






# DIALYSIS RESEARCH



## What's It All About?



This brochure explains the basics of dialysis research. It will help you understand what research is and what it might mean to participate. This information may be helpful for patients, care partners, or dialysis clinic staff.



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# What Is Research?

**Research** is a process that helps us discover new knowledge. It is the gathering of information, sometimes called **data**, or the testing of an idea.

A **researcher** is the person who designs the research. A researcher gets help from a group of people, known as a **research team**. Each team member has a special role.

**Clinical Research** is the study of health and illness in people. Examples include:

- Exploring the cause of a disease
- Testing an intervention (like a new drug or program) to see if it will help symptoms
- Learning how certain behaviors or habits affect health

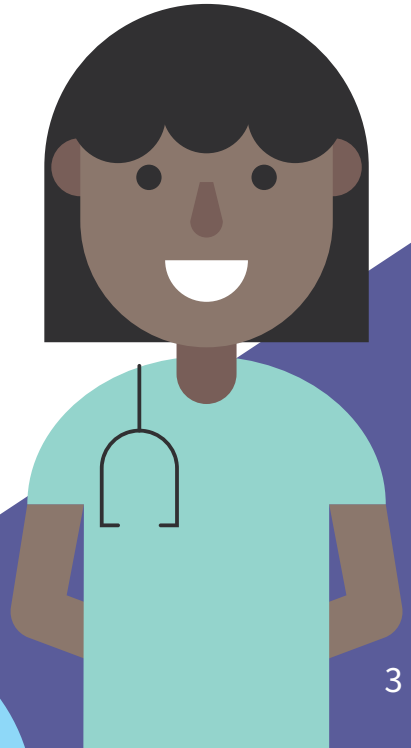
**Dialysis Clinical Research** is the study of health and illness in people on dialysis. Examples of studies might include:

- Trying to find the cause of itching
- Testing if a medicine makes bones stronger
- Learning how a new dialysis machine makes people feel after dialysis

All research starts with a question. Researchers then design a study to help answer the question. A **research study design** is the scientific approach used to answer the research question. It outlines how and when to collect specific information.

Researchers must follow a written plan, or **protocol**. This makes sure the study is done the same way with all **participants** (people who take part in a study).

Research is not about money. It's about knowing that we are doing something to benefit patients in the long run.



# What Are Some Types of Research?

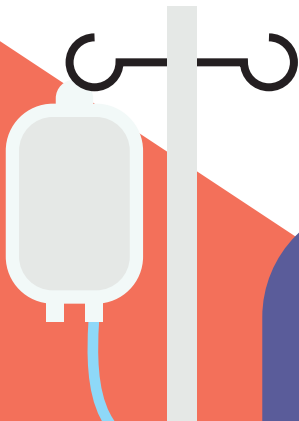
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One type of research is called **Observational Research**. These studies involve observing or monitoring groups of people and looking at a specific result or piece of information. The researchers don't control the treatment or program being tested. These studies often provide information to guide future research.

**Two types of observational research are cohort studies and survey studies.**



We want to be involved in something bigger... To be a part of something that's bigger, that touches more lives.



**Type:** **Cohort Study**

**What is It:** A research study where researchers monitor a group of people over time

- Examples:**
- Discover things that make it less likely for patients to be admitted to the hospital
  - Find things that might prevent blood pressure drops during dialysis
- 

**Type:** **Survey Study**

**What is It:** A research study where researchers collect information from people through surveys, interviews, or focus groups

- Examples:**
- Written survey about your experience on dialysis
  - Phone interview about your dialysis-related symptoms
  - Focus group about your experience starting dialysis

# What Are Some Types of Research?

## 2

Another type of research is called **Experimental Research**. These studies test an intervention, like a new drug or program, to see if it is effective and safe.

Experimental studies are done with 2 groups of people:

- Experimental group – tries the intervention
- Control group – does not try the intervention

Researchers assign participants to a group. This can be done randomly or by a specific process. After, they compare the results of the 2 groups. The control group may be able to get the intervention after the study.

**Type:** **Clinical Trial**

**What is It:** A research study that tests a medical intervention with people

- Examples:**
- Safety of a new device to measure fluid or water weight
  - Safety of a new drug for bone disease
  - Effectiveness of a new drug for low blood counts
  - Effectiveness of a new dialysis clinic program to increase transplants

# What Do You Need to Know?



It is your choice to take part in a research study.



If you participate, you can stop at any time.



Your decision will not affect your medical care.

An **Institutional Review Board** (or **IRB**) is a group of people who makes sure that researchers protect the rights and safety of participants. An IRB must approve a research study before it can start.

**Informed consent** is the process a researcher uses to give you information about a study. This happens before you decide to participate. It usually includes:

- The purpose of the study
- What participants will be asked to do as part of the study
- What risks or benefits might be involved
- How long the study will take and where it will happen
- Who to contact for more information about the study

# What Are Your Research Rights?

**Every person who is asked to be in a clinical research study has the right to:**

## Decide to Participate or Not

- 1 Decide to participate without being rushed.
- 2 Be free of pressure when deciding to participate.
- 3 Decide not to participate in the study.
- 4 Quit after the study starts, without any penalty.





## Be Told Important Information

- 5 Be told the purpose of the study.
- 6 Be told what will happen and what the procedures are.
- 7 Be told about the potential risks of the research study.
- 8 Be told what benefit they may expect from participating.
- 9 Be told if there will be no direct benefit to them.
- 10 Be told what medical care is available during the study.

## Ask Questions and Stay Informed

- 11 Ask questions about the study, before, during or after.
- 12 Receive a copy of the informed consent form to keep.

# Why Participate?

**There are many reasons people might want to participate in a research study:**

- Help improve the lives of others
- Be part of something larger than yourself
- Contribute to the advancement of knowledge
- Learn new things
- Learn from others' experiences
- Have interest in the research study topic

This research may not help me, but it may help somebody down the line.

I would be willing to participate in research to help anybody in the future that would have the same thing that I had.



# Questions You Might Ask

## **About the Research Study:**

- Why are you doing this study?
- Why should I participate?
- Who is paying for the study?
- How long will the study last?

## **About Participating:**

- What will I do if I choose to participate in this study?
- Will I go some place else to participate in this study?
- Will the study change my dialysis treatment or care?
- What will happen if I participate but decide to quit later?

## **About Study Risks and Benefits:**

- How will this study help me if I decide to participate?
- How will this study help other dialysis patients?
- What are the potential risks or discomforts in this study?

## **Other:**

- How will you keep my health information safe?
- Who do I contact if I have questions about the study?
- How do you plan to share the results with participants?

# Want To Learn More? **ASK** a member of your medical team! Or go to:

**[www.kidney.org/atoz/content/clinical-trials](http://www.kidney.org/atoz/content/clinical-trials)**

This National Kidney Foundation website provides information on clinical trials.

**[www.nih.gov/health-information/nih-clinical-research-trials-you/basics](http://www.nih.gov/health-information/nih-clinical-research-trials-you/basics)**

This National Institutes of Health website provides information on clinical trials in Q & A form.

**[www.clinicaltrials.gov](http://www.clinicaltrials.gov)**

This National Institutes of Health website lists clinical research studies from all over the world.

**[www.kidneyandtransplant.cochrane.org/ongoingtrials-kidney-disease](http://www.kidneyandtransplant.cochrane.org/ongoingtrials-kidney-disease)**

This Cochrane website allows you to look for research studies on kidney disease and related treatments.



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