

## Clinical Research Education Day



5:00 – 8:00 PM

**Health Screenings** Indoor Quad— Body Mass Index, Blood Pressure, A1c Point of Care, Blood Sugar, HIV Rapid Tests, Hepatitis C Screenings

5:00 – 8:00 PM

**Information Alley** Indoor Quad—Exhibit Area and Boxed Dinners

6:00 – 6:30 PM

**Opening Remarks** Curry Student Center Ballroom  
Jill McNair, Director, AWARE for All

### Keynote Presentation

*What Clinical Research Means to You*

Allison B. Goldfine, MD

Section Head of Clinical Research, Joslin Diabetes Center

6:30 – 7:15 PM

### Speaker Panel—Clinical Research Discussion

Moderator: Karen Burns White, Deputy Associate Director Initiative to Eliminate Cancer Disparities—Dana-Farber/Harvard Cancer Center

#### *Oncology Focus*

Karen Marie Winkfield, MD, PhD

Director, Hematologic Services

Department of Radiation Oncology

Massachusetts General Hospital

#### *Diabetes Focus*

Marie E. McDonnell, MD

Director of the Diabetes Program

Brigham and Women's Hospital, Division of Endocrinology,

Diabetes and Hypertension

#### *Memory Loss and Brain Research Focus*

Jonathan Jackson, PhD

Cognitive Neuroscientist, Brandeis University

#### *Major Depression Focus*

J. Alexander Bodkin, MD

Director, Clinical Psychopharmacology Research Program, McLean Hospital

7:15 – 7:45 PM

### Patient Testimonials

#### *Our Medical Heroes*

Meet everyday people who have participated in clinical research. Hear their stories about why they participated and how it made a difference.

Moderator and Panelist: Benjamin D. Perkins—Associate Director for Community Engagement at the Fenway Institute at Fenway Health

Jim Kirk—Parkinson's Disease Foundation Research Advocate

LuAnne Bonanno—Type 2 Diabetic and Study Participant

Danielle Panetta—Diabetes Patient Advocate

& Member of Insulindependence Board of Directors

### Thank You Ceremony for Clinical Research Volunteers

Raffle for prizes

Complete surveys #1 and #2  
to be entered into the drawing

**MUST BE PRESENT TO WIN**

**WIN  
PRIZES!**

# Search Clinical Trials

## Having trouble finding a clinical trial? *We can help!*

Finding clinical trials can be confusing, whether you are looking for trials for a specific disease, as a healthy volunteer, or for a loved one in need. CISCRP's Search Clinical Trials service provides free clinical trials searches for people who are having trouble finding trials on their own. Search Clinical Trials staff will work with you to understand your needs and will help you find clinical trials in your community.

All you need to do is provide us with your:

- Medical condition
- Zip code, state, or province
- Distance willing to travel
- Age
- Gender
- Contact information



### JUST CALL US:

1-877-MED HERO (1-877-633-4376)

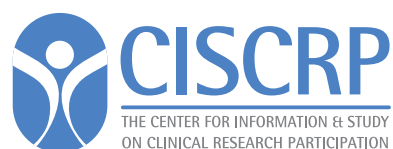
### OR CHECK OUT OUR WEBSITE:

<http://www.SearchClinicalTrials.org>



Our staff will search dozens of clinical trial listings for trials for you. We will send you the results by e-mail or USPS. You will also receive a free educational brochure with key questions to ask the research staff so you can decide if the clinical trial is right for you.

CISCRP is not involved in recruiting patients for clinical trials nor are we involved in conducting clinical trials. We are dedicated to educating, informing, and empowering those who would like to be active participants in the clinical research process. CISCRP is neither recommending nor endorsing any of the clinical trials it finds through the Search Clinical Trials service.





October 27, 2014

Dear AWARE for All attendees, supporters and friends:

It is with great pride and excitement that we welcome you to *AWARE for All – Boston*. Today serves as an important milestone in building awareness about both clinical research participation and the crucial role that clinical research volunteers play in advancing medical science.

We would like to thank all the members of the Planning Committee for their assistance in bringing *AWARE* back to Boston and developing this important program. We are very grateful for the support from national sponsor EMD Serono, Inc., a subsidiary of Merck KGaA Darmstadt, Germany, and local sponsors including: Brigham and Women’s Hospital—Division of Diabetes, Dana-Farber Cancer Institute, Dana-Farber/Harvard Cancer Center—Initiative to Eliminate Cancer Disparities, Fenway Institute at Fenway Health, Harvard School of Public Health Office of Human Research Administration serving the Harvard Longwood Medical Area Schools (MHS, HSPH, and HSDM), Lazarex-MGH Cancer Care Equity Program, and Sugar MGH.

The terrific response *AWARE for All* has received from this community has been heartwarming and convinces us even further of the important need this program fills. With the assistance of over 30 community partners, brochures were distributed, posters were displayed, and announcements and articles were included in newsletters and on websites throughout the State.

Special thanks to Fenway Institute at Fenway Health, the Joslin Diabetes Center, MassResearch, and the Multicultural Affairs Office at MGH for providing and staffing today’s health screenings. It is a great service to the community to be providing screenings for Blood Pressure, Body Mass Index, Glucose, Point of Care A1c, Hepatitis C, and HIV Rapid Tests. Please be sure to visit the health screenings tonight between 5 pm-8 pm.

We are also very grateful to tonight’s researchers, all of whom gave up their Monday evening to share their knowledge and expertise with *AWARE for All* attendees. In addition, we would like to thank our patient panelists, all of whom will be sharing their thoughts and stories in our closing session. These Medical Heroes have all participated in clinical research trials, and we are certain their personal stories will captivate you.

Please remember to fill out the evaluations before and at the conclusion of the Keynote presentation. We value your input and appreciate your participation in *AWARE for All – Boston*!

Kind regards,

Jill McNair  
Director, AWARE for All

Ken Getz  
Founder & Chairman of the Board



## **Planning Committee**

*CISCRP wishes to thank the AWARE—Boston planning committee for all their hard work and dedication to make this program come to fruition!*

### **Brigham and Women's Hospital, Diabetes Management Service**

Margo Hudson, Associate Physician

### **Dana-Farber/Harvard Cancer Center**

Karen Burns White, Deputy Associate Director, Initiative to Eliminate Cancer Disparities

### **EMD Serono**

Melaina Boyce, Principal Clinical Operation Lead, Late Stage Clinical Operations | Global Clinical Operation  
Kristin Sanderson, Senior Clinical Operations Lead, Early Stage Clinical Operations | Global Clinical Operations

### **Fenway Institute at Fenway Health**

Benjamin D. Perkins, Administrative Director for Community Engagement

### **Harvard School of Public Health Office of Human Research Administration serving the Harvard Longwood Medical Area Schools (HMS, HSPH, HSDM)**

Alyssa Speier, QA/QI Specialist, Office of Human Research Administration

### **Joslin Diabetes Center**

Sharon Harpel, Vice President for Research Administration

### **Northeastern University Bouvé College of Health Sciences**

Dierdre A. Jordan, Associate Cooperation Education Coordinator

### **Lazarex-Massachusetts General Hospital Cancer Care Equity Program**

Elizabeth A. Powell, Program Manager

Thank you to everyone who attended this evening. The Greater Gift Initiative will be donating a vaccine to a child in need on your behalf. Learn more about this initiative by visiting: [www.greatergiftinitiative.org](http://www.greatergiftinitiative.org).

# AWAREforAll

## Community Partners and Exhibitors

Please visit the following community partners exhibiting and providing information in the Indoor Quad!

