DECAMP

BIOMARKER RESEARCH

Detection of Early Lung Cancer among Military Personnel

RECRUITMENT MANUAL

Version 3 – July 1, 2015

INTRODUCTION

Recruitment of participants constitutes a significant portion of the workload associated with the DECAMP studies. Therefore, the DECAMP project at your site will operate more effectively and efficiently if you develop and implement a well-thought out recruitment plan.

The recruitment strategies presented in this manual are intended to combat the anticipated barriers to DECAMP participant accrual, such as:

1) Informing patients of their eligibility for the trial (increasing knowledge of the trial in the community and encouraging referral from a pulmonologist or radiologist);
2) Discussing costs, including costs not covered by insurance and potential additional travel for protocol procedures (especially to comply with DECAMP-2 screening procedures);
3) Describing the long-term benefits of a trial that has no immediate treatment benefit; and
4) Adequately educating participants about the tasks associated with submitting samples.

DECAMP investigators should note that all recruitment and patient education materials must be reviewed and approved by your local IRB prior to implementation. At some participating sites, the IRB may require review and approval of your site-specific recruitment plan.

DECAMP Recruitment Goals

As part of the DECAMP studies, patients will be asked to complete a questionnaire and submit blood, urine, nasal, buccal, sputum, bronchial brushing, bronchial biopsy, and lung tissue specimens for banking once enrolled in the study. Bronchial brushings are obtained via bronchoscopy. In addition to the above requirements, DECAMP-2 patients will undergo two (2) bronchoscopy procedures; three (3) blood, urine, buccal, sputum, and nasal sample collections; and four (4) CT scans.

The required sample size for DECAMP-1 is 500 participants, and DECAMP-2 is 880.
Accrual goals for participating DECAMP sites are as follows:

ACRIN Inst #	Institution Name	DECAMP-1 Accrual Goal	DECAMP-2 Accrual Goal
4790	VA Boston Healthcare System	32	39
4791	VA North Texas Health Care System	28	31
4792	VA Eastern Colorado Health Care System	28	31
4793	Nashville VA Medical Center	40	55
4714	Philadelphia VA & UPenn Medical Centers	32	39
4794	VA Pittsburgh Healthcare System	28	31
4278	Roswell Park Cancer Institute	32	39
4438	VA Greater LA Health Care System	40	55
4795	National Naval Medical Center	60	140
4796	Naval Medical Center San Diego	60	140
4238	Brooke Army Medical Center	60	140
4797	Naval Medical Center Portsmouth	60	140

In order to meet these aggressive accrual targets, DECAMP sites require recruitment strategies that minimize barriers to recruitment and emphasize rapid recruitment of the required number of individuals, as well as retention of participants for the entire trial duration.

Essentials of Recruitment Planning

It is essential that the recruitment process take into account factors that will optimize the type and number of participants enrolled in the study while minimizing time and expense. Failure to meet target accrual goals can affect the "power" of a study, making it less successful in providing quality results.

Delays can result in increases in cost, workload, and pressure from funding agencies. Therefore, in order to have a successful recruitment campaign, it is important to:

(1) Develop a specific site recruitment plan;
(2) Monitor the response of the plan set forth;
(3) Evaluate the campaign's effectiveness; and
(4) Revise and further refine the plan as necessary.

The steps required to develop a successful recruitment plan are described below.

Develop a site recruitment plan

It is critical to think about the recruitment plan and media campaign early and address the development of the plan using a team approach. First, review the study protocol and other materials to gain an understanding of the scope of work and, from that understanding, build an appropriate site team responsible for developing and implementing the recruitment plan and overall study conduct. The most successful approach involves convening this group regularly throughout the course of the study. Often, this can take the form of weekly/monthly meetings with all representatives present – the Principal Investigator, Co-investigators and referring physicians, Study Coordinator, Research Associates, Public Relations Department representative (if applicable), etc.

As you begin to develop your recruitment plan:

- Examine the DECAMP-1 & DECAMP-2 inclusion and exclusion criteria. Assess where your site team can best capture individuals that will meet these requirements. In addition, it is important to get a good sense of/map out the demographics of the catchment area in which you are looking to recruit. Plan to monitor the catchment area to assess areas of high recruitment during the study.

- Set site goals (refer to accrual goal table). How many participants per month are you comfortably able to see with the current processes in place at your site? Be sure to review those goals and whether or not you are meeting them as part of your campaign's ongoing effectiveness reviews.

- Review staffing patterns. You will need to decide on the staffing structure and number of personnel needed to meet your goals. It is a good idea to involve key personnel at your site in the planning of staffing structure and formulate a plan to train your personnel adequately on the recruitment plan and study designs. You will want to establish a back up system of staff for issues like cross training. You may go so far as to document specific duties and procedures in a formal site recruitment/training manual.

Choose your recruitment strategies

Media Strategies. We are exposed to so much print, radio, and television advertising we might be tempted to assume that media strategies and tactics for participant recruitment are quite simple. However, they can be as complex and sophisticated as the protocol itself. It is important to note, though, that media strategies are only one part of the entire recruitment plan. Therefore, this section should be used in conjunction with the other, equally important components outlined throughout this document.

The primary objective of a media strategy for participant recruitment is to create interest in the DECAMP protocol(s) that leads to action – usually a phone call to inquire further. To do this, we need to figure out:

- **What to say:**

  Be mindful of language that might be considered coercive. To spur interest, focus recruitment materials on explanations of the study's potential long-term impact and eligibility requirements. For example, "Are you a current or former smoker?" may perk a potential participant's ears to listen to the rest of your message. Your IRB will need to approve all final advertising materials as well as any scripted call guides or other materials that interface with potential participants.

- **How to say it:**

  It is critical to balance regulatory considerations with the media vehicles available. For example, a television advertisement will most likely be held to 30 seconds, a print advertisement might be only 15 to 25 words, and a radio ad will have no visual content. The challenge is to engage the target audience and build community around the study's objectives while maintaining compliance with regulatory requirements.

