

## It is Your Right to Know

When you join a research study you have the right to be fully informed about the study. You should make sure you understand why the study is being done, what will happen to you during the study, and what the possible risks of the study are. You need this information so you can make the best choice for yourself and decide whether or not to join the study. The information that the research team must tell you in writing or during discussion includes:

- It is **your choice** whether you want to be in the research study. You do not have to join the study. If you do choose to join it, you can leave the study at any time.
- You **do not give up** any rights or benefits by joining this study.
- **Why the study is being done** and what the researchers hope to learn from the research.
- What the **research procedures** are and how they are different from the regular medical care you would get for your disease or condition.
- What **study drug or study device** will be used in the study, if any, and how it is different from the regular medical care you would get for your disease or condition.
- What **discomforts or risks** you might experience from being in the study.
- What **benefits**, if any, you might get from being in the study. It is possible that you might not experience any personal benefit from being in the study.
- What **other treatments**, drugs, or devices are available outside of the study that might help you. Be told about the **risks and benefits** of these other options so that you can compare them to the risks and benefits of being in the study.
- Possible medical treatment if you have any **side effects** from being in the study.
- Possible treatment, if any, that is available to you **after the study** is done.

### You should also:

- **Ask any questions** you have about the study or the research procedures before you join the study, and while you are on the study. (To see some sample questions to ask, see the NIH IRB pamphlet "Are You Thinking About Joining an NIH Research Study?")
- **Decide** whether you want to join the research study without any pressure placed on you or excessive incentives. (You should not be pressured by others to take part in the study).
- **Take as much time** as you need to decide whether or not to join. You are free to consult with family members, your regular doctor or any other person you trust when making this decision.
- **Be given a copy** of the signed and dated consent form so you can refer to it later.

Contact the office below if you have questions about this pamphlet or your rights as a research subject.

### OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS (OHSRP)

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