African Community Health Initiatives

Harvard Aging Brain Study at MGH

American Cancer Society

Health Care for All

Alzheimer's Association

Hummingbird IRB

Asthma and Allergy Foundation of America -New England Chapter

Joslin Diabetes Center

Brain Plasticity and Neuroimaging Laboratory Department of Anatomy and Neurobiology, Boston University School of Medicine

Lazarex-Massachusetts General Hospital Cancer Care Equity Program

Boston University's Alzheimer's Disease Center

MassResearch

MGH Brain Aging and Dementia

Brigham and Women's Hospital, Diabetes & Research Program

NAACP—Boston Health Committee

The Center for Information and Study on Clinical Research Participation (CISCRP)

National Multiple Sclerosis Society, Greater New England Chapter

The Consortium of Rheumatology Researchers of North America, Inc. (CORRONA, LLC)

Parkinson's Disease Foundation

Cure Alzheimer's Fund

Ragon Institute of MGH, MIT, & Harvard

Dana-Farber/Harvard Cancer Center

ResearchMatch

Fenway Institute at Fenway Health

Research Compliance/Assurance & Programs (IRB), Joslin Diabetes Center

The Greater Gift Initiative

TargetCancer Foundation

Harvard School of Public Health Office of Human Research Administration

Women of Wisdom: The Holistic Healing Center

## Health Screenings

Please visit the following health screenings in the Indoor Quad!

*Point of Care A1c and Blood Pressure, provided by The Joslin Diabetes Center*

*Body Mass Index, Blood Pressure, and Glucose Testing, provided by MassResearch*

*Blood Pressure and Glucose, provided by MGH's Multicultural Affairs Office*

*HIV Rapid Tests and Hepatitis C Testing, provided by the Fenway Institute at Fenway Health*



## **Tonight's Speakers**

### **Opening Remarks**

Jill McNair, Director of *AWARE for All*, CISCRP

### **Keynote Presentation**

Dr. Allison Goldfine, Section Head of Clinical Research, Joslin Diabetes Center

### **Speaker Panel — Clinical Research Discussion**

Moderator: Karen Burns White, Deputy Associate Director, Initiative to Eliminate Cancer Disparities, Dana-Farber/Harvard Cancer Center

Dr. Karen Marie Winkfield, Department of Radiation Oncology, Massachusetts General Hospital

Dr. Jonathan Jackson, Neuroscientist, Brandeis University

Dr. Marie E. McDonnell, Director of the Diabetes Program, Brigham and Women's Hospital, Division of Endocrinology, Diabetes, and Hypertension

Dr. J. Alexander Bodkin, Director, Clinical Psychopharmacology Research Program, McLean Hospital

### **Patient Testimonials**

Moderator: Benjamin D. Perkins, Associate Director for Community Engagement  
Fenway Institute at Fenway Health

Danielle Panetta, Diabetes Patient Advocate & Member of Insulindependence Board of Directors

Jim Kirk, Parkinson's Disease Foundation Research Advocate

LuAnne Bonanno, Type 2 Diabetic and Study Participant



## **Presenter Bios—Boston 2014**

*Keynote Presentation: What Clinical Research Means to You*

**Allison Goldfine, MD**

Associate Professor, Harvard Medical School

Section Head of Clinical Research, Joslin Diabetes Center

Dr. Goldfine's research focuses on identification of pathways relevant to development of type 2 diabetes, and cardiovascular complications of the disease. Her work spans the initial physiologic studies needed to identify pathways of interest to larger scale clinical trials of new treatment options. She recently completed term as a voting member on the Endocrine and Metabolic Disease Advisory Committee to the Food and Drug Administration, and has served on the American Diabetes Association Practice Guideline Committee. She serves as Joslin's Head of Clinical Research as an Associate Professor of Medicine at Harvard Medical School.

*Research Panel Moderator*

**Karen Burns White**

Deputy Associate Director

Initiative to Eliminate Cancer Disparities

Dana-Farber/Harvard Cancer Center

Karen Burns White, Deputy Associate Director for the Initiative has leads the Initiative to Eliminate Cancer Disparities at Dana-Farber/Harvard Cancer Center (DF/HCC) in Boston, Massachusetts since 2001. As Deputy Associate Director, Ms. Burns White coordinates the planning and implementation of the Center's efforts to increase minority participation at all levels of the Cancer Center activities. A particular focus for the center is on the reduction of health disparities with an emphasis on cancer-related disparities. Ms. Burns White has co-lead the implementation of an integrated structure that involves a multi-prong approach including community engagement, cultural competency, recruitment and retention of minority faculty and training. Ms. Burns White also has a long history of involvement with civic and community organizations. She has served on a variety of boards of directors including the Susan G. Komen for the CURE – Massachusetts Affiliate where she also led their grant making program. She currently serves as a member of the Massachusetts Comprehensive Cancer Advisory Committee whose primary responsibility is to identify priorities and develop strategies for program development and implementation the state cancer control plan.



## Presenter Bios—Boston 2014

### *Research Panelist*

#### **Karen Marie Winkfield, MD, PhD**

Assistant Professor, Harvard Medical School  
Department of Radiation Oncology  
Massachusetts General Hospital

Dr. Karen Winkfield is a Radiation Oncologist at the Massachusetts General Hospital Cancer Center. She graduated with a BS in Biochemistry from Binghamton University in NY, where she was awarded a Howard Hughes undergraduate fellowship to pursue research in enzymology. She completed her MD and PhD degrees at Duke University, and has the distinction of being the 2nd black woman to graduate from the Medical Scientist Training Program at Duke. She then completed her medical training as a Clinical Fellow at the Harvard Radiation Oncology Program.

Dr. Winkfield specializes in the use of radiation therapy in the treatment of hematologic malignancies. Her research is focused on understanding and addressing sociocultural barriers that contribute to disparities in cancer outcomes. Her goal is to develop a platform for discussion that will enable accurate and timely dispersal of clinical information in the black community, address cultural barriers to accessing and accepting appropriate cancer care, and encourage policymakers to invest in initiatives designed to address inequalities in the health care delivery system. In 2013, she launched her personal website [www.DrKarenWinkfield.com](http://www.DrKarenWinkfield.com) to encourage and invite community discourse around a variety of healthcare topics discussed during her monthly radio show and in her blog entitled "A CLEAR Conversation on Health."

### *Research Panelist*

#### **Jonathan Jackson, PhD**

Neuroscientist, Brandeis University

Dr. Jonathan Jackson is a cognitive neuroscientist investigating behavioral, genetic, neurological, physiological, and cognitive changes as people get older as well as in individuals with Alzheimer's disease. His work focuses on the intersection of these methods as a basis for early detection of Alzheimer's disease, particularly in the absence of overt memory problems. He has particular expertise in cognitive topics such as attentional control, episodic memory, mindfulness meditation, and personality. He is currently a Postdoctoral Fellow in Neuroscience at Brandeis University.





## Presenter Bios—Boston 2014

### *Research Panelist*

#### **Marie E. McDonnell, MD**

Director of the Diabetes Program

Brigham and Women's Hospital, Division of Endocrinology, Diabetes and Hypertension

Dr. McDonnell is the director of the diabetes program at Brigham and Women's Hospital in Boston in the Division of Endocrinology, Diabetes and Hypertension as of May, 2014. She was associate professor at Boston University School of Medicine and has a pending appointment with Harvard Medical School. She is an associate editor of *Endocrine Practice*, and currently serves on the Pharmacologic Management of Obesity guideline through the Endocrine Society..

A graduate of Boston University School of Medicine, Dr. McDonnell completed her residency in internal medicine at New York Presbyterian Hospital-Columbia, where she also served as Chief Medical Resident. She then returned to Boston for her fellowship in Endocrinology at Boston Medical Center, after which she joined the faculty at Boston University School of Medicine to serve as Director of Inpatient Diabetes. In 2013, she was appointed Director of Diabetes at Boston Medical Center. In these roles, she created an academic inpatient diabetes program that has served to increase diabetes services and campus-wide education for providers and nurses. Expanding the model for appropriate acute diabetes care, she has developed unique multidisciplinary open access clinics for diabetes rapid assessment in collaboration with the emergency department and other groups.

### *Research Panelist*

#### **J. Alexander Bodkin, MD**

Director, Clinical Psychopharmacology Research Program

McLean Hospital

J. Alexander (Alec) Bodkin, M.D. attended Yale University School of Medicine (class of '85) and the McLean Hospital psychiatry residency program, where he was chief resident in Affective Disorders. He then completed a post-residency fellowship in depression research under the late Dr. Jonathan Cole. He has been a full-time clinical researcher since 1994, investigating potential new medical remedies for depression and anxiety. He directs McLean Hospital's Clinical Psychopharmacology Research Program.



