IRB GUIDELINES
FOR DEVELOPMENT OF THE PARENTAL CONSENT FORM

BEHAVIORAL AND SOCIAL SCIENCE RESEARCH

The following instructions and examples are provided to assist in development of the Parental Consent Form. All forms should be submitted suitable for reproduction (printed single sided) using a 12 point font and 1 inch margins. Each page of the consent form should be full without inappropriate divisions: sections can be split (some on one page, some on another page) so that large blank areas do not exist. Upon final approval, all pages must include the IRB number in the upper left corner, the page numbers in the upper right corner and a participant's initial blank in the lower right corner.

The following should be considered when developing the consent form:

1. The informed consent form must be written in the second person. When combined with conditional language, utilization of the second person de-personalizes the consent form and reflects the existence of voluntary decision making on the part of the prospective subject.

2. The informational content of the elements of informed consent should not be mixed or repeated unless necessary. Information presented under any given element should be reasonably complete and restricted to content appropriate to that element. This helps the parent of the prospective subject focus on each individual element of consent thereby increasing the validity of the consent process.

3. The consent form must be written in simple enough language so that it is readily understood by the least educated parent of the subjects to be utilized. Normally the highest level of language in the consent form should equate to an eighth grade standard. Scientific terms should be avoided when possible.

Title of this Research Study

List the title in this section exactly as it appears on the IRB Application using all capital letters and bold type.

Invitation

Invite the parent of the prospective subject to allow their child to participate in the study using the following standard invitation to participate:

You are invited to allow your child to take part in this research study. The information in this form is meant to help you decide whether or not to allow your child to take part. If you have any questions, please ask.

Why is your child being asked to be in this research study?

Explain succinctly and simplistically why the prospective subject is eligible to participate. As appropriate, major eligibility criteria may be included in this section (eg "You are being asked to be in this study because you are over 12 years old).

If pregnant or breastfeeding women are excluded from this study (section II.4.b of application) include the following standard statement:

If your child is pregnant, nursing an infant, or plans to become pregnant during this study, she may not be in this study.

What is the reason for doing this research study?

This section should state the scientific purpose of the study. If appropriate, brief background material may be provided to help the parent of the potential subject understand why the research is being done.

What will be done during this research study?

Describe the procedures chronologically using simplistic language, short sentences (1-3 lines) and short paragraphs (less than 6 sentences). The use of sub headings and charts or diagrams helps to organize this section and increase readability.

What are the possible risks of being in this research study?

Identify each intervention with a subheading and then state the associated risk(s) using simplistic language (section II.12 of application). The most serious and common risks should be addressed first followed by disclosure of uncommon and less serious risks in a separate paragraph, if warranted. Provide incidence data if available and appropriate.

Alternately, if there are no known risks this should be stated.

What are the possible benefits to your child?

If direct subject benefits can reasonably be anticipated as a result of participating in the protocol (section II.15 of application), then describe these possible benefits. Conclude with the following standard clause:

Your child may not get any benefit from being in this research study.

If direct subject benefits are NOT anticipated, then use the following standard clause:

Your child is not expected to get any benefit from being in this research study.

What are the possible benefits to other people?

State the possible benefits to society in terms of advancement of knowledge. Please be as specific as possible ("the research will help determine and avoid general statements of benefit ("The research will benefit other children who……)

What are the alternatives to being in this research study?

Describe, in reasonable detail alternatives the child may have available
Alternately, use the following standard clause if applicable:

Instead of being in this research study you can choose that your child not participate.

What will your child being in this research study cost you?

This section should state the financial obligations the parent (or the child) will incur as a result of participating in the study, and whether any financial obligations will be increased as a result of procedures performed solely for research purposes (section II.19 of application).

If there are no financial obligations to the subject then use the following standard clause:

There is no cost to you to have your child be in this research study.

Will you or your child be paid for being in this research study?

If the parent or the child will receive compensation for participating in the research, state the amount of compensation and conditions for payment (section II.20 of application). A prorated payment system should be used when appropriate. If no compensation is provided, then use the following standard clause:

You and your child will not be paid to be in this research study.

Who is paying for this research?

For commercial studies:

The sponsor of the research is [name of sponsor]. Oakwood University receives money from the sponsor to conduct this study. [or] The sponsor of the research is [name of sponsor]. Oakwood University receives money from the sponsor to conduct this study. The investigator receives a small payment from the sponsor which is used for … [for example, educational purposes].

For studies supported by extramural or intramural research grants:

This research is being paid for by grant funds from [name of granting agency]. Oakwood University receives money from [name of granting agency] to conduct this study. [or] This research is being paid for by grant funds from [name of granting agency]. Oakwood University receives money from [name of granting agency] to conduct this study. The investigator receives a small payment from [the granting agency] which is used for … [for example, educational purposes].

