# SPIROMICS

# Endpoints Ascertainment Procedure Supplements

## Version 1.1

## January 23, 2015

**Endpoints Ascertainment Procedure Supplements**

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## Supplement 1. Example Event Summary Form (ESF) for Pulmonary Diagnosis

**EVENT ID: X000000100101**

| SPIROMICS ID: | Gender: | Age at Baseline: | Age at Event: | Height | Predicted PEF | BMI |
|---|---|---|---|---|---|---|
| X0000010 | F | 55 | 56 | 161.00 | 27.9 | |

**Event Date** 12/28/2009    Date of arrival: [mm/dd/yyyy]    Date of discharge: [mm/dd/yyyy]

**ICD-9 Discharge Codes:**

786.50      486       493.20       99.21

## ER, hospital or observation:

### Doctor's diagnosis
Reason in doctor's notes that this event may be exacerbation of COPD:
Reason in doctor's notes that event may be exacerbation of asthma:

### Signs and symptoms
Any of the following signs or symptoms at the time of the event:
- New onset or increase in cough:
- New onset or increase in sputum production
- New onset or increase in sputum purulence
- New onset or increase in wheezing
- New onset or increase in dyspnea
- Crackles / rales
- Wheezing or rhonchi

### History
History of any of the following:
- Asthma
- Emphysema
- Chronic obstructive pulmonary disease (COPD)

### Tests
Any of the following signs on chest x-ray or chest CT at any time during this event?
- Hyperinflation
- Flattened diaphragms
- Emphysema
- Infiltrate/consolidation
- Pulmonary edema
- Pleural effusion

Sputum or respiratory fluid culture results

**Prior PFTS:** Percent predicted $FEV_1$:            FEV1/FVC:

### Peak flows
Date of first PEF(R) taken after hospital/ED arrival: (mm/dd/yyyy)
First PEF recording (L/min)
Worst PEF recording (L/min) during this hospitalization

### *TREATMENTS / MEDICATIONS*

Antibiotics

Inhaled short-acting beta-agonists (i.e., albuterol, xopenex)                                             No/NR 0    Yes 1

Inhaled short-acting anticholinergics (i.e., atrovent, ipratropium)

Inhaled long-acting beta agonists

Inhaled long-acting anticholinergics

Inhaled corticosteroids

Systemic corticosteroid (oral or IV)

CPAP or BiPap

Mechanical Ventilation

## Supplement 2. Morbidity and Mortality Committee – Principles of Mortality Adjudication

The Morbidity and Mortality Committee will designate cause of death by probable cause. Causes of death will be grouped by general categories, e.g. Respiratory, Cardiovascular, Cancer, or Other. If a cause of death cannot be ascertained, the cause of death will be classified as Unknown. The general principles used in this classification are listed:

1. All diagnoses of cancer should be corroborated by the primary medical record. If the primary medical record cannot be obtained to confirm the diagnosis, this should be affirmatively stated in the documentation, and the committee will determine a diagnosis based on their best judgment.

   a. Patients who die with an uncured cancer will be designated as dying from the cancer. For example, a patient with documented gastric cancer who dies of gastrointestinal hemorrhage will be classified to have died from gastric cancer. A patient who dies from neutropenic sepsis while undergoing chemotherapy for lymphoma will be classified as dying from lymphoma.

   b. Based on the medical information, patients who have cancers that are not expected to result in death from complications of the disease or treatment such as localized skin or urogenital cancer may be considered to die of other causes.

2. Death certificates should be obtained in all cases. If they cannot be obtained, it should be affirmatively stated in the documentation.

3. If medical records are inadequate and cannot be obtained as affirmatively stated in the documentation, a cause of death will be adjudicated based on the best available evidence of record. If a probable cause of death cannot be adjudicated, it will be classified as unknown.

4. The primary cause of death should be attributed to the disorder that causes the patient to present for medical treatment. This should be distinguished from terminal events that are the immediate cause of death.

   - For example, if a patient is admitted to the hospital with a COPD exacerbation, from which they do not fully recover, and the patient subsequently develops complications such as pneumonia, respiratory failure, renal failure, sepsis, cardiac arrhythmia or myocardial infarction, the primary cause of death will be attributed to COPD.

   - For example, if a patient undergoes surgery for cancer and dies from complications of the surgery or during the immediate post-operative period, the primary cause of death will be attributed to cancer, even if the cancer was potentially curable by the surgery.

   - For example, if a patient is admitted to the hospital with pneumonia and develops complications such as respiratory failure, gastrointestinal bleeding, etc. the cause of death will be attributed to pneumonia. If it is unclear if a patient is admitted with a COPD exacerbation or pneumonia, the cause of death will be based on the hospital admission chest radiograph. If pneumonia is present

on the admitting chest radiograph (or within 48 hours of presentation), the cause of death will be designated pneumonia.  If pneumonia is present only on subsequent chest radiographs (beyond 48 hours after presentation), the cause of death will be designated as COPD.