- **Where to say it:**

  Our targeted demographic, the demographics of your local area, the scale of the program at your site, and the budget will ultimately dictate your mix of print, radio, television, mass mailings, internet, or other media sources. Each format has strengths that can be leveraged for our target audience as well as weaknesses that can be minimized in most situations. For example, an advertisement outside located at eye-level in a designated smoking area may be of higher impact and lower cost than a television advertisement mid-day while military personnel are working.

- **When to say it:**

  It is critical to understand the media habits of the target audience for DECAMP in order to maximize the desired response and investment. For example, when is the target audience most likely to intersect with the advertisement? At routine appointments to follow up on COPD or emphysema for DECAMP-2? At pulmonologist or surgical follow-up visits for DECAMP-1? Where do people who smoke gather in your local area? Is there a "smoke shop" where you might post a flyer?

  It will be valuable to outline the basic tenets of each media format available to you before deciding upon and implementing your media strategy. The positioning and content of the advertisement may be the most important parameters of your campaign.

Public Relations Department Engagement Discuss the recruitment plan with your site's public relations (PR) department. The PR team can assist in strategizing how to inform the medical community about DECAMP and access media outlets for free. Public relations strategies may include:

- Press releases
- Public service announcements
- Media events, including health fairs
- Presentations
- Letters
- Luncheons

Recruitment Materials Some recruitment materials may be ordered centrally from ACRIN headquarters (brochures and posters), while others will be the responsibility of each site (letters on intuition's letterhead, post cards or appointment cards, newsletter or website advertisements, etc.).

- ***Centrally Printed Recruitment Materials***
  1. *Brochures (DECAMP-1 Appendix B & DECAMP-2 Appendix C)*
     ACRIN will print and store the DECAMP-1 & DECAMP-2 brochures, and update content as appropriate based on protocol amendments. Participating sites can request additional copies of the brochure. Please submit requests for additional brochures to Irene Mahon (imahon@acr.org) or decamp_suppliesrequest@acr.org.
     - Initial shipment: 50 copies
     - Sites will be able to personalize brochure with local information via a sticker/label on the back panel, but text will not be changed.
     - Brochure may be used in direct mail recruitment efforts, placed in health care providers' offices, placed in senior centers, displayed at health fairs, etc., after local IRB approval.

  2. *Posters (DECAMP-1 Appendix D & DECAMP-2 Appendix E)*
     The DECAMP-1 poster (.pdf available to sites) will be printed by ACRIN. Space is provided for you to include site-specific contact information. Sites are permitted to personalize the poster template with local information and reproduce it, but text cannot be changed. You will be able to order additional copies of the poster upon request.

  3. *Eligibility Cards for Referring Physicians (DECAMP-1 Appendix F & DECAMP-2 Appendix G)*

- ***Locally Printed Recruitment Materials***
  Participating sites are encouraged to use institution letterhead to produce recruitment letters; reach out to potential participants in your encashment area via e-mail distribution lists and local mailing lists; and develop advertisements for local newsletters or websites. The following templates are provided to assist with local recruitment and advertising:

  1. *Newsletter advertisement template (DECAMP-2 Appendix H)*

  2. *Newsletter article template (DECAMP-1 Appendix I)*

  3. *Short-letter template (DECAMP-1 Appendix J)*

  4. *E-mail broadcast template (DECAMP-1 Appendix K)*

  5. *Craig's List advertisement template (DECAMP-2 Appendix L)*

- ***Other Recruitment Materials***
    1. *DECAMP Patient Recruitment Web Site* (www.decampresearch.com or www.decampresearch.org)
       The DECAMP website was developed and will be maintained by ACRIN, and serves as a resource for patients. Key information available on the DECAMP website includes: Study Design, Eligibly Criteria, Participating Institutions, Contact Information, Driving Directions, and a link to MapQuest. In addition, the DECAMP website provides links to patient education resources, such as information on participating in a clinical trial and smoking cessation programs, and links to third-party resources that are supporting and promoting the DECAMP studies, such as the DOD Lung Cancer Research Program (DOD LCRP) web page. The patient website also provides an opportunity to link DECAMP information with your local institution's "Home Page" or DECAMP-specific portal.

       The DECAMP website 'News' tab includes a link to a video interview with DECAMP PI, Dr. Avi Spira, as described below.

    2. *DECAMP Video* (http://cdmrp.army.mil/pubs/video/lc/spira_video.shtml)
       The DOD's Congressionally Directed Medical Research Programs (CDMRP) website includes a video interview with DECAMP PI, Dr. Avi Spira. In the video, Dr. Spira discusses the DECAMP consortium infrastructure, background and significance of the DECAMP research, and the importance of the DECAMP clinical trials.
       The DECAMP patient website includes a link to the video in the 'News' tab.

    3. *DECAMP Logo* (*Appendix A*)
       The DECAMP logo is IRB-approved for use on recruitment communication and letterhead, as well as any materials that communicate the results and/or follow-up of DECAMP screening exams.

Running the operation

ACRIN encourages personnel to share their successes and continuing obstacles during DECAMP site teleconferences, or at any time with study project managers. Sharing information among the internal team will allow for community trouble shooting of new or ongoing issues.

- ***Getting started: Tracking and monitoring systems***

  Tracking and monitoring systems should be designed and implemented as your recruitment efforts begin. The system is used to document all recruitment efforts, to monitor short and long-term goals, and to calculate yields and costs – which ultimately provide a site with rapid feedback as to which recruitment strategies prove most effective. These data may include calculating the number of participants enrolled and randomized as a result of the various media efforts and the costs of advertising per phone screen. Simple charts of this information can distinguish between successful and unsuccessful tactics, and how to adjust ongoing recruitment planning.

