in the right pane. On the WDMAC server (right pane), navigate to the directory "HOSP-MRA" and then click and drag the file you want to transfer from the left pane into "HOSP-MRA."



2. **Await email acknowledgment from WDMAC**

   WDMAC will send an acknowledgment email to the site's Data Manager confirming receipt of the records within 3 business days. If there are problems with the file (e.g., wrong medical record attached, unredacted identifiers), the email will state this and the site will be asked to resubmit the file.

   After acknowledgement, acceptable medical record packets will appear in the Ascertainment Dashboard as "completed".

3. **Temporarily store paper copies of records in locked cabinets**

   The original records should be stored by WIHS sites until the end of the visit process is complete. Once central edits and queries have been finalized, then then electronic files may be deleted and the paper copies may be shredded. Alternatively, sites may choose to keep the electronic files on a secure server for future research use by local investigators for approved WIHS projects.

APPENDIX A: GUIDELINES FOR MEDICAL RECORDS REQUEST

	Death	AIDS	Cancer	TB	Hospitalizations					
					MI	Heart Failure	Stroke	CAD-related procedure	PAD-related procedure	Other
Coding summary with ICD-10-CM codes *	√	√	√	√	√	√	√	√	√	√
Discharge summary/ Discharge medication report *	√	√	√	√	√	√	√	√	√	√
Laboratory report (serology, cytology, smear, culture, etc.) *	√	√	√	√	√	√	√	√	√	√
Clinical history and/or progress notes**	√	√	√	√	√	√	√	√	√	√
Procedure report, delivery or operating room notes			√		√	√	√	√	√	√
Emergency Department report					√	√	√	√	√	√
Histology at biopsy			√							
Radiology (MRI, CT, PET, Ultrasound, X-ray, etc.)						√ (chest x-ray)	√ (CT scan, ultra-sound)			
Lumbar puncture report							√			
12 lead ECG reports					√	√	√	√		
Cardiac biomarker reports					√	√		√		
Cardiac catheterization report					√	√		√		
Arteriogram reports					√	√	√	√	√	
Stress test report					√	√		√		
Pulse oximetry report						√				
Echocardiography report					√	√	√	√		
RVG or MUGA report					√	√		√		
Nuclear studies report							√			
Carotid studies report							√	√		
Autopsy or Medical examiner report	√									
Death Certificate	√									

*** Required**

**** Nurse's notes should not be used as a source for clinical history/progress notes**

APPENDIX B: WIHS CRITERIA FOR CLINICAL DIAGNOSIS

CONDITION	WIHS DISEASE CODE	ICD-10 CM CODE	DEFINITIVE	PRESUMPTIVE
BREAST CANCER	106	**C50 Malignant neoplasm of breast** • C50.0 Malignant neoplasm of nipple and areola • C50.1 Malignant neoplasm of central portion of breast • C50.2 Malignant neoplasm of upper-inner quadrant of breast • C50.3 Malignant neoplasm of lower-inner quadrant of breast • C50.4 Malignant neoplasm of upper-outer quadrant of breast • C50.5 Malignant neoplasm of lower-outer quadrant of breast • C50.6 Malignant neoplasm of axillary tail of breast • C50.8 Malignant neoplasm of overlapping sites of breast • C50.9 Malignant neoplasm of breast of unspecified site **D05 Carcinoma in situ of breast** • D05.0 Lobular carcinoma in situ of breast • D05.1 Intraductal carcinoma in situ of breast • D05.8 Other specified type of carcinoma in situ of breast • D05.80 is a specific ICD-10-CM diagnosis code D05.80 Other specified type of carcinoma in situ of unspecified breast • D05.9 Unspecified type of carcinoma in situ of breast	Any other histologic type with biopsy proven. Ductal carcinoma in situ (DCIS) Lobular carcinoma in situ (LCIS)	

CONDITION	WIHS DISEASE CODE	ICD-10 CM CODE	DEFINITIVE	PRESUMPTIVE
CERVICAL CANCER, INVASIVE	101	**C53 Malignant neoplasm of cervix uteri** • C53.0 Malignant neoplasm of endocervix • C53.1 Malignant neoplasm of exocervix • C53.8 Malignant neoplasm of overlapping sites of cervix uteri • C53.9 Malignant neoplasm of cervix uteri, unspecified	1. Biopsy with evidence of invasive carcinoma. **NOTE: Carcinoma in Situ (CIS) does NOT constitute a case of confirmed invasive cervical cancer.**	
KAPOSI'S SARCOMA	102	**C46 Kaposi's sarcoma** • C46.0 Kaposi's sarcoma of skin • C46.1 Kaposi's sarcoma of soft tissue • C46.2 Kaposi's sarcoma of palate • C46.3 Kaposi's sarcoma of lymph nodes • C46.4 Kaposi's sarcoma of gastrointestinal sites • C46.5 Kaposi's sarcoma of lung • C46.50 Kaposi's sarcoma of unspecified lung • C46.51 Kaposi's sarcoma of right lung • C46.52 Kaposi's sarcoma of left lung • C46.7 Kaposi's sarcoma of other sites • C46.9 Kaposi's sarcoma, unspecified	1. Biopsy from any site ever + for KS.	1. Clinical diagnosis by dermatologist, oncologist or HIV clinician.
LYMPHOMA (non-Hodgkin's) (for Hodgkin's Lymphoma, see "Other Cancers," below)	103	**C82 Follicular lymphoma** • C82.0 Follicular lymphoma grade I • C82.1 Follicular lymphoma grade II • C82.2 Follicular lymphoma grade III, unspecified • C82.3 Follicular lymphoma grade IIIa • C82.4 Follicular lymphoma grade IIIb • C82.5 Diffuse follicle center lymphoma • C82.6 Cutaneous follicle center lymphoma • C82.8 Other types of follicular lymphoma • C82.9 Follicular lymphoma, unspecified	1. Biopsy proven.	

