

APPENDIX C INFORMED CONSENT FORM MODEL

This is an approved informed consent format. Use this to prepare your own form. The IRB will expect to see this language and these sections included in your form.

Please include a header and footer. The header should have the protocol number (example: IRB # 2007006 Informed Consent). The footer should have the version, page # of total pages, and place for patient 's initials (example: Version 7/11/01 page 1 of 5 Patient's initials ____). Each time the informed consent is changed, the version should reflect the change.

OKLAHOMA STATE UNIVERSITY Center of Health Sciences PATIENT INFORMATION AND CONSENT FORM

Title of Project: **BOLD** _____

Investigator(s): **BOLD**

(Give name(s), title(s), department(s), and telephone number(s)).

Sub-Investigator(s): **BOLD**

(Give name(s), title(s), department(s), and telephone number(s)).

You are being asked to take part in a research study. If this consent form contains any words you do not understand, please ask you doctor or the staff to explain these words so that you understand them. This consent form contains important facts to help you decide if it is in your best interest to take part in this study.

The purpose of this research is to:

The approximate number of participants involved in the study.

The procedures to be followed are:

(This section must include a fair and understandable explanation of the nature of the activity, its purpose, the duration of the participant's participation, and the procedures to be followed, including identification of any procedures which are experimental.)

You may expect the following (physical and/or mental) discomforts during the course of this research:

By participating in this research, you may be exposed to the following (physical, mental, and/or social) risks:

A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant.

This research may result in the following benefits to you:

Tissues or other materials from experimental participants will be used only for research and destroyed at the conclusion of the experiments, except when it may be discovered that these may have potential long term value. When and if that occurs and before commercial development, the principle investigator, University, and experimental participant will negotiate a contract as to details of ownership. I understand that my participation in this study does not forfeit any rights to these materials, which I would otherwise possess.

OR

Any specimen(s) (e.g., tissue, blood, urine) obtained for the purposes of this study will become the property of the Oklahoma State University Center for Health Sciences. Once you have provided the specimens you will not have access to them. The specimen(s) will be discarded or destroyed once they have been used for the purposes described in the protocol

The following are alternative investigative procedures or treatments, which might be more advantageous to you:

The information obtained from or about me will be kept confidential to the following extent:
(If participant information is not to be kept fully confidential, indicate the extent to which it will be protected It should note the possibility that the Food and Drug Administration may inspect the records..)

By state statute the following paragraph must be included in each Informed Consent. The bolded sentence must remain bolded.

By signing this form, you agree to allow the use and disclosure of your medical information for the purposes described above. **The information you authorize may include records which may indicate the presence of a communicable or noncommunicable disease.** With this knowledge you authorize and consent to the use and disclosure of information as described in this document to the people identified in this form. A copy of this authorization form will be given to you.

Your participation in this research study is voluntary. You are free to refuse to participate in any procedure and to refuse to answer any question at any time, and are free to withdraw your consent, and to withdraw from the research at any time without penalty.

A statement should be included with anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent.
(example: Your doctor, the sponsor company, or the FDA also has the right to stop the study at any time, with or without your consent for any of the following reasons: if you have an adverse or serious effect from the study medications, if you need a treatment not allowed in this study, if you do not keep appointments, etc)

If you have any questions about your rights while in this research study, please contact Dr. Paul Rock at 918-828-4066.

If you have questions about your medical treatment or if you feel you have an injury from participation, you may call _____ *(name of contact)* at _____ *(telephone number)* for assistance or advice.

(For projects containing physical risks to participants only)

Oklahoma State University-Center for Health Sciences will not provide compensation and will not provide medical treatment without charge for any injury as a result of and during the course of this research investigation.

If either compensation or medical treatment is provided, also provide a source where additional information on the limits and restrictions can be obtained by the participant.

By agreeing to participate in this research and signing this form, you do not waive any of your legal rights, nor is the investigator(s), sponsor, the institution or its agents free from liability for negligence.

As the person changes to first person in the following paragraph, please bold this paragraph:

I have read and been given information about this research study and the risks involved have been explained to me. Any questions I may have had were answered to my satisfaction and I have been told who to contact should additional questions arise. As a result, I give my informed consent to participate in this research. I will receive a copy of this consent form.

Participant or Parent/Guardian Signature

Date

NOTE:

The informed consent should be written at a 8th grade rural level.
All elements of this consent form must be explained to the participant or legal representative. Actually reading the consent to them IS A VERY GOOD IDEA to assure they have received the information. The study participant must be given an opportunity to ask any questions. All questions asked must be answered before they sign the consent.
The informed consent form signed by the patient must have a stamped approval by the IRB on each page. Once approved, the principal investigator will be sent an original stamped with the approval. He/she may use this original to make copies for participant signature.
The patient must receive a copy of the signed informed consent form to take home.

ASSENT FORM

FDA guidelines now require studies involving children to include an assent form. The purpose of this form is to make sure this group of patients understands the study, what their participation will mean to them, and that they agree to participate. This form should be written in language they can understand. This may mean several forms (*example: the explanation would be different for a 5 year old versus a 15 year old*). There are currently no specific guidelines about what information must be included. The OSRP recommends you include as much of the above information as deemed applicable.