AWAREforAll

CHICAGO

Stritch School of Medicine
Loyola University
Monday, September 28, 2015

Clinical Research Education Day

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

MUST BE PRESENT TO WIN

5:00 – 8:00 PM **Health Screenings**, Rooms 160 and 170 —
Blood Pressure, Stroke Risk, Medication Counseling,
Memory Tests and Cognitive Assessment, Skin Care

5:00 – 8:00 PM **Information Alley**, Room 160 — Exhibit Area

6:00 – 6:30 PM **Opening Remarks & Boxed Dinners**, Tobin Hall
Sarah Ebner, MBA, MPH, CISCRP Advisory Board Member,
ACRP-Chicagoland Chapter Treasurer, Investigator Support Services President

Keynote Presentation
What Clinical Research Means to You
Patrick Stiff, MD
Professor of Medicine, Director, Cardinal Bernardin Cancer Center

6:30 – 7:15 PM **Speaker Panel — Clinical Research Discussion**
Moderator: Tom Layden, MD, Hepatology/Pathology, Professor,
Director of the Clinical Research Office, Loyola University

Overview of a Medical Oncologist's Approach to a Patient with Melanoma
Sunandana Chandra, MD, MS
Assistant Professor and Medical Oncologist, Northwestern University

Alzheimer's Research Focus
Steve Satek, MBA, President and Founder, Great Lakes Clinical Trials

Oncology Research Focus
Joseph Clark, MD
Professor of Medicine, Loyola University Chicago Stritch School of Medicine

Diabetes Research Focus
Gail Gannon, APN, FNP-C, Manager of Clinical Trials, Kovler Diabetes Center

7:15 – 7:45 PM **Participant 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: Sarah Duffey, Clinical Trial Recruitment and Education Specialist,
Robert H. Lurie Cancer Center

Don Simmonds — Parkinson's Disease Foundation Research Advocate

Heather Schumacher — Patient of Post-Stem Cell Transplant for Lymphoma,
Patient & Research Advocate

Jeff Studzinsky — Stage 4 Non-Hodgkin's Lymphoma,
Kidney Transplant and Diabetic Patient

Sandy Sojka, Ph.D, RN — Caregiver

7:45 – 8:00 PM **Thank You Ceremony for Clinical Research Volunteers**

Raffle for prizes

WIN PRIZES!

KEEP THE CONVERSATION ALIVE.

Your participation at AWARE for All – Clinical Research Education Days played an important role in advancing the future of clinical research. Thank you for building awareness about participating in clinical research and helping fuel the discussion about advancing medical science.

We hope you keep impacting patients and the public by taking action to move medicine forward.

"Thank you to the millions that participate in clinical trials each year, and to the rest of us who admire them for doing so."

– Center for Information and Study on Clinical Research Participation

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

AWAREforAll

September 28, 2015

Dear AWARE for All attendees, supporters and friends:

It is with great pride and excitement that we welcome you to *AWARE for All – Chicago*. 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 Chicago and developing this important program. We are very grateful for the support from national sponsors EMD Serono, Inc., a subsidiary of Merck KGaA Darmstadt, Germany, and the Lupus Research Institute. Thank you to host sponsor Loyola University Chicago, and to our local sponsors including: Advanced Clinical and Great Lakes Clinical Trials.

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 Chicago and the Greater Illinois area.

Special thanks to Loyola University and Great Lakes Clinical Trials for providing and staffing today's health screenings. It is a great service to the community to be providing screenings for Blood Pressure, Stroke Risk, Medication Counseling, Memory Tests and Cognitive Assessment, and Skin Care screenings. Please be sure to visit the health screenings tonight between 5 pm-8:00 pm in Rooms 160 and 170.

We are also very grateful to tonight's researchers, all of whom gave up their Monday evenings to share their knowledge and expertise with *AWARE for All* attendees. In addition, we would like to thank our participant panelists, all of whom will be sharing their thoughts and stories in our closing session. These Medical Heroes have all participated in clinical 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 Opening presentation. We value your input and appreciate your participation in *AWARE for All – Chicago*!

