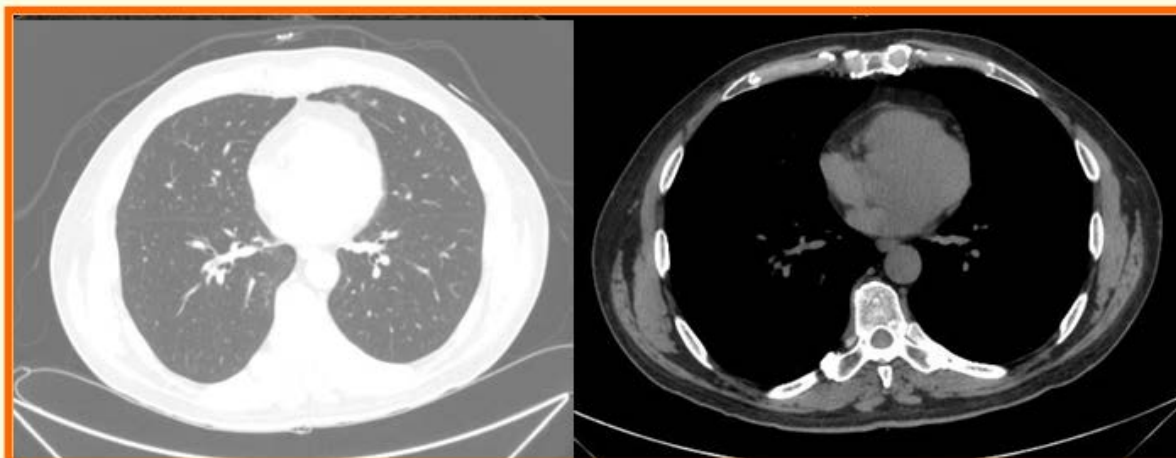


# Site Imaging Manual

## ACRIN 4704/DECAMP-2



**Detection of Early Lung Cancer Among Military Personnel  
Study 2 (DECAMP-2): Screening of Patients with Early Stage  
Lung Cancer or at High Risk for Developing Lung Cancer**

Version:	3.0 Final
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**History of Revisions:**

17-June-2013	1.0	Initial Release to Sites
02-June-2014	1.1	Added Lung/Bone algorithm
03-Dec--2014	1.2	Update to comply with Protocol Amendment 3. Edited 3.1, 3.2, 4.1, 4.2, 6.2 and updated TRIAD 4.2 language
17-June-2015	2.0	Updated to comply with Amendment 4. Edited Schema Removed Group A. Edited Fields 1.0, 2.1, 3.1 deleted, 4.1 deleted, 4.3 edited, 5.1 deleted, 5.2 edited.
07-Feb-2018	3.0	Clarified Submission Language section 1.0, 6.1, 6.2

## Letter of Introduction

Dear Fellow Researchers,

This ACRIN 4704 Imaging Manual contains the guidelines for image acquisition, processing, storage, shipping, and documenting of all imaging data collected in the **ACRIN 4704 trial, “Detection of Early Lung Cancer Among Military Personnel Study 2 (DECAMP-2): Screening of Patients at High Risk for Developing Lung Cancer.”**

To successfully meet the study objectives, it is critical that the participating sites follow the instructions and guidelines outlined in this manual.

Quality Control (QC) review of all image data will be performed by the ACR Imaging Core Laboratory. This review will be performed in a timely fashion as part of ACRIN standard operating procedures. If any protocol deviations or technical issues are identified during the QC review, an ACR Core Lab Imaging Technologist will contact your site to provide feedback expeditiously. This will allow your site to make any necessary adjustments early in the conduct of the study.

The ACRIN 4704 Research Team wishes to thank you in advance for your diligence in adhering to the procedures described in this manual and to ensuring the integrity of the image data collected for the study. Please do not hesitate to contact us.