- If a patient is admitted to hospice care for a designated chronic terminal condition (e.g. COPD, CHF), then the terminal condition will be the designated cause of death.

5. Included within cardiovascular causes of death will be two subcategories, "sudden death" and "sudden cardiac death."  Sudden Death is defined as death that occurs within 24 hours of being observed alive and without evidence of a deteriorating medical condition.  Sudden Cardiac Death is defined as death that occurs within 1 hour of being observed alive and without evidence of a deteriorating medical condition.  If the interval between death and last being observed alive is greater than 24 hours, and there is no other known cause of death, the cause of death will be classified as "Unknown."  The diagnosis of myocardial infarction will require pathologic evidence, or evidence of medical record including electrocardiographic tracings, blood enzyme measurements, and compatible clinical findings.

6. In cases of out of hospital death, the site coordinator or site physician should interview family or witnesses to ascertain the following information:
   - When was the person last known to be alive?
   - When was the person found to be deceased?
   - What were the events surrounding the death?
   - Did the decedent have any symptoms or change in health status that preceded the death?  Special reference should be made to dyspnea, febrile illnesses, chest pain, abdominal pain, syncope, seizures, paralysis and change in mental status.
   - Were there recent medical visits or recent changes in medication?
   - Was an autopsy performed?
   - Permission to obtain medical records should be requested from next-of-kin.

## Supplement 3. Scanning and Redacting

The GIC will provide each site with a document scanner and Adobe Acrobat Professional Version 9.5 or higher to create PDFs of your electronic files. This ensures the proper level of file security.

Place all documents for each event, including the Medical Record Shipping Cover Letter, in Table 1 order and scan using the scanner set to black and white document and save as a PDF in a secure location. Open the case with Adobe Acrobat Professional 9.5 or higher. You will need to right-click on the document and choose "Open With" and "Adobe Acrobat 9.5" to access full functionality. Double-clicking on the PDF will only open the document in Adobe Reader.

Once the file is open with Adobe Pro, insert a header (found in the Document tab menu) with the appropriate Event ID from the Event ID Tracking Report in the upper right-hand corner. This header should appear on every page of the document.

Redaction
To redact, open the medical record case with Adobe Acrobat Professional 9.5 or higher. Select Mark for Redaction.
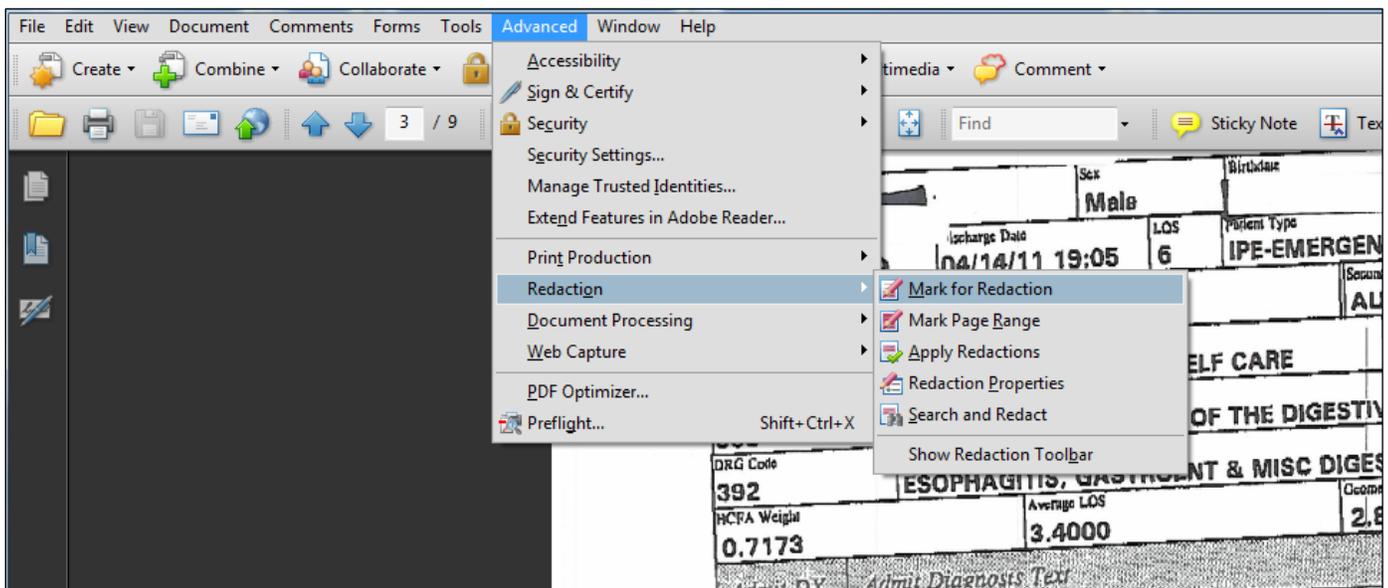