Kind regards,

Jill McNair

Jill McNair
Director of Education, Outreach and Community Support

Ken Getz

Ken Getz
Founder & Chairman of the Board

AWAREforAll

Planning Committee

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

Astellas Pharma US, Inc.
Barbara Klauke, Senior Manager ISR Operations, Medical Affairs

Bridge Clinical Research
Owen Garrick, MD, President & COO

CAHG, Inc.
Don Sickler, Group Account Supervisor

The Center for Healthcare Innovation
Joseph Gaspero, President & Co-Founder

EMD Serono
Colleen Ferris, Senior Clinical Trial Leader
Lisa Fortin, Senior Clinical Trial Manager

Great Lakes Clinical Trials
Steve Satek, MBA, President & Founder

Healthcare Research Network
David Warren, President

Investigator Support Services
Sarah Ebner, MBA, MPH, President

Loyola University
William Adams, Biostatistician, Clinical Research Office
Tom Layden, MD, Hepatology/Pathology, Professor, Director of the Clinical Research Office
Ceil Petrowsky, MSN, Manager of Cancer Clinical Trials Office, Loyola University Medical Center
Jessica Shore, Senior Director, Sponsored Clinical Research

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Planning Committee—Continued

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

Lupus Research Institute
Diane Gross, National Program Director

Lupus Society of Illinois
Mary Dollear, Vice President

Metropolitan Chicago Healthcare Council's Clinical Research Exchange (MCHC)
Joel Villegas, Project Coordinator

Midwest Clinical Support, Inc. (MCSI) Investigator Site Network
Dan Ulrey, President & CEO

Northwestern University
Sara Duffey, Clinical Trial Recruitment and Education Specialist, Lurie Comprehensive Cancer Center
Jessica MacLean, Manager of Community Relations, Lurie Comprehensive Cancer Center
Grisel Robles-Schrader, MPA, Research Portfolio Manager for Community & Stakeholder Engagement, Center for Community Health
Ashley Sipocz, Regulatory Coordinator, Clinical and Translational Sciences Institute (NUCATS)

PAREXEL International
Almenia Garvey, M.Sc., Associate Director, Site Alliances—Feasibility and Enrollment Solutions

AWAREforAll

Community Partners and Exhibitors

Thank you to our community partners, many of whom are exhibiting and providing information in Rooms 160, 170, and at the Registration Table!

Association of Clinical Research Professionals (ACRP) Chicagoland Chapter

ALS Association—Greater Chicago Chapter

Alzheimer's Association, Greater Illinois Chapter

American Lung Association

EMD Serono

Frenova Renal Research

Geriatric Behavioral Health Unit, Gottlieb Memorial Hospital

Gilda's Club—Chicago

Great Lakes Clinical Trials

The Greater Gift Initiative

Healthcare Research Network

Immune Tolerance Network

Investigator Support Services

Leukemia & Lymphoma Society

Loyola University's Cardinal Bernardin Cancer Center

Loyola University's Clinical Trials Office

Loyola University's School of Nursing

Loyola University's Stritch School of Medicine

Lupus Research Institute

Lupus Society of Illinois

Midwest Clinical Support, Inc. (MCSI) Investigator Site Network

National Association of Down Syndrome

The Northwestern University Clinical and Translational Sciences (NUCATS)

Northwestern University's Feinberg School of Medicine

Northwestern University's Lurie Comprehensive Cancer Center

Oakstreet Health

PMG Research of Christie Clinic
Center

Proviso Partners for Health

University of Illinois

Health Screenings

Please visit the following free health screenings:

Blood Pressure, Stroke Risk, Medication Counseling, provided by Loyola University, in Room 160
Memory Tests and Cognitive Assessments, provided by Great Lakes Clinical Trials, in Room 160
Skin Care, provided by Loyola University, in Room 170

AWAREforAll

Tonight's Speakers in Tobin Hall

Opening Remarks
Sarah Ebner, MBA, MPH, President, Investigator Support Services
Treasurer, ACRP Chicagoland Chapter
Advisory Board Member, CISCRP

Opening Presentation
Patrick Stiff, MD, Professor of Medicine, Director, Cardinal Bernardin Cancer Center

Speaker Panel — Clinical Research Discussion
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Jeff Studzinsky—Stage 4 Non-Hodgkin's Lymphoma, Kidney Transplant and Diabetic Patient

Sandy Sojka, Ph.D., RN, Caregiver

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 cystic fibrosis?
- How do genes affect illness?
- Do people's environments affect their health?
  - Where they live?
  - What they eat?
  - How much they exercise?

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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?

