CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

AWAREforAll DUBLIN

FREE COMMUNITY HEALTH EVENT

TRINITY TRANSLATIONAL MEDICINE INSTITUTE
WEDNESDAY, 5 DECEMBER 2018

5:00PM – 8:00PM
Health Checks & Information Alley
Blood Pressure and Pre-Paid Flu Vaccine Vouchers

6:00PM – 6:10PM
A Warm Welcome from CISCRP
Ellyn Getz, Senior Manager, Development & Community Engagement, The Center for Information & Study on Clinical Research Participation

6:10PM – 6:15PM
Keynote Address
Rose Kidd, Senior Vice President, Global Clinical Operations ICON plc.

6:15PM – 6:45PM
Overview Presentation
"What Clinical Research Means to You"
Fionnuala Keane, BSc, PhD, Chief Operating Officer
Health Research Board - Clinical Research Coordination Ireland

6:45PM – 7:45PM
Panel Discussion
A chance to hear from local research professionals and study participants about their experiences in clinical research

7:45PM – 8:00PM
Hamper Raffle & Closing Remarks
A Special Thank You to Research Champions

Complete onsite survey to be entered into the hamper raffle
Must be present to win

WIN PRIZES!

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AWAREforAll

December 5, 2018

Dear *AWARE for All* attendees, supporters and friends:

It is with great pride and excitement that we welcome you to *AWARE for All – Dublin*. 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 new medicines.

We would like to thank all the members of the Planning Committee for their assistance in bringing *AWARE* to Dublin and in developing this educational, outreach programme. We are very grateful for the support from our National sponsor Merck KGaA, Darmstadt, Germany, Benefactor sponsors ICON plc., The Medical Research Network, and Longboat, Patron Sponsor Dublin Brain Bank, and Outreach Supporters Health Research Board—Clinical Research Coordination Ireland, The Medical Research Charities Group (MRCG), The Wheel, Cystic Fibrosis Ireland, The Wellcome Trust—HRB Clinical Research Facility at St James's Hospital, IPPOSI, CenterWatch and The Conference Forum.

The warm response *AWARE for All* has received from this community has been heartwarming and convinces us even more of the important need this programme fills. With the assistance of over 200 community organisations, electronic invitations were shared, posters were displayed, and announcements and articles were included in newsletters and on websites throughout the country.

Special thanks to Boots Pharmacy and COPD Support Ireland for providing and staffing today's health checks. It is a great service to the community to be providing blood pressure and pre-paid flu vaccine vouchers. Please be sure to visit the health checks down the hall between 5:00pm – 8:00pm.

We are also very grateful to today's researchers for sharing their knowledge and expertise with *AWARE for All* attendees. In addition, we would like to thank our study participant panelists whose personal stories are captivating, powerful, and inspirational.

Please remember to fill out the surveys at the conclusion of the overview presentation. We value your input and appreciate your participation in *AWARE for All – Dublin*! To continue the conversation and learn about other helpful resources, we encourage you to visit www.ciscrp.org.

Kind regards,

Ken Getz
Founder & Board Chair
CISCRP

Ellyn Getz
Senior Manager Development & Community Engagement
CISCRP

Hope Ventricelli
Events Coordinator
CISCRP

AWAREforAll

Planning Committee

CISCRP wishes to thank the AWARE—Dublin planning committee for all their hard work and dedication to bring this programme to fruition!

Cystic Fibrosis Ireland

Philip Watt, CEO & Chairperson of Medical Research Charities Group (MRCG)

Health Research Board—Clinical Research Coordination Ireland (HRB—CRCI)

Fionnuala Keane, PhD, Chief Operating Officer
Alex Sumner, CRDI

The Centre for Information & Study on Clinical Research Participation (CISCRP)

Caroline Casey, CFO & Director of Operations
Ellyn Getz, Senior Manager, Development & Community Engagement
Ken Getz, Founder & Board Chair
Jim Keen, Associate Director, Marketing, Promotion, and Outreach
Katherine Marriott, Marketing and Communications Coordinator
Leslie Perez, Marketing and Communications Coordinator
Hope Ventricelli, Events Coordinator
Johanna Walsh, Community Engagement and Events Marketing Coordinator

ICON plc.

Vanessa Byrne, Marketing Automation Manager
David Greene, Vice President of Marketing

Irish Platform for Patient Organisations, Science and Industry (IPPOSI)

Mel Connors, Executive Assistant
Derick Mitchell, PhD, Chief Executive

Longboat

Jim Lane, Chief Business Officer
Paddy Wall, Senior Manager Strategic Partnerships

The Medical Research Charities Group (MRCG)

Avril Kennan, PhD, CEO

Planning Committee

CISCRP wishes to thank the AWARE—Dublin planning committee for all their hard work and dedication to bring this programme to fruition!

Merck

Rodrigo Garcia, MD, Head Global Clinical Applications and Innovation

Emma Silva, Corporate Communications Manager

The Medical Research Network (MRN)

Zara Broadfield, Marketing Manager
Graham Wylie, MD, CEO

Roche

Myra O'Dwyer, Clinical Operations Manager

Trinity College Dublin

Michelle Hendrick, Executive Officer, Haematology

University College Dublin

Peter Doran, BSc, PhD, Interim Director, Ireland East Hospital Group Clinical Research Network

Associate Professor, UCD School of Medicine

The Wheel

Gert Ackerman, Communications Coordinator
Femi Atoyebi, Information Systems Management Expert
Hugh O'Reilly, Director of Development
Johnny Sheehan, Membership and Regional Coordinator

Community Supporters

Thank you to all of the community organisations who helped to spread the word about this important programme!