Sincerely,

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*1818 Market Street- Suite 1600*

*Philadelphia, PA 19103*

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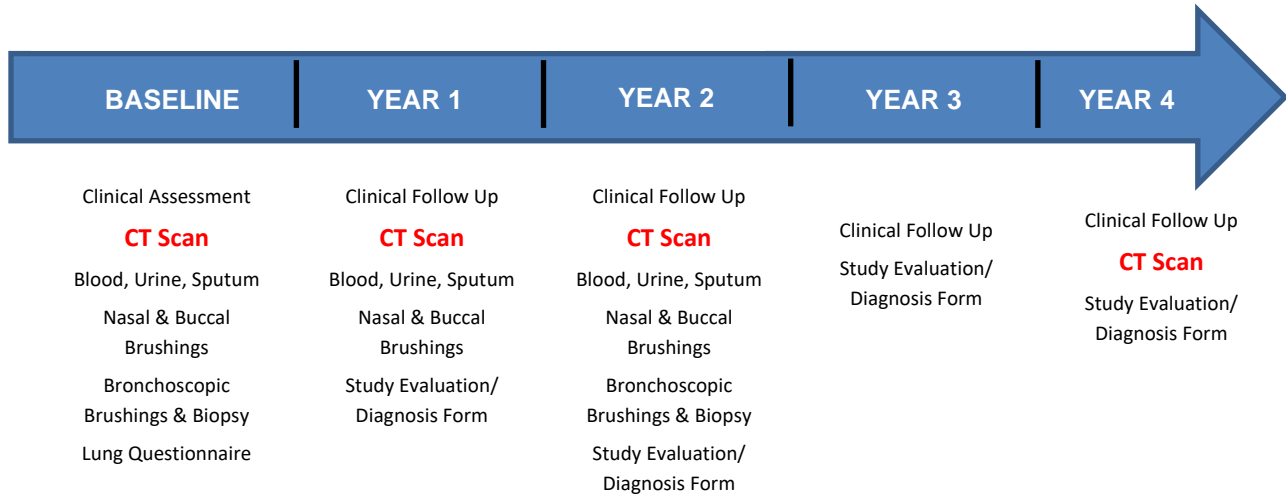
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## ACRIN 4704 DECAMP-2 Study Schema

### Longitudinal Screening Cohort\*



**\*Note:** Should a participant undergo surgery during the trial’s four-year timeline, then surgical tissue samples will be required. If the participant is diagnosed with lung cancer during the trial timeline, then the Study Evaluation and Diagnosis Form will be completed at the time of diagnosis, no further study procedures will be conducted, but a final assessment of vital status and treatment/response will be required at year 4.

### 1.0 Overview of Imaging Requirements

<b>TRIAD Installation</b>	TRIAD should be installed for secure, electronic submission of imaging to ACR Imaging Core Lab.
<b>Image Acquisition</b>	Submission of baseline, year 1, year 2, and year 4 low dose CT Chest
<b>Image Submission</b>	ACRIN 4704 imaging should be submitted in DICOM format to the ACR Imaging Core Lab via TRIAD. All imaging should be submitted <b>as soon as reasonably possible</b> after acquisition and must include an Image Transmittal Worksheet (ITW).
<b>Data Queries</b>	The core lab will issue queries, as needed, based on QC review of imaging.

**General Trial Requirements:**

- All CT exams must be acquired on a low dose  $\geq 16$  slice helical scanner

## **2.0 Study Aims**

The goal of this project is to improve lung cancer surveillance in high-risk individuals by identifying biomarkers of preclinical disease and disease risk. Minimally invasive and non-invasive biospecimens for lung cancer diagnosis will be examined. Biomarkers that identify individuals at highest risk lung cancer, identified prior to the appearance of concerning symptoms, could increase the effectiveness of lung cancer surveillance and the efficiency of lung cancer chemoprevention clinical trials. Achieving these goals would improve the detection and treatment of early stage and incipient lung cancer, while restricting the risk of these procedures to those individuals who currently exhibit the early molecular warning signs of impending disease.

These goals will be accomplished through the following specific aims:

### **2.1 Primary Aims**

- Discover new genomic and proteomic biomarkers in the airway and blood for preclinical detection of lung cancer using a longitudinal cohort.

### **2.2 Secondary Aims**

- Examine the change in biomarker values as a function of time prior to clinical diagnosis using a longitudinal cohort
- Develop an integrated clinical and molecular model for the assessment of lung cancer risk.
- Validate the ability of biomarkers to detect prevalent disease and predicting incident disease in a longitudinal cohort (internal validation)
- Validate the ability of biomarkers to detect preclinical lung cancer in two independent screening cohorts (Nashville Early Detection of Lung Cancer Project and National Heart, Lung and Blood Institute Lung Health Study) that have airway and blood samples available (external validation). Examine the change in biomarker values as a function of time prior to clinical diagnosis.