  These data should be monitored weekly/monthly:
    1. Total number of responses to all recruitment methods;
    2. Comparisons of media (type vs. type);
    3. Ratio of preliminary screen passes to fails;
    4. Number of scheduled potential participants;
    5. Number of pending appointments;
    6. Number of people that did not qualify;
    7. Number of people that qualified but did not participate;
    8. Reasons for non-participation;
    9. Number that drop-out, are lost-to-follow-up, or complete the trial.

- ***Prescreening***
  It may be helpful and efficient to obtain as much eligibility information via the DECAMP 'Eligibility Checklist' before approaching a potential participant at a clinic visit. The U.S. Department of Health and Human Services, National Institutes of Health HIPAA Privacy Rule "Activities Preparatory to Research" provision permits covered entities to use or disclose protected health information for purposes preparatory to research, such as to aid study recruitment. The preparatory to research provision allows investigators to identify prospective research participants.

  If your institution permits identification of prospective research participants, study coordinators may review medical records, nodule registries, radiology logs and/or other institutional resources to identify patients who may meet the study's eligibility criteria. Another common method for pre-screening may include telephone interviews. Please comply with your institution's policy on the activities preparatory to research/study recruitment provision.

  Participating institutions must submit and obtain approval and/or acknowledgement of the institution-specific recruitment plan from their local IRB, if applicable, prior to implementation. All recruitment materials to be used in pre-screening, including the telephone interview script, must be reviewed and approved by both ACRIN and the local IRB. All participating institutions must comply with their local IRB guidelines and must satisfy the informed consent requirements of HHS regulations.

  Once deemed to be eligible for DECAMP, then the eligible participants may be invited to the clinic for a screening/enrollment visit.

- ***Screening/enrollment visits***
  The screening/enrollment visit is scheduled after a participant is deemed to be eligible via the Eligibility Checklist. A second visit should be scheduled if the potential participant wants time to consider joining the study.

- ***Reporting the success of your recruitment plan***
  DECAMP sites will participate in weekly teleconferences to report the number of patients screened for participation and the number of patients enrolled. Study coordinators will discuss:
    - Recruitment methods that have been most successful;
    - Recruitment methods that have not been successful;
    - Problems you have been encountering either with recruitment efforts or with the trial in general; and
    - Any noticeable trends.

Conclusion

Your recruitment efforts are greatly appreciated. You play a vital role in the conduct and continued success of the DECAMP consortium, and in these efforts to find tools for early diagnosis of lung cancer. The DECAMP protocol team will work with you to ensure that your recruitment goals are met. Please feel free to contact the team if you have questions or would like to discuss your local recruitment plan. A sample/template DECAMP recruitment plan that incorporates multiple strategies suggested in this manual is included as *Appendix M.* Please use the sample plan as a reference and template as you develop a site-specific plan.

Appendix A
DECAMP Logo Example
Contact Irene Mahon (imahon@acr.org) for artwork file (.jpg)

Appendix B
DECAMP-1 Brochure (Version Amendment 3)

Page 1:

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STUDY INFORMATION

Every year, about one million Americans participate in clinical studies to help researchers gather important information about tests and treatment methods. When recently surveyed, the majority of study participants reported receiving excellent care and viewed their participation as a positive experience.

About Indeterminate Pulmonary Nodules
You are being asked to participate in this study because you have been diagnosed with an indeterminate pulmonary nodule. Indeterminate pulmonary nodules are small, round-shaped growths that often occur in the lungs from scarring, inflammation, or infection. These nodules can be benign (noncancerous) or malignant (cancerous).

Lung cancer is the leading cause of death from cancer in the United States and the world, with cigarette smoking as its major cause. The number of lung cancer related deaths has remained essentially unchanged over the last 3 decades, in part because of our inability to detect lung cancer at its earliest and potentially curable stage.

Military personnel have higher rates of smoking than the general population, as well as exposure to other carcinogens. These issues result in a significantly higher incidence of lung cancer among military personnel and veterans. It is therefore important to develop new approaches for the early detection of lung cancer in this high-risk population.

This photo is a CT scan of the lungs. The arrow points to a pulmonary nodule.

PURPOSE OF THE STUDY

This study is being carried out to check the ability of different types of tests to predict if the nodule seen on your imaging scan is benign or will become malignant.

You will receive standard-of-care clinical examinations, work-ups, and imaging scans to follow your condition, in addition to study-specific biospecimen collections. The results of these collections will be compared with your final diagnosis. This information may be used in the future to diagnose similar nodules in other patients.

STUDY PARTICIPATION

If you join this study, you should have been recently diagnosed with a lung nodule. Your treatment is not part of the study. You will need to be willing to complete the samples collections for the study. A total of 500 patients from seven Veterans Administration hospitals, four designated military treatment facilities, and one academic hospital will take part in this study. Study participation is voluntary, and you may choose to withdraw at any time. Your decision to join or not to join this study will not affect your medical care.

Trial Conduct Information

National Trial Principal Investigators
Avrum Spira, MD, MSc
Boston University School of Medicine, Boston, MA

Mitchell Schnall, MD, PhD
University of Pennsylvania, Philadelphia, PA

Program Coordinators
Emily Maple, Program Grant Coordinator
Boston University
72 East Concord Street
Boston, MA 02118

Irene Mahon, DECAMP Project Manager
American College of Radiology
Imaging Network
1818 Market Street, Suite 1600
Philadelphia, PA 19103

For Local Trial Information, Contact:

Research Sponsor
Funding for the DECAMP trial is made available by the Department of Defense (DoD) Lung Cancer Research Program.

More Information
Please visit www.decampresearch.org for more information about the study and healthy lung resources.

More comprehensive information on clinical trials is available on the National Cancer Institute (NCI) Web site http://cancertrials.nci.nih.gov.

