Hemophilia Federation of America™

Understanding Clinical Trials & Research Studies

Participants* should feel free to ask questions about their participation in a clinical trial or research study prior to signing up. Here are questions you should ask about a clinical trial or research study and what you should learn when those questions are answered.

*Research participants are sometimes referred to as Human Subjects.

LEARNING OBJECTIVES: WHAT YOU WANT TO LEARN

- Is a written copy of the research procedures available?
- What are the benefits and risks of this clinical trial/research project?
- How will I be informed if there are changes to this clinical trial/research project?
- Am I waiving any of my rights by signing this consent form?
- May I ask a person I trust to read this document?
- Will my name and address be kept confidential or will it be shared with others?
- How will my information be stored to protect my privacy?
- Can I refuse to participate in this research project?
- What if I change my mind after I agree to participate?
- How do I withdraw my consent after I sign the form?
- If I withdraw my consent and stop participating, what will happen with my information that already was collected?
- Are there negative consequences if I withdraw my consent?
- *(In case of pharmaceutical trials)* Will I be given the actual medication or a placebo?
- *(If English is not your first language)* Is the information available in my language?

LEARNING OUTCOMES: WHAT YOU CAN SAY YOU LEARNED

- The purpose of the research.
- The name, address, and phone number of the Principal Investigator of the clinical trial/research project.
- How long I am expected to participate.
- If any of the medications or procedures are experimental.
- The possible risks or discomforts.
- If there are any alternative procedures or courses of treatment.
- If my information and medical records will be kept confidential.
- If I will be paid for my participation.
- The medical treatments available if I get injured/suffer harm from the clinical trial/research project.
- Who I can call if I have questions.
- If I am required to participate in this study.
- If there is a penalty if I refuse to participate.
- If there is a penalty if I stop participating at any time.

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Rights & Responsibilities of the Informed Consent Process

The informed consent process involves information being shared between a patient or research participant* and the doctor or researcher. The patient or research participant has a right to be informed, but he/she also has a responsibility to ask questions. The doctor or researcher has the responsibility to conduct ethical care or research and the responsibility to be honest about all aspects of the medical or research process.

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PATIENT AND PARTICIPANT RIGHTS AND RESPONSIBILITIES

- Have your questions answered to your satisfaction BEFORE you agree to treatment or to participate as a research participant.
- Understand the purpose of the treatment/research to which you are agreeing.
- Understand you can refuse treatment and you can refuse to participate in the treatment or research.
- Understand you can stop treatment or withdraw from the research project after it has started.**
- You have a right to privacy.

DOCTOR AND RESEARCHER RESPONSIBILITIES

- Discuss the purpose of the treatment or research.
- Provide patient/research participant with enough time to consider whether he/she wants to take part in the treatment or join the research project.
- Do not force or strongly influence a patient/participant to take part in a treatment or join a research project.
- Discuss the risks and benefits of participating in the treatment or research.
- Respect the privacy of the patient/research participant.
- Adhere to and honor the ethical guidelines established for human subject research when conducting studies.