## **Presenter Bios—Boston 2014**

*Patient Panelist and Moderator*

**Benjamin D. Perkins**

Associate Director for Community Engagement  
Fenway Institute at Fenway Health

Benjamin Perkins, MA, MDiv, is currently employed as the Associate Director for Community Engagement at the Fenway Institute at Fenway Health, where he oversees the department's the community engagement, outreach, and education efforts. He has also served as project director of the federally funded HIV-prevention feasibility study for The BROTHERS Project (locally named "Project SOS [Saving OurSelves]"), also at the Fenway Institute at Fenway Health, and serves as a co-investigator for a research study address discrimination and mistrust among HIV-infected Black men.

A native of Los Angeles, Benjamin holds a B.A. in geography from the University of California at Los Angeles, an M.A. in Clinical Psychology from Antioch University at Los Angeles, and a master's of Divinity (M.Div) from Harvard University.

*Patient Panelist*

**Danielle Panetta**

Diabetes Patient Advocate & Member of Insulindependence Board of Directors

Danielle Panetta is an attorney in Boston, Massachusetts. She has been living with Type 1 Diabetes for almost two decades. Danielle is committed to using her voice as motivation for other patients to implement healthy behaviors and take control of life with an incurable disease. In her journey of living the healthiest life possible, she has competed in 200-mile relays, half-marathons, triathlons and countless road races. Danielle is on the Board of Directors of Insulindependence; a nonprofit organization dedicated to uniting, expanding and supporting the active Diabetes community. She has participated in various clinical research projects and is currently involved in the PERL study through Joslin Diabetes Center.



## Presenter Bios—Boston 2014

### *Patient Panelist*

#### **Jim Kirk**

Parkinson's Disease Foundation Research Advocate

Jim Kirk recently left a 40-year career in science, marketing, and research to spend more time with his wife, Rita, his three daughters, and six grandchildren. He has had Parkinson's for 11 years, but still plays tennis (adequately) and golf (don't ask!). Jim received his BA from Harvard and an MA from Stanford. In the first half of his working life, Jim served stints as a science educator, a product developer and marketer for Gillette, and division manager at Ocean Spray. Jim and three business partners then founded and built a pharmaceutical education and market research firm. The team was acquired by Quintiles, the largest clinical trials and pharmaceutical services firm in the world. As practice leader for the group, Jim worked closely with both marketing and R&D management at many of the industry's most successful firms. Major projects included helping define the improvement targets for new drugs based on marketplace needs, evaluating the market potential for promising new compounds, and understanding drivers and barriers to successful clinical trials. Jim focuses now on helping corporate R&D and commercial teams to understand the needs of the Parkinson's patient, as well as the key factors for conducting well-recruited clinical trials.

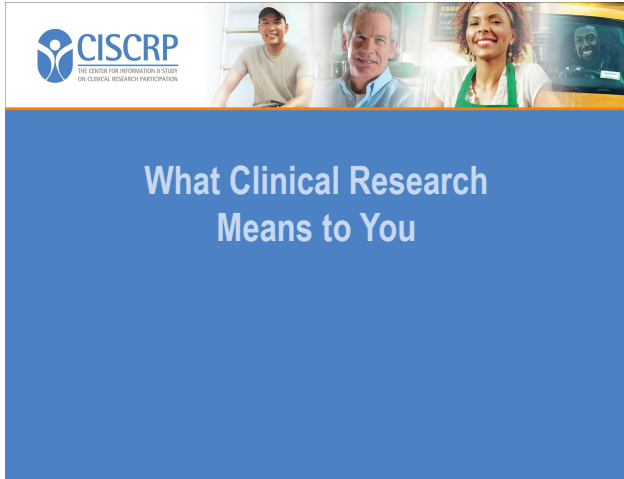
If you are interested in being involved in a current trial for a new Parkinson's Disease treatment, contact: Cathi-Ann Thomas ([617-638-7737](tel:617-638-7737) [neurocat@bu.edu](mailto:neurocat@bu.edu) ) at the Boston University Medical Center. You can also reach Jim at [jimckirk@gmail.com](mailto:jimckirk@gmail.com) and he can provide you with more information about the trial.

### *Patient Panelist*

#### **LuAnne Bonanno**

Type 2 Diabetic and Study Participant

LuAnne Bonanno is a wife, mother of 3 and grandmother of 1 with 2 more on the way. She served as Mrs. Essex County 2009, spending the year of her reign travelling throughout the county promoting local agriculture and the Topsfield Fair. She is a regular and long time volunteer at the fair. As a member of Quota International, a service organization devoted to the deaf and hearing impaired and disadvantaged women and children, she has served as president, secretary and has taken on several leadership roles at the State level. She recently joined the Northeast chapter of Les dames D'Escoffier, an organization devoted to women in food, and is one of only a handful of farmers in this group. Along with her husband, she owns and operated Pleasant Valley Gardens in Methuen, a fresh market wholesale vegetable farm that sells produce to Market Basket, Whole Foods and many small farm stands in the Merrimack Valley. She has recently begun a mentorship program with YWCA, serving as a budget buddy to a domestic violence survivor in the Greater Lawrence area.



Have you ever taken an allergy medicine? Have you ever given your child a pain reliever? Perhaps you have a friend or a family member who is a cancer survivor.

If so, you can thank a clinical research volunteer.

Around the world people are living longer, healthier lives because someone they never met took part in a clinical research study. And that research helped find a way to prevent, treat or cure a certain medical condition.

That's why we like to call these volunteers "Medical Heroes".



Most people don't understand what clinical research is all about. Some people are afraid. They may think clinical research volunteers are treated like "guinea pigs." Or they've heard news stories about clinical trials that have gone wrong. Or they still remember past abuses when there were no protections in place for clinical research volunteers.

That's why, at CISCRP, we believe in 'Education before Participation.' We think the more people understand about research, the more they'll appreciate those who are research volunteers. And the more likely they'll be to think about volunteering.

## What do we learn from studies?

- How well does a new drug work or not work?
- Is there a better way to treat a disease like diabetes?
- How do genes affect illness?
- Does where people live change their health?



What we learn from clinical research studies improves public health.

And it all starts with these questions.

Researchers can only answer these questions with the help of clinical research volunteers.

## What is a clinical trial?

- Scientific study that answers a medical question.
  - Is a treatment safe?
  - Does it improve a certain medical condition?
  - Does it have side effects?
  - How should people take it?
  - Is it any better than medicines that are already on the market?



So what is a clinical trial? It is a carefully designed study where researchers ask volunteers to do something -- like take a new drug or take several medicines at once -- so they can answer a specific medical question.

Is a treatment safe? Does it improve a certain medical condition? Does it have side effects? How much should people take? Is it any better than medicines that are already on the market?

Because researchers don't have the answers to all these questions, there are risks to participating in a clinical trial. But in all cases, something was learned from the clinical research study that helped improve public health.

## A clinical trial is NOT the same as standard of care

- Standard of Care
  - Routine care
  - Has been tested and approved
  - Works for most people
- Clinical Trial
  - Looks for answers to a question
  - Still learning how it works



It's important to understand that being in a clinical trial is not the same as going to your doctor for care. When you go to your doctor, she will give you a treatment that has already been tested and approved by the government. This is called "routine" or "standard of care." This is the care we know works for most people. This is the care you would get if you go to the doctor for regular check ups or if you had a health problem.

An example of usual care is a person breaks a bone and the doctor applies a cast. We know how it works for most people. An example of a clinical trial is: checking whether a new drug keeps breast cancer from coming back.

## People are different

We need all types of volunteers



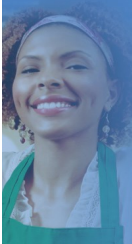
You cannot fully understand something by studying just one group of people.

We know that things like being male or female, age, race and ethnic background – affect the way people respond to diseases and treatments. For example, Alzheimer’s disease happens twice as often in women than men. Type-2 diabetes and asthma are more common in African Americans. Hispanics, Asian and White women are more likely to develop osteoporosis. Children respond to drugs differently than adults.

That’s why scientists need all different types of people to volunteer for research.

