

Dear Friends,

In medicine, teamwork allows us to better address the needs of our patients. The team concept keeps us all working together with the patient at the center.

On pages one and two, the research process is explained using the team approach. Of greatest importance are the “players”- the research participants. Without their dedication, we wouldn’t have a “win”.

One of the Clinical Research Unit’s (CRU) team leaders is Dr. Wilson Tang. He explains the importance of community involvement, including efforts to enhance education and research, on page three.

Other contributors to the CRU team are Drs. Kirwan and Navaneethan. On pages one and three, you will find their recently published study results. Everyday, they work together with the research team: nurses, coordinators, volunteer study participants and the local and national boards that protect the safety of research volunteers. It is only when each member of the team is successful that there is a win!

We can accomplish great things when we act as a team!

Sincerely,

Serpil C. Erzurum, MD
Director, Clinical Research Unit

Meet the Research Team!

Research involves a lot of people who do different things, much like a sports team has different coaches, players, and officials. Each person, in research and on a sports team, plays an important role.

Meet the team:

Head coach: the researcher, also called the principal investigator

Assistant coaches: the research staff

Players: the research study volunteer

Fans: people to talk to, including friends and family

Referees: the people that protect your safety

On a research team, the researcher or principal investigator is like the head coach of a sports team. The head coach is an expert in the research topic and could be a medical doctor,

a scientist or a community member. They are the person asking the research question and therefore plan and lead the research study. Throughout the study, the head coach follows a play book, also called a protocol, which is a set of instructions they must follow. Keep in mind, everyone in the research study has rules to follow!

The next members of the research team are the research staff, who are like the assistant coaches of a sports team. The research staff handle most of the day-to-day activities for the head coach. Research staff have special training and can be nurses and coordinators. They work very closely with the head coach and are your personal support, especially when you have questions about the research study.

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Recent Study Findings

Non-Alcoholic Fatty Liver Disease (NAFLD) is one of the most common forms of chronic liver disease in the US. Closely linked with obesity, it is estimated that 20-30% of adult Americans are affected, many without knowing it. Obesity causes a buildup of fat in the liver that can lead to liver scarring or liver failure.

A study led by John Kirwan, PhD, showed people with NAFLD can fight the buildup of harmful fat in the liver by walking an hour a day at a brisk pace.

The small study was conducted at Cleveland Clinic, studied 15 people over seven days and was funded by the National Institutes of Health. To participate in a NAFLD study, contact Dr. Mangesh Pagadala at pagadam@ccf.org.



Meet the Research Team

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The most important members of the research team are the study volunteers, who are like the players on a sports team. Just as there is no sports team without players, researchers cannot complete their study without study volunteers. Research studies need all kinds of people to volunteer, just as sports teams need different people to play different positions. Volunteers of all ages, genders, races and ethnicities are needed,

because some treatments work differently in people. Healthy people can also volunteer to take part in research.

People to talk to, family and friends are like the fans at the game. They may have good questions to think about before taking part in the study. They also can help support you during your participation in the study.

Referees help teams follow certain rules. In sports these rules protect the safety of the players. In research, rules protect the safety of volunteers and just like in sports, there are different rules and regulations for different types of research. Referees are the people that protect your safety, both nationally and locally. For example, at the national level, the Food and Drug Administration (FDA) has an official guide, or set of rules, that all researchers must follow.

Locally, Institutional Review Boards (IRB) help researchers follow the rules. The IRB is a group of people who look at the research study and check closely to see that rules are followed wherever the research will be done. Research goes on at hospitals, colleges and other places, and the IRB helps to keep volunteers safe by overseeing study activities at these locations. There are other local referees whose job is to support volunteers more directly. These people are often called “participant advocates” or “research subject advocates.” They are there to support you and can be contacted at any time.

As you can see, the research process involves many different players: researchers, research staff, study volunteers, personal support and national and local people to protect your safety. In the end, it is your choice to take part in a research study, and it is important to ask questions and to understand the process.

Things to Consider:

If you're considering taking part in a research study, learn as much as possible about the study before taking part. Here are some questions you might want to ask:

- What is the purpose of the study?
- What types of tests and experimental treatments are involved?
- Why do researchers think the treatment being tested may work? Has it been tested before?
- Will the study directly benefit me?
- What are the risks?