Age Action Ireland
Alpha 1 Foundation
Alzheimer's Ireland
ARC Cancer Support Centres
Arthritis Ireland
Asthma Society Ireland
Ballybough Community Centre
Barbara Ware Community Centre
Boots Pharmacy
Breakthrough Cancer Research
CAN
Cross Cancer Research
Cancer Trials Ireland
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The Conference Forum
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DIT Student Health Service
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Galway, Evidence Synthesis Ireland, Cochrane Ireland
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Hope Hands On
HRB-Clinical Research Facility, Mercy University Hospital
HRB - CRCI
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Irish Lung Fibrosis Association
Irish Medical Independent
Irish Times
Kildare Now
Le Cheile Donnycarney Community & Youth Centre
Longboat
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Trinity - St. James's Hospital
TTMI - Haematology & BD
UCD
Vertex
Warrenmount Community Education Centre
The Wheel
Women in Research
Women in Technology and Science
Women's Way

Agenda

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Blood Pressure and Pre-Paid Flu Vaccine Vouchers

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6:15PM—6:45PM: Overview Presentation—*What Clinical Research Means to You*
Dr. Fionnuala Keane, BSc, PhD, Chief Operating Officer
Health Research Board—Clinical Research Coordination Ireland (HRB—CRCI)

6:45PM—7:45PM: Panel Discussion about Clinical Research in Ireland
Chair: Avril Kennan, PhD, CEO, Medical Research Charities Group (MRCG)

Martina Hennessy, Associate Professor Medical Education, Pharmacology & Therapeutics
Director of Wellcome Trust—HRB—Clinical Research Facility at St. James's Hospital

Jilllian McNulty, Cystic Fibrosis Campaigner & Research Champion

Dr. Tomás Carroll, PhD, Associate Lecturer, Department of Medicine
Royal College of Surgeons in Ireland (RCSI)
Chief Scientist, Alpha-1 Foundation Ireland

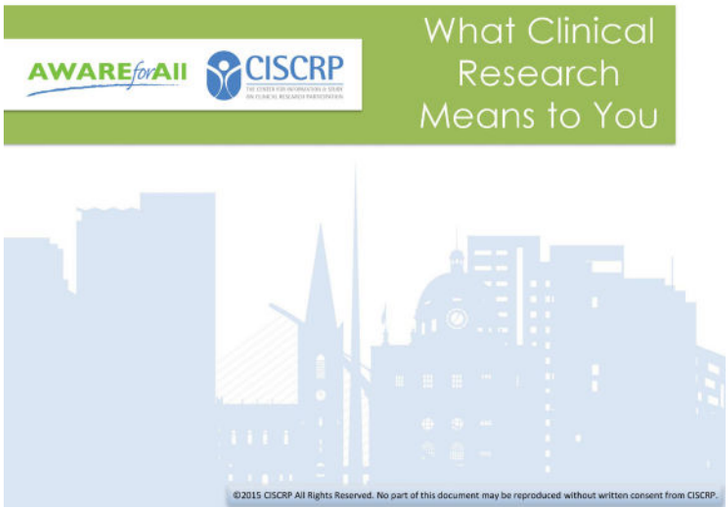
Dr. Ruben E. Keane, Quality and Regulatory Affairs Director
HRB-Clinical Research Facility, Mercy University Hospital

Patrick Kivlehan, Oncology Research Champion & Cancer Trials Ireland Advocate

Dr. Margaret Dunne, Research Assistant Professor, Trinity College Dublin

Dr. Patrick Murray, Dean of Medicine and Head of School
Professor of Clinical Pharmacology, UCD Clinical Research Centre

7:45PM—8:00PM: Hamper Raffle & Closing Remarks, Special Thanks to Research Champions



Welcome to AWARE for All—Clinical Research Education Day. We're thrilled that so many of you are joining us to learn more about clinical research.

This programme is brought to you by CISCRP, the Center for Information and Study on Clinical Research Participation.

Our goal is to help you understand the clinical research process – including the risks and benefits of participating.

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 "Research Champions."

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 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 feel empowered to make decisions about their health

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?
- 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 a question like this:

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

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?

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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

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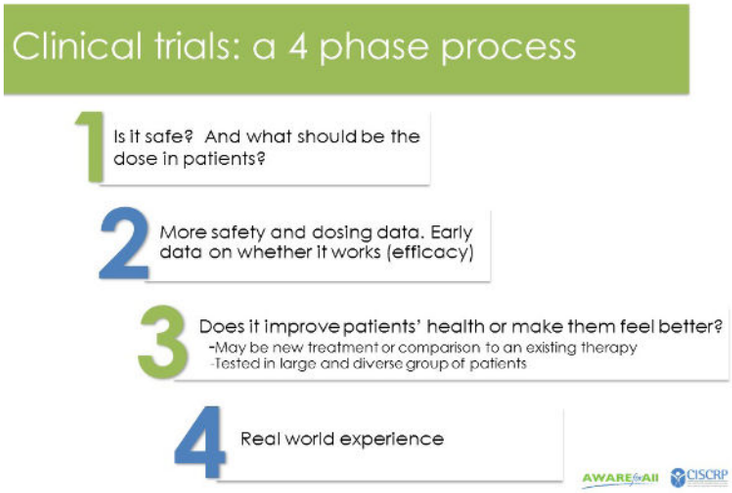
It's important to understand that being in a clinical trial is not the same as going to your doctor for care. When you go to your doctor, she will give you a treatment that has already been tested and approved by the government. This is called "routine" or "standard of care." This is the care we know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