This will bring up one of two redaction cursors (image courtesy of Rick Borstein).
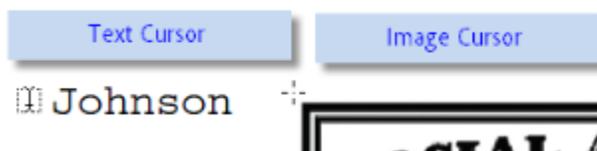
While reading through the file, left click, hold and drag the text or image cursor over the text you want to redact so it is enclosed in a blue shadowed box. Release the cursor and a red redaction box will remain to indicate your selection. If you don't see a red box, the text is not selected for redaction and you may need to go back and click on Mark for Redaction again. To correct the area selected, use CTRL-Z to delete the red redaction box. If the text cursor is making it hard to select specific text, hold down the CTRL key to force the + image cursor.



Once the entire document has been reviewed and text for redaction selected, go back to Advanced and choose Apply Redactions. A dialog box opens warning that redactions are permanent. Click Yes to complete the redactions.
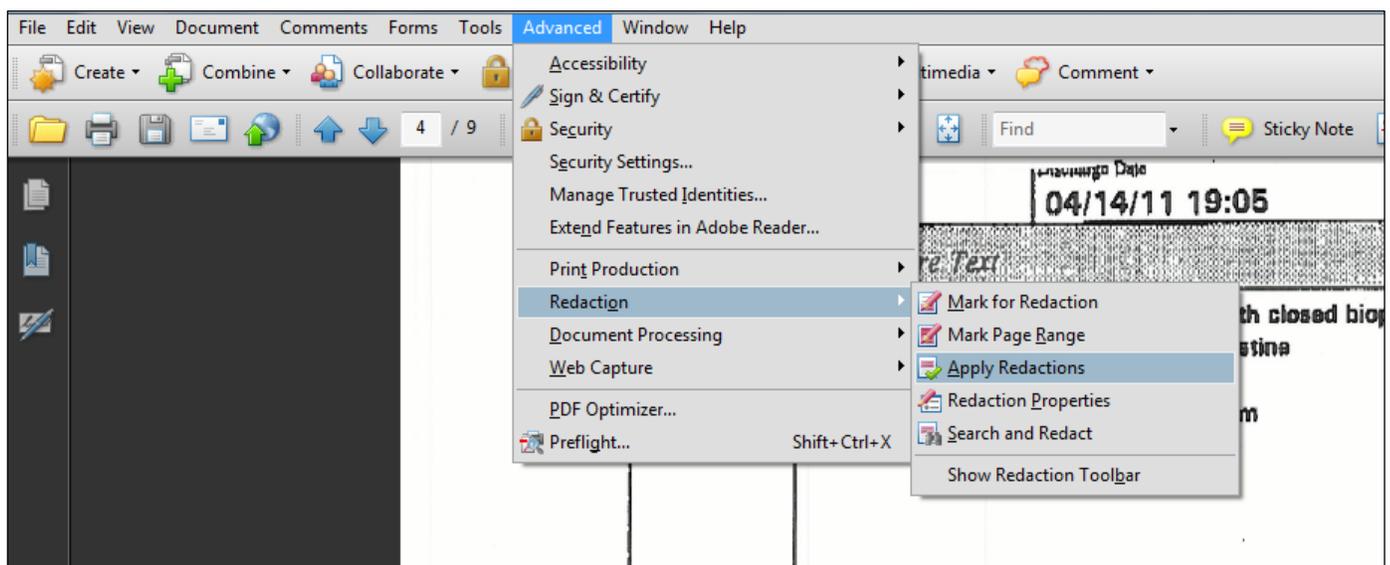
When this is complete, a second dialog box opens up asking if you want to complete other functions, just click on No. Save the file – Adobe will ask if you want to replace the current file. Click Yes.