AWAREforAll CISCRP

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

AWAREforAll CISCRP

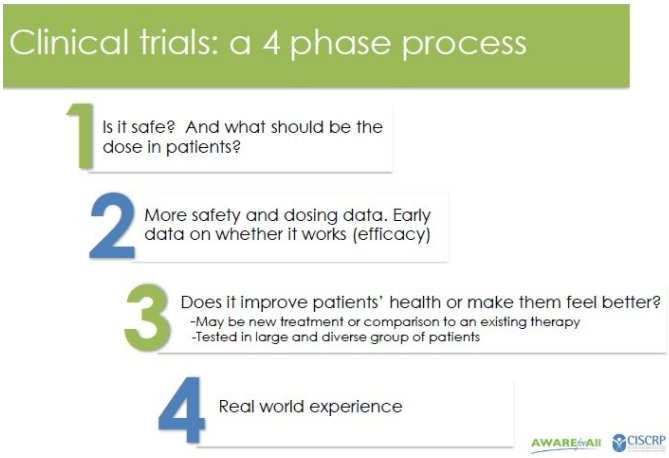
It's important to understand that being in a clinical trial is not the same as going to your doctor for care. When you go to your doctor, she will give you a treatment that has already been tested and approved by the government. This is called "routine" or "standard of care." This is the care we know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

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.



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

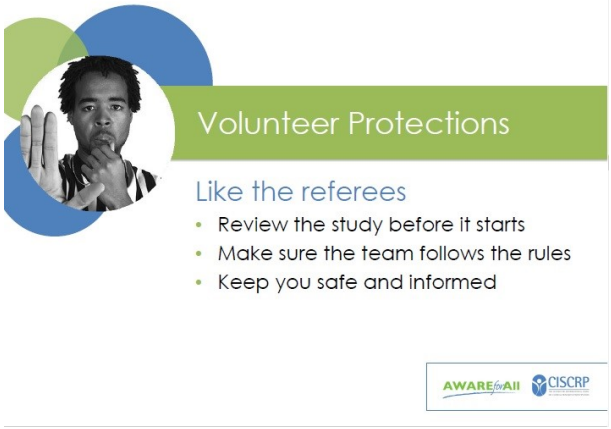
Research involves a lot people who do different things. Like members of a sports team, clinical trials have coaches, players, and officials and each person has an important role to play.

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.

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 principle investigator and is the main contact for volunteers.

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



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.

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.

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.

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.

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.

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

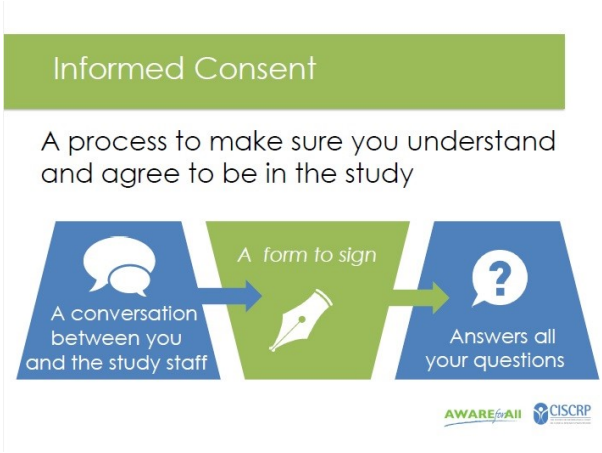
Just like a football game there are rules and not everyone can be on the field at the same time.

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.



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.

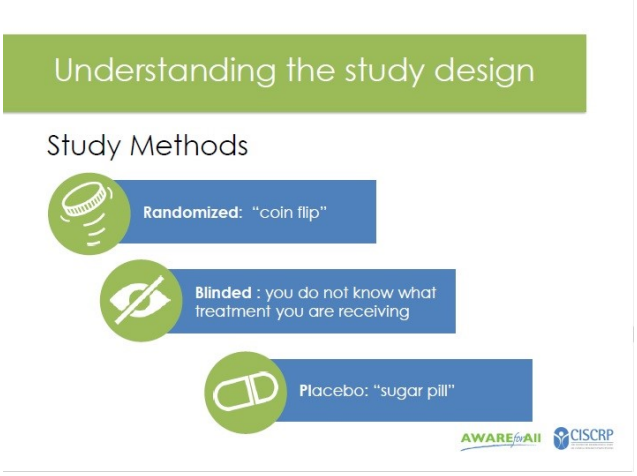
As a research volunteer you have rights. You have the right to understand the purpose, benefits, risks and side effects of the clinical trial.