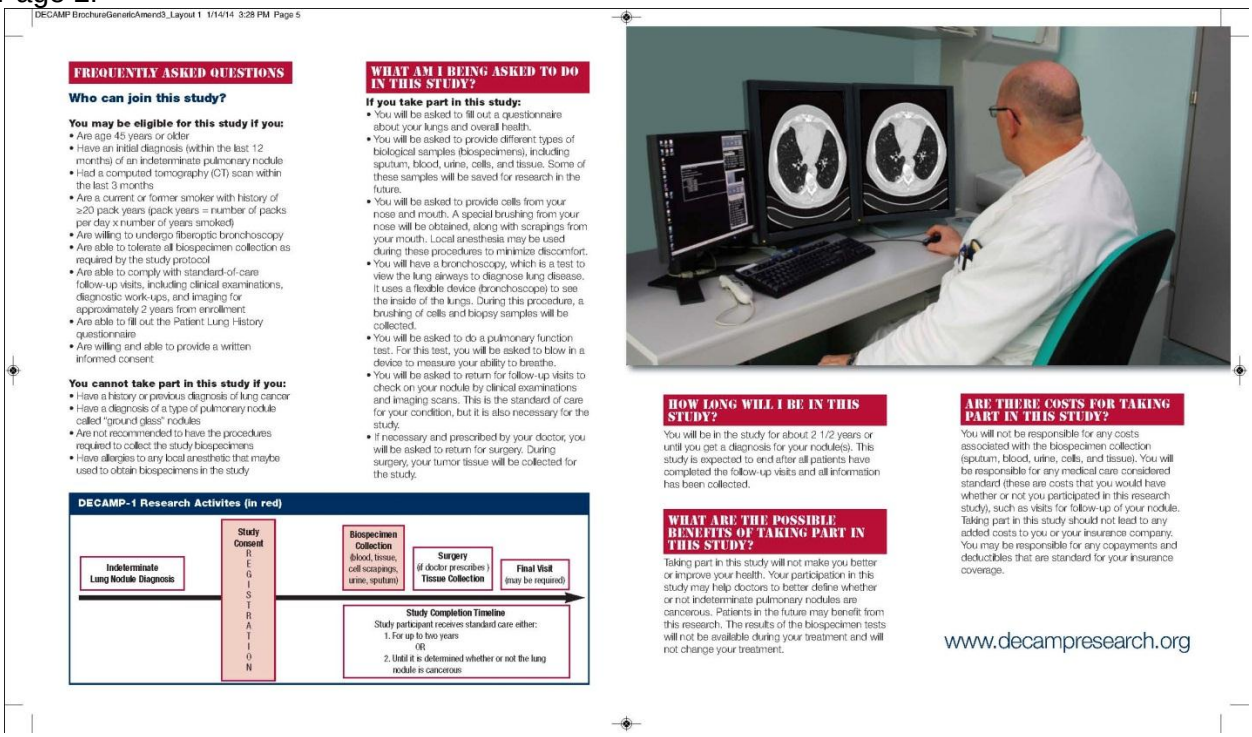
Brochure version: Amendment 3

DECAMP
BIOMARKER RESEARCH

Detection of Early Lung Cancer Among Military Personnel - Study 1

DECAMP-1: A Study for Diagnosis and Surveillance of DOD & VA Eligible Patients with Indeterminate Pulmonary Nodules

Page 2:



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FREQUENTLY ASKED QUESTIONS

Who can join this study?

You may be eligible for this study if you:
- Are age 45 years or older
- Have an initial diagnosis (within the last 12 months) of an indeterminate pulmonary nodule
- Had a computed tomography (CT) scan within the last 3 months
- Are a current or former smoker with history of ≥20 pack years (pack years = number of packs per day x number of years smoked)
- Are willing to undergo fiberoptic bronchoscopy
- Are able to tolerate all biospecimen collection as required by the study protocol
- Are able to comply with standard-of-care follow-up visits, including clinical examinations, diagnostic work-ups, and imaging for approximately 2 years from enrollment
- Are able to fill out the Patient Lung History questionnaire
- Are willing and able to provide a written informed consent

You cannot take part in this study if you:
- Have a history or previous diagnosis of lung cancer
- Have a diagnosis of a type of pulmonary nodule called "ground glass" nodules
- Are not recommended to have the procedures required to collect the study biospecimens
- Have allergies to any local anesthetic that maybe used to obtain biospecimens in the study

WHAT AM I BEING ASKED TO DO IN THIS STUDY?

If you take part in this study:
- You will be asked to fill out a questionnaire about your lungs and overall health.
- You will be asked to provide different types of biological samples (biospecimens), including sputum, blood, urine, cells, and tissue. Some of these samples will be saved for research in the future.
- You will be asked to provide cells from your nose and mouth. A special brushing from your nose will be obtained, along with scrapings from your mouth. Local anesthesia may be used during these procedures to minimize discomfort.
- You will have a bronchoscopy, which is a test to view the lung airways to diagnose lung disease. It uses a flexible device (bronchoscope) to see the inside of the lungs. During this procedure, a brushing of cells and biopsy samples will be collected.
- You will be asked to do a pulmonary function test. For this test, you will be asked to blow in a device to measure your ability to breathe.
- You will be asked to return for follow-up visits to check on your nodule by clinical examinations and imaging scans. This is the standard of care for your condition, but it is also necessary for the study.
- If necessary and prescribed by your doctor, you will be asked to return for surgery. During surgery, your tumor tissue will be collected for the study.

DECAMP-1 Research Activites (in red)

HOW LONG WILL I BE IN THIS STUDY?

You will be in the study for about 2 1/2 years or until you get a diagnosis for your nodule(s). This study is expected to end after all patients have completed the follow-up visits and all information has been collected.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS STUDY?

Taking part in this study will not make you better or improve your health. Your participation in this study may help doctors to better define whether or not indeterminate pulmonary nodules are cancerous. Patients in the future may benefit from this research. The results of the biospecimen tests will not be available during your treatment and will not change your treatment.