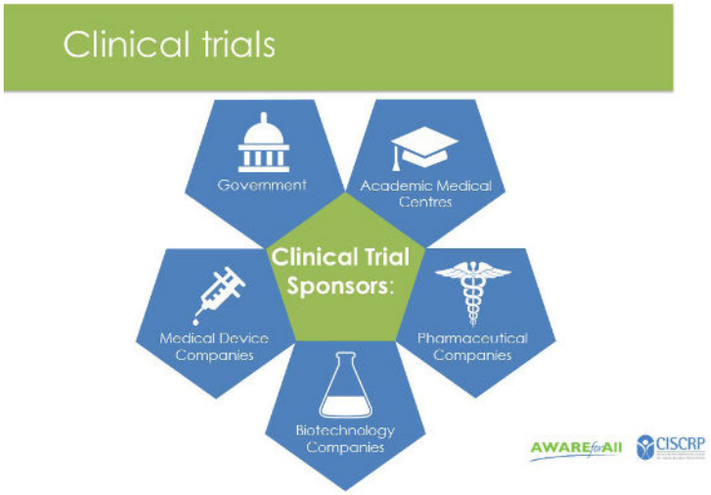
During phase 1 studies, a drug is tested for the first time with a very small number of volunteers. And often these are healthy volunteers. The goal of these trials is to learn what is a safe dose. And how does it work in the body? Is it harmful?

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.

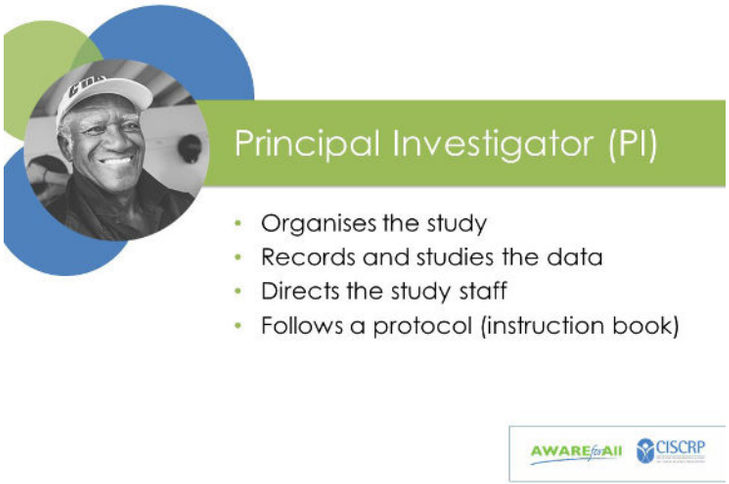
Phase 4 studies happen after a treatment has been approved by an Ethics Review Committee. They usually involve large numbers of patients who are regularly taking a medicine. Phase 4 studies look at real world experience and check to see if the drug works well over a long time.

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



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

Research involves a lot people who do different things. Each person has an important role to play.



The Principal Investigator is responsible for organising and leading the study as well as recording and studying the data. The PI also directs the team.

The principal investigator follows an instruction book, which is called the study "protocol." The protocol is a set of instructions that everyone must follow. It's the plan for how the study will be carried out.

The research staff members assist the Principal Investigator, or lead research doctor. The Clinical Research Coordinator handles the day-to-day activity at the research site.

There are others who help protect the safety of volunteers by making sure research teams follow the rules. These regulatory and quality affairs representatives review the study before it starts. They keep you safe and give you all the information. The number of these individuals 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 Ethics Review Committee. It's the law. The Ethics Review Committee 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 Ethics Review Committee know if there are any changes in the study plan or if volunteers experience serious injuries or side effects. The Ethics Review Committee can end a trial if it feels volunteers are not safe.

Regulatory bodies from the federal government are also involved – this group is called the HPRA.

Regulatory centres review studies, inspects research centers and monitors research groups. The regulatory bodies have 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. Without them, research can't happen.

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

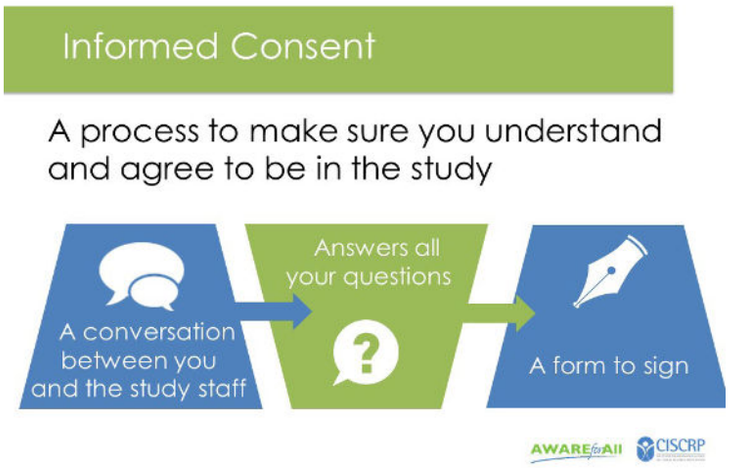
Your friends and family may provide you a support system while you are taking part in a study. It is good to talk to your friends and family about the clinical study. They can help you come up with questions to ask your doctor about the study. They can also support you while you participate. In the end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

The research team has a list of requirements for the participants. Let's talk about eligibility first. A 10-year-old would never be allowed to play on a pro rugby 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 you're eligible to participate. The next question you have to ask yourself is: Do I choose to participate? Well, that depends, right? You can't say whether or not you want to participate without understanding the rules of the game. What are your responsibilities as a volunteer? How long will the trial last? What are the risks and benefits of participating? What are you going to get in exchange for participating?