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!

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.

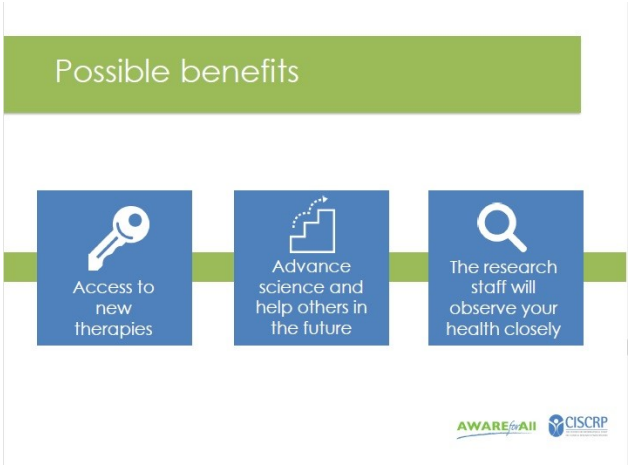


Scientists set up their studies so that their research will be fair. They also want their research to be accurate and unbiased. In other words, they don't want their own ideas about what they think should happen in a trial to influence the results.

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.

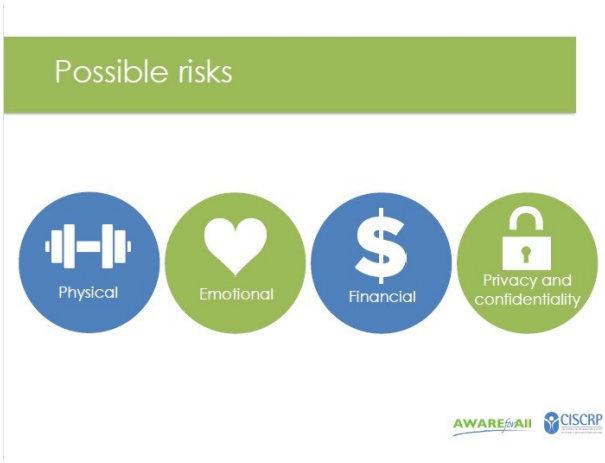
In some trials, researchers will use a "placebo". A placebo looks like medicine but has no medicine in it. Sometimes the placebo is referred to as a "sugar pill" or "dummy drug." What's interesting is that even though the placebo has no medicine in it, there are times when people who are taking a placebo 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.



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.



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.

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.

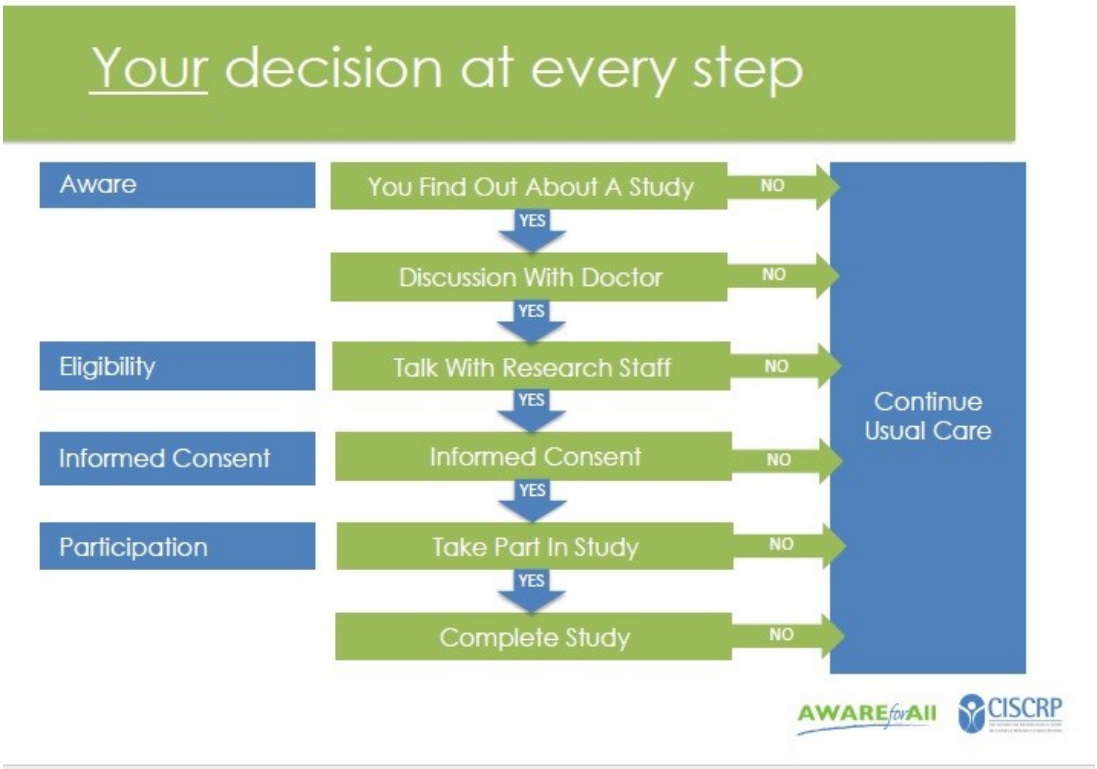
Volunteering takes time and effort, be sure you have the time to participate and if you don't just let the study staff know that this is not a good time. You can always stop your participation and volunteer in other ways or in future research.

