

January 14, 2004

TO: Clinical Research Investigators and Coordinators

FROM: Dusty Layton  
Office of Research Compliance and Assurance

RE: Human Subjects Bill of Rights

One of the primary responsibilities of the USA Institutional Review Board is to ensure that individuals considering participation in human subject research are fully informed of their rights under federal regulations and University policy. The practice of presenting research subjects with a Bill of Rights at the time of the consenting process has been approved by the Institutional Review Board. The intent of this document is to inform potential subjects as to their rights when being recruited for clinical research studies. Any individual who is requested to consent to participate as a subject in a research study or requested to consent on behalf of another must be given a copy of this document.

The Bill of Rights is to be given to potential subjects along with a copy of the consent form. This information should be reviewed **prior** to the consent form. As a result of this new procedure, there should be a reference at the end of the consent form indicating that the subject has received the Bill of Rights. Therefore, the consent should read, "I acknowledge receiving and reading the Medical Research Subject's Bill of Rights". This new procedure takes effect immediately for all new studies. For all active research studies, the consent revision should be incorporated at the time of annual renewal.

A copy of the Bill of Rights is enclosed and available on the IRB website at <http://southmed.usouthal.edu/com/research/humansubjects.html>

Thank you for your cooperation, as we are committed to the protection of the rights and welfare of every individual who elects to participate in human research. Should you have any questions, please contact the Office of Research Compliance @ 460-6625.

cc: Pamela Horner, IRB Office  
Charles Rich, M.D., IRB Chair  
John Rothrock, M.D.  
Samuel J. Strada, Ph.D.

**UNIVERSITY OF SOUTH ALABAMA MEDICAL RESEARCH  
SUBJECT'S BILL OF RIGHTS**

If you are invited to participate as a subject in a medical research study or are asked to consent on behalf of another, you have the right to:

1. Be informed of the purpose of the research.
2. Be given an explanation of the procedures to be followed in the research protocol and of any drug or device to be used.
3. Be given a description of any discomfort, risk, or potential medical complication that reasonably could be expected to occur as a consequence of participation in the research study.
4. Be advised of any potential benefits from your participation in the research, if applicable.
5. Be informed of any procedures, drugs or devices that might be of help to you and provide an alternative to participation in the research.
6. Be informed of the process required to receive medical treatment promptly should complications arise as a result of your participation in the research.
7. Be given an opportunity to ask any questions concerning the research.
8. Be instructed that you may discontinue your participation in the research study at any time without jeopardizing the future medical care you receive at USA.
9. Be given a copy of a signed and dated written consent form, whenever written consent is required.
10. Be given the opportunity to decide freely and without undue pressure from others whether or not to participate in the research.