## Clinical trials: a 4 step process

- Phase 1: safety
- Phase 2: how much to take & side effects
- Phase 3: does it work better than the current drug and how does it work in different groups of people
- Phase 4: real world experience



During phase 1 studies, a drug is tested for the first time with a very small number of volunteers. And often these are healthy volunteers. The goal of these trials is to learn what is a safe dose. And how does it work in the body? Is it harmful?

In phase 2 studies, researchers begin to understand how well a drug works. And if it is safe for patients who have a specific disease or condition. Like phase 1, safety is still the main goal. Phase 2 studies look to answer such basic questions as: how much should people take? And what are the usual side effects?

Only about one-third of drugs that enter clinical testing ever successfully complete phase 2 and progress to larger, phase 3 studies. This stage provides hard facts about a drug from a large group of patients. At this stage, researchers may check the drug’s safety and how well it works in different groups of patients. Or the trial may compare the new drug with an already approved drug.

Phase 4 studies happen after a treatment has been approved by the Food and Drug Administration. They usually involve large numbers of patients who are regularly taking a medicine. Phase 4 studies look at real world experience and check to see if the drug works well over a long time.

This whole process of all phases could take over ten years!

## Clinical trials

- Clinical Trial Sponsors:
  - Government
  - Academic Medical Centers
  - Pharmaceutical Companies
  - Biotechnology Companies
  - Medical Device Companies



Clinical trials can be sponsored by the government, academic medical centers, pharmaceutical companies, biotechnology companies or medical device companies.

## Part 2: The Research Team and Informed Consent

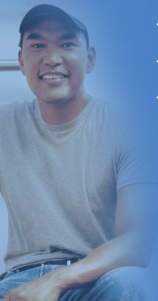
All members of the team are important



Research involves a lot of people who do different things. Like members of a sports team, clinical trials have coaches, players, and officials and each person has an important role to play.

## Principal Investigator (PI)

- Like the head coach
  - Organizes the study
  - Records and studies the data
  - Directs the study staff
  - Follows a protocol (play book)



The Principal Investigator (PI) is like the head coach of a team. He or she is responsible for organizing and leading the study as well as recording and studying the data. The PI also directs the team.

Like a head coach, the principal investigator follows a play book, which is called the study “protocol.” The protocol is a set of instructions that everyone in the game must follow. It is the plan for how the study will be carried out.

## Clinical Research Coordinator (CRC)

- Like the assistant coach
  - Handles day-to-day activities
  - Works with principal investigator (PI)
  - Main contact for volunteers



The research staff members are like assistant coaches who help the Principal Investigator. The Clinical Research Coordinator handles the day-to-day activity at the research site. He or she has easy access to the principal investigator and is the main contact for volunteers.

If you have questions about the trial or your health, ask the coordinator.

## Volunteer Protections

- Like the referees
  - Review the study before it starts
  - Make sure the team follows the rules
  - Keep you safe and informed



Referees help protect the safety of volunteers by making sure teams follow the rules. The referees review the study before it starts. The referees keep you safe and give you all the information. The number and type of referees involved in a trial depends on the research being conducted.

## Volunteer Protections

- Institutional Review Boards (IRB)
  - Make sure a trial is ethical and fair
  - Make sure there is not too much risk for volunteers
  - Researchers must inform the IRB if there are any changes to the study plan
  - Or if the volunteers experience serious injuries or side effects
  - Can end a trial if it feels volunteers are not safe



Every clinical trial is reviewed, approved and watched over by an independent local committee called an Institutional Review Board or IRB. It's the law. The IRB makes sure a trial is ethical and fair and that there is not too much risk for volunteers. During the trial, researchers must let the IRB know if there are any changes in the study plan. Or if volunteers experience serious injuries or side effects. The IRB can end a trial if it feels volunteers are not safe.

## Volunteer Protections

- Food and Drug Administration
  - Reviews studies
  - Inspects research centers
  - Monitors research groups
  - Has the final say as to whether or not a treatment is approved



Referees from the federal government are also involved.

The Food and Drug Administration reviews studies, inspects research centers and monitors research groups. The FDA has the final say in whether or not a treatment is approved.



## Volunteers

- Like the players
  - The MOST important team member
  - There are lots of studies to choose from
  - Healthy volunteers needed too!



Now let's talk about the most important members of the team: The research volunteers. Volunteers are like the players on the field. Without them, research can't happen.

We need all different types of people to participate in clinical research. You do not even need to be sick. A lot of research involves healthy volunteers.

## Friends, family and your supporters

- Like the fans
  - People to talk to about the study
  - Help you ask questions about the study
  - Support you during the study



Your friends and family may provide you a support system while you are taking part in a study. It is good to talk to your friends and family about the clinical study. They can help you come up with questions to ask your doctor about the study. They can also support you while you participate. In the end it is your job to make the final decision if you will participate in the study.

## Eligibility Criteria

Who is the right player for the game?



Everyone has the chance to participate in research - you just have to find the study that is right for you.

Just like a football game there are rules and not everyone can be on the field at the same time.

The research team has a list of requirements for the participants just like the coaching staff draft players. Both the coaches and the players have to know the game and agree to work together.

Let's talk about eligibility first. A 10-year-old would never be allowed to play on a pro football team, right? Why? Because it would be too dangerous.

Just like in sports, clinical trials have "eligibility criteria." These are guidelines that say who can or can't be in a study. Eligibility criteria protect people if a trial might be too risky for them. This helps researchers get results that are correct and mean something.

If you're considering a trial, you must be honest with researchers about your health. Lying or hiding information to get into a trial could endanger your safety and ruin the study.

## Informed Consent

- A process to make sure you understand and agree to be in the study
  - A conversation between you and the study staff
  - A form to sign
  - Answers all your questions



OK, let's assume the coaches say you're eligible to play. The next question you have to ask yourself is: Do I choose to play? Well, that depends, right? You cannot say whether or not you want to participate without understanding the rules of the game. What are your responsibilities as a player? How long will the game last? What are the risks and benefits of playing? What are you going to get in exchange for playing?

The "informed consent" process is designed to answer all these questions and is required by the FDA and IRB. This is one of the most important parts of research and it's a term you're going to hear a lot. Before any volunteer can participate in a trial, he or she must read, understand and sign the informed consent form. This is a long form that lists your rights as a volunteer. It includes detailed facts about the trial. It describes your job as a volunteer and any procedures or tests you'll need to have. It will warn you about any known or unknown side effects of the study drug. It describes the benefits of participating in the trial. By signing the form you're saying that you understand the trial and are agreeing to do what the study asks.

The informed consent form is a complex document. The study staff should go through it carefully with you and answer all your questions. You should never feel rushed or pressured to sign the form.

It is important to note that the IRB can ask the researcher to translate the informed consent form to a language the volunteer speaks.

## You have rights and responsibilities

- To understand the study
- To ask questions and get answers
- To quit at any time



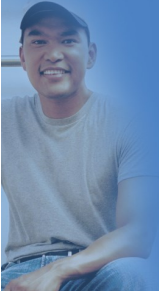
As a research volunteer you have rights. You have the right to understand the purpose, benefits, risks and side effects of the clinical trial.

You have the right to ask any questions and discuss any concerns with the research staff at any time during the trial. And you have the right to full, complete and clear answers.

Most importantly, you have the right to quit the trial at any time for any reason. You are a volunteer and are free to leave the trial if you choose to. The research staff will help you do this safely!

## Part 3: Should I or Shouldn't I?

What's right for me?



You've heard a lot about clinical trials and your rights and responsibilities as a volunteer. But I'm sure a lot of you are still struggling with the most basic question: "Should I participate or not?"

Deciding to take part in a clinical trial is a personal decision. What's right for the person sitting next to you may not be right for you.

## Understanding the study design

- Study Methods
  - Randomized
  - Blinded
  - Placebo



Scientists set up their studies so that their research will be fair. They also want their research to be accurate and unbiased. In other words, they don't want their own ideas about what they think should happen in a trial to influence the results.

To set up fair studies, scientists will often split volunteers into groups by chance. This is like a coin toss. The researcher and the volunteer do NOT get to decide which group the volunteer will be in. This is called a "randomized" study.

Sometimes researchers will go a step further and "blind" a study. This means that the volunteer and the researcher both do NOT know which treatment the volunteer is receiving.