CONDITION	WIHS DISEASE CODE	ICD-10 CM CODE	DEFINITIVE	PRESUMPTIVE
		C83 Non-follicular lymphoma • C83.0 Small cell B-cell lymphoma • C83.1 Mantle cell lymphoma • C83.3 Diffuse large B-cell lymphoma • C83.5 Lymphoblastic (diffuse) lymphoma • C83.7 Burkitt lymphoma • C83.8 Other non-follicular lymphoma • C83.9 Non-follicular (diffuse) lymphoma, unspecified **C84 Mature T/NK-cell lymphomas** • C84.0 Mycosis fungoides • C84.1 Sézary disease • C84.4 Peripheral T-cell lymphoma, not classified • C84.6 Anaplastic large cell lymphoma, ALK-positive • C84.7 Anaplastic large cell lymphoma, ALK-negative • C84.A Cutaneous T-cell lymphoma, unspecified • C84.Z Other mature T/NK-cell lymphomas • Mature T/NK-cell lymphomas, unspecified **C85 Other specified and unspecified types of non-Hodgkin lymphoma** • C85.1 Unspecified B-cell lymphoma • C85.2 Mediastinal (thymic) large B-cell lymphoma • C85.8 Other specified types of non-Hodgkin lymphoma • C85.9 Non-Hodgkin lymphoma, unspecified		

CONDITION	WIHS DISEASE CODE	ICD-10 CM CODE	DEFINITIVE	PRESUMPTIVE
LYMPHOMA, CNS (non-Hodgkin's) (for Hodgkin's Lymphoma, see "Other Cancers," below)	104	• C83.8 Other non-follicular lymphoma	1. Histologic evidence (tissue biopsy, aspirate, or at autopsy). **OR** 2. Cytologic evidence obtained from CSF.	1. Presence of CNS lesions on imaging scan (CT, SPECT or PET) consistent with lymphoma. **AND EITHER** 2a. Unresponsive to empiric toxoplasmosis treatment or Toxo IgG Ab negative. **OR** 2b. Positive Epstein Barr Virus (EBV) PCR.
OTHER CANCER (e.g., Hodgkin's Lymphoma, lung, liver, colon, etc.) (for non-Hodgkin's Lymphoma, see "Lymphoma" or "Lymphoma, CNS," above)	105, 107, 108, 109, 110, 112	Please see link for specific ICD-10 Codes http://seer.cancer.gov/tools/conversion/2014/ICD9CM_to_ICD10CM_2014CF.pdf	**1.** Biopsy with evidence of cancer.	

CONDITION	WIHS DISEASE CODE	ICD-10 CM CODE	DEFINITIVE	PRESUMPTIVE
METASTATIC CANCER	111	Please see link for specific ICD-10 Codes http://seer.cancer.gov/tools/conversion/2014/ICD9CM_to_ICD10CM_2014CF.pdf	**EITHER** 1a. Known cancer diagnosis proven by biopsy or cytology. **AND** 1b. Biopsy or cytology of the same type of cancer in another distant site. **OR** 2. In absence of initial known diagnosis of cancer, cytologic or histologic evidence of distant spread from initial source of disease at time of initial diagnosis.	1. Cancer diagnosis proven by biopsy or cytology. **AND** 2. Radiologic lesion suggestive of distant spread from initial source of disease.
TUBERCULOSIS **121 = in lungs** **122 = in blood** **123 = in lymph nodes** **124 = in other body part** **127 = TB meningitis**	121, 122, 123, 124, 127	**A15 Respiratory tuberculosis** • A15.0 Tuberculosis of lung • A15.4 Tuberculosis of intrathoracic lymph nodes • A15.5 Tuberculosis of larynx, trachea and bronchus • A15.6 Tuberculous pleurisy • A15.7 Primary respiratory tuberculosis • A15.8 Other respiratory tuberculosis • A15.9 Respiratory tuberculosis unspecified **A17 Tuberculosis of nervous system** • A17.0 Tuberculous meningitis • A17.1 Meningeal tuberculoma • A17.8 Other tuberculosis of nervous system	1. Isolation of *M. tuberculosis* from fluid or tissue.	