The "informed consent" process is designed to answer all these questions and is required by the HPRA and Ethics Review Committees. 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 HPRA 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.

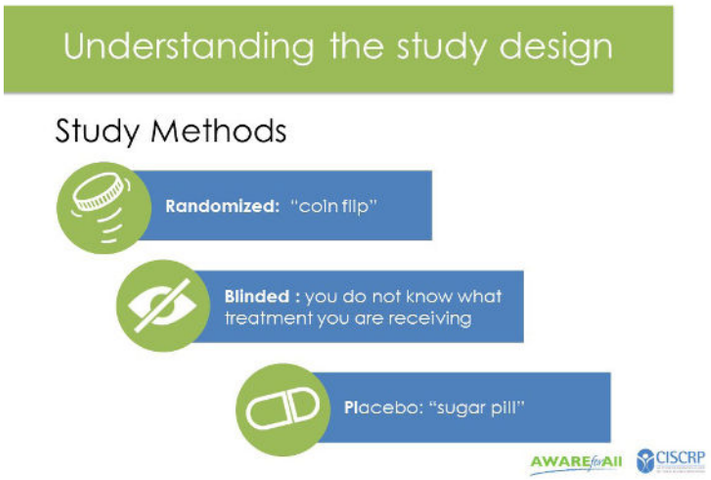
You have the right to ask any questions and discuss any concerns with the research staff at any time during the trial. And you have the right to full, complete and clear answers.

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.

In this section of our presentation, I'd like to talk about some of the risks and benefits you should consider. And questions you should ask before making your decision.

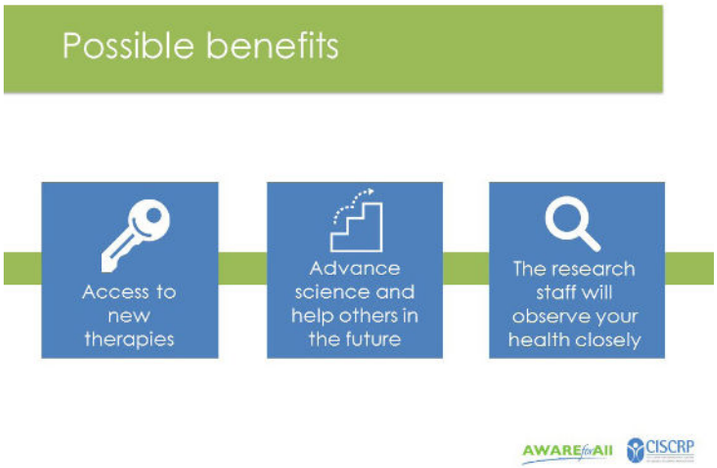


Scientists set up their studies so that their research will be fair. They also want their research to be accurate and unbiased. In other words, they don't want their own ideas about what they think should happen in a trial to influence the results.

To set up fair and unbiased studies, volunteers may be split into different study groups. This is usually done by chance using a computer program and is similar to a coin toss. The researcher and the volunteer do NOT get to decide which group the volunteer will be in. This is called a "randomised" study.

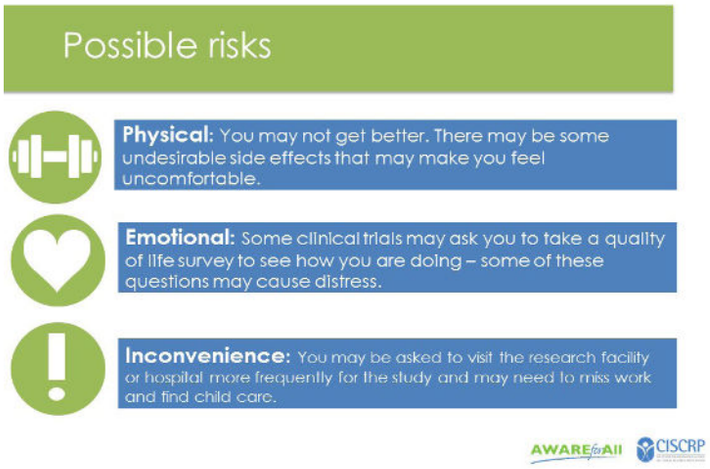
Sometimes researchers will go a step further and "blind" a study. This means that the volunteer and the researcher both do NOT know which treatment the volunteer is receiving.

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." 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



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.

Inconvenience: You may be asked to visit the research facility or hospital more frequently than usual for the study and may need to miss work and find child care.

It's important that all of your doctors know if you are in a clinical trial.