In some trials, researchers will use a "placebo". A placebo looks like medicine but has no medicine in it. Sometimes the placebo is referred to as a "sugar pill" or "dummy drug." What's interesting is that even though the placebo has no medicine in it, there are times when people who are taking a placebo improve or feel better during a trial. This is called the "placebo effect". As a clinical research volunteer, even if you are on a placebo, you will be closely monitored.

## Possible benefits

- Access to new therapies
- Advance science and help others in the future
- The research staff will observe your health closely



Deciding whether or not to participate in a clinical research trial is an important, personal decision. Here are some of the reasons why people say they get involved in research trials.

- ✓ Get access to brand new therapies that are not yet available on the market;
- ✓ Advance science and help others with their condition
- ✓ The research staff will observe your health closely

SOME, but NOT ALL trials will pay for volunteers' travel costs and pay you for your time and commitment. The amounts vary widely. Getting paid should never be your only reason for volunteering.

## Possible risks

- Physical
- Emotional
- Financial
- Privacy and confidentiality



All research involves risk – because we are asking a question and do not know what will happen. Researchers do their best to ensure that you are safe, but there are no guarantees. You need to be comfortable with the risks that you might experience.

There can be physical risks. You may not get better. You may even get worse or you may be uncomfortable.

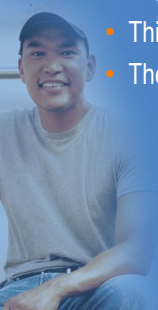
Emotional risk - Most clinical trials ask you to take a quality of life survey to see how you are doing – some of these questions can be upsetting or cause distress

Financial risk – there could be out of pocket expenses such as parking, child care and missing work. Some insurance companies do not cover research so be sure to check with your insurance provider.

Privacy and confidentiality – usually your health information is private, when you agree to participate in research, you are giving permission for researchers to collect information about you. Researchers must follow rules that protect your privacy and your information.

## Things to consider...

- All your doctors need to know you are in a clinical trial
- This will require your time and commitment
- The clinical trial could end at any time



Be sure to let all your doctors know you are in a research trial and have a contact number for the research staff with you in case of an emergency.

Volunteering takes time and effort, be sure you have the time to participate and if you don't just let the study staff know that this is not a good time. You can always stop your participation and volunteer in other ways or in future research.

Even if you want to continue to participate, your doctor, the referees, or the company making the drug could stop the study – be sure to ask these questions when you sign the consent form.

## Education before participation

- Do your homework
- Take your time
- Ask questions



Many volunteers drop out of studies because they didn't fully understand what they were signing up for. Both the volunteers and the research suffer when this happens.

- ✓ Do your homework. Learn about the trial and ask questions. Read all the information provided by the study staff. You may even go on-line to research the treatment being studied.
- ✓ Take your time. There is absolutely nothing wrong with asking a researcher to slow down or explain something using simpler words.
- ✓ Ask questions. Talk about your concerns with the study staff, your doctor and your friends and family. Bring a friend or family member to study visits so they can ask questions too. Try tape recording your visits or take notes so you can refer to the information later and follow up with questions as needed.

If you decide to join a study, you should feel confident that you have made an informed choice. You should feel comfortable that the trial staff will support you and answer all your questions.

# Your decision at every step



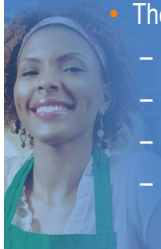
Here's a handy way to think about it, at every step.

You start by becoming aware of a certain study. You think you're interested so you discuss it with your doctor. If you're still interested, you need to know all the details. So you talk to the research staff and find out whether you're eligible. If it sounds like something that's right for you, you can choose to sign the informed consent.

But even while you're taking part in the study, continue to ask questions and decide whether you choose to complete the study or not.

## Want to learn more?

- Your doctor
- Advocacy groups
- Pharmaceutical and biotechnology companies
- The Internet
  - [www.clinicaltrials.gov](http://www.clinicaltrials.gov)
  - [www.centerwatch.com](http://www.centerwatch.com)
  - [www.researchmatch.org](http://www.researchmatch.org)
  - [www.ciscrp.org](http://www.ciscrp.org)



Remember, today's presentation is an important first step. Now it's up to you to learn more about clinical trials.

The best place to start is with your doctor. You can also get information from your local research center, disease advocacy groups, medical journals and conferences.

There are also a number of web sites devoted to clinical trials. ClinicalTrials.gov is a site maintained by the National Institutes of Health (NIH) that includes trial and enrollment information. CenterWatch.com lists trials that are enrolling volunteers. You may also check ResearchMatch.org to join a matching service for clinical trials. In addition, many pharmaceutical and biotechnology companies list active trials on their web sites.



## *Thank you...*

to the millions of people who give  
the gift of participation in clinical trials each  
year and to the rest of us who admire  
them for doing so.



Research volunteers truly are Medical Heroes without whom medical science cannot move forward. I'd like to sincerely thank you for taking time today to learn about the clinical research process. And I strongly encourage you to share what you've heard with your friends, family and people throughout your community.

On behalf of all of us, I'd like to say "thanks to the millions of people who give the gift of participation in clinical trials each year; and to the rest of us who admire them for doing so."

For More Information Visit:  
[www.ciscrp.org](http://www.ciscrp.org)

CISCRP provides a free search service  
designed to help patients find trials that  
might be right for them.

Call 1-877-MED-HERO

## Should I or Shouldn't I?

### How to Weigh the Benefits and the Risks



Participating in a clinical trial is an intensely personal decision, and the stakes differ for each person.

For those with a serious, advanced stage disease, even a slight chance of getting a more effective treatment makes the decision easy.

For healthy volunteers or people with less critical conditions, potential side effects and other factors need to be balanced against the desire to take part. Most people who consider trial participation do some soul-searching as they weigh the pros and cons.

**Potential Benefits**— there are several reasons that people may choose to participate:

√ **To gain access to new treatments**

There's the chance that an experimental treatment or a new and better treatment will help your condition improve. Many clinical trials have introduced treatments that were more effective than those that were currently available.

√ **To advance science and help others who have the illness**

Helping to develop new treatments that could aid thousands and advance science is a powerful motivation. Many people with this goal are willing to assume some risk because they feel they are contributing toward making the world a better place.

√ **To earn extra money**

For some people, the compensation offered is an attractive incentive to participate.

√ **To receive free medical care**

The experimental treatment is typically free to the participant. In addition, while volunteers are taking part in the trial, site staff usually monitors their vital signs and pays attention to other symptoms and health factors.

√ **To gain access to new treatments**

There's the chance that an experimental treatment or a new and better treatment will help your condition improve. Many clinical trials have introduced treatments that were more effective than those that were currently available.

√ **To advance science and help others who have the illness**

Helping to develop new treatments that could aid thousands and advance science is a powerful motivation. Many people with this goal are willing to assume some risk because they feel they are contributing toward making the world a better place.

*I know what I went through with chemotherapy treatment. If I can in any way help someone else not go through that, it can't be anything but good. The trial I'm in is for a possible new treatment for breast cancer and could help millions of people down the road. That in itself outweighs any possible chances of major side effects [for me].*

- Jennie, a volunteer in a breast cancer relapse prevention trial

**Potential Risks**—there are many things to consider:

√ **You might get a placebo (a pill or treatment that has no effect) instead of the test drug**

Some tests include a control group that gets a placebo—at least for part of the test period— and if so, your disease is not treated during that clinical time frame.

√ **You may be exposed to harmful side effects**

Although many volunteers experience no side effects or only minor effects, there are potential risks with an experimental treatment. This factor may weigh especially heavily on healthy volunteers.

√ **A standard treatment is already available**

If your current treatment is helping you even slightly, you may feel that's better than trying a new treatment that might not work at all. You'll also probably have to stop taking your current treatment, which could lead to a relapse.

√ **Taking part in a trial may be inconvenient**

You may have to get frequent injections or have blood drawn regularly; undergo exams or possibly quit smoking, drinking or other activities that are routine for you. Visiting the test site, monitoring your physical responses, and keeping a journal, if required, may be burdensome to you.