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.

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.



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.

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.

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

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

Call 1-877-MED-HERO or visit
www.searchclinicaltrials.org

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.

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

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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, a service of the National Institutes of Health.

Debunking Common Myths About Clinical Trials

MYTH: ***Clinical trial volunteers are merely human guinea pigs.***

FACT: You may be hesitant to participate in a clinical trial out of concern that you will be treated as a set of symptoms upon which to test an investigational drug rather than as a human being with a medical need. Or, you might worry that you will be given completely untested drugs without fully understanding the clinical trial or providing consent. In fact, strict guidelines are in place to ensure that you and all other clinical trial volunteers are treated fairly and ethically. Before an investigational drug can be given to people who volunteer to participate in clinical trials, scientists must complete a rigorous screening and preclinical testing process, which can take up to six years to complete. Additionally, every clinical trial also has a thorough informed consent process to help you understand your rights as a participant, including the right to leave the trial at any time if you change your mind about wanting to participate.

MYTH: ***Informed consent is just reading and signing a piece of paper.***

FACT: Informed consent for a clinical trial involves much more than just reading and signing a piece of paper. Rather, it involves two essential parts: a document and a process. The informed consent document includes all the information you will need to help make a decision about taking part in the clinical trial, including all the known information about the safety and potential efficacy of the investigational drug being studied in the trial. The informed consent document also describes the purpose of the clinical trial, explains the visits and procedures to be done, and includes the possible risks and benefits of participating in a way that is easy to understand. The informed consent process provides you with ongoing explanations that will help you make educated decisions about whether to begin or continue participating in a trial. Researchers and health professionals know that a written document alone may not ensure that you fully understand what participation means. Thus, informed consent is an ongoing, interactive discussion, rather than a one-time informational session.

MYTH: ***Clinical trials are dangerous because they use new practices and medicines.***

FACT: Clinical trials are designed for research purposes, and as a result, some level of risk is involved. However, investigational drugs are given to clinical trial participants only after the drugs have gone through a rigorous testing process and scientific evidence indicates that the drug is likely to be effective and safe for use in humans. In addition, keeping you safe when you volunteer to participate in a clinical trial is a top priority for everyone involved in the trial. For example, all clinical trials are reviewed before they start by an institutional review board (IRB), a committee made up of doctors, scientists and community members who have the responsibility to protect clinical trial participants. The purpose of IRB review is to ensure both before and during the trial that appropriate steps are taken to protect your rights and safety. During the clinical trial, researchers frequently and rigorously assess and monitor participants' safety. These are just some of the ways in which your safety and well-being are prioritized before a clinical trial begins and throughout the trial process.

MYTH: ***If I join a clinical trial, I might get a "sugar pill" or placebo instead of a real drug.***

FACT: A placebo is a product that looks exactly like the investigational drug but does not cause harm or good. The decision about whether to use a placebo in a clinical trial is based on how serious the illness is, whether an existing treatment is available and other considerations that ensure a high standard of ethics. If you have a serious or life-threatening disease, the best available treatment (called "standard of care") will be used instead of a placebo.

MYTH: ***Once I decide to participate in a clinical trial, I will not be able to change my mind.***

FACT: Clinical trials rely on voluntary participation. You are free to leave a clinical trial at any time, even after you have signed an informed consent and received the investigational drug or placebo. However, you should always let the clinical trial team know before you decide to leave the trial because some medicines cannot be stopped safely without a doctor's help.