Each page of the scanned medical records or death certificates must be checked and the following items redacted:

Participant and family member names and/or initials, addresses, and telephone numbers
Participant birth date and Social Security number
Hospital and healthcare system names, facility initials, street addresses, and telephone numbers
Institutional letterheads and/or logos
All healthcare staff names, initials, provider numbers, pager and extension numbers
Medical record numbers
Health plan ID numbers
Account numbers
Lab, test, or procedure accession numbers, order numbers, or exam numbers
Dictation job and confirmation numbers
Electronic mail addresses
Web addresses or URLs, IP addresses

The following items should *not* be redacted:

Participant age, gender
Admit and Discharge dates
Healthcare staff titles or departments (i.e., MD, RT, Cardiology)
On death certificates, do not blind causes of death

## Supplement 4. Tables 1-3

Table 1. Documents to be obtained if available for all deaths occurring while hospitalized OR if an ED visit or hospitalization has occurred in the setting of relevant diagnoses (Tables 2 and 3).

| | |
|---|---|
| 1 | Coding summary with ICD-9 or ICD-10 codes |
| 2 | Admission History and Physical |
| 3 | Discharge Summary (#2 and #3 maybe one note for ED visits) |
| 4 | General labs (blood) |
| 5 | Microbiology labs (blood, sputum, tracheal and bronchial fluid) |
| 6 | Procedure or surgical reports |
| 7 | Spirometry report |
| 8 | Echo report |
| 9 | Pulse oximetry report |
| 10 | Arterial blood gas report |
| 11 | Discharge medication report |
| 12 | Chest X-ray report |
| 13 | Chest CT scan report |
| 14 | Pulmonary angiography |
| 15 | V/Q Lung scan |
| 16 | Autopsy or Medical examiner report |
| 17 | 12-lead EKG reports and cardiac enzyme lab reports for MI and CAD cases only |

Table 2. ICD-9-CM codes and diagnoses that require attainment of additional records (see Table 1).

| Diagnoses requiring abstraction | |
|---|---|
| Acute upper respiratory infection | 465.X |
| Acute bronchitis | 466.X |
| Viral Pneumonia | 480.X |
| Pneumococcal pneumonia | 481.X |
| Other bacterial pneumonia | 482.X |
| Pneumonia due to other specified organism | 483.X |
| Bronchopneumonia, organism unspecified | 485.X |
| Pneumonia, organism unspecified | 486.X |
| Influenza | 487.X |
| Influenza | 488.X |
| Bronchitis | 490.X |
| Chronic bronchitis 491<br>With acute exacerbation 491.21 | 491.X |
| Emphysema | 492.X |
| Asthma 493<br>Unspecified 493.0<br>With status asthmaticus 493.1<br>With acute exacerbation 493.2 | 493.X |
| Bronchiectasis | 494.X |
| COPD | 496.X |
| Pneumonitis due to solids and liquids | 507.X |
| Empyema | 510.X |
| Pleurisy | 511.X |
| Pneumothorax | 512.X |
| Abscess of lung and mediastinum | 513.X |
| Pulmonary congestion and hypostasis (includes pulmonary edema NOS) | 514.X |
| Other diseases of lung including but not exclusive to:<br>Acute pulmonary edema of lung, unspecified 518.4<br>Pulmonary insufficiency following trauma and surgery 518.5<br>Acute respiratory failure 518.81 | 518.X |
| Heart Failure | 428.X |
| Additional diagnoses or procedures if listed on coding summary or reported by patient where additional records are needed | Mechanical Ventilation not in the setting of a surgical procedure<br>Lung Transplantation, or any hospitalization where the patient reports they were treated for a respiratory problem |
| For abstraction but not adjudication | |
| Lung cancer | 162.X or 163.X |
| Diabetes | 249.X 250.X |
| Venous thrombosis (DVT) | 453.X |
| Pulmonary embolus | 415.X |
| Osteoporosis | 733.X |
| Hip Fracture | 820.X 821.X |
| Myocardial Infarction | 410.X, 411.X |
| Coronary artery disease | 414.X |
| Stroke or transient ischemic attack | 433.X, 434.X, 435.X |

Table 3. ICD-10-CM codes and diagnoses that require attainment of additional records (see Table 1).

| Diagnoses requiring abstraction | |
|---|---|
| Acute upper respiratory infections of multiple and unspecified sites | J06.X |
| Influenza due to identified avian influenza virus | J09.X |
| Influenza due to identified influenza virus | J10.X |
| Influenza, virus not identified | J11.X |
| Viral pneumonia | J12.X |
| Pneumonia due to Streptococcus pneumonia | J13.X |
| Pneumonia due to Haemophilus influenza | J14.X |
| Bacterial pneumonia, not elsewhere classified | J15.X |
| Pneumonia due to other infectious organisms, not elsewhere classified | J16.X |
| Pneumonia in disease classified elsewhere | J17.X |
| Pneumonia, organism unspecified | J18.X |
| Acute bronchitis | J20.X |
| Acute bronchiolitis | J21.X |
| Unspecified acute lower respiratory infection | J22.X |
| Bronchitis, not specified as acute or chronic | J40.X |
| Simple and mucopurulent chronic bronchitis | J41.X |
| Unspecified chronic bronchitis | J42.X |
| Emphysema | J43.X |
| Other chronic pulmonary disease which includes but is not exclusive to:<br>COPD with acute lower respiratory infection (J44.0) excluding influenza<br>COPD with acute exacerbation (J44.1)<br>Other specified COPD (J44.8) | J44.X |
| Asthma | J45.X |
| Status asthmaticus (includes acute severe asthma) | J46.X |
| Bronchiectasis | J47.X |
| Respiratory conditions due to inhalation of chemicals, gases, fumes and vapors | J68.X |
| Pneumonitis due to solids and liquids | J69.X |
| Respiratory conditions due to other external agents | J70.X |
| Adult respiratory distress syndrome | J80.X |
| Pulmonary edema | J81.X |
| Abscess of lung and mediastinum | J85.X |
| Pyothorax | J86.X |
| Pleural effusion, not elsewhere classified | J90.X |
| Pleural effusion in conditions classified elsewhere | J91.X |
| Pneumothorax | J93.X |
| Other pleural conditions | J94.X |
| Postprocedural respiratory disorders, not elsewhere classified | J95.X |
| Respiratory failure, not elsewhere classified | J96.X |
| Other respiratory disorders | J98.X |
| Heart Failure | I50.X |