√ **You may incur unexpected costs**

Although in most clinical trials the study drug and the direct cost of care are paid for by the study sponsor, there may other costs associated with the visits, including, but not limited to lodging and transportation costs to visit the test site.

**How to Decide**— two key questions can help you make this important decision:

√ **Do I have all of the information that I need to make an informed choice?**

It's important to know as much as possible about the treatment and the trial requirements so that you can weigh all the factors. Get information about the trial goals, potential side effects, and what you'll be required to do.

Start by getting information from the research center that will be conducting the trial, but use other information sources as well. Keep in mind the research center may have its own motivations for conducting a trial, and its goals may be different from yours.

Get a second opinion about the trial you're interested in; ask your doctor, other health professionals, family, and friends.

√ **How far am I willing to go?**

Only you can answer the question of how hard you're willing to push yourself to get information required and to be willing to comply with the trial requirements. Your motivation to participate will influence how much you're willing to put yourself out.

*This article was originally published in the June/July 2009 issue of CISCRP's Medical Heroes newsletter.*



## FREQUENTLY ASKED QUESTIONS ABOUT CLINICAL TRIALS

*Choosing to participate in a clinical trial is an important personal decision. These frequently asked questions will give you some basic information about what clinical research is and what it means to be a participant. If you have more questions about clinical research in general or about specific trials, talk to your doctor, family, friends and research staff, and take advantage of the resources in this handbook.*

### **What Is a Clinical Study?**

A clinical study involves research using human volunteers (also called participants) that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials and observational studies. ClinicalTrials.gov includes both interventional and observational studies.

### **Clinical Trials**

In a clinical trial (also called an interventional study), participants receive specific interventions according to the research plan or protocol created by the investigators. These interventions may be medical products, such as drugs or devices; procedures; or changes to participants' behavior, for example, diet. Clinical trials may compare a new medical approach to a standard one that is already available or to a placebo that contains no active ingredients or to no intervention. Some clinical trials compare interventions that are already available to each other. When a new product or approach is being studied, it is not usually known whether it will be helpful, harmful, or no different than available alternatives (including no intervention). The investigators try to determine the safety and efficacy of the intervention by measuring certain outcomes in the participants. For example, investigators may give a drug or treatment to participants who have high blood pressure to see whether their blood pressure decreases.

Clinical trials used in drug development are sometimes described by phase. These phases are defined by the Food and Drug Administration (FDA).

### **Observational Studies**

In an observational study, investigators assess health outcomes in groups of participants according to a protocol or research plan. Participants may receive interventions, which can include medical products, such as drugs or devices, or procedures as part of their routine medical care, but participants are not assigned to specific interventions by the investigator (as in a clinical trial). For example, investigators may observe a group of older adults to learn more about the effects of different lifestyles on cardiac health.

### **Who Conducts Clinical Studies?**

Every clinical study is led by a principal investigator, who is often a medical doctor. Clinical studies also have a research team that may include doctors, nurses, social workers, and other health care professionals.

Clinical studies can be sponsored, or funded, by pharmaceutical companies, academic medical centers, voluntary groups, and other organizations, in addition to Federal agencies such as the National Institutes of Health, U.S. Department of Defense, and U.S. Department of Veterans Affairs. Physicians, health care providers, and other individuals can also sponsor clinical research.

### **Where Are Clinical Studies Conducted?**

Clinical studies can take place in many locations, including hospitals, universities, doctors' offices, and community clinics. The location depends on who is conducting the study.

## How Long Do Clinical Studies Last?

The length of a clinical study varies, depending on what is being studied. Participants are told how long the study will last before enrolling.

## Reasons for Conducting Clinical Studies

In general, clinical studies are designed to add to medical knowledge related to the treatment, diagnosis, and prevention of diseases or conditions. Some common reasons for conducting clinical studies include:

- Evaluating one or more interventions (for example, drugs, medical devices, approaches to surgery or radiation therapy) for treating a disease, syndrome, or condition
- Finding ways to prevent the initial development or recurrence of a disease or condition. These can include medicines, vaccines, or lifestyle changes, among other approaches.
- Evaluating one or more interventions aimed at identifying or diagnosing a particular disease or condition
- Examining methods for identifying a condition or risk factors for that condition
- Exploring and measuring ways to improve the comfort and quality of life of people with a chronic illness through supportive care

## Participating in Clinical Studies

A clinical study is conducted according to a research plan known as the protocol. The protocol is designed to answer specific research questions as well as safeguard the health of participants. It contains the following information:

- The reason for conducting the study
- Who may participate in the study (the eligibility criteria)
- The number of participants needed
- The schedule of tests, procedures, or drugs and their dosages
- The length of the study
- What information will be gathered about the participants

## Who Can Participate in a Clinical Study?

Clinical studies have standards outlining who can participate, called eligibility criteria, which are listed in the protocol. Some research studies seek participants who have the illnesses or conditions that will be studied. Other studies are looking for healthy participants. And some studies are limited to a predetermined group of people who are asked by researchers to enroll.

**Eligibility.** The factors that allow someone to participate in a clinical study are called inclusion criteria, and the factors that disqualify someone from participating are called exclusion criteria. These are based on things such as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions.

## How Are Participants Protected?

Informed consent is a process in which researchers provide potential and enrolled participants with information about a clinical study. This information helps people decide whether they want to enroll, or continue to participate, in the study. The informed consent process is intended to protect participants and should provide enough information for a person to understand the risks of, potential benefits of, and alternatives to the study. In addition to the informed consent document, the process may

involve recruitment materials, verbal instructions, question-and-answer sessions, and activities to measure participant understanding. In general, a person must sign an informed consent document before entering a study to show that he or she was given information on risks, potential benefits, and alternatives and understands it. Signing the document and providing consent is not a contract. Participants may withdraw from a study at any time, even if the study is not over. See Questions to Ask a health care provider or researcher about participating in a clinical study.

**Institutional review boards.** Each federally supported or conducted clinical study and each study of a drug, biological product, or medical device regulated by FDA must be reviewed, approved, and monitored by an institutional review board (IRB). An IRB is made up of physicians, researchers, and members of the community. Its role is to make sure that the study is ethical and the rights and welfare of participants are protected. This includes making sure that research risks are minimized and are reasonable in relation to any potential benefits, among other things. The IRB also reviews the informed consent document.

In addition to being monitored by an IRB, some clinical studies are also monitored by data monitoring committees (also called data safety and monitoring boards).

Various Federal agencies, including the Office of Human Subjects Research Protection (OHRP) and FDA, have the authority to determine whether sponsors of certain clinical studies are adequately protecting research participants.

### **Relationship to Usual Health Care**

Typically participants continue to see their usual health care providers while enrolled in a clinical study. While most clinical studies provide participants with medical products or interventions related to the illness or condition being studied, they do not provide extended or complete health care. By having the participant's usual health care provider work with the research team, the participant can make sure that the study protocol will not conflict with other medications or treatments being received.

### **Considerations for Participation**

Participating in a clinical study contributes to medical knowledge. The results of these studies can make a difference in the care of future patients by providing information about the benefits and risks of therapeutic, preventative, or diagnostic products or interventions.

Clinical trials provide the basis for the development and marketing of new drugs, biological products, and medical devices. Sometimes, the safety and the effectiveness of the experimental approach or use may not be fully known at the time of the trial. Some trials may provide participants with the prospect of receiving direct medical benefits, while others do not. Most trials involve some risk of harm or injury to the participant, although it may not be more than the risks related to routine medical care or disease progression. (For trials approved by IRBs, the IRB has decided that the risks of participation have been minimized and are reasonable in relation to anticipated benefits.) Many trials require participants to undergo additional procedures, tests, and assessments based on the study protocol. These will be described in the informed consent document for a particular trial. A potential participant should also discuss these issues with members of the research team and with his or her usual health care provider.

## Questions to Ask

Anyone interested in participating in a clinical study should know as much as possible about the study and feel comfortable asking the research team questions about the study, the related procedures, and any expenses. The following questions might be helpful during such a discussion. Answers to some of these questions are provided in the informed consent document. Many of these questions are specific to clinical trials, but some also apply to observational studies.