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MYTH: ***Clinical trials may include painful or unpleasant parts.***

FACT: Like all medical interventions, clinical trials have potential benefits and risks, such as side effects or pain. Processes and procedures can be different for each clinical trial. Some, like in general medical care, may be unpleasant or carry risks. However, the doctor will talk to you about what to expect, and the procedures and risks will be listed in the informed consent document for you to consider while you are deciding whether to participate. The IRB will also ensure that the benefits and risks are carefully weighed and that the trial is reviewed for unnecessary harm or discomfort before it starts.

MYTH: ***I have heard that some people who try to volunteer for a clinical trial are told by the research team that they are not eligible to be in the trial. The process seems unfair.***

FACT: Every clinical trial has a protocol, which is a plan that describes what will be done during the trial, how the trial will be conducted and why each part of the trial is necessary. The protocol for the clinical trial also includes eligibility criteria which includes guidelines for who can and cannot take part in the trial. Common eligibility criteria include age group, gender, having a certain type or stage of cancer, having received (or not received) certain medicines in the past, medical history and current health status. It is important to note that eligibility criteria are not used to reject you personally. These guidelines are used to identify the people most likely to benefit from the clinical trial. The criteria are also necessary to help ensure that researchers will be able to answer the research questions about the investigational drug that they plan to study.

MYTH: ***Being in a clinical trial won't help me.***

FACT: Before you decide to participate in a clinical trial, you should speak with your doctor or the research team about the trial design and the possible risks and benefits of participating. If you choose to participate, you may have the opportunity to receive an investigational drug that is not available to people outside the trial. The clinical trial research team will watch you closely, perhaps even more closely, than your own doctor or nurse during your regular office visits. And, because trials have detailed treatment plans (called protocols), you may get additional tests and lab work that might not be part of your usual care. According to CISCRP's 2013 Perceptions and Insights study, some trial volunteers also report great personal satisfaction in the fact that they have played a key role in advancing medical science and helping scientists find new treatments that will help more people live longer, better lives.

MYTH: ***Being in a clinical trial is expensive and isn't covered by medical insurance.***

FACT: Volunteers for clinical trials rarely have to pay any costs related to participating in the trial. There are two types of costs associated with a clinical trial: research costs and patient care costs. Research costs are those associated with conducting the trial, such as data collection and management, research physician and nurse time, analysis of results, and tests performed purely for research purposes. These costs are usually covered by the sponsoring organization, such as the biopharmaceutical company, and are not the patient's responsibility. Patient care costs are costs that are not covered by the research sponsors doing the clinical trial, such as the costs for routine care including doctor visits, hospital stays, clinical laboratory tests, x-rays and other clinical trial-related activities that would be done even if you were not in the trial. Many health insurance carriers will cover patient care costs, but you should ask the clinical trial research team which costs will be your responsibility and also check with your health insurance carrier about the coverage they provide for clinical trial participants before making the decision about participating in a clinical trial.

MYTH: ***If there is a clinical trial that might help me, my doctor will tell me about it.***

FACT: Your doctor may not know about all available clinical trials that might benefit you. The National Institutes of Health has an online database that you, your family or doctor can search to find appropriate trials: www.clinicaltrials.gov. Alternatively, it's often worth making contact with a patient advocacy organization to help you navigate the process. Many of them have tailored services that can help you with your search and help you understand the options.

If you are thinking about participating in a clinical trial and have additional questions, you should talk to your doctor or a patient advocacy organization for your disease or condition.

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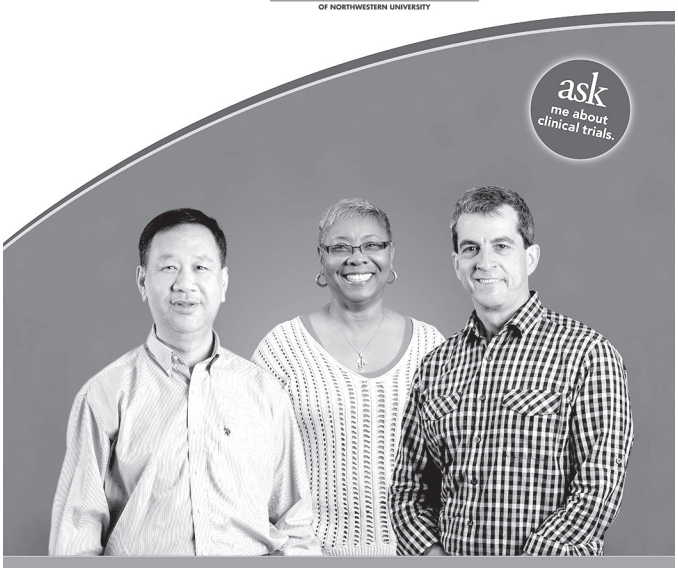