ARE THERE COSTS FOR TAKING PART IN THIS STUDY?

You will not be responsible for any costs associated with the biospecimen collection (sputum, blood, urine, cells, and tissue). You will be responsible for any medical care considered standard (these are costs that you would have whether or not you participated in this research study), such as visits for follow-up of your nodule. Taking part in this study should not lead to any added costs to you or your insurance company. You may be responsible for any copayments and deductibles that are standard for your insurance coverage.

www.decampresearch.org

Appendix C
DECAMP-2 Brochure (version April 2015)

Page 1

About DECAMP Study 2
Doctors want to determine the best way to monitor people who are at high risk for developing lung cancer. This monitoring is often called "lung cancer surveillance." The study's goal is to identify biomarkers that can be collected easily from patients to obtain information about their risk for developing lung cancer.

What are biomarkers?
With cancer, "biomarkers" is most often used to describe substances found in blood, other body fluids, or tissue that can be measured through a specialized test. The levels of these substances may help doctors learn if, or how quickly, a cancer is developing. Biomarkers that identify the early signs or presence of cancer could improve lung cancer surveillance, as well as the detection and treatment of early-stage cancer.

DECAMP Study 2 will include approximately 800 study participants who are current or former smokers and have one additional risk factor for lung cancer.

PURPOSE OF THE STUDY:

You are being asked to participate in this study because you are at high risk for developing lung cancer. Approximately 50 study participants are expected to develop lung cancer during the 4-year study period. Doctors will compare the biomarkers of these study participants to the biomarkers of study participants who do not develop lung cancer. By comparing the biomarkers of the two groups, the study doctors hope to discover specific biomarkers that will help identify which patients are most likely to develop lung cancer.

Trial Conduct Information

National Trial Principal Investigators
Avrum Spira, MD, MSc
Boston University School of Medicine, Boston, MA

Mitchell Schnall, MD, PhD
University of Pennsylvania, Philadelphia, PA

Program Coordinators
Emily Maple, Program Grant Coordinator
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Boston, MA 02118

Irene Mahon, DECAMP Project Manager
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1818 Market Street, Suite 1720
Philadelphia, PA 19103

For Local Trial Information, Contact:

Research Sponsor
Funding for the DECAMP trial is made available by the Department of Defense (DoD) Lung Cancer Research Program.

More Information
Please visit www.decampresearch.org for more information about the study and healthy lung resources.

More comprehensive information on clinical trials is available on the National Cancer Institute (NCI) Web site http://cancertrials.nci.nih.gov.

Brochure Version:
April 2015

DECAMP
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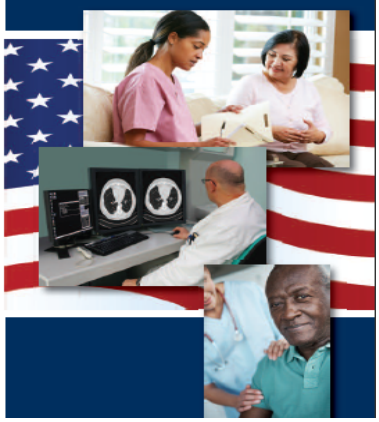
Detection of Early Lung Cancer Among Military Personnel

DECAMP Study 2

Screening of Patients at High Risk for Developing Lung Cancer

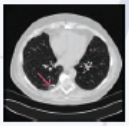


Page 2

STUDY INFORMATION

Every year, about 1 million Americans participate in clinical trials to help researchers gather important information about tests and treatment methods. When recently surveyed, the majority of study participants reported receiving excellent care and viewed their participation as a positive experience.

About DECAMP
Lung cancer is the leading cause of death from cancer in the United States and in the world, with cigarette smoking as its major cause. The number of lung cancer related deaths in the U.S. has remained essentially unchanged over the last 3 decades, in part because of our inability to detect lung cancer at its earliest and potentially curable stage.



The image above is a CT scan. The arrow is pointing to a lung nodule.

Military personnel have higher rates of smoking than the general population as well as a greater potential for exposure to other cancer-causing substances. Therefore, military personnel and veterans have a significantly higher incidence of lung cancer. The Detection of Early Lung Cancer Among Military Personnel (DECAMP) research project is working to develop new ways to detect lung cancer early that, in the future, may help all people at high risk for this disease.

DECAMP research includes two studies:

DECAMP Study 1: A Study for Diagnosis and Surveillance of Department of Defense and Veterans Administration Eligible Patients with Indeterminate Pulmonary Nodules

DECAMP Study 2: Screening of Patients with Early Stage Lung Cancer or at High Risk for Developing Lung Cancer

This brochure provides more information about DECAMP Study 2 for patients considering participation.

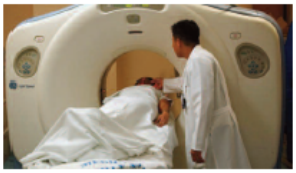
FREQUENTLY ASKED QUESTIONS

Who can join this study?

You may be eligible to participate if you:
- Are 50 to 79 years old
- Are a current smoker (smoke at least 10 cigarettes each day for at least 25 years) ***OR*** a former smoker who quit no more than 20 years ago and has at least 20 "pack years" of smoking
  - Pack years = number of packs smoked per day x number of years smoked
- Have emphysema or chronic bronchitis, which are two forms of chronic obstructive pulmonary disease (COPD), or have at least one first-degree relative (parent, brother or sister, child) who has been diagnosed with lung cancer
- Are willing to undergo fiber optic bronchoscopy
- Are able to tolerate the biospecimen collections required for the study

You cannot participate in this study if you have been previously diagnosed with lung cancer.