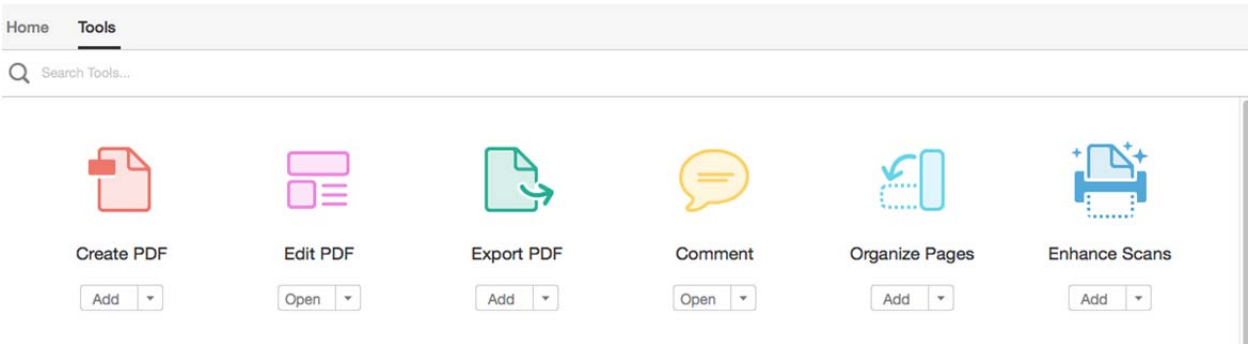
CONDITION	WIHS DISEASE CODE	ICD-10 CM CODE	DEFINITIVE	PRESUMPTIVE
		• A17.9 Tuberculosis of nervous system, unspecified **A18 Tuberculosis of other organs** • A18.0 Tuberculosis of bones and joints • A18.1 Tuberculosis of genitourinary system • A18.2 Tuberculous peripheral lymphadenopathy • A18.3 Tuberculosis of intestines, peritoneum and mesenteric glands • A18.4 Tuberculosis of skin and subcutaneous tissue • A18.5 Tuberculosis of eye • A18.6 Tuberculosis of (inner) (middle) ear • A18.7 Tuberculosis of adrenal glands • A18.8 Tuberculosis of other specified organs **A19 Miliary tuberculosis** • A19.0 Acute miliary tuberculosis of a single specified site • A19.1 Acute miliary tuberculosis of multiple sites • A19.2 Acute miliary tuberculosis, unspecified • A19.8 Other miliary tuberculosis • A19.9 Miliary tuberculosis, unspecified		

APPENDIX C: INSTRUCTIONS FOR ELECTRONIC REDACTION

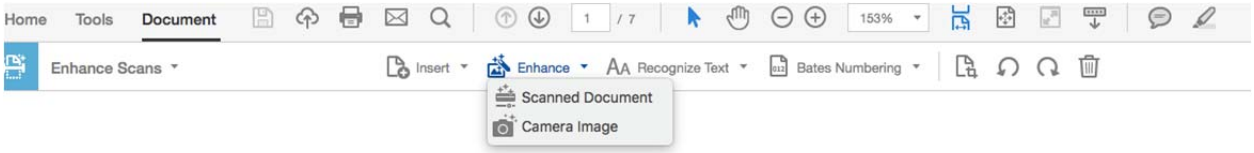
A. Using Adobe Acrobat Pro Software:

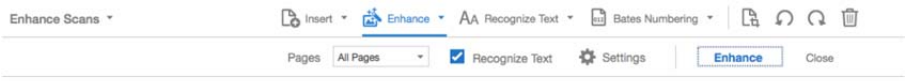
1. Preparing the Document for Redaction

Prior to redacting medical records, staff should attempt to enhance the quality of the scanned document in order to facilitate text recognition. Once you have opened the target file in Adobe Pro, select the "**Enhance Scans**" option from the Tools menu found on the top ribbon.



The "Enhance Scans" tools will automatically open on the ribbon above your document. Select the options for "**Enhance-> Scanned Document**"**.** A sub-menu will appear where you will need to ensure that the options marked "All Pages" and "Recognize Text" are selected.