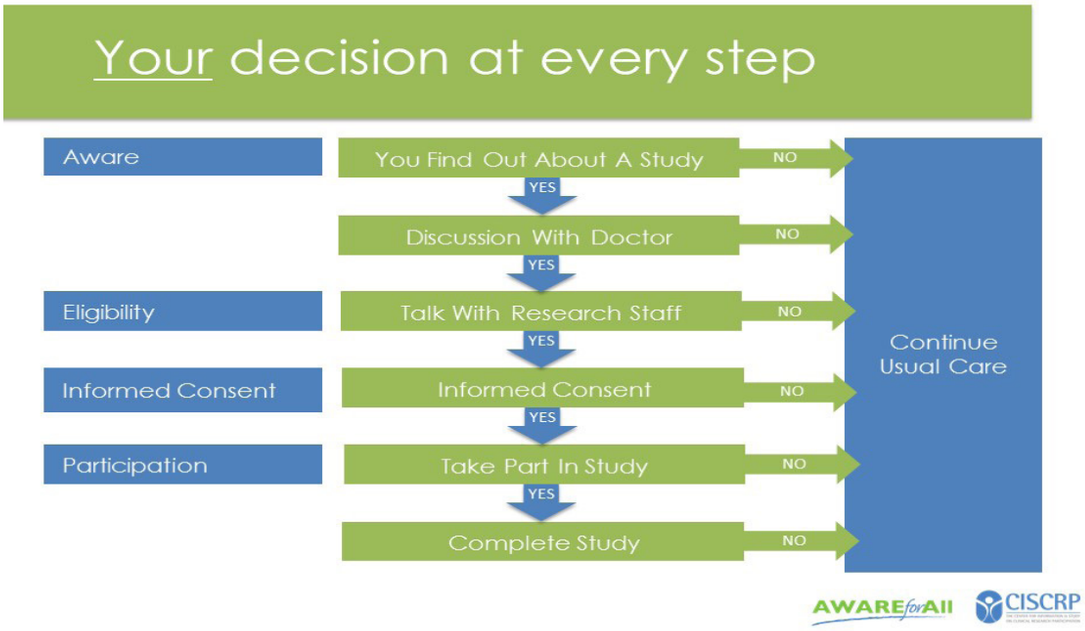
This will require your time and commitment – Volunteering takes time and effort. Be sure you have the time to participate and if you don't just let the study staff know that this is not a good time. You can always stop your participation and volunteer in other ways or in future research.

The clinical trial could end at any time – even if you want to continue to participate, your doctor, the regulatory bodies, 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. Informed consent is an on-going process – not a one shot deal.

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. They are listed on this slide for your reference.

CISCRP provides a free search service designed to help patients find trials that might be right for them. Or you may talk to your doctor, research site, friends and family to help find resources for you.

Research volunteers truly are Research Champions 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 play a more active role in their own health care**

Many participants feel empowered to learn as much as possible about their health conditions and are asked to share ways in which their experience in studies can be improved.

√ **To better track your health**

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

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**
A study may include a 'dummy' treatment group which is matching in appearance to the active treatment. Participants will be randomly assigned to receive the placebo (also known as a sugar pill or dummy drug) or the active treatment.

√ **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 may be asked 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.

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 centre that will be conducting the trial, but use other information sources as well. Keep in mind the research centre 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; it has been updated with guidance from the HRB—CRCI.

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 clinical research?

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 and clinicaltrialsregister.eu includes both interventional and observational studies.

What is a clinical trial?

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.

What is an observational study?

In observational studies, study doctors assess health outcomes in groups of participants. The study may involve the collection of biological samples and the use of questionnaires or interviews to better understand the mechanisms of a disorder. Participants may receive interventions (which can include medical products such as medicines or devices) or procedures as a part of their routine medical care, but participants are not assigned to specific interventions by the study doctor (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 (lead study doctor), 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, academia, voluntary groups, and other organisations. 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?

Study protocols include a set of predefined eligibility criteria outlining who can participate. Research participants are evaluated for eligibility by their study doctor. This is an important principle of clinical research that helps to produce reliable results and to ensure it is considered safe for the participant to be included. The criteria used are based on factors such as age, gender, the type and stage of disease, previous treatment history and other medical conditions. It is important to note that inclusion and exclusion criteria are not used to reject people personally; they help ensure that researchers will be able to answer the questions they plan to study.

How are participants protected?

All clinical research studies undertaken in Ireland must comply with the highest national and international ethical standards and relevant regulations.

To take part in a clinical study, every participant must voluntarily sign a consent form that explains the research study, the foreseeable risks, potential benefits, other appropriate treatment options and where to find further information. It also explains one's rights as a participant in the study. If at any time a participant is not comfortable with the study, they have the right to withdraw. Confidentiality of records and data are also assured.

Relationship to usual health care

Typically participants continue to see their GP 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 GP 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. Many trials require participants to undergo additional procedures, tests, and assessments based on the study protocol. These will be described in the informed consent form (ICF) for a particular trial. A potential participant should also discuss these issues with members of the research team and with his or her GP.

Commonly used terms

Patient information leaflet (PIL): For each clinical study, there is a PIL which explains why you have been asked to take part, what the study is about and what it will involve. Also included are the potential risks and known side effects, as well as the alternative treatment available should you choose not to participate. The purpose of the PIL is to provide you with all information necessary to decide if you wish to take part or not. Your participation in a clinical study is always voluntary, and deciding not to take part will not affect your continued medical care. Before you can be enrolled into a research study, you must read the PIL and give written informed consent. After signing, you are still free to withdraw from the study at any time.

Randomised trial: This is a process by which participants are assigned to a treatment group in a trial. Participants are randomly allocated to one or other of the different treatment groups in the trial, there is no identifiable pattern; therefore, no one can predict which treatment the participant will receive. Randomisation is performed to prevent bias in the trial, by ensuring balance across the groups.

Blinded trial: In a blinded trial, participants are not aware of which treatment group they have been assigned to. In the case of a double-blind trial neither the participant nor the research team are aware of the treatment group assigned. Blinding is used to prevent bias.

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 form. 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 any 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.