What am I being asked to do?
If you take part in this study, you will:
- Fill out a lung questionnaire
- Do the following once each year for 3 years:
  - Provide different types of biological samples (called "biospecimens"), including sputum, blood, urine, cells, and tissue. All biospecimens will be stored for future research.
  - Provide cells from your nose and mouth by brushings from your nose and scrapings from your mouth.
- Have a bronchoscopy the first and third year you are in the study. A bronchoscopy is a test to view the lungs using a flexible device (called a "bronchoscope"). During this procedure, brushings of cells and biopsy samples will be collected.
- Have a CT scan (an imaging study to evaluate the health of your lungs) when you enroll and in years 1, 2, and 4.
- Do the following once each year for 4 years:
  - Have a physical examination and diagnostic work-up
  - Do a pulmonary function test, which measures your ability to breathe when you blow into a special device



How long will I be in the study?
You will be in the study for about 4 years. Study participants who are diagnosed with lung cancer during the study will not continue to have any further study-related procedures. This study is expected to end after all patients have completed the follow-up visits and all information has been collected.

What are the possible benefits of taking part in the study?
Taking part in this study will not make you better or improve your health. Your participation in this study may help doctors discover biomarkers to help identify patients who can most benefit from lung cancer surveillance. Patients in the future may benefit from this research. The results of the biospecimen tests will not change your treatment.

Are there costs for taking part in the study?
You will not be responsible for any costs associated with the biospecimen collection (sputum, blood, urine, cells, and tissue). You will be responsible for any medical care considered standard (these are costs that you would have whether or not you participated in this research study). Taking part in this study should not lead to any added costs for you or your insurance company. You may be responsible for any copayments and deductibles that are standard for your insurance coverage.

www.decampresearch.org

Appendix D
DECAMP-1 Poster (Version Amendment 3)

DECAMP Poster GenericAmend3_Layout 1 1/14/14 3:32 PM Page 1

VOLUNTEERS ARE INVITED TO PARTICIPATE IN THE STUDY:

DECAMP 1 - DETECTION of EARLY LUNG CANCER AMONG MILITARY PERSONNEL

✔ Are you 45 years or older?

✔ Are you a current or former heavy smoker*?

* Defined as ≥20 pack years … pack years are determined by:
number of packs smoked/day X number of years smoked

✔ Have you been told you have a lung nodule?

You may be eligible to participate in a study aimed at helping diagnose lung cancer in the future.

Open to all eligible beneficiaries
(active duty, retired, family members & spouses)

If interested, please contact:

DECAMP
BIOMARKER RESEARCH
Detection of Early Lung Cancer among Military Personnel

Sponsored by the Department of Defense (DOD) Lung Cancer Research Program
Poster version: Amendment 3

Appendix E
DECAMP-2 Poster (Version April 2015)

Volunteers are invited to participate in DECAMP

DETECTION of EARLY LUNG CANCER AMONG MILITARY PERSONNEL

DECAMP Study 2:
Screening Patients at High Risk for Developing Lung Cancer

If you...

- Are aged 50 to 79 years
- Have either:
  - Emphysema or chronic bronchitis (often referred to as chronic obstructive pulmonary disease, or COPD)

    OR
  - At least one immediate family member (parent, brother or sister, child) diagnosed with lung cancer
- Are either a current or former heavy smoker

You may be eligible to participate in a study aimed at helping diagnose lung cancer in the future

Open to all eligible beneficiaries
(active duty, retired, family members & spouses)

If interested, please contact:

DECAMP
BIOMARKER RESEARCH
Detection of Early Lung Cancer among Military Personnel

www.decampresearch.org

Sponsored by the Department of Defense (DOD) Lung Cancer Research Program
Poster Version: April 2015

Appendix F
DECAMP-1 Eligibility Card (Version 8/6/2014)

DECAMP
BIOMARKER RESEARCH
Detection of Early Lung Cancer among Military Personnel

Decamp Study 1: Diagnosis and Surveillance of Indeterminate Pulmonary Nodules

Inclusion Criteria

- Patients aged 45 years or older
- Diagnosed with an indeterminate pulmonary nodule (0.7 - 3.0 cm)
- Nodules must be of appropriate size at enrollment, but nodule(s) may have been first identified within 12 months prior to enrollment
- Current or former smoker with ≥ 20 pack years (pack years = number of packs smoked per day x number of years smoked)
- Willing to undergo fiberoptic bronchoscopy
- Able to tolerate biospecimen collections
- Able to comply with standard of care (initial and follow up) visits including clinical exams, diagnostic work-ups, and imaging for two years

Exclusion Criteria

- History or previous diagnosis of lung cancer
- History of diagnoses of pure ground glass opacities w/ no indeterminate pulmonary nodules
- Contraindications to nasal brushing or fiberoptic bronchoscopy procedure
- Allergies to any local anesthetic that may be used to obtain biosamples in the study

If you have a patient who may qualify for this study, please contact:

Version: 08-06-2014

Appendix G
DECAMP-2 Eligibility Card (Version 8/6/2014)

DECAMP
BIOMARKER RESEARCH
Detection of Early Lung Cancer among Military Personnel

DECAMP Study 2 – Group B: Patients at High Risk for Lung Cancer

Inclusion Criteria

Patients with a history of **COPD, emphysema** or at least **one first-degree relative with a lung cancer diagnosis** who are:

- 50 to 79 years old
- Current or former smokers
  - ≥ 10 cigarettes/day for at least 25 years duration for current smokers, or
  - ≥ 20 pack years for former smoker who quit 20 years ago or less (pack years = number of packs smoked per day x number of years smoked)
- 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 up to four years or until diagnosis of lung cancer