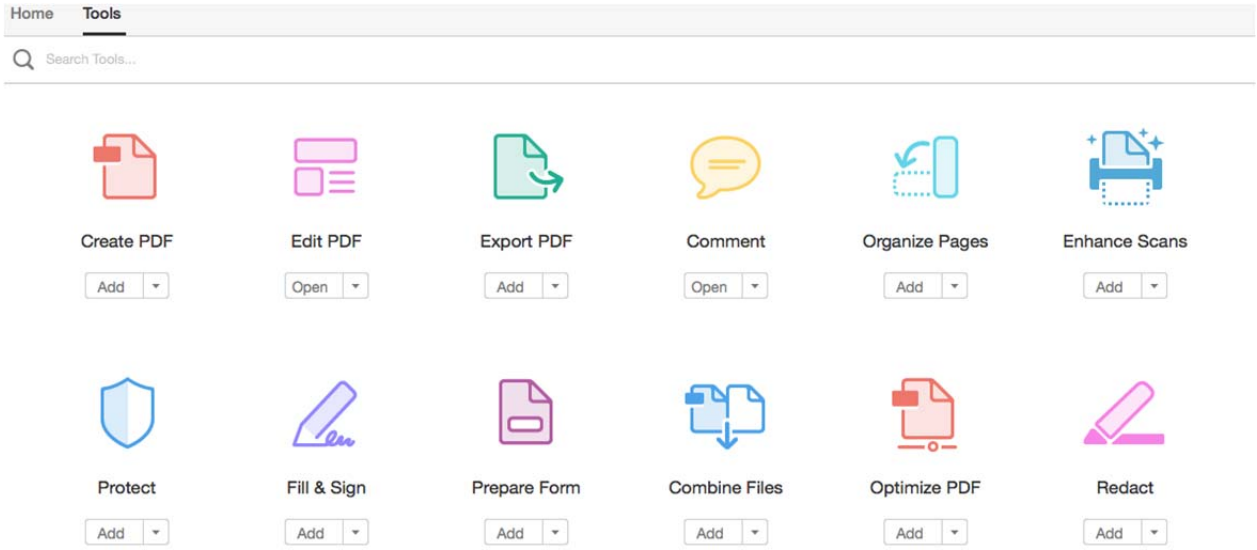




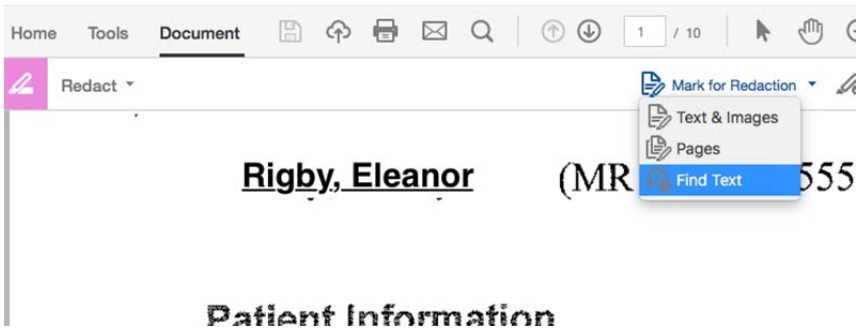
Once OCR text recognition has been applied to the entire document make sure to save the file.

2. Redacting Text & Graphics

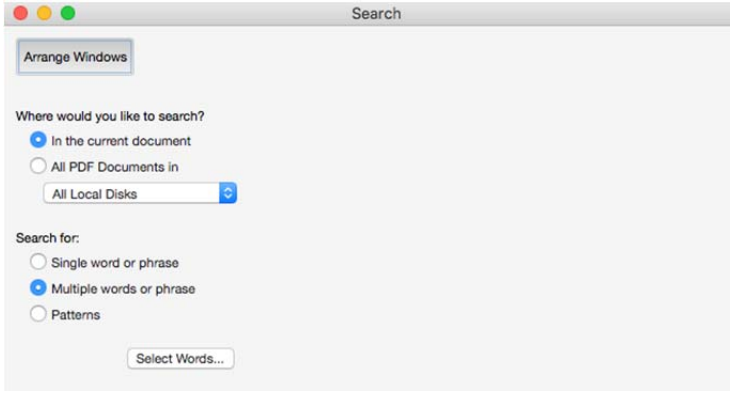
To redact medical records, staff should once again go to the Tools menu where they will select "**Redact".**



The "Redact" tool will automatically open on the ribbon above your document. Select the options for "**Mark for Redaction-> Find Text**".

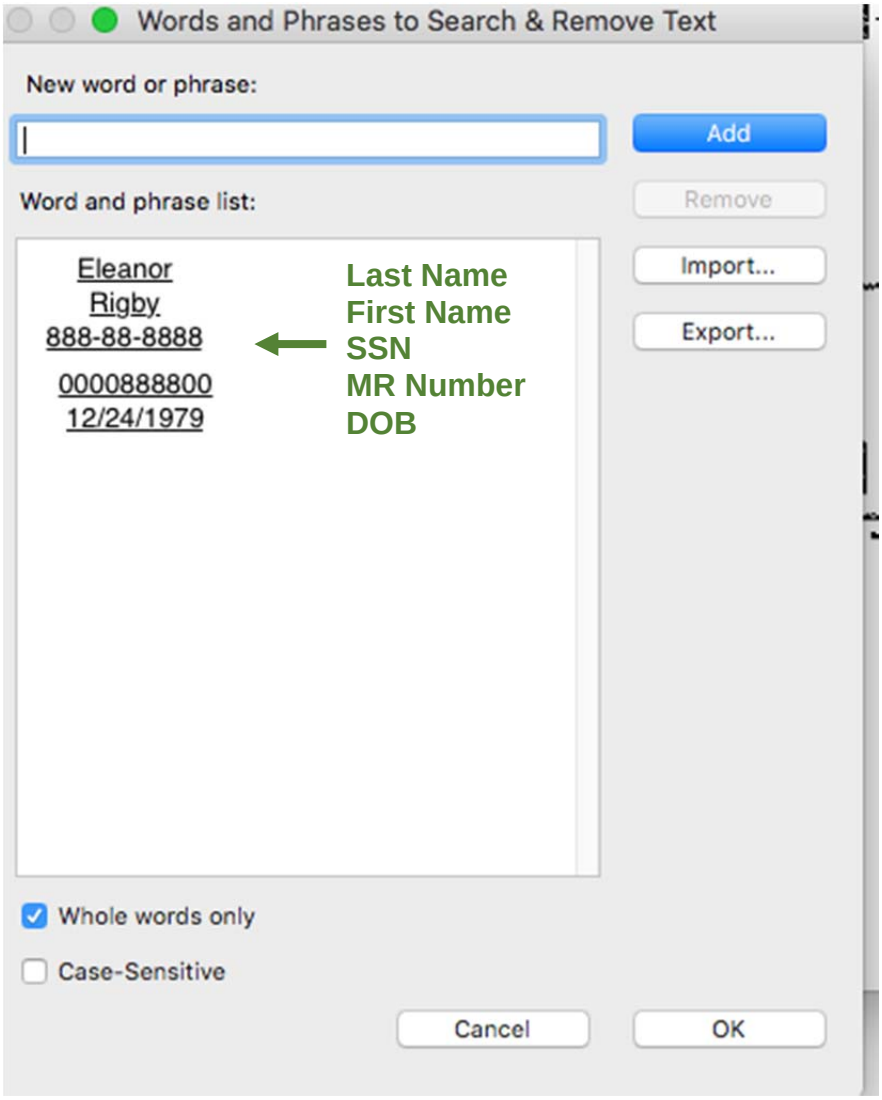


A new menu will appear where you will need to identify the search terms that AdobePro will use as it marks the document for redaction. Ensure that you are searching the "**Entire Document**" for "**Multiple Words and Phrases**".



