APPROVED
May 13, 2005
WIRB®
Olympia, WA

RESEARCH SUBJECT INFORMATION AND CONSENT FORM
DONOR

TITLE:	SAFETY STUDY IN RETINAL TRANSPLANTATION FOR AGE RELATED MACULAR DEGENERATION
PROTOCOL NO.:	None WIRB® Protocol #20050380
SPONSOR:	Norman D. Radtke, M.D., PSC Louisville, Kentucky United States
INVESTIGATOR:	Norman D. Radtke, M.D. Suite 240 3 Audubon Medical Plaza Louisville, Kentucky 40217 United States
SITE(S):	Norman D. Radtke, M.D., PSC Suite 240 3 Audubon Medical Plaza Louisville, Kentucky 40217 United States Norton Audubon Hospital One Audubon Plaza Louisville, Kentucky 40217 United States
STUDY-RELATED PHONE NUMBER(S):	Norman D. Radtke, M.D. 502-636-2823 (24-Hour Pager) 800-643-8197

This consent form may contain words that you do not understand. Please ask your counselor to explain any words or information that you do not clearly understand. You may have an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

You, _____, have made a voluntary decision to end your pregnancy before reading this form.

PROCEDURES

Research with this valuable tissue has a high potential to help people. You have been invited to participate in a research study concerning retinal transplantation. This specific research, sponsored by the University of Louisville, Department of Ophthalmology, is developing techniques to transplant embryonic eye tissue. These experiments are aiming to prevent blindness or to restore eyesight in subjects with different retinal diseases for which there are no cures.

The research requires no involvement or participation other than your agreement to allow the use of this tissue.

Any information about you will remain private and the scientists using the aborted tissue will have no information about the origin of the tissue.

Neither the attending physician nor the counselor involved with the abortion has any connection with the studies to use fetal tissue in retinal transplantation research. Your participation in research is limited to your allowing the use of your fetal tissue for transplantation. An additional two teaspoons of blood will be collected at the time that routine blood tests are required before abortion.

Part of the blood sample necessary for the abortion procedure will be used to confirm that you have no infections (for example, HIV virus, hepatitis viruses). If your blood sample tests positive for HIV, you will be referred to a professional counselor. If your blood tests positive for hepatitis or other viruses, you will be referred for medical treatment. Your state law requires that the results of positive tests for HIV and hepatitis be reported to a local health agency. This is the legal obligation of the medical personnel.

By allowing the use of your tissue for research, you place no restriction on who might receive a transplant, and you will not be informed about who might receive such a transplant. Your identity will not be made available to the recipient.

RISKS

There are no risks to you other than those which might normally be encountered during the abortion process. There are no changes in the surgical procedures due to your consent to take part in this study.

NEW FINDINGS

You will be told about any new information that might change your decision to be in this study.

BENEFITS

There will be no direct benefits to you.

COSTS

The blood test for the HIV virus, the virus that causes AIDS, and hepatitis viruses will be done at no cost to you.

ALTERNATIVES

This is not a treatment study. Your alternative is not to participate in this study.

CONFIDENTIALITY

Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies which are contracted by the sponsor to have access to the research information during and after the study.

The information will also be given to the U.S. Food and Drug Administration (FDA). It may be given to governmental agencies in other countries where the study procedure may be considered for approval. Medical records which identify you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by:

- the sponsor;

and may be looked at and/or copied for research or regulatory purposes by:

- the FDA;
- Department of Health and Human Services (DHHS) agencies;
- governmental agencies in other countries; and
- the Western Institutional Review Board® (WIRB®).

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. Researchers using the aborted tissue will have no identifying information about your identity. The results of this research study may be presented at meetings or in publications. If research information is published at a later date, your identity will not be revealed.

VOLUNTARY PARTICIPATION/WITHDRAWAL

The decision to allow the use of your tissue is entirely voluntary on your part. You may refuse to participate without any loss of rights. If you decide to withdraw your consent after agreeing to participate, you may do so without any loss of rights.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent.

SOURCE OF FUNDING

Funding for this research study will be provided by Norman D. Radtke, M.D., PSC.

QUESTIONS

If you have questions in the future about the research study, please ask your attending counselor.

If you have any questions about your rights as a research subject, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: ClientServices@wirb.com.

WIRB is a group of people who perform independent review of research.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT

I agree to allow this aborted tissue, to be used for the eye research mentioned above.

I have read the information in this consent form (or it has been read to me). I have been given the opportunity to ask questions. All my questions about the study and my participation in it have been answered.

I authorize the release of my medical records for research or regulatory purposes, including the results of HIV and/or hepatitis testing, to the sponsor, the FDA, DHHS agencies, governmental agencies in other countries, and WIRB®.

By signing this consent form, I have not waived any of the legal rights which I otherwise would have as a subject in a research study.

SIGNATURES

_____
Donor Subject Name (printed)

_____ _____
Signature of Donor Subject Date signed

_____ _____
Signature of Attending Counselor Date signed

---------- Use the following only if applicable ----------

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to participate in the research study.

_____ _____
Signature of Impartial Witness Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.

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**STATEMENT BY ATTENDING PHYSICIAN
INVOLVED IN OBTAINING FETAL TISSUE**

_____
NAME OF TISSUE DONOR

I have no connections with the studies to use fetal tissue in retinal transplantation research, and this has been explained to the woman.

The woman has decided for the abortion before she was invited to donate the tissue in retinal transplantation research and before she signed the consent form for donating the tissue.

The tissue donated is from a dead nonviable fetus (macerated tissue). The donor places no restriction on who might receive a transplant of this tissue. The donor will not be informed about who might receive such a transplant. The donor has stated in writing that she consents for use of the tissue in research.

No alteration of the timing, method, or procedures used to terminate the pregnancy was made solely for the purpose of obtaining the tissue. There are no known additional medical risks to the woman or risks to her privacy that might be associated with the donation of the tissue. This has been explained to the woman.

The abortion was performed in accordance with the applicable State Law. The tissue has been donated by the woman in accordance with the written consent form signed by her.

_____ _____
SIGNATURE OF ATTENDING PHYSICIAN DATE SIGNED

STATEMENT OF PRINCIPAL INVESTIGATOR

_____
NAME OF TISSUE RECIPIENT

In the research being carried out, the investigator with the principal responsibility for conducting the research has ensured that the person receiving the tissue is aware that: (1) the donor tissue is human fetal tissue which has been obtained pursuant to an induced abortion, and (2) the tissue was donated for research purposes.

Prior to obtaining the consent of a person to be a recipient of a tissue transplant, the principal investigator has required a written acknowledgment by the potential recipient that such information has been received.

The principal investigator has had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy made solely for the purpose of obtaining the tissue for research.

The principal investigator has also provided the above information to all other persons involved in this research.

_____ _____
SIGNATURE OF PRINCIPAL INVESTIGATOR DATE SIGNED