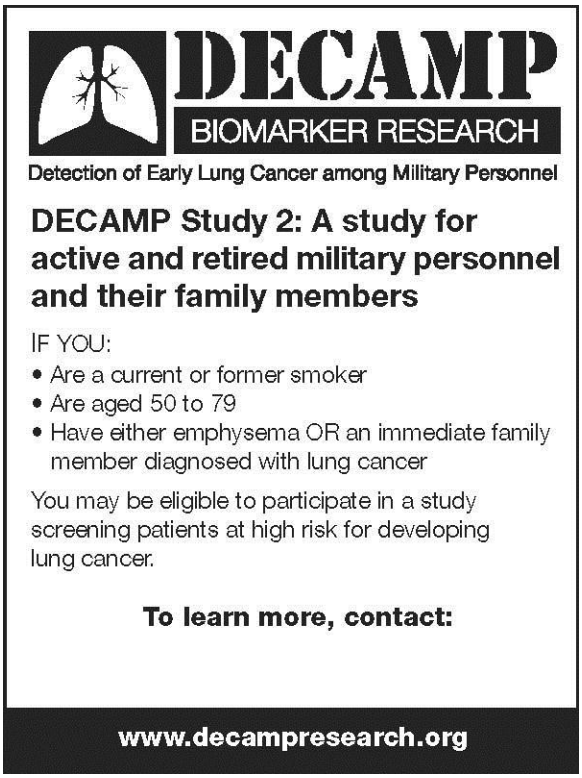
Exclusion Criteria

- Contraindications to nasal brushing or fiberoptic bronchoscopy
- Allergies to any local anesthetic that may be used to obtain biosamples in the study
- History/prior diagnosis of lung cancer

If you have a patient who may qualify for this study, please contact:

Version: 08-06-2014

Appendix H
DECAMP-2 Newsletter Advertisement Template



Appendix I
DECAMP-1 Newsletter Article Template

[Insert DECAMP Site Name] is recruiting adults to participate in a clinical trial that may uncover new ways to detect lung cancer at its very earliest and most curable stage. Lung cancer is the number one cancer killer of both men and women in the United States. Signs and symptoms of lung cancer most often do not occur until the disease is at an advanced stage, when a cure is not possible.

The [Insert DECAMP Site Name] is one of 14 US veteran and military medical facility members of a new consortium called "Detection of Early Lung Cancer Among Military Personnel," or DECAMP. "We see a high incidence of lung cancer among veterans and military personnel," says []. "Specifically, these individuals have much higher rates of smoking than the general public and may be exposed to other cancer-causing substances during their service time." The consortium's goal is to identify and validate molecular biomarkers (measurable substances found in body fluids and tissue) that can determine the presence of early-stage lung cancer or the likelihood it will develop.

The first DECAMP study is now recruiting [veterans and their dependents] age 45 years and older who are current or former heavy smokers and have a recent diagnosis from a chest CT scan of an "indeterminate" lung nodule—a small, round growth whose benign or cancerous status is difficult to determine. Five hundred study participants at high risk for lung cancer will be enrolled in the study.

Study volunteers will undergo noninvasive or minimally invasive procedures in order to provide a variety of biospecimens, including cells scraped from the lining of their nose, mouth, and lungs. These biospecimens, along with those from samples of a participant's blood, urine, and sputum, will be analyzed using microarray analysis technology. This advanced testing procedure measures the activity of the thousands of genes within a cell to determine which genes are "turned on" or "turned off" as a result of exposure to toxins.

[Insert local PI quote or use suggestion] "Using the information obtained from the microarray analyses, we aim to develop lung cancer biomarkers that can be measured in biospecimens readily obtained with minimal patient discomfort, to reliably confirm if an indeterminate lung nodule is likely to be cancerous. Such results would have an immediate impact on the way we practice medicine and in improving the care of patients who have an abnormal chest CT scan finding," says [Insert PI Name].

The DECAMP consortium was formed in response to an early lung cancer detection initiative announced by the US Department of Defense, the consortium's sponsor. It brings together the leading lung cancer research groups in the United States in an effort to expand the understanding of molecular biomarkers for lung cancer and to enable the earlier detection of the disease.

For more information, [Insert local contact information] or visit www.DECAMPresearch.org.

Appendix J
DECAMP-1 Short Letter Template

[Name of facility] is pleased to announce its participation in the DECAMP (**D**etection of **E**arly Lung **C**ancer **A**mong **M**ilitary **P**ersonnel) consortium conducting lung cancer biomarker research. The DECAMP consortium is a multidisciplinary research initiative funded by DoD that includes 7 veteran hospitals, 4 military treatment facilities, and 3 academic hospitals. This project is evaluating different types of tests to better determine whether difficult-to-diagnose lung nodules seen on a computed tomography (CT) imaging scan are cancerous. The goal is to improve the efficiency of the diagnostic evaluation of patients with indeterminate lung nodules. The study is available for military members (active duty or retired) and their eligible family members.

PARTICIPATION CRITERIA:

1. Patients aged 45 or older
2. Diagnosed (within the last 12 mos.) with an indeterminate pulmonary nodule (0.7-3.0 cm)
3. Current or former smoker with >/= 20 pack years.
4. No previous history of lung cancer.

If you have a patient or know someone who qualifies for the study, please contact:

[List facility contact information]

Appendix K
DECAMP-1 E-mail Broadcast Template

Subject: DECAMP Research Study at [Insert Site Name]

[Insert Site Name] was selected as one of the DECAMP (Detection of Early Lung Cancer Among Military Personnel) study sites conducting biomarker research. DECAMP is a multidisciplinary and translational research consortium funded by DoD which includes 7 VA Hospitals, 4 designated Military Treatment Facilities, and 3 academic hospitals as clinical study sites. This project is being carried out to check the ability of different types of tests to predict if the nodules seen on imaging scan are benign or malignant. The goal is to improve the efficiency of the diagnostic evaluation of patients with indeterminate pulmonary nodules. The study is available for military members (active duty or retired) and their eligible family members.