### **3.0 Study Overview**

The Detection of Early lung Cancer Among Military Personnel (DECAMP) consortium is a multidisciplinary and translational research program that includes 7 Veterans Administration Hospitals (VAH), the 4 designated Military Treatment Facilities (MTF) and two academic hospitals as clinical study sites, several molecular biomarker laboratories, along with Biostatistics, Imaging, Bioinformatics, Pathology and Biorepository cores. The DECAMP Coordinating Center will facilitate rapid selection, design and execution of clinical studies within this multi-institutional consortium.

The ACRIN 4704 study, will recruit a high-risk longitudinal screening cohort

#### **3.1**

For this longitudinal screening cohort we will enroll 800 participants who currently or historically smoked cigarettes and who have a 10 year Bach risk model of lung cancer

> 2.5% (5). We will include participants 50 to 79 years old, with  $\geq 10$  cigarettes/day for at least 25 years duration for current smokers, or  $\geq 20$  pack years for former smokers who quit 20 years ago or less. In order to further enrich for lung cancer risk, participants also will have COPD/emphysema or at least one first-degree relative with a diagnosis of lung cancer. These patients will be followed for a total of 4 years with annual follow-up visits. A form describing current health status will be completed annually. Should a participant be diagnosed with lung cancer during the study timeline, the person will discontinue study-related procedures and, at year 4, the treating physician will need to complete a form describing vital status and treatment/response for the participant. We anticipate a 2% lung cancer prevalence rate (prevalent disease defined as that which is apparent on baseline CT scan or diagnosed within 6 months of enrollment) and a 1.5% annual incidence rate in this population. The ~50 lung cancer incident cases that develop over the follow-up period will be matched by clinical site to 50 participants who do not develop lung cancer during this same follow-up period, in order to provide a set of 100 participants for the biomarker studies.

## **4.0 Participant Selection/ Eligibility Criteria**

### **4.1 Inclusion Criteria for longitudinal screening cohort**

- Ages 50 to 79 years
- Smoking status: Current or former cigarette smoker (≥10 cigarettes/day for at least 25 years' duration for current smokers, or ≥20 pack years for former smokers who quit 20 years ago or less)
- History of Chronic Obstructive Pulmonary Disease (COPD), emphysema, or at least one first-degree relative with a diagnosis of lung cancer
- Willing to undergo fiberoptic bronchoscopy
- Able to tolerate all biospecimen collection as required by protocol
- Able to comply with standard-of-care follow-up visits, including clinical exams, diagnostic work-ups, and imaging for a maximum of four years or until diagnosis of lung cancer
- Able to fill out Patient Lung History questionnaire
- Willing and able to provide a written informed consent

### **4.2 Exclusion Criteria**

- Contraindications to nasal brushing or fiberoptic bronchoscopy, including: ulcerative nasal disease, hemodynamic instability, severe obstructive airway disease (i.e., disease severity does not allow for bronchoscopic procedures), unstable cardiac or pulmonary disease, as well as other comorbidities leading to inability to protect airway, or altered level of consciousness
- Pre-existing pulmonary nodule (s) only if the treating physician determines the nodule presents a risk for cancer
- Allergies to any local anesthetic that may be used to obtain biosamples in the study
- Weight greater than that allowable by the CT scanner.

## 5.0 CT Image Acquisition

Radiation exposure must be as low as possible for all CT imaging. It is recommended that the imaging studies be acquired in full inspiration.

### 5.1 Protocol-Specific Imaging Requirements

- CT Scans to be performed at: Baseline and at years: 1, 2, and 4
- Scans require a minimum 16-slice CT scanner capable of low dose helical CT
- The same display field of view (DFOV) (subject dependent) defined at baseline must be utilized throughout the participant's follow-up scans to allow for a volumetric analysis of the data
- All CT scans may be acquired at 2.5 to 5 mm but must be reconstructed separately into 1 mm slice thickness using the soft tissue and Bone/Lung algorithm