- What is being studied?
- Why do researchers believe the intervention being tested might be effective? Why might it not be effective? Has it been tested before?
- What are the possible interventions that I might receive during the trial?
- How will it be determined which interventions I receive (for example, by chance)?
- Who will know which intervention I receive during the trial? Will I know? Will members of the research team know?
- How do the possible risks, side effects, and benefits of this trial compare with those of my current treatment?
- What will I have to do?
- What tests and procedures are involved?
- How often will I have to visit the hospital or clinic?
- Will hospitalization be required?
- How long will the study last?
- Who will pay for my participation?
- Will I be reimbursed for other expenses?
- What type of long-term follow-up care is part of this trial?
- If I benefit from the intervention, will I be allowed to continue receiving it after the trial ends?
- Will results of the study be provided to me?
- Who will oversee my medical care while I am in the trial?
- What are my options if I am injured during the study?

*Information adapted from resources provided by [ClinicalTrials.gov](http://ClinicalTrials.gov), a service of the National Institutes of Health.*



We are proud to support the **2014 AWARE for All Clinical Research Education Day**. CISCERP's continuing efforts to improve clinical research complements our mission to provide the best care possible for our patients.

---



## BRIGHAM AND WOMEN'S HOSPITAL

Division of Endocrinology, Diabetes and Hypertension  
Diabetes Program

[www.brighamandwomens.org](http://www.brighamandwomens.org)

A FOUNDING MEMBER OF  PARTNERS<sup>®</sup>  
HEALTHCARE

**Do you think you might be at risk for diabetes?**

**Does anyone in your family have diabetes?**

**Are you overweight?**

The Center for Human Genetic Research at Massachusetts General Hospital seeks men and women over the age of 18 who are either healthy or at risk for diabetes and not currently on diabetes medication for a research study exploring the influence of genetic background on the response to established type 2 diabetes treatments.

**Participants will be asked to visit the hospital twice in seven days.**

**The total time commitment is five hours for the first visit and three hours for the second visit.**

**Compensation will be provided up to \$100 and a free meal.**

**Contact Ayesha at (617) 643-5419 or Marlene at (617) 643-5419 or email [sugarmgh@partners.org](mailto:sugarmgh@partners.org)**



**SUGAR-MGH**

[sugarmgh@partners.org](mailto:sugarmgh@partners.org)  
(617) 643-5417 or (617) 643-5419

**Study to Understand the Genetics of  
the Acute Response to Metformin and  
Glipizide in Humans**

Massachusetts General Hospital  
Brigham and Women's Hospital  
Joslin Diabetes Center  
Broad Institute



# HARVARD

## SCHOOL OF PUBLIC HEALTH



---

For over 100 years the Harvard School of Public Health has been committed to providing the highest level of education to public health scientists, practitioners, and leaders; fostering new discoveries leading to improved health; strengthening health capacities and services for communities; and informing policy debate, disseminating health information, and increasing awareness of health as a public good and fundamental right through learning, discovery, and communication.

Sponsored by:



Office of Human Research Administration

[www.hsph.harvard.edu/ohra](http://www.hsph.harvard.edu/ohra)

---



MASSACHUSETTS  
GENERAL HOSPITAL

CANCER CENTER

**Lazarex-MGH**  
Cancer Care Equity Program

*The Lazarex-MGH Cancer Care Equity Program strives to promote awareness about and access to cancer clinical trials through community outreach and education, financial assistance, and patient navigation.*

This program works to provide financial assistance for the unique challenges of clinical trial participation. Eligible patients may qualify for assistance with travel and lodging costs. Program eligibility is determined based on each individual patient.

**For additional information or to apply to the program, contact:**

Elizabeth Powell, Program Manager

Email: [eapowell@partners.org](mailto:eapowell@partners.org)

Phone: 617-643-5970

Web: [www.massgeneral.org/cancer/lazarex](http://www.massgeneral.org/cancer/lazarex)





**Dana-Farber/Harvard Cancer Center – Initiative to Eliminate Cancer Disparities and Dana-Farber Cancer Institute are proud to support CISCRP and the 2014 AWARE for All Clinical Research Education Day.**



**NCI** DANA-FARBER/HARVARD  
**CCC** CANCER CENTER  
A Comprehensive Cancer Center  
Designated by the National Cancer Institute





Our mission is to advance global health and highlight the **greater good of clinical trial participation** by gifting a vaccine to a child in honor of every clinical trial volunteer.

**GreaterGiftInitiative.org**

 Like us on Facebook and follow us on Twitter  @ggiGreaterGift

FENWAY  HEALTH

---

**B E A H E R O**

we know you're out there!

---

**Fenway Health** is conducting many exciting research projects and you could make a difference by being a part of it.

For more information, call **617.927.6450**  
or email **[TFIResearch@fenwayhealth.org](mailto:TFIResearch@fenwayhealth.org)**

ANSIN BUILDING | 1340 BOYLSTON STREET | BOSTON MA | 02215



## **Boston Branch NAACP Health Committee**

### **Making a difference in our community**

The Boston Branch of the NAACP has been at the forefront of challenging inequities of all kinds for over 100 years. As one of the oldest branches in the NAACP, the work of the Boston Branch has made an indelible mark in Greater Boston and the Commonwealth of Massachusetts, making it a better place to live and to raise our families. Today, the Boston NAACP continues to challenge inequities and tackle many of today's complicated issues, including health care. The Health Committee

1. Works to promote, protect and maintain the health of the African American community
2. Educate, Advocate and Promote Community Wellness
3. Advocates for equal access to health education, care, treatment and research for all African Americans
4. Sponsors health-related activities such as health forums, fairs and workshops highlighting issues of importance to the African American community

### **Get Involved**

The commitment and requirements needed to be a member of the Health Committee are:

- Be an NAACP member
- Be able to attend monthly meetings
- Be willing to do follow up committee work as assigned
- Desire to improve the health and well-being of our communities

### **Contact**

To learn more or to join the Boston Branch NAACP Health committee, contact Joyce Clark, Health Committee Chair at [Health@BostonNaacp.org](mailto:Health@BostonNaacp.org)

[www.facebook.com/NaacpBostonHealthCommittee](http://www.facebook.com/NaacpBostonHealthCommittee)



A research opportunity is out there for **everyone**.

Aware for **All** partnered with **ResearchMatch**.  
Now **you** can, too.

## WHAT IS RESEARCHMATCH?

ResearchMatch is an online research recruitment and engagement service that matches you to research studies at academic medical research institutions around the country. As a registered volunteer on ResearchMatch, research teams search for you so all you have to do is wait to be matched to a study and then decide if you want to participate!

Registered researchers will have access to thousands of volunteers on researchmatch.org who may meet the criteria they need for their studies. More and more volunteers join every day so the chances of making a positive match become greater and the timeline to discovery gets shorter.

Get involved and Get matched today!



## HOW DO I GET INVOLVED?

Signing up is free and anyone can join. Learn more about researchmatch and consider joining the team today!

[www.researchmatch.org](http://www.researchmatch.org)

## When it comes to diabetes, there's Type 1 and Type 2.



## Fortunately, we're type A.

You could say we're driven. Or relentless. Whatever word you choose, we're passionate about our work. Our team of dedicated researchers focuses exclusively on diabetes, bringing hope, new treatments and ultimately a cure.

If you'd go to any lengths to beat diabetes, we're just your type.



**Joslin Diabetes Center**

One Joslin Place • Boston, MA, 02215 • [joslin.org](http://joslin.org) • 617.309.2400

## Brain Imaging Study of Aging and Memory Problems

Have you or a loved one been diagnosed with cognitive (thinking or memory) impairment?

*Adults (ages 60 to 80) wanted for research study looking at characteristics of normal aging and changes in the brain and cognition (thinking and memory) in individuals with memory problems and mild cognitive impairment.*

- Study includes approximately 4 visits. (Visits may be added or subtracted based on your preference and study constraints.)
- Visits include tests of memory and thinking, neurological evaluations, blood draws, & brain imaging.
- Payment for complete participation is \$470.