Next, you will need to enter in all of the search terms. Make sure to enter in search terms as they will appear in the document. In cases where an item may appear in different permutations (e.g., Eleanor Rigby; Rigby, Eleanor; Ms. Rigby) we suggest breaking apart the

search terms and entering in each separately to maximize the effectiveness of the search tool.



Once Adobe has completed searching for all the terms you listed, red boxes will appear around all of the matches that have been identified.

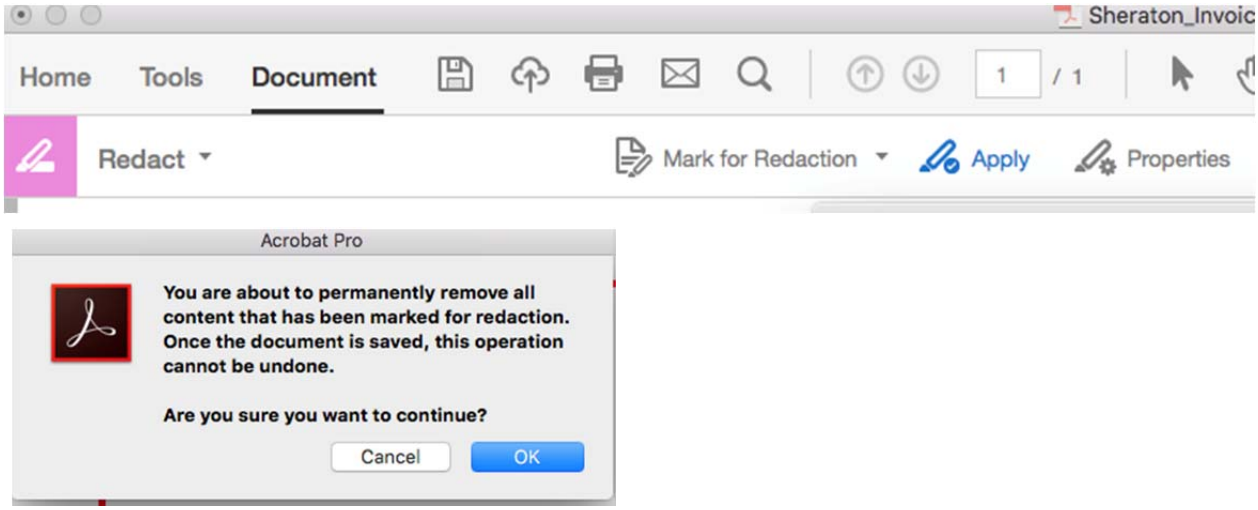
There may be cases in which Adobe Pro misses phrase that were identified- for example, the DOB in the example below. In most cases, this is due to quality of the original scan which may not allow for complete text recognition. These items will have to be manually selected- the process for manual redaction is outlined in Section G.3)

Rigby Eleanor (MR # 0000888800

Patient Information

Patient Name	Sex	DOB
Rigby, Eleanor	Female	12/24/1979

To redact the items that have been identified, select the "**Apply**" option from the Redaction toolbar location at the top of the document. A pop-up screen will ask you to confirm the redaction.



The redacted document will contain permanent redaction boxes around all of the marked items. Make sure to save this document.

[redacted] (MR #[redacted]

Patient Information

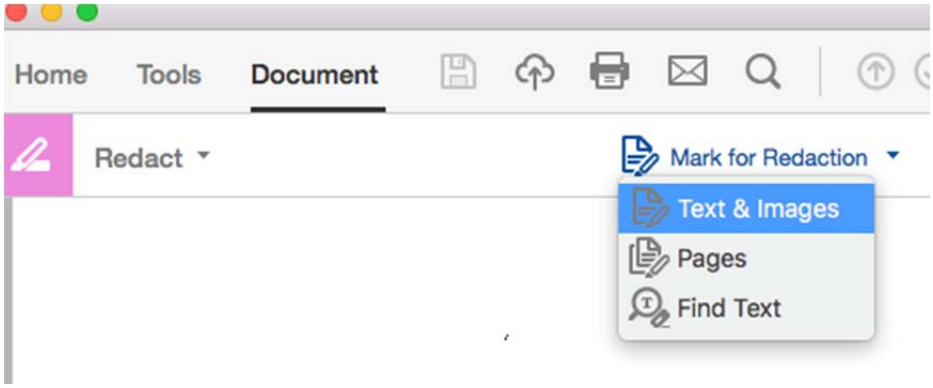
Patient Name	Sex	DOB
[redacted]	Female	12/24/1979

Visit Information

	CSN
9/27/2016 10:06 AM	20255947414

HAR Location

If the text-recognition has failed to identify redaction phrases within your document, you will need to manually redact the items that were missed. To manually identify items for redaction select **"Mark for Redaction-> Text & Images**" from the Redaction toolbar on the top of your Adobe Pro window.



Use your mouse to select the text that remains to be redacted. Selected text will automatically be framed by a red box to signify that it has been marked for redaction.