| Additional diagnoses or procedures if listed on coding summary or reported by patient where additional records are needed | Mechanical Ventilation not in the setting of a surgical procedure<br><br>Lung Transplantation, or any hospitalization where the patient reports they were treated for a respiratory problem |
|---|---|
| **For abstraction but not adjudication** | |
| Lung cancer | C33.X, C34.X, C38.4 |
| Diabetes | E1X.X |
| Venous thrombosis | I80.X, I81.X, I82.X |
| Pulmonary embolus | I26.X |
| Osteoporosis | M80.X, M81.X, M82.X |
| Hip fracture | S72.X |
| Myocardial infarction | I20.X, I21.X, I22.X, I23.X, I24.X |
| Coronary artery disease | I25.X |
| Stroke or transient ischemic attack | I63, I64, G45.X |

## Supplement 5. File Transfer to the GIC

FileZilla FTP will be used for secure transfer of completed medical record files to the GIC. Please follow host institution protocol for downloads. We strongly recommend having your IT safely download and configure FileZilla for your secure network and the number of users you want.

Once FileZilla is installed, open and click on File, then Site Manager.
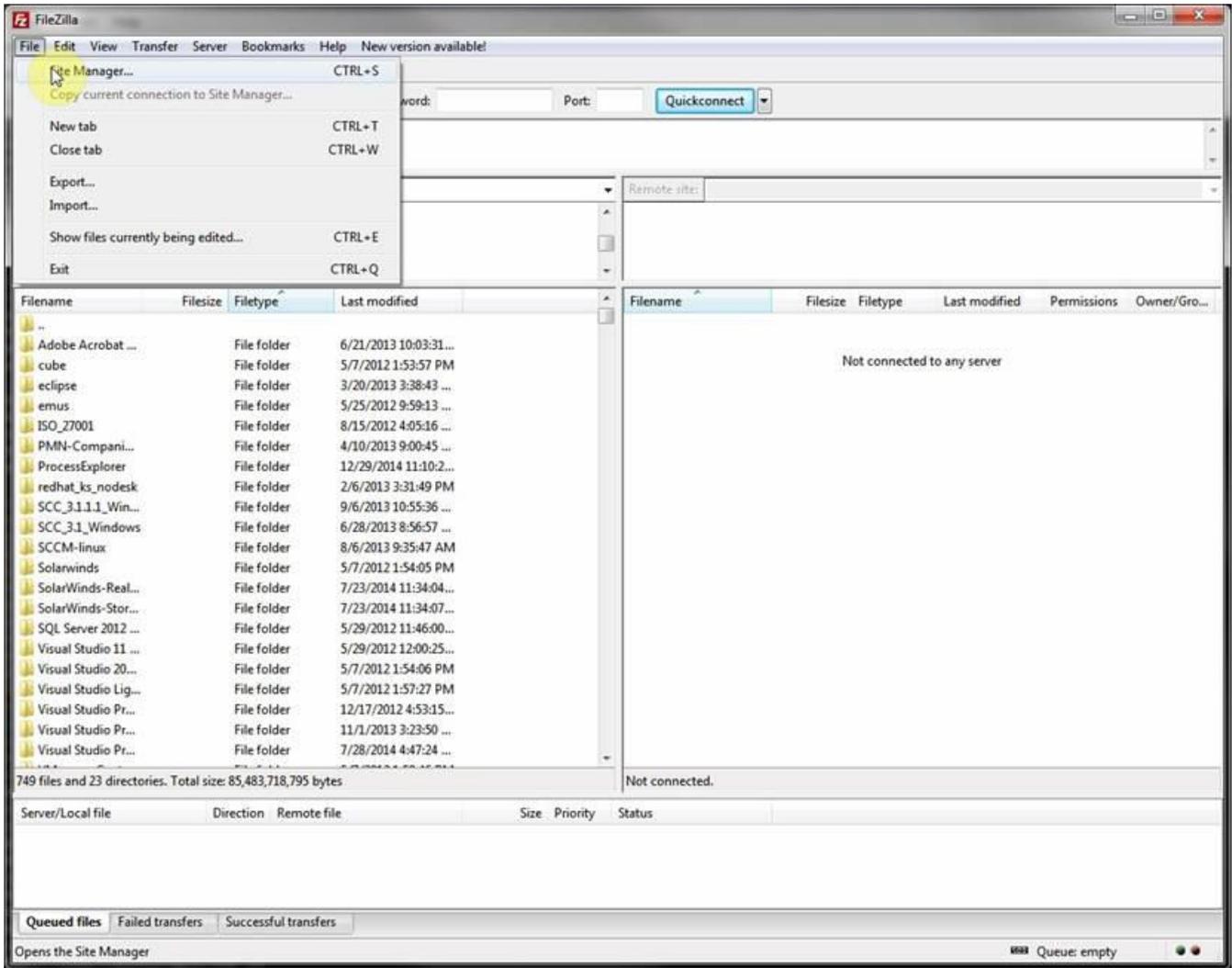


