RESEARCH AND YOU: KNOW YOUR RIGHTS
BILL OF RIGHTS FOR PEOPLE TAKING PART IN RESEARCH STUDIES

If you are asked to be in a research study (to take part, participate, give your consent) or if you have been asked to consent (allow, give permission) for someone else—such as your child or an elderly or very ill relative—you have the right to:

1. Be told that the study (also called experiment, trial, survey) is research.
2. Be told what the study is trying to learn and why this will be useful.
3. Be told what you will be asked to do in the study and how long it will take in words you can understand.
4. Be told about any discomforts or risks (harm or danger) that you might be exposed to from the study.
5. Be told about steps that will be taken to reduce these risks or dangers and to care for you if they occur.
6. Learn about any benefits (good things) that may happen to you from being in the study.
7. Be told in a medical study if there are other treatments or medicines you could take instead of being in the study—are there alternatives to the study that might help you?
8. Be told that you can refuse to be in the study or that you can change your mind about being in the study at any time and that no hard feelings or harm will come to you from this.
9. Ask questions about the study until you feel you understand it.
10. Receive a copy of the signed and dated consent form.
11. Feel that your decision is your own and that you were not pressured to take part in the study.
12. Contact the University of Alabama IRB if you feel you were not treated fairly or that the study did not match what you were told.
QUESTIONS TO ASK ABOUT BEING IN A STUDY

The investigator should give you an explanation of the study that answers most of these questions. If not, ask. DON’T BE SHY! Also ask yourself about how you feel about this.

1. Has this study been approved by the University of Alabama IRB—or another IRB?
2. What interests me about this study?
3. Who gains or benefits from this study—do I? People like me in the future? Scientists or health caregivers? Society at large?
4. When and where does this study take place?
5. How long will it last?
6. Are there any out-of-pocket costs or expenses for me?
7. Is this study SAFE for me—or do I feel that the RISKS OR DANGERS are acceptable?
8. Do I feel I can trust the investigator/researcher?
9. Do I feel that deciding to be in this study is my own free will—or do I feel pressure from someone to be in it?
10. How do I contact the investigator if I have questions or concerns about the study?
11. What university source do I contact if I have questions or concerns about this study?
12. If I really wanted to quit, would I be able to?
13. Am I learning anything from being in this study?
14. Will I be told, and how, if new information about the study comes along and risks or benefits change?
15. How is the confidentiality of the information I provide protected? Who will have access to the information obtained from me?
16. Can I find out the results of the study?

AFTERWARDS: Was I treated as I expected to be? Would I do this again? Would I recommend being in a study to others?
WHAT ARE MY RESPONSIBILITIES IN A STUDY?

If you agree to be in a study, you have responsibilities to yourself and to the principal investigator (PI--the person doing the study). You should:

1. Read the consent form, weigh the risks and benefits, and ask the PI any questions you have. You should know what procedures will be done in the study, how much time you will spend, when the study will start and end, and whether you will receive any compensation for your help.

2. Keep a copy of the consent form for your records.

3. Do what you are asked to do. Keep appointments or call ahead of time if you cannot.

4. Answer questions and keep records honestly—useful research depends on accurate, honest, ethical subject participation. Remember your answers and results are confidential.

5. Report any and all unanticipated problems with the research to the PI right away. This could be anything from a change in symptoms to an auto accident that will interfere with your participation to a piece of study equipment or device that does not work right or an actual injury that may be due to the research.

6. If you have complaints or concerns about the study, contact the PI or the Research Compliance Officer at the sponsoring university or company. Contact information for these people will be on the consent form (another reason to keep the consent form).

For studies done by University of Alabama faculty or students, the number to call is 205-348-5152. Also, you may click on “COMPLAINTS” on this website and complete the Concern or Complaint Form online. (WEBSITE UNDER CONSTRUCTION May 2008).

7. You may ask for a summary of the study results if you wish.
INFORMATION FOR PARENTS & GUARDIANS: RESEARCH AND CHILDREN:

Many types of research involve children. Some examples are research on vaccines, drugs, or other treatments for children’s diseases; studies of children’s physical, social, or intellectual development; and studies of how children are affected by world events. Because children are still growing and developing, they are considered a “vulnerable population”—one that needs special protection in research because they are not yet fully mature or capable. Because they are vulnerable, children under legal age cannot give their own informed consent to participate in research. Instead, the parent(s)/guardian must make this decision and give permission for the child to be in a research study. In addition, if children are able to understand an explanation suited to their age, they will also be asked to give ASSENT—to agree—to be in the study. This does not take the place of true consent.

As the child’s parent or guardian, it is your responsibility to protect the child’s wellbeing and safety. An investigator must give you the full explanation of the study and ask you to give your informed consent. But YOU must ask whatever questions you have and decide whether this study is right for your child. Here are things to think about or ask if not explained by the investigator:

1. What is my child being asked to do?
2. How long will being in this study take—do I want to make the commitment or have my child involved for this length of time?
3. What are the benefits, if any, to my child? Are there benefits to other children or society? What are the risks or dangers or harm that may come to my child from this study?
4. Is the data being collected sensitive—for instance, does it involve genetics, sex, drug abuse, or criminal behaviors?
5. Will the researchers know my child’s identity?
6. How will my child’s identity be protected?
7. Are there transportation, cost, or conflict with work problems for me?
8. Does the study require that my child miss class or other school activities?
9. Does my child want to be in this study?
10. Are there any advantages or disadvantages of being in (or not being in) this study?
11. Do I trust this investigator?