[redacted] [redacted] (MR # [redacted]

Patient Information

Patient Name
[redacted] [redacted]

Sex
Female

DOB
12/24/1979

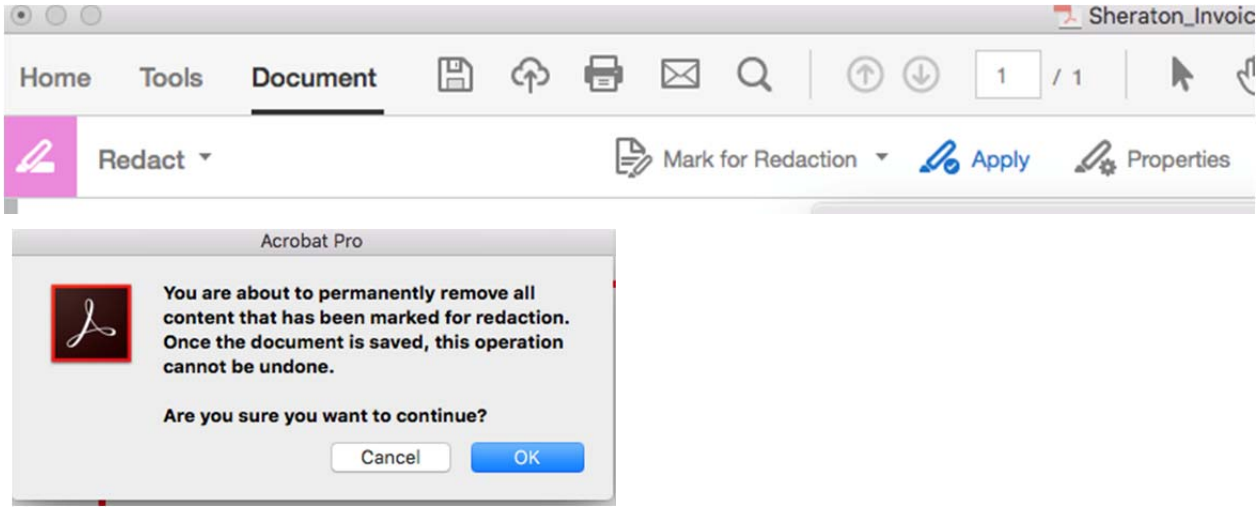
Visit Information

9/27/2016 10:06 AM

CSN
20255947414

HAR Location

To redact the items that have been identified, select the "**Apply**" option from the Redaction toolbar location at the top of the document. A pop-up screen will ask you to confirm the redaction.



The redacted document will contain permanent redaction boxes around all of the marked items.

[redacted] [redacted] (MR # [redacted]

Patient Information

Patient Name
[redacted] [redacted]

Sex
Female

DOB
[redacted]

Visit Information

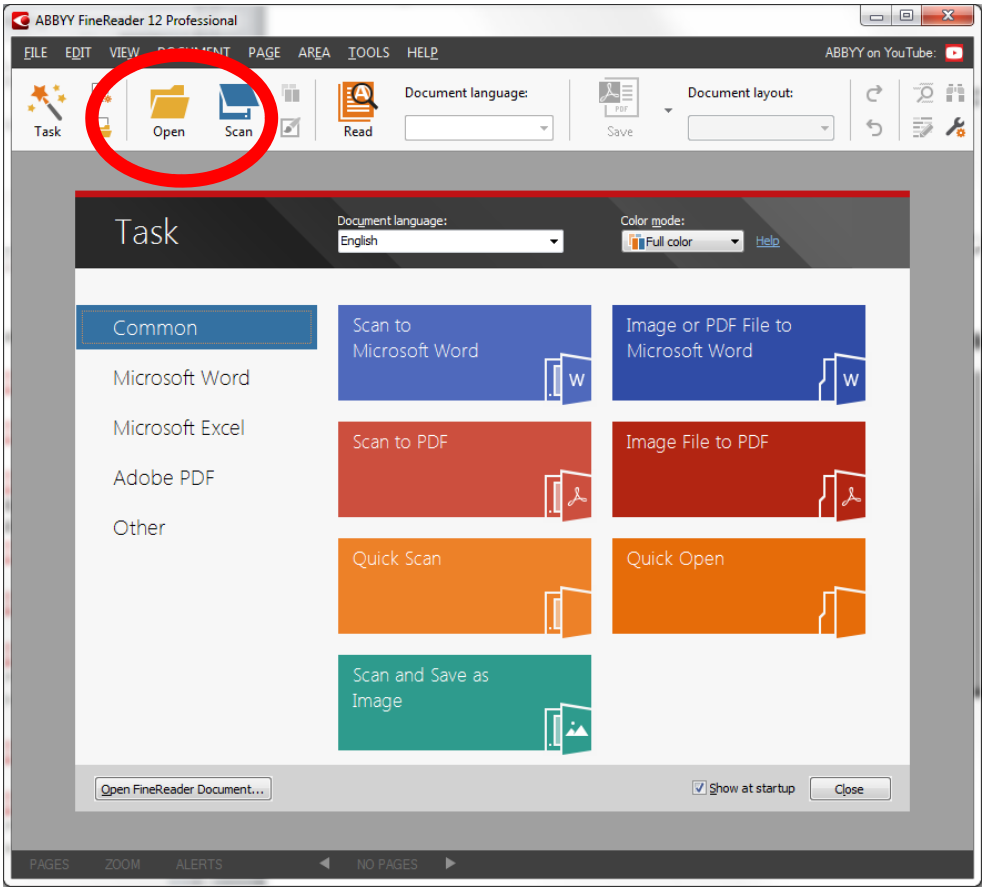
3. **Save the PDF file**.