This brings up the Site Manager screen. For the first time in, click on the New Site button and type in a name for the ftp connection to the GIC (ex. "CSCC SPIR-CU"). Then on the right-hand side, enter or select the information as shown below for Host, Protocol, and Encryption. Your site's unique User name

and Password will be sent securely under separate cover. Then click on Connect. The next time you come in to FileZilla, you can just select the GIC site name on the left-hand My Sites panel to connect.
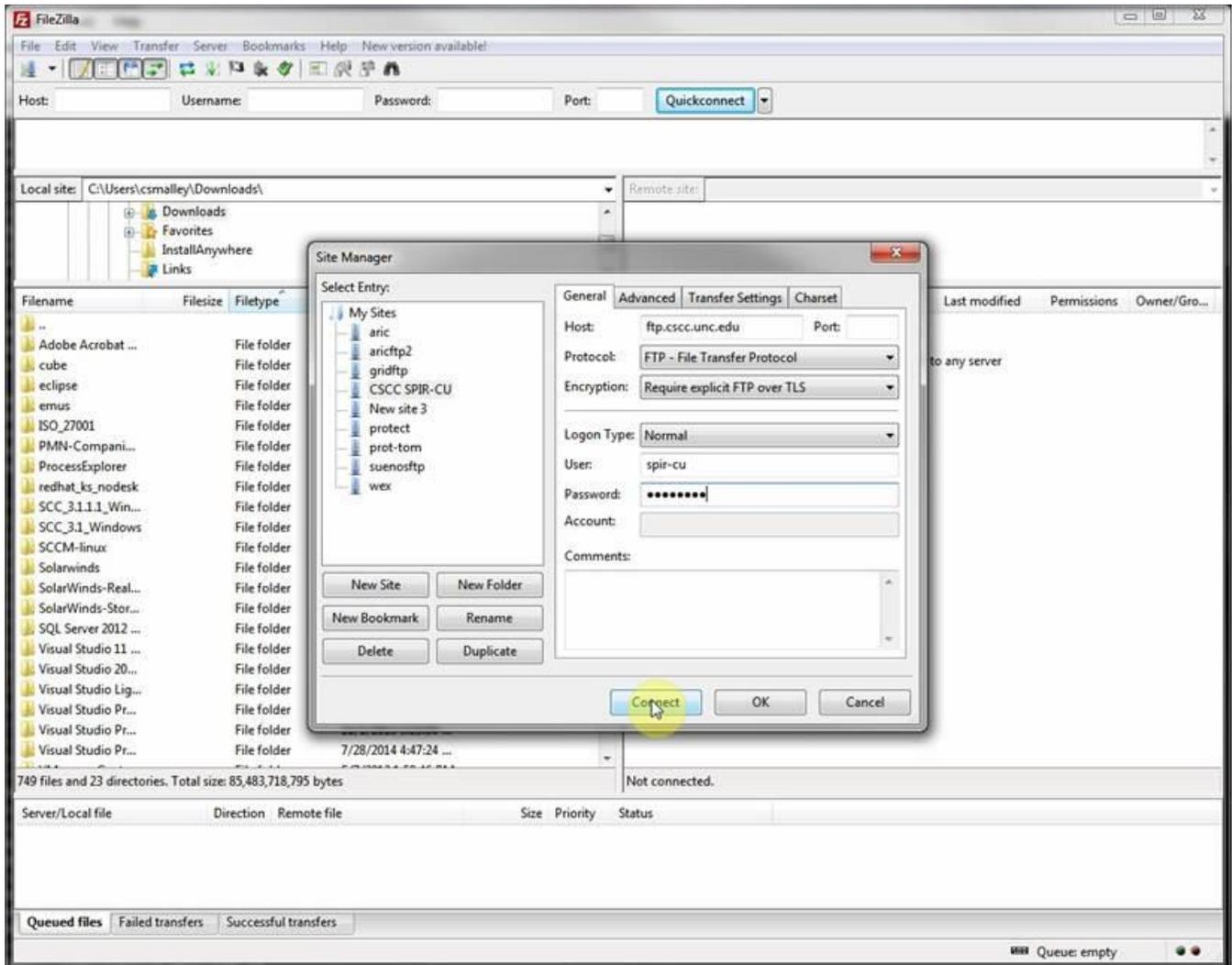
