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 = glossary definition








Participating in a Clinical Trial: Rights and Responsibilities

How are your rights protected?



You will want to know your rights and responsibilities as you think about joining a clinical study. Laws in the [United States](#), Canada and the European Union exist to protect study subjects and help them to understand the details about a study. Additional legal protections are given for pregnant women, human fetuses, neonates and **children**.


What kind of information can you get about the study?

You may get details about a clinical study in many ways. A member of the *research team*  may contact you and or your primary care doctor may speak with you about a study. You may see a brochure or information sheet that gives some details about a study. But the most important way to get information is through the *consent form* . This form is required by law to explain:


- that the **study involves research**
- **why the study is being done**
- the **length of time** the *subject*  will be in the study
- the **procedures** to be followed and which are experimental
- potential **risks or discomforts** to the *subject* 
- potential **benefits** to the subject or to others
- appropriate **alternative procedures** or courses of treatment that might be good for the *subject* 
- How **privacy of records** or *confidentiality*  will be maintained
- whether any **compensation or medical treatments are available if injury occurs** and, if so, what they consist of, or where information may be found
- **whom to contact for answers** about the research and research *subjects'*  rights
- **whom to contact in the event of a research-related injury** to the *subject* 
- that **participation is voluntary**, refusal to participate will involve no penalty or loss of benefits and that the *subject*  may stop the study at any time.

What are your rights?

- You have the right to be informed as fully as possible, to understand what has been explained to you and to be given time to ask questions and have them answered by one of the *investigators* 
- Your consent to join a study must be voluntary and you must not be forced in any way to agree to join.
- You have the right to stop the study at any time and continue to receive your regular care. It will not harm your relationship with your doctors and nurses if you choose to stop the study.
- You must not be given promises of benefits that are not likely to result from being in a study.
- You must be given a copy of a signed and dated written *consent form* . The form must be written in simple language that you can understand.

- The *research team*  will tell you how you may reach them in case you have questions or concerns.

What are your responsibilities?

- Consider the extra time and effort that may be needed to be in a study.
- When you decide that your child will be in a study, it is important to follow the study instructions very carefully. This may mean giving the proper doses of study medicine at the right time, returning for each study visit and letting the study team know if your child had any *adverse effects*  from the treatment.
- Keep in regular contact with the study team. Let the research team know if your address, email or phone number changes and how you can best be reached. Call the research team if you will not be able to go to one of the study visits. They will want to know that you are okay and will help you to find another time that is good for you. Talk with them if you have transportation, childcare or other needs. Often, the study team can help you to find other resources to help you during the study.
- If you decide to leave the study, talk with a member of the study team before you do so. Your child may need to be placed on a different medicine or need a certain test so you can leave the study safely. On the Children and Clinical Studies website, watch the video "[What if I Want to Leave the Study?](#)" for more information.

 [Should My Child Join a Study?](#)

[Ensuring Safety in PHN Studies](#) 

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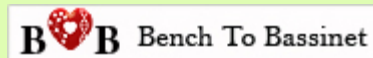
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Last updated: June 2, 2010 10:42 AM