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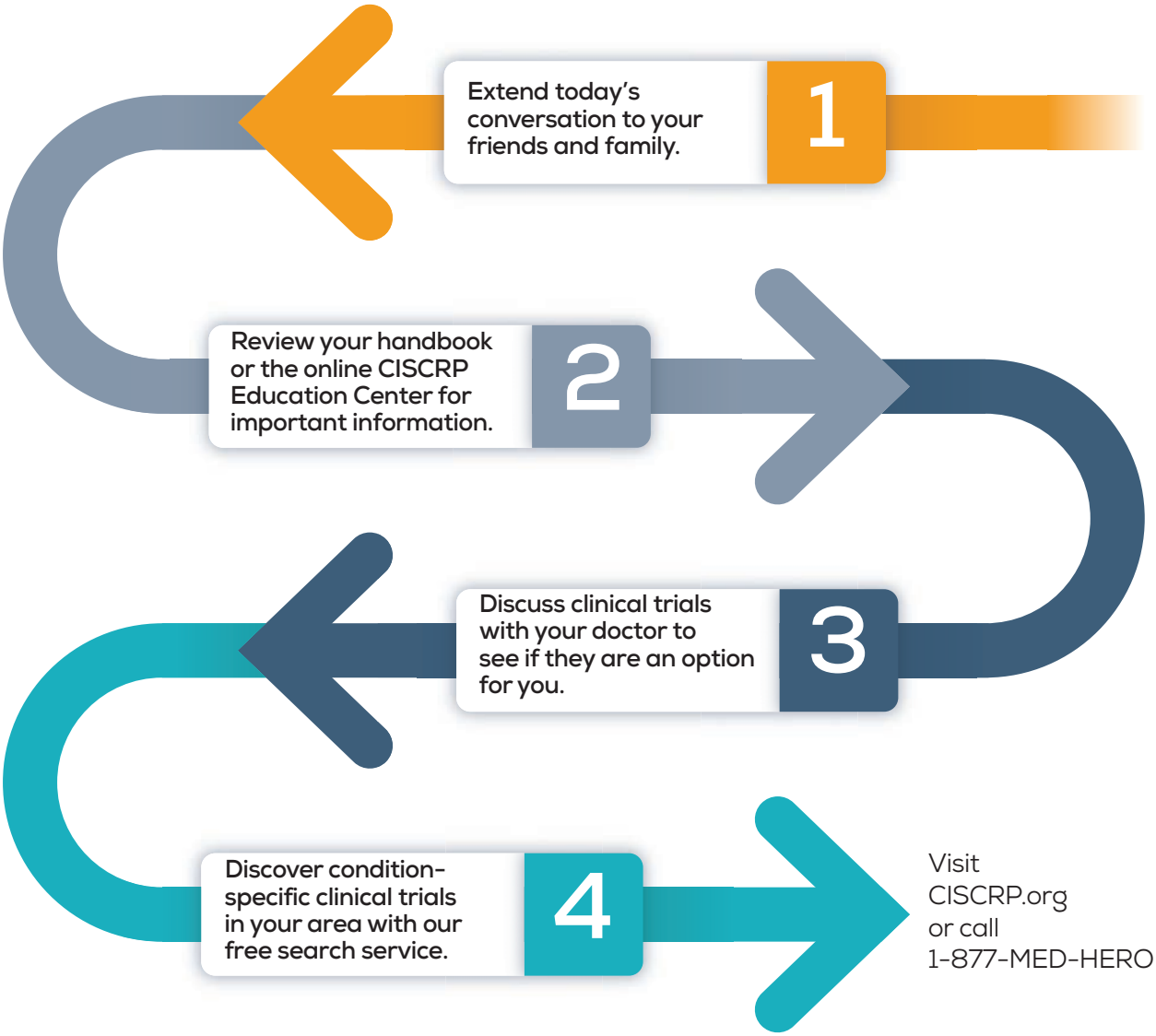

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