The first time you sign on, you will get an "Unknown certificate" screen.  If the common name is "*.cscc.unc.edu" then you can check the Always Trust check box and click OK to connect.
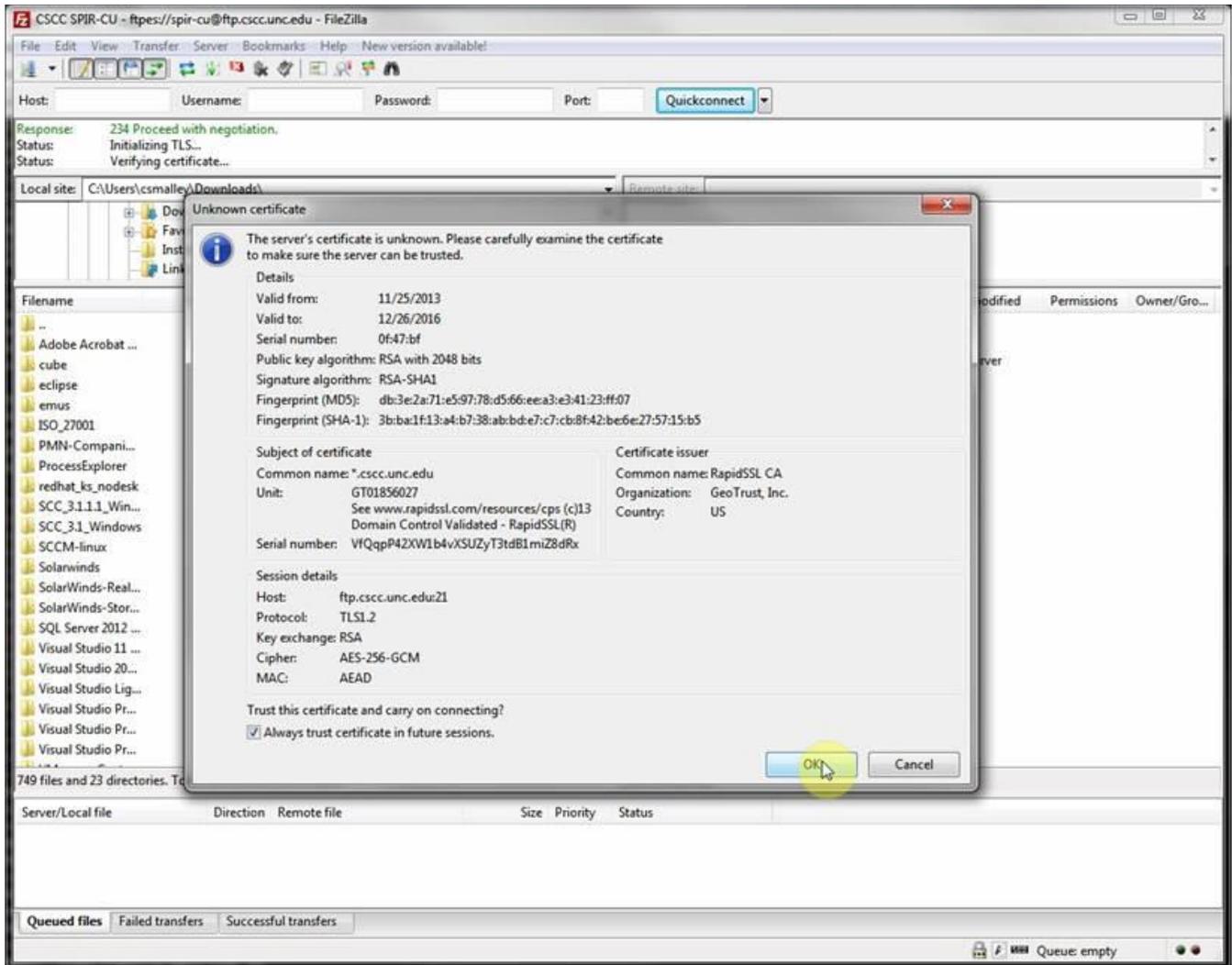
Once you are connected, in the left panel navigate to the location of files for transfer on your system. The right-hand panel shows files sitting on our ftp server. Click and drag files from the left panel over to the right panel to copy files over to the GIC ftp server.
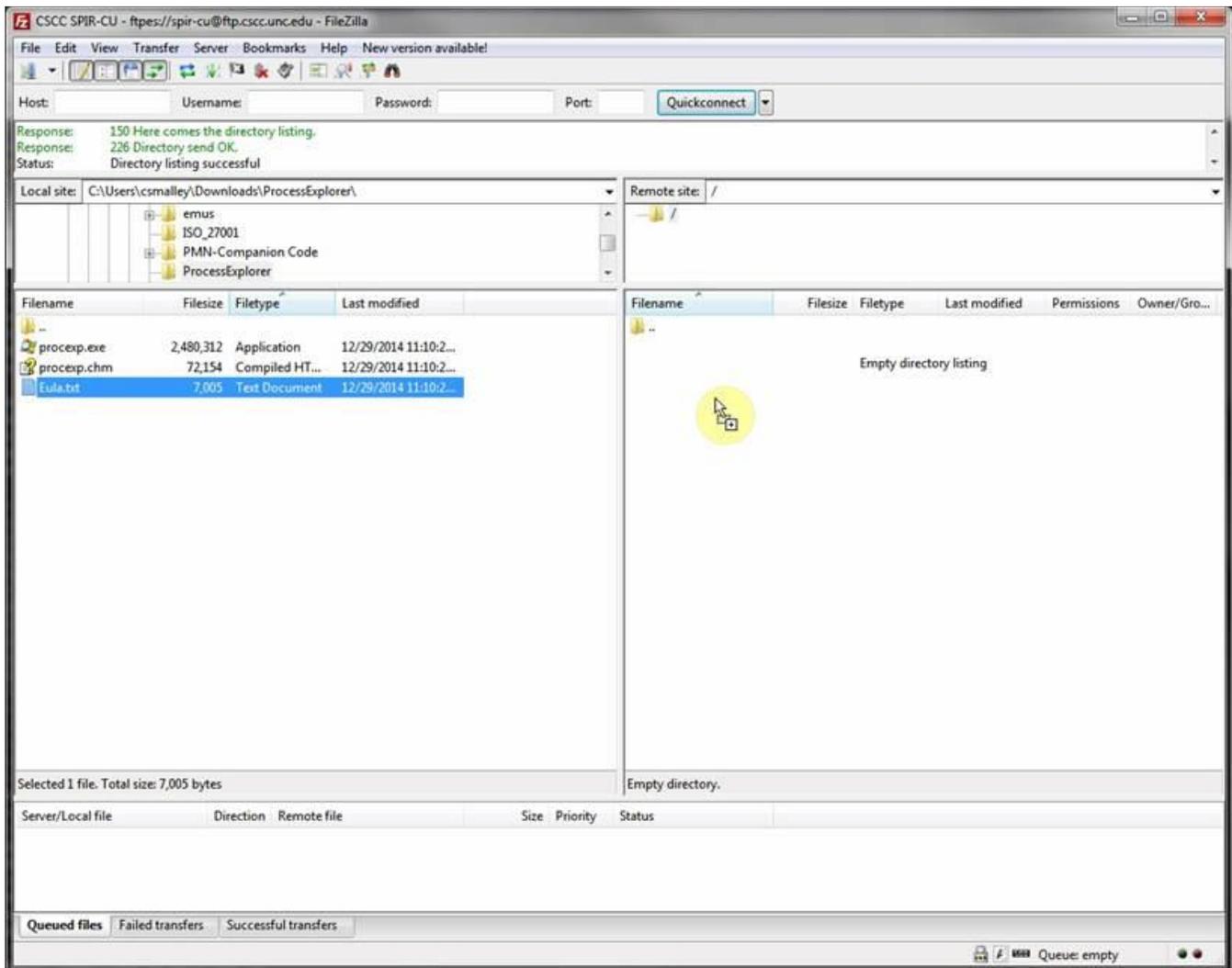


When you're finished transferring files, click the "X" to break the connection or click on "Server" and then "Disconnect". A script goes through every 30 minutes or so and moves the files from the server into the GIC system, so if you've copied a file over and then don't see it, it has probably been moved.

## Supplement 6. Support Contact List

**Policy Questions**            Betsy Carretta            besty.carretta@unc.edu
                                                          (919) 962-2190

**Medical Record Questions**    Michele Inishi            minishi@email.unc.edu
                                                          (919) 962-3440

**Case Query/Receipt Questions**  Nell Malone             dlmalone@email.unc.edu
                                                          (919) 966-9518