

Clinical Research Flashcards

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What's a clinical research trial?

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- **Clinical Research Trials** are research studies that help to look at new treatment for conditions.
- **Clinical Research studies** help kids and adults living with long-term illnesses to find better ways to live each day with their conditions.
- **All clinical research** studies are designed to help us understand if new medicines or treatments are safe, helpful, and well-tolerated by kids.
- **Some researchers** study brand-new drugs, vaccines, or medical devices.
- **Some researchers** study new ways to look at existing treatments to see if they might be able to help with different conditions.



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Why do people decide to participate in a clinical study?

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- **Choosing to participate** in a clinical research study can be a good way to gain more knowledge.
- **Volunteers that enroll** in a research study become "participants". Participants are able to help researchers understand how to prevent, treat, and detect disease.
- **Participating may provide** researchers information leading to a cure for a condition.
- **Healthy participants** participate to help others in the future.
- **Participants with medical** conditions also like to help others. They also participate to possibly receive a new medicine that is not currently on the market or to help other kids just like themselves.
- **Some kids may enroll** to get access to a new treatment because their current medicine is not working enough.
- **Many people like to know** that they are helping to advance science around the world.



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**Who is present at the first
research visit?**

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- **At the first research visit**, participants bring their parents or other grown-up, as they meet with the research team.
- **The research team** may include a doctor or investigator and others that help in doing the research, like a nurse or a person called a coordinator.
- **If the participant needs** help with translation, an interpreter may be there.



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**What is the first meeting
with the research team
like?**

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- **The first meeting** can be exciting, scary, fun, or even a relief after having a lot of anticipation about your first meeting.
- **Participants often explain** that they felt a combination of feelings at their first meeting.
- **It is just like when** they meet anyone for the very first time or experience a new situation.
- **The research team** is there to help you and make sure that you are healthy and well during the study.



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**What types of questions
might you have and who
answers them?**

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- **Some participants** have a lot of questions and some have only a few.
- **Many kids want** to know more about what is going to happen next or if they will be able to continue to do their favorite activities.
- **Some might want** to know if they will visit a hospital or a clinic for their study or if they will meet a new research team or if their regular doctor will be there.
- **All questions are** good questions, and the study team is there to help answer them.



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What does “voluntary” research mean?

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- Volunteers that enroll in a research study become "participants".
- Voluntary research means that enrolling into the clinical research trial is the decision of you and your grownup.
- This also means that anyone that agreed to participate, can leave the study at any time, for any reason.



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What is an assent?

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- This is the word that is used when a child agrees to a study.
- Assent is a form of consent or 'permission' that a person under the age of 18 gives to participate in the clinical research study.
- Even though a child has not reached legal adult age, they still need to provide permission to participate.



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What is an placebo?

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- A placebo is a harmless pill, liquid or powder that has no active medicine in it.
- It is a fake.
- Placebos are given to better understand how the active (or new research) pill, liquid, or powder works during a clinical research study.
- Often by giving some participants a placebo, researchers can quickly tell if the active (research) pill, liquid or powder is working.
- Participants are always told if placebos will be used in the study right at the beginning of the clinical research study but will not be told if they have received a placebo or if they have received active medicines.



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**When do you stop a
research study and what
happens when you stop a
research study?**

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- **No one has to be** in a clinical research study, and no one has to stay in one.
- **Participants have** the right to stop or leave a research study at any time.
- **There should never** be any pressure to stay in a study.
- **If a participant wants** to leave a study, they have the right to continue their medicines and treatments just like before the study started.



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**What things do people like
about participating in
clinical research?**

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- A lot of participants share that being in a study makes them feel good about helping science.
- Being in a study may be beneficial to a participant's condition.
- They may receive new treatments, individualized care, and a larger support team.



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What are some not so good things about clinical research?

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- The study may not be helpful for your condition.
- You may experience more negative side effects than positives.
- It may take time away from things that you do at home or school.



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**Why is it important to
answer questions from the
clinical research team
about your participation in
the study?**

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- It is important to answer questions from the clinical research team during a study for a lot of reasons.
- **Sharing their experiences** and feedback helps researchers to know how they feel, how the treatment is going, or other important information.



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What happens during a research study visit? How is this different from a regular doctor visit?

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- A research study visit can look a lot like a doctor visit.
- Some things are the same.
- The researcher and the doctor can be the same person.
- The setting can be the same clinic you already go to.
- The treatments might be the same too.
- The biggest difference is that clinical research studies are helping to find out about the future health of patients through a larger group of study participants and a doctor visit is focusing on just one person and providing individualized care.



Start Again

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