Sources for further information

If you are interested in becoming a participant in research, please consult with your own doctor in the first instance. You may also wish to contact your patient representative organization or publically available clinical research registers. Here are some relevant websites for information:

- Irish Platform for Patient Organisations, Science, and Industry (IPPOSI): www.ipposi.ie and www.clinicaltrials.ie. The websites and associated documents are part of an IPPOSI information campaign intended to advise the public about taking part in clinical trials, including information specifically tailored for different age groups of children.
- The European Medicines Agency has a publicly accessible database of drug clinical trials: www.clinicaltrialsregister.eu
- The United States authorities have created a website where trials conducted around the world can be found: www.clinicaltrials.gov

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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info@ciscrp.org
Toll Free: 877-633-4370

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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MEDICAL RESEARCH NETWORK

MRN'S long term vision is to support the ability to run clinical trials fundamentally based in the community

OUR **HOME TRIAL SUPPORT** SERVICE TAKES THE CLINICAL TRIAL TO THE PATIENT BY CONDUCTING VISITS IN THE HOME

HOW OUR HOME TRIAL SUPPORT SERVICE BENEFITS PATIENTS

- We can design clinical trials to offer convenient, tailored care.
- Conducting clinical trial visits in the patient's home, school or work environment reduces the travel burden patients and their carers or families face.
- Home Trial Support makes the trial comparative to normal standard of care (i.e. on a marketed product).

Most importantly, it enables a patient to maintain a normal life. Children can still attend school, adults can develop a career and families can enjoy time together.

HOW OUR HOME TRIAL SUPPORT SERVICE BENEFITS SITES

- Better convenient care for their patients.
- Site staff can utilize their time most efficiently.
- Increased patient recruitment and patient retention, leads to better site performance.
- Wider geographic recruitment area per site.
- Higher productivity per site (as there will be fewer on site visits).

OUR **SITE NURSE SUPPORT** SERVICE PROVIDES SPONSORS AND CLINICAL RESEARCH SITES WITH EXPERIENCED RESEARCH NURSES TO ASSIST WITH CLINICAL TRIALS AT SITES

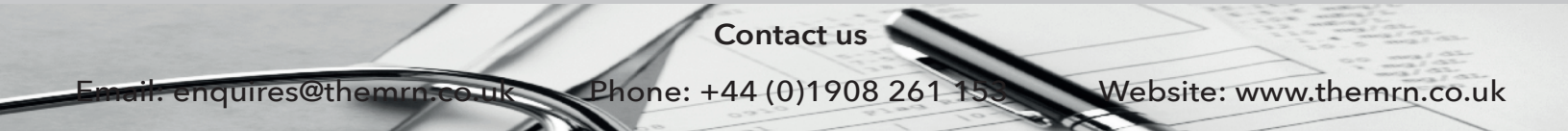
HOW OUR SITE NURSE SUPPORT SERVICE BENEFITS PATIENTS

- Increased likelihood of being considered for a trial.
- More site staff time for screening procedures and questions.
- Better standard of care during visits.

HOW OUR SITE NURSE SUPPORT SERVICE BENEFITS SITES

- Dedicated resource to identify patients.
- Better patient recruitment rates per study.
- Help with high number of patients in trials.
- Potential to conduct a higher number of clinical trials that otherwise, would not be possible.

Learn more about MRN: @MedResNet Medical Research Network



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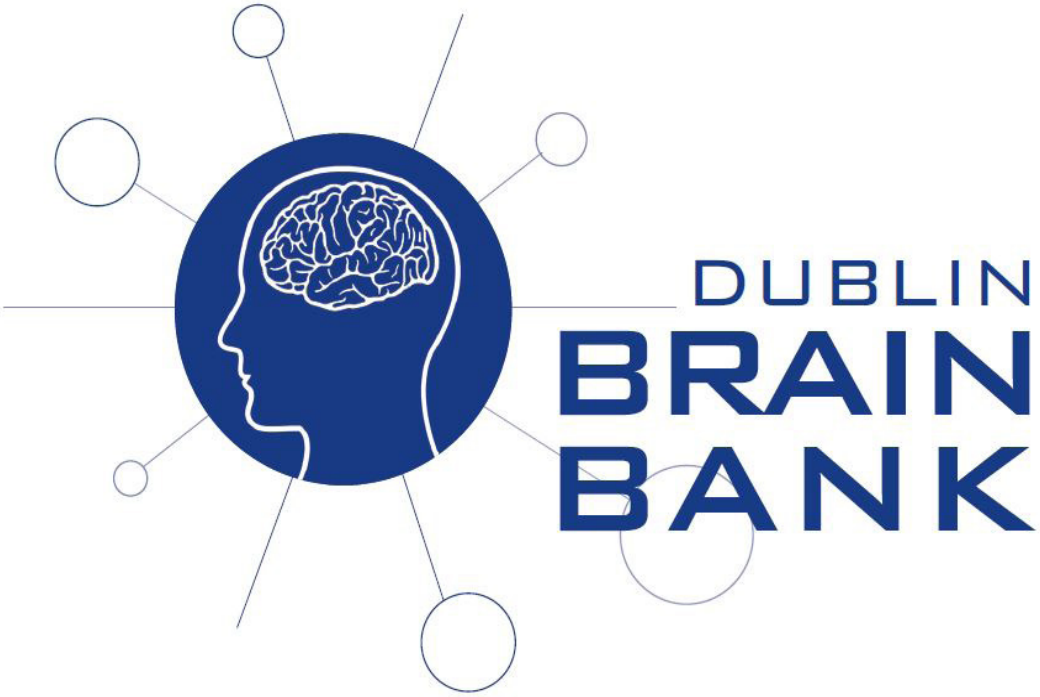


Dublin Brain Bank offers the opportunity to support medical science in a very tangible manner.

We facilitate the donation of brain tissue to medical and scientific research, and to provide Irish and international researchers with access to brain tissue to conduct research into neurological disorders.