PARTICIPATION CRITERIA:

1. Patients aged 50 or older
2. Diagnosed (within the last 12 mos.) with an indeterminate pulmonary nodule (0.7-3.0 cm)
3. Current or former smoker with $\geq$ 30 pack years.
4. No previous history of lung cancer.

If you have a patient or know someone who qualifies for the study, please contact:
PI: [Insert PI Name / Phone # / Contact information]
AI: [Insert AI Name / Phone # / Contact information]
Clinical Research Coordinator: [Insert RA/Coordinator Name / Phone # / Contact information]

Appendix L
DECAMP-2 Craig's List Advertisement Template

Researchers from the [*insert site name / department*] are conducting a research study in a population considered to be at high risk for developing lung cancer. The goal of this research study is to evaluate whether the presence of specific biomarkers (substances or genes found in samples of bodily fluids and tissue) can be used as a tool in detecting and diagnosing early stage lung cancer in those who do not have lung cancer but are at an increased risk for getting lung cancer.

You may be eligible to participate in this research study if you:

- Are between the ages of 50-79 years old
- Are a current of former smoker
- Have been diagnosed with COPD/Emphysema or have a family member who was diagnosed with lung cancer

This research study involves annual follow-up visits and research procedures for up to 4 years. [Compensation will be provided – *insert if applicable*].

If you are interested in volunteering or would like to obtain additional information about this research study please call [*insert phone number*].

Appendix M
EXAMPLE / TEMPLATE: Components of Site-Specific DECAMP Recruitment Plan

Examples of Activities to Proactively Recruit Participants
DECAMP sites should create a diverse recruitment plan aimed at promoting DECAMP and its goals in your local community and creating avenues to identify potentially eligible patients who can be approached and asked to join the study. This sample recruitment plan includes suggestions only and should supplement what you know about your community, what creative methods you will include in your approach, and what resources are available to you.

1. Engage local clinicians and utilizing the VA & MTF network and resources;
2. Engage the media;
3. Target the general public; and
4. Involve health professional organizations and advocacy and volunteer groups.

Engage local clinicians and utilizing the VA & MTF network and resources

- Advertise and promote to VA/MTF staff.
- Place/distribute pamphlets in the Primary Care Clinic, Branch Clinics, and the CT scan waiting room.
- Collaborate with home oxygen department and your local smoking cessation program staff.
- Post informational flyer on bulletin boards where appropriate throughout the facility.
- Present at Grand Rounds and/or tumor board.
- Present to Pulmonary Department and/or Radiology Department staff.
- Present to branch medical clinics.
- Coordinate with patient referral center staff to facilitate the selective referral of a network patient with pulmonary nodules to the DECAMP study coordinator or PI.
- Plan educational sessions with the referral staff on the inclusion criteria and details of the study.
- If approved by the local IRB, review nodule tracking databases or nodule registries to identify patients that meet nodule size and other inclusion criteria.
- If approved by the local IRB, review medical records to identify patients that meet nodule size and other inclusion criteria.
- Place advertisements on the TRICARE website.
- Provide brief article in facility newsletter
- Explore where the video with Dr. Spira's overview of the DECAMP trial might be placed for viewing in clinic waiting rooms (http://cdmrp.army.mil/pubs/video/lc/spira_video.shtml).
- Encourage sites to offer participants additional comforts as a courtesy for their study participation, i.e., free parking at the treatment facility the day of their bronchoscopy visit, a free cafeteria/café voucher for the day of their bronchoscopy visit, discount coupon/special rate for local hotel if an overnight stay is required; local IRB approval may be required for these courtesy measures.

Engage the Media
Sites should look to proactively engage the media in the recruitment effort initially and throughout the entire study. As possible, work with the institutions public relations/communications department to carry out activities. Ideas for the site to focus a story or press release on DECAMP include:

- Have a press release ready or hold a media event at your site at the half way recruitment point, or at the six month and year recruitment time points.
- Offer the local media a press conference after your site opens to enrollment. Ask your site PI to speak about the studies, outline eligibility, and explain the goals/potential national and military impact.
- Explore having the PI engage in radio interviews on local stations
- Explore the possibility of creating print and/or video Public Service Announcements (PSAs) for local placement.

- Provide periodic releases to markets where referral sites are located (such as the “first 100" accrual stat).
- Suggest interviews with local spokespersons.
- Post an informational ad in the local newspaper.
- Place an add on ‘Craig’s List’

Increase Awareness Of DECAMP Among Members of the General Public Through Existing Opportunities and Concentrated Outreach

- The DECAMP website (www.decampresearch.org) will include information about the studies, including participating sites and contact information.
- Place/distribute pamphlets at Health Fairs.
- Presentation to the local chapters of organizations such as the Better Breathers Club-American Lung Association.
- Participate in local events sponsored by Lung Cancer Alliance, American Cancer Society, and American Lung Association.
- Refer potential participants to advocacy websites (National Cancer Institute, Lung Cancer Alliance, American Cancer Society, American Lung Association).
- Check on the date of your site’s state Lung Cancer Awareness Month and promote the study along with awareness materials – the national month is November. States may differ, however, or proclaim a week or day, so sites should check.
- Coordinate DECAMP promotion with New Year’s Eve smoking cessation resolutions (sites may strategically place PSAs with information on how to quit smoking AND promote DECAMP at the same time).
- Coordinate with the Great American Smokeout in November. Sites may want to partner with the local group who coordinates this, as well as the American Cancer Society, to create PSAs.
- Provide information to senior centers, perhaps in coordination with flu shot clinics.
- Place flyers and other information at the VFW or military golf courses.
- Place an add on ‘Craig’s List’

Involve Health Professional Organizations as Well as Advocacy and Voluntary Groups in the Education Effort

- Contact colleagues at local pulmonary centers and outside facilities that could educate potentially eligible patients about the DECAMP research opportunity.
- Provide health professionals with information to share with potential participants.
- Place print ads and articles in organization publications and medical journals and newsletters.