Source: NIH News in Health

Studies Looking for Volunteers

- **Diabetes and Bariatric Surgery**

Studying how surgery can reverse Type II Diabetes
Chytaine Hall 216-445-3983

- **Healthy Volunteers**

Studying the risk of developing heart failure in healthy adults
Michael Finucan 216-636-6153

- **Healthy Volunteers**

Extended blood collection to study human health and disease
Dr. van Duin 216-445-7846

- **HIV: Human Immunodeficiency Virus**

Studying the loss of fat in HIV patients
Jackie Fox 216-444-4590

- **Immune System**

Studying the influence of aging on fighting infection
Dr. van Duin 216-445-7846

- **Kidney Disease & Weight Loss**

Studying obesity, kidney disease and diabetes
Dr. Navaneethan 216-444-7753

- **Lung Disease**

Studying severe asthma, Pulmonary Arterial Hypertension (PAH), and working to identify the causes of lung diseases
Michelle Koo 216-445-1756

- **Nutrition**

Studying effects of diet on body composition
Julianne Filion 216-445-5553



Dr. Wilson Tang: In the Heart of the Community



Dr. Tang

One doctor working in the heart of Cleveland's communities is also interested in the hearts and well-being of their community members.

W. H. Wilson Tang, MD, is a cardiologist (heart doctor) and Research Director of Heart Failure at Cleveland Clinic, one of his primary research interests.

About five million people nationwide have heart failure, a condition in which their hearts have trouble pumping blood through their bodies.*

Together with Dr. Anjali Maroo at Fairview Hospital, the research team is currently conducting the Firefighters' Health Study, a

screening program for firefighters and an outreach effort to enhance education and research in the community.

About 100 firefighters die each year while on duty and almost half of these deaths are actually cardiac (heart) related deaths. Every day, firefighting duties expose firefighters to extreme physical stress.

The Firefighters' Health Study is screening 400 firefighters and Emergency Medical Services Personnel (EMS) to look at heart disease and other heart and lung risk factors from the same people who rescue us everyday.

Outside of fire stations, Dr. Tang is currently conducting the Cleveland Heart and Metabolic Study

(CHAMPS), funded by the National Institutes of Health (NIH).

CHAMPS is studying the risk of developing heart failure in healthy adults. Specifically, the study is looking at the role of chemical reactions that cause the heart not to work properly.

Over the next five years, the study is looking for 2,000 research volunteers with no known heart failure or weakening of the heart.

For more information on the CHAMPS study, call 216-636-6153 or email champs@ccf.org.

To make an appointment with Dr. Tang, call 216-444-6697.

*Source: NIH News in Health



July 2011: Clinical Research Unit staff at a local Fire Station conducting the Firefighters' Health Study

Metabolic Syndrome linked to Kidney Disease

People with metabolic syndrome, a condition linked to high blood pressure, low HDL (good cholesterol) and diabetes, are at an increased risk for heart disease and stroke. In a recent study, metabolic syndrome has been linked to kidney disease. The kidneys have three jobs: to filter extra water and wastes out of your blood, make urine and control blood pressure. In people with kidney disease, the kidneys may not be able to function well enough to maintain health. Study author Sankar Navaneethan, MD, says "people with metabolic syndrome have a 55 percent increased risk of kidney problems."



How can you prevent kidney disease and lower your risk for metabolic disease?

- Eat a healthy diet of vegetables, fruit, lean protein and whole grains
- Losing excess weight to decrease excess fat in the waist
- Lowering blood pressure, LDL (bad cholesterol) levels and blood sugar

For information on a study about obesity, kidney disease and diabetes, contact 216-444-7753.

Source: NIH News in Health

TIMEPOINTS

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TIMEPOINTS provides the latest information and education on opportunities for people to volunteer and participate in clinical research projects at Cleveland Clinic.

Charlotte Bhasin, Editor
Lauren Verbic, Associate Editor
Clinical Research Unit, Desk M51
9500 Euclid Avenue
Cleveland, OH 44195

Info: 216-445-6018
Fax: 216-636-3329

Cleveland Clinic info:
www.clevelandclinic.org

Clinical Research Unit info:
www.clevelandclinic.org/cru

Get REAL!

REAL (Research, Education, Awareness and Learning) is a committee comprised of research and community specialists from various fields at Case Western Reserve University, Cleveland Clinic, MetroHealth and University Hospitals.

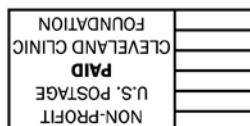
The REAL program provides education to local communities about medical and health research. It can provide speakers or a manned booth to explain what medical and health research is about, who makes up the research team and how to take part in a research study. REAL stresses that taking part in a research study involves several steps, with each ultimately being the decision of the research volunteer.

If you would like to include the REAL program at your next community event, please contact Mary Ellen Lawless at 216-778-1304 or mell15@case.edu. Past events have included the Cleveland Asian Festival, Clyde Rahman Center, Otis Moss Health Fair, Wade Oval Wednesday, Susan G. Komen Education Committee, American Heart Association Heart Walk and Eliza Bryant Village Health Fair.

Upcoming events:

9/24 Buckeye Neighborhood Health Fair
10/5 and 10/27 Solon Senior Center

Who makes up the Research Team? See inside.



RANKED
ONE OF
AMERICA'S
TOP
HOSPITALS

The Cleveland Clinic Foundation
Clinical Research Unit
9500 Euclid Avenue / M51
Cleveland, OH 44195