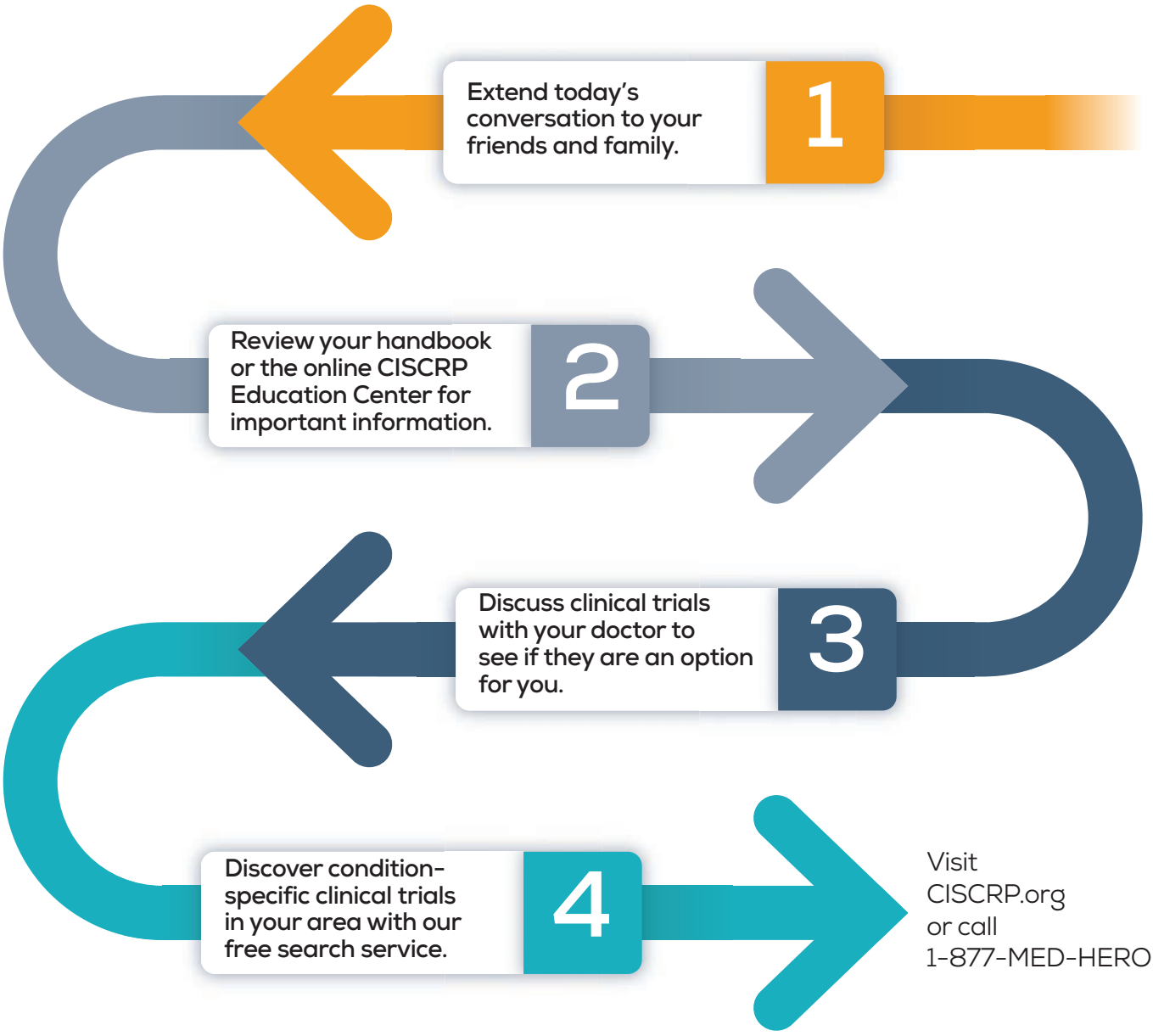
Through the study of this precious brain tissue, researchers aim to develop our understanding of the mechanisms underlying neurological disorders, enabling improvements in the diagnosis and treatment of these disorders, and ultimately leading to increased quality of life for patients.

To find out more, visit www.rcsi.ie/brainbank or call 01 809 2706.

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.



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"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

PASSIONATE ABOUT VOLUNTARY ACTION

Ireland's charities have changed millions of lives for the better.

Our 10,000 charities:

- give a voice to thousands of communities
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- mobilise 300,000 volunteers who contribute millions of hours of work every year.

The Wheel is Ireland's national association of community and voluntary organisations, charities and social enterprises.

We passionately believe that community and voluntary action improves and enriches our communities and society.

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the wheel

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The Wheel complies with good practice standards in the areas of finance, governance and reporting.

medical research charities group

Unity is our Strength

The Medical Research Charities Group (MRCG), is the national umbrella group of medical research and patient support charities, which represents the joint interests of charities specialising in restoring health through medical research, diagnosis and treatment and, where possible, the prevention of disease. Our members represent well over 1 million patients in Ireland. A core belief of the group is that today's health research is tomorrow's healthcare.

Tallaght Traveller Community Development Project

Traveller Rights are Human Rights

Tallaght Travellers Community Development Project (TTCDP) is a partnership between Travellers and Settled people working together to achieve human rights and equality for Travellers. We work to address the issues Travellers living in the Tallaght catchment area, who as an ethnic minority group, face racism discrimination marginalisation and exclusion. We aim to create opportunities that enable Travellers to bring about improvements in their status, life chances and living conditions which validates and respects Traveller culture and ethnicity. Programs include education (homework club) Men's Health Worker and Youth Work (personal development, recreational activities, drug prevention and IT training) advocacy for accommodation and equality, Primary Health Care for Travellers Project (PHCTP) and information and referral for resources.