   To do this, go to **FILE | Save Document As** and use the file explorer to search for the appropriate location on your computer to save the file. Remember to name the files using the naming convention below:

   ID[ETN]-[Seq Num]-[Date of cover form generation in YYYY-MM-DD].pdf

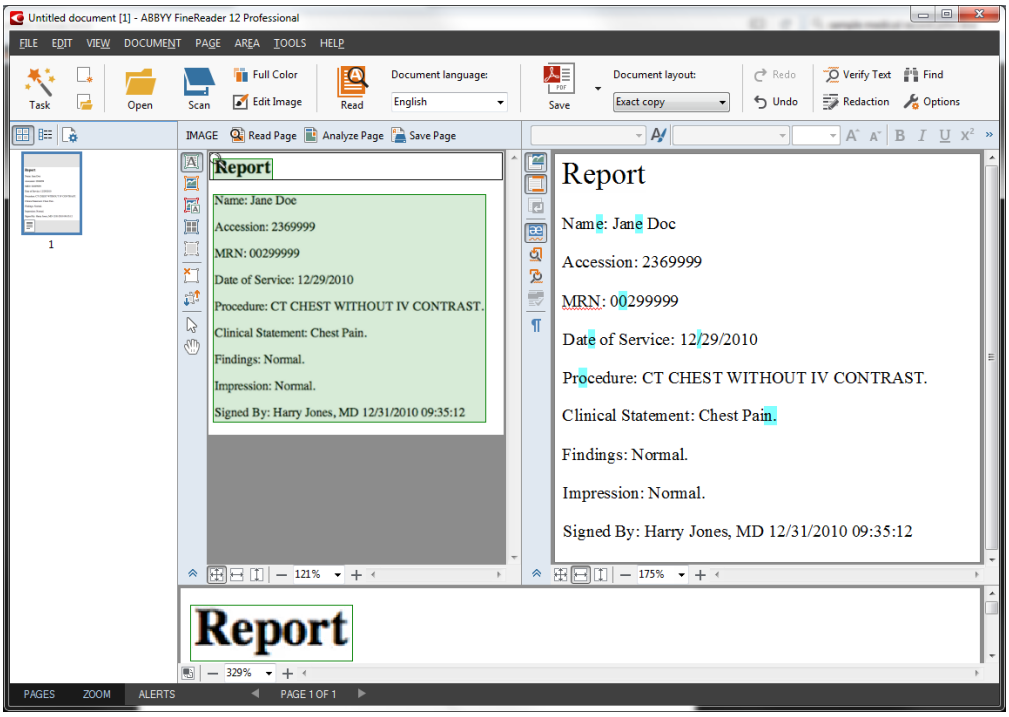
B. Using ABBYY FineReader 12 Software:

1. Open ABBYY FineReader 12.
2. Click on the Open icon:



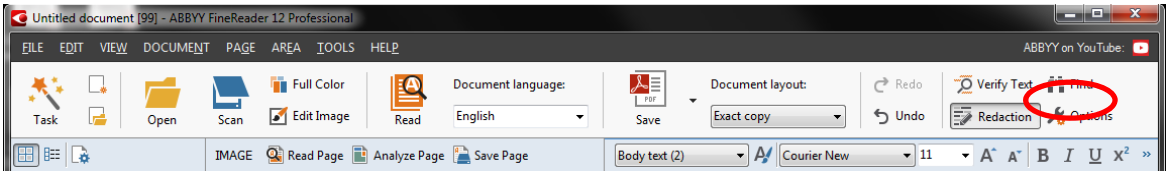
3. Navigate to the PDF of the medical record file you would like to redact.
4. Wait while the program reads in and analyzes/recognizes the text in your document. This may take several minutes. The bottom of the window will show the progress being made:

5. When the recognition is complete, the program will be ready to search for identifiers that you enter into the program. The original document will be in the left hand pane and the version of the document with recognized text will be in the right hand pane.



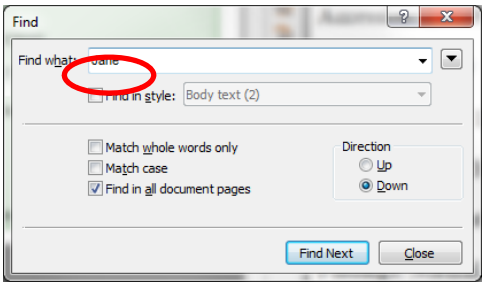
Source of sample medical record: http://dclunie.blogspot.com/2012/08/a-simplified-medical-document-format.html.

6. Automated/assisted searching: This is use of the Search feature to allow the program to help find instances of the identifier you wish to redact. The program will find most instances of this identifier, but it may not find all of them.
   a. Click on the Find icon in the Toolbar to start searching:



   b. In the Find window that opens up, enter the identifier term that you would like to search for.

For example, you enter the word “Jane” in the “Find what” field.

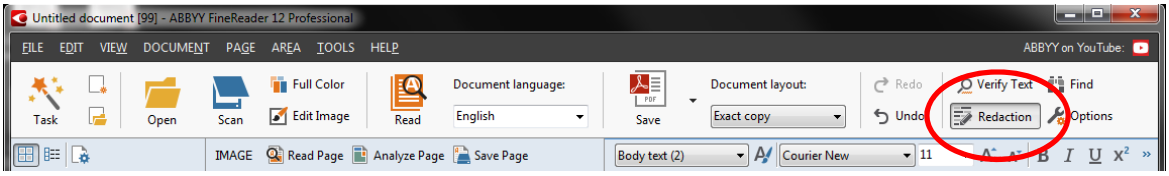


Example of identifiers that can be searched include:

Jane	first name
Doe	last name
12/29/2010	DOB
12-29-2010	DOB
888-88-8888	SSN
00299999	medical record number

c. Click “Find Next”, which will lead to the next instance of the identifier.