Series	Protocol Requirement
Scout/Topogram	<ul style="list-style-type: none"> <li>• 100 kV</li> <li>• 10-40 mA</li> <li>• Acquire on inspiration</li> </ul>
Axial	<ul style="list-style-type: none"> <li>• Slice Thickness: 2.5mm – 5.0mm</li> <li>• Slice Spacing: 2.5mm – 5.0mm</li> <li>• mA: As Low As Reasonably Attainable</li> <li>• Dose Modulation: if available</li> <li>• Acquire on inspiration</li> <li>• Spiral / Helical Volumetric scan</li> </ul>
Post Processing Reconstructions from Raw Data	<ul style="list-style-type: none"> <li>• Axial Plane ( Required )               <ul style="list-style-type: none"> <li>○ Slice Thickness: 1mm</li> <li>○ Slice Spacing: 1mm</li> <li>○ Soft Tissue Algorithm (Kernel)</li> <li>○ Bone/Lung Algorithm (Kernel)</li> </ul> </li> </ul>
	<ul style="list-style-type: none"> <li>• Sagittal Plane ( Optional )               <ul style="list-style-type: none"> <li>○ Slice Thickness: 1mm</li> <li>○ Slice Spacing: 1mm</li> <li>○ Bone/Lung Algorithm (Kernel)</li> </ul> </li> </ul>
	<ul style="list-style-type: none"> <li>• Coronal Plane ( Optional )               <ul style="list-style-type: none"> <li>○ Slice Thickness: 1mm</li> <li>○ Slice Spacing: 1mm</li> <li>○ Bone/Lung Algorithm (Kernel)</li> </ul> </li> </ul>



***Please Note:***

- Protocol **requires 1mm x 1mm axial reconstructions**. Sagittal and Coronal reconstructions are optional to assist possible future secondary analysis

## **6.0 Image Submission**

Each participating site is required to submit all acquired diagnostic and follow-up images of study participants to the ACR Imaging Core Laboratory as follows:

### **6.1 Image Transmittal Worksheet (ITW)**

All image submissions must include an Image Transmittal Worksheet (ITW). An ITW is used during the exam QC review to verify a complete transfer of images to the ACR Imaging Core Laboratory. The ITW is completed in the Medidata Rave data management system. Upon the completion of this form, an email will be automatically generated to notify ACR core lab personnel of the imaging submission. Core lab personnel will be in contact if there are any issues with the ITW content and images received.

### **6.2 Image Submission via TRIAD**

TRIAD® is ACR's proprietary image exchange application that will be used as the sole method of data transfer to the ACR Clinical Research Center Core Laboratory for this trial. ACRIN will provide installation on one or several computers of choice within the institutional "firewall" and on the institutional network; internet access is required. The TRIAD application can then be configured as a DICOM destination on either scanner(s) and/or PACS system for direct network transfer of study related images into the TRIAD directory. When properly configured, the TRIAD software de-identifies, encrypts, and performs a lossless compression of the images before they are transferred to the ACRIN image archive in Philadelphia. Each participating site is required to submit all acquired diagnostic and follow-up images of study participants to the ACR Imaging Core Laboratory. Imaging should be submitted to the ACR Imaging Core Lab via TRIAD 4 as soon as reasonably possible after image acquisition. Prompt submission of all image data is essential to ensure proper compliance with the protocol and the required thin slice imaging.. For support in sending the images via the Internet using TRIAD, contact the representatives of the core lab via email: [Triad-Support@phila.acr.org](mailto:Triad-Support@phila.acr.org), or by phone: 215-940-8820.

### **6.3 Image Submission via CD/DVD Media**

For sites that are unable to submit via TRIAD, please submit all image data in DICOM format via a CD/DVD and label with the following information:

- Site Name
- Trial Name (ACRIN 4704)
- Date of Imaging (DD-MMM-YYY)
- Type of Imaging (e.g. Chest Xray [CXR], CT Chest, PET-CT)

Ship all disk media, along with a copy of the ITW to:

American College of Radiology  
1818 Market St., Suite 1720  
Philadelphia, PA 19103

*Attn: ACRIN 4704 Imaging Technologist*

## **7.0 Image Quality Control (QC)**

### **7.1 ACR Imaging Core Laboratory QC Technical Review**

The ACRIN 4704 protocol requires participating centers to meet technical specifications of the CT Scanners and work to adhere to protocol requirements for data uniformity and image quality. Required parameters for image acquisition are outlined in the protocol and provided in this manual. The ACR Imaging Core Laboratory will provide ongoing QC of imaging throughout the trial. The core lab will provide feedback to sites as appropriate, including training during early trial imaging to ensure high-quality images. Repeat of imaging will not be requested once the trial is under way.

### **7.2 Image Data Queries**

If it is found during the QC review that the submitted exam has missing data or does not follow the protocol guidelines detailed in this manual, a query to the dedicated participating site personnel will be generated in the iMedidata Rave data management system. Sites are expected to resolve data queries expeditiously. Queries not resolved **within 7 business days** will be sent to the ACRIN 4704 trial team for additional follow-up.