**For more information, please call 617-643-7721 or email [brainstudy@mgh.harvard.edu](mailto:brainstudy@mgh.harvard.edu)**

Massachusetts General Hospital  
Departments of Radiology and Neurology &  
The Martinos Center for Biomedical Imaging in  
Charlestown Navy Yard



**TargetCancer  
Foundation**

Funding Innovative  
Rare Cancer Research

Join us for  
**A Night to TargetCancer: The 5th Annual  
TargetCancer Foundation Gala  
Thursday, November 6  
Microsoft NERD Center, Cambridge MA**

Learn more at  
[www.targetcancerfoundation.org](http://www.targetcancerfoundation.org)

*What if there were  
an HIV vaccine?*



**We believe  
that the best hope  
for eliminating the  
AIDS epidemic  
is the development of a safe,  
effective and affordable vaccine.**

If you would like to support our research by being involved in a study, we are looking for volunteers, either HIV-positive or negative.

Contact our Clinical Department and we will discuss opportunities for participation.

[ragonclinicalresearch@partners.org](mailto:ragonclinicalresearch@partners.org) | 855.724.0557

**Ragon Institute**  
of MGH, MIT and Harvard



[ragoninstitute.org](http://ragoninstitute.org)

# Women of Wisdom

118 Washington St.  
North Easton, MA  
508-230-3680

- \* New Age Gift Shop
- \* Book & Music Store
- \* Holistic Center
- \* Workshops & Classes
- \* Schools of Wisdom
- \* Psychics & Mediums



WomenofWisdomInc.com

# HELP US FINISH THE FIGHT AGAINST CANCER.

**DONATE NOW  
CANCER.ORG/FIGHT**



THE OFFICIAL SPONSOR  
OF BIRTHDAYS.®

© 2014 American Cancer Society, Inc.

## OUR VISION IS A WORLD WITHOUT ALZHEIMER'S DISEASE

Participate.  
Volunteer.  
Donate.

Help  
**#ENDALZ**

alzheimer's  association®  
Massachusetts/New Hampshire Chapter

*More than  
**5 million**  
in the  
U.S. have  
Alzheimer's.*

*Nearly  
**two-thirds**  
of those are  
**women.***

*Another  
American  
develops  
Alzheimer's  
**every  
67 seconds.***

800.272.3900  
alz.org/MANH



## Cure Alzheimer's FUND

is funding research  
with the highest  
probability of preventing,  
slowing or reversing  
Alzheimer's disease.

**Join us in the fight  
to end Alzheimer's!**

For more information, go to **curealz.org**  
or call **877-CURE-ALZ (287-3259)**



Celebrating 30 years as Massachusetts's  
leading health care  
consumer advocacy organization



Have a question about your health insurance?  
Call our free HelpLine: 800-272-4232  
[www.hcfama.org](http://www.hcfama.org)

## Diabetes...with Asthma or COPD?

Doctors are currently seeking adults for a clinical research study of an investigational inhaled insulin for diabetes.

*You may be eligible for this clinical research study if you:*

- Have been diagnosed with type 1 or type 2 diabetes for at least 12 months
- Are at least 18 years of age and have asthma, or are at least 40 years of age and have chronic obstructive pulmonary disease (COPD)
- Have never smoked or have given up smoking at least 6 months ago.

*During the 14-month (64-week) clinical research study you will receive:*

- Study-related care from a team of doctors and nurses at no cost
- All study drugs at no cost

**If you are interested in learning more about this clinical research study, please contact MassResearch**

781-647-7200  
(x101 Melissa or x102 Liz)  
[studies@massresearch.com](mailto:studies@massresearch.com)

**BOSTON  
UNIVERSITY**

Alzheimer's Disease Center

The Boston University Alzheimer's Disease Center was established in 1996 and is in its third funding cycle. The Center is funded primarily by an Alzheimer's Disease Core Center (ADCC) grant from the National Institute on Aging and is one of 29 federally-funded Alzheimer's Disease Centers nationwide. Our goal is to help reduce the human and economic costs associated with Alzheimer's disease through the advancement of knowledge.

*The three primary missions of our Center are to:*

1. Conduct and facilitate cutting-edge Alzheimer's disease research
2. Enhance clinical care for Alzheimer's disease patients and their families
3. Provide education regarding Alzheimer's disease to both professional and lay audiences in the greater Boston area and beyond.

[www.bu.edu/alzresearch/](http://www.bu.edu/alzresearch/)



[www.corrona.org](http://www.corrona.org)





<http://hummingbirdirb.com>



Asthma and Allergy  
Foundation of America®

*NEW ENGLAND CHAPTER*

Education and advocacy  
to help New Enlanders  
live better with asthma,  
allergies and food allergies

- Individual and family support, consultation and referrals
- Educational Support Groups
- Training for child care providers, school nurses and health professionals
- Patient education
- Media and community awareness
- Support for research

Tel: 781-444-7778

[www.asthmaandallergies.org](http://www.asthmaandallergies.org)

E-mail: [aafane@aafane.org](mailto:aafane@aafane.org)



**AFRICAN  
COMMUNITY  
HEALTH  
INITIATIVES**

**ACHI is here to help!**

With your health insurance, food assistance, patient navigation, and health education needs.



We are a 501(c)3 non-profit and our mission is to support and improve the health of Africans living in Massachusetts by promoting access to quality culturally competent health and social services through education, research and community partnerships

101 Tremont Street, Suite 415, Boston  
(857) 753-4886

Email: [info@africancommunityhealthinitiatives.org](mailto:info@africancommunityhealthinitiatives.org)  
[www.africancommunityhealthinitiatives.org](http://www.africancommunityhealthinitiatives.org)

**MS**  
National  
Multiple Sclerosis  
Society

**PARTICIPATING IN  
CLINICAL  
TRIALS**

People with MS, and sometimes family members, can make a difference by volunteering for clinical treatment trials and other research studies.

Read more about these opportunities:  
[nationalMSSociety.org/research](http://nationalMSSociety.org/research)



HEALTHY  
HEART  
RESEARCH  
STUDIES

Volunteering for Research

High blood pressure and diabetes impact the health of millions of people. At Brigham and Women's Hospital in the Department of Endocrinology, Diabetes, and Hypertension, we are working to better understand the effects of high blood pressure and diabetes on the heart and kidneys.

**Boston University  
is seeking healthy  
participants, 55-85yrs,  
for research study on  
exercise and  
brain function.**

Email [brainex@bu.edu](mailto:brainex@bu.edu)  
for information.

Come by our booth to learn more  
about our research studies!

We need **YOU!**

Feel free to contact Caitlin at 617-525-7357

---

### **Do you consider yourself "out of shape" and are living an inactive lifestyle with little physical exercise?**

The Brain Plasticity and Neuroimaging Lab is currently enrolling healthy men and women, aged 18-35 or 55-85 years, in a research study on exercise and brain function. The purpose of the research study is to examine the effects of regular physical exercise on cognitive (thinking) processes and on the function and structure of the brain.

The total duration of the research study is about 4 months. We will ask you to meet with our team in person for approximately 7 study visits. In addition, we will ask you to participate in a 3-month exercise training program with 3 weekly exercise sessions.

*Exclusion criteria include the following conditions:* uncontrolled high blood pressure, heart disease or other heart conditions, breathing problems or other lung conditions, obesity, difficulty walking, neurological or psychiatric disorders, metal in body, smoking, diabetes.

You can earn up to \$335 total for completed study visits and receive trainer-supervised exercise training at no cost to you.

Interested participants may email [brainex@bu.edu](mailto:brainex@bu.edu) or call 617-638-5261 for more information.



Our teamwork with  
research institutions means

Eric

gets to be part of  
his team.

At EMD Serono, we forge partnerships that can make a difference. We have an enduring commitment to fulfilling unmet needs and providing meaningful solutions. Our end goal isn't the bottom line, it's a better tomorrow. As an organization with a long-standing history of industry expertise, we continue to shape the future of healthcare. **We are EMD Serono. Nice to meet you.**

EMDSerono



US-NON-0713-0009

# AWARE *for* ALL

## Boston Clinical Research Education Day

October 27, 2014  
Curry Student Center, Northeastern University

NATIONAL SPONSOR



### HOSTED BY



### LOCAL SPONSORS



### IN COLLABORATION WITH