For NIH funded cooperative group studies:

Oakwood University receives money to provide administrative support for the [name of cooperative group] studies. No money is provided specifically for the conduct of this study.

For unfunded studies, include as applicable:

This research is being paid for by … [for example, Faculty Development Fund Oakwood University].

How will information about your child be protected?

Investigators should review carefully their study protocols and ensure that all required items of the HIPAA authorization are included in the consent document in clear, simplified language and in the exact sequence described.

Required*

Your child's PHI (Protected Health Information) will be shared, as necessary, with the Institutional Review Board (IRB) and with any person or agency required by law. You are also allowing the research team to share your child's PHI with other people or groups listed below. All of these persons or groups listed below are obligated to protect your child's PHI.

if multi-institution study where PHI will be shared with other researchers, add:

researchers at (name of institutions) involved in this study;

Required* if the research is sponsored, add:

Your child's PHI may also be shared with [Name of sponsor], which sponsors this research and provides funds to Oakwood University to conduct this research; and [if applicable] [name of Chief Research Officer (CRO)] which has been hired by the sponsor to coordinate the study; and [if applicable] [name of cooperative group]; and [if applicable] a Data and Safety Monitoring Committee (DSMC). However, the law does NOT require that this organization [*or* these organizations do not] protect(s) your child's PHI.

Required*

You are authorizing us to use and disclose your child's PHI for as long as the research study is being conducted.

There is currently no plan to end this study, so your information may be kept and used indefinitely.

if information is withheld from the subject (see IRB Application section II.25) add:

Information obtained in the course of the research that will not be shared with you or your child is:

[insert details of the information to be withheld].

By signing this authorization, you are temporarily giving up your right to see this research related information while the research is going on. You will be able to see this information if you wish after the research is completed.

Required*

You may cancel your authorization for further collection of PHI for use in this research at any time by contacting the principal investigator in writing. However, the PHI which is included in the research data obtained to date may still be used. If you cancel this authorization, your child will no longer be able to participate in this research.

What are your child's rights as a research subject?

Use the following standard clause:

Your child has rights as a research subject, and you have rights as the parent of a research subject. These rights have been explained in this consent form and in *The Rights of Research Subjects* that you have been given. If you have any questions concerning your rights or complaints about the research, talk to the investigator or contact the Institutional Review Board (IRB) by:

- Telephone (256-726-7000). Institutional Review Board Chair
- Mail: Oakwood University Institutional Review Board, Chair, 7000 Adventist Blvd. NW, Huntsville, Alabama 35896

What will happen if you decide not to allow your child to be in this research study?

Use the following standard clause:

> You can decide not to allow your child to be in this research study. Deciding not to allow your child to be in this research study will not affect his/her relationship with the investigator, or with Oakwood University. Your child and he/she will not lose any benefits to which he/she is entitled.

What will happen if you decide to have your child stop participating once he/she has started?

Use the following standard clause. This section should be revised as appropriate):

> Your child can stop being in this research study ("withdraw") at any time before, during, or after the research begins. Deciding to withdraw will not otherwise affect your child's care or your child's relationship with the investigator or with Oakwood University. Your child will not lose any benefits to which he/she is entitled.
>
> You may be taken off the study if you don't follow instructions of the investigator or the research team. You may also be taken off the study if:
>
> *[include other cases as appropriate]*
>
> If the research team gets any new information during this research study that may affect whether you would want to continue being in the study you will be informed promptly.

Documentation of informed consent

Use the following standard clause:

> You are freely making a decision whether to allow your child to be in this research study. Signing this form means that (1) you have read and understood this consent form, (2) you have had the consent form explained to you, (3) you have had your questions answered and (4) you have decided to have your child be in the research study.

If you have any questions during the study, you should talk to one of the investigators listed below. You will be given a copy of this consent form to keep.

Signature of Parent: Date: Time:

For studies which involve children 13 to 18 years of age include the following standard clause:

You (ages 13 – 18) are agreeing to be in this research study. You have had someone explain the study to you, and answer your questions.

Signature of Subject: Date: Time:

For all studies include the following <u>certification</u> clause:

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject's parent and, as appropriate, the subject. In my judgment, the parent possesses the legal capacity to give informed consent to have the child participate in this research and is voluntarily and knowingly giving informed consent to participate.

Signature of Person obtaining consent: Date:

Authorized Study Personnel

List by name those personnel authorized to document consent as listed in the IRB Application. Use the following subheadings: Principal Investigator, Secondary Investigator(s), Participating Physicians and Participating Health Care Personnel. Include day phone numbers for all listed individuals. For greater than minimal risk studies, include night/home phone numbers and/or other direct contact mechanism. List other study personnel and contact information as appropriate.