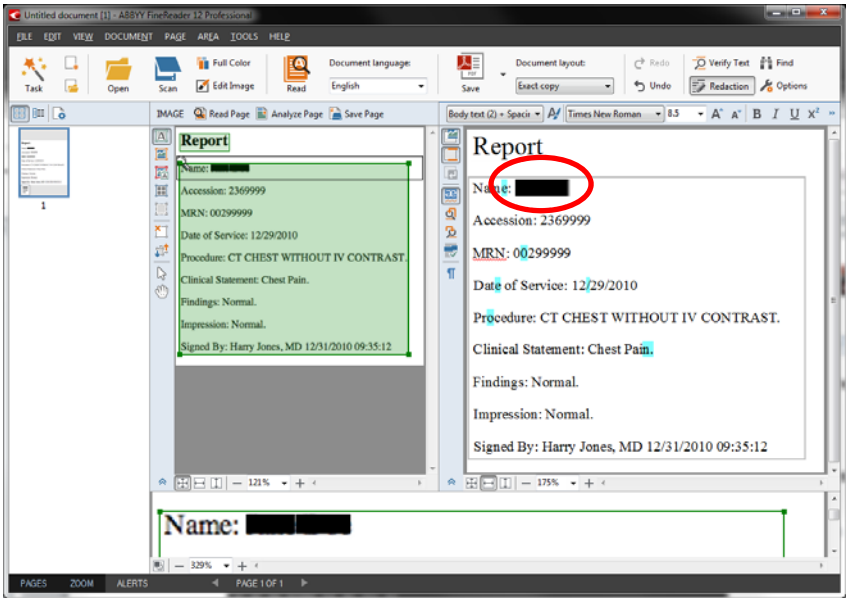
d. After the first time a correct instance of the identifier is recognized, click on the Redaction icon in the Toolbar:



e. To redact, use the cursor to select the identifier(s) on the associated page located in the right hand pane. This will redact, or black out, the characters in the original document on the left hand pane. You can double-click to more quickly black out a specific identifier.

Even if you search for a single identifier (e.g., first name), you can select a longer phrase (e.g., the participant’s full name) and the entire selection highlighted will be redacted.

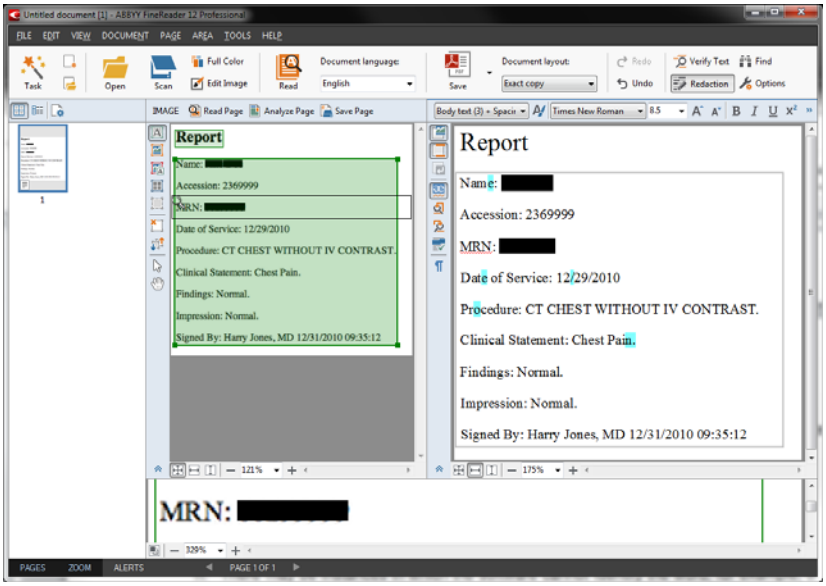
Note that if you black out some characters by mistake, you can undo the last redaction by pressing Ctrl+Z or by clicking the Undo button on the main toolbar.



f. Continue Steps (c) through (e) until you get to the end of the entire document and have redacted all recognized instances of that term.

g. Then, continue from Step (a) for other identifiers/terms that you would like to automatically search for (e.g., medical record number, SSN, home address, etc.)

   For example, the screenshot below shows redaction of the MRN:



h. There may be instances in which the software cannot identify the word, for example, if the photocopy of the records is unclear. In this scenario, manual searching of the document for all instances of identifiers will be needed.

7. Manual searching: Automated searching may not find all instances of an identifier. Furthermore, it is imperative that the file be reviewed at least once more in order to manually search for any identifiers that may have been missed.

a. To redact a word, repeat the procedure of clicking on the Redaction icon and then, on the right-hand pane, using the cursor/arrow to select the relevant identifier, or alternatively, by double-clicking on the identifier. This will redact, or black out, the characters in the original document on the left hand pane.

b. Occasionally, identifiers will not be recognized as text by the program. You will know this because on the left hand pane, the text will not have a colored box around it. In this situation, you will need to use the cursor to create a box the area containing the text on the left hand pane, and then right-click. Then, select "Change Area Type to Background Picture". Once this is done, then the identifier can be redacted by selecting the area to be redacted on the right-hand pane as before.

8. When finished, save the file as a PDF file.

   To do this, go to **FILE | Save Document As PDF Document.**

   The default save mode is "Text under the page image", which means that the entire page image is saved as a picture, and the recognized text is placed underneath. Therefore, the document is fully searchable document but looks virtually the same as the original. Any text that was redacted has already been eliminated and therefore is not searchable.