SCSI

Sickle Cell Society Ireland

Sickle cell Society Ireland (SCSI) is a parent - patient led organization committed to caring for people affected by sickle cell in Ireland. We promote sickle cell awareness through partnership work at local, national, European and global levels. Our vision is committed to raising public awareness of sickle cell and improving health and wellbeing of people affected by sickle cell in Ireland through health promotion, education & awareness, research and development and family support. To promote our vision, a nationwide #SickleCellMatters Campaign led by our Sickle Cell Initiative for Youths Project (SCI-FY project) was launched in 2015. The #SickleCellMatters campaign was launched in partnership with CMRF Crumlin and endorsed by Irish Blood Transfusion Services, Royal College of Surgeons in Ireland and Irish Patients Association. More recently we have launched a sickle cell education research in partnership with the Royal College of Surgeons in Ireland.

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Interested in More Ways to Stay Involved with CISCRP?

Participate in One of Our Editorial Panels!

About This Opportunity

CISCRP's Communicating Trial Results program provides study volunteers with the results of their clinical trials written in plain language. To develop these summaries, we call upon medical professionals, patient advocates and members of the public to form Editorial Panels that review plain language summaries before they are sent to study volunteers.

Who Can Participate?

- ✓ General member of the public with no health or research background
- ✓ Patient or patient advocate with a disease or condition
- ✓ Healthcare professional who does not currently work in the clinical trial enterprise

If you are interested in participating or would like to learn more about this opportunity, please contact **Rachel Weitzner**, our Editorial Panel and Engagement Associate.

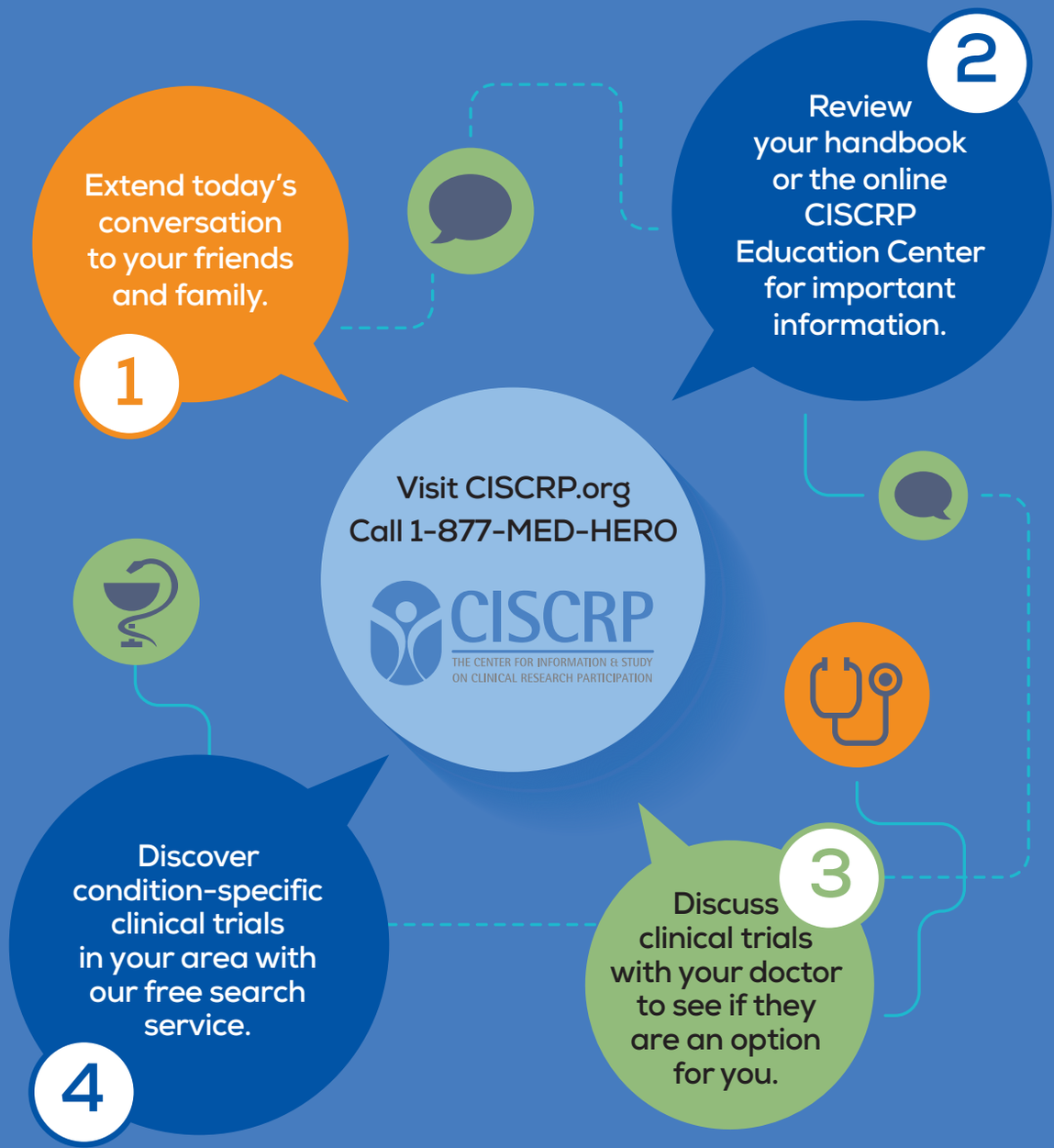
Email: rweitzner@ciscrp.org

Phone: 617-725-2750 x108

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.



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– Center for Information and Study on Clinical Research Participation

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