**TEMPLATE FOR PARENT/GUARDIAN AND CHILD PERMISSION FORM**

**IRB # (**assigned upon approval): **Approval Date:** **Expiration Date:**

**Title.** State the title exactly as it appears on the IRB application in capital letters and bold type.

**Salutation.** Dear Parent or Guardian,

**Introduction and invitation.** Introduce yourself and your role (student investigator and program of study), and invite the parent or guardian to decide whether or not to give permission for their child to participate. You can use the following standard language:

> Your child is invited to take part in this research study. The information in this form is meant to assist you in the decision of whether or not to give permission for your child to take part. If you have any questions, please ask.

**Why are you being asked to be in this research study?** In ordinary language, explain why the child is eligible to participate. As appropriate, include eligibility criteria in this section. For example,

> Your child is being asked to be in this study because she or he participates in aquatic therapy.

**What is the reason for doing this research study?** This section should state the scientific purpose of the study in *non*-scientific language. Provide brief background material to help the parent/guardian and potential participant understand why the research is being done in clear, simple terms without reference to the participant.

**What will be done during this research study?** Describe the procedures chronologically using ordinary language, brief sentences, and frequent paragraph breaks. Use subheadings to help organize the procedures and enhance readability.

The description of procedures should include when the research activities will take place, where they will occur, and how much time will be required. If it is important for the parent/guardian and child to know prior to consenting that the study involves randomization, explain that participants will be assigned by chance to a study group. Describe each study group and indicate any specific requirements, such as follow-up interviews, surveys, or tests.

**What are the possible risks of being in this research study?** In a separate paragraph, describe the most serious and common risks first, followed by full disclosure of the less serious and uncommon risks, if warranted. Risks common to social-behavioral research may include loss of privacy and confidentiality and emotional or psychological distress. If there are no known risks, state the following:

> There are no known risks to your child from being in this research study.

*Note: The potential risks described in the Risks and Benefits sections in the application must (in ordinary language) reflect those described to the parent/guardian and child.*

**What are the possible benefits to you?** If direct benefits can be reasonably anticipated as a result of participation, describe these possible benefits and conclude with the following:

> However, your child may not get any direct benefit from being in this research study.

If direct participant benefits are *not* anticipated, use this sentence instead:

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

**What are the possible benefits to other people?** State the possible benefits to other (society) in terms of advancement of knowledge and/or ultimate possible benefits to persons in the potential subjects' position.

*Note: The potential benefits described the Risks and Benefits sections must reflect (in ordinary language) those described to the parent/guardian and child.*

**What are the alternatives to being in this research study?** In clear detail, describe the alternatives the potential subject may have to being in the study. Alternately, use the following standard clause as applicable:

> Instead of your child being in this research study, you can decide that your child will not participate.

**What will being in this research study cost you?** State the time commitment and any financial obligations that the child and parent/guardian will incur as a result of participation. If there are no financial obligations, use the following standard line:

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

**Will you be paid for being in this research study?** If the participant will receive compensation or reimbursement for participating in the research, state the amount of compensation and conditions for payment. If no compensation is provided, use the following sentence:

> You or your child will not be paid or compensated for being in this research study.

**What should you do if you have a problem during this research study?** Your estimation of risk determines what additional information to include in this section. Clarkson College will not approve studies that pose greater than minimal risk to participants. For studies classified as minimal risk, use the following standard sentences:

> Your welfare and your child's welfare are the major concern of every member of the research team. If you or your child has a problem as a direct result of being in this study, you or your child should immediately contact one of the people listed at the end of this consent form.

**How will information about you be protected?** Begin with the following standard line:

> Reasonable steps will be taken to protect your privacy, your child's privacy, and the confidentiality of all study data.

Next, if the research requires collection of sensitive information (social, financial, legal, or otherwise) from the prospective participant, add to the previous standard line a brief description of the precautions you will use to protect that data and conclude with the following:

> The only persons who will have access to your research records are the study personnel, the Institutional Review Board (IRB), and any other person or agency required by law. The information from this study will be presented at Graduate Symposium and may be published in scientific journals or presented at scientific meetings. However, your identity will be kept strictly confidential.

*Note: If you will share or distribute information from this study to other entities, including study site management, you must disclose that to the parent/guardian and child for fully informed consent.*

**What are your child's rights?** You can use the following sentences:

> Your child has rights as a research participant. These rights have been explained in this consent form and in "The Rights of Research Participants" that you have been given. If you have any questions concerning your rights or your child's rights, talk to the investigator(s) or contact the Clarkson College Institutional Review Board (IRB) at 402.552.3100.

**What will happen if you or your child decides not to participate in this research study or decide to stop participating once it starts?** You can use the following clause:

> You or your child can decide not to be in this research study or can stop being in this research study at any time before, during, or after it begins. Deciding not to be in this research study or deciding to withdraw will not affect your relationship with the investigator(s), Clarkson College, or [name(s) of any other sites or entities].
>
> Your child will not lose any benefits to which she or he is entitled. If the research team gets any new information during this research study that may affect whether you would want your child to continue being in the study, you will be informed promptly.

**Documentation of informed (signed) consent.** Use the following 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 give permission for your child to be in the research study. If you or your child has any questions during the study, talk to one of the investigators listed below. You will be given a copy of this consent form to keep.

Signature of Parent/Guardian: _____ Date and Time: _____

Signature of Child: _____ Date and Time: _____

**Participant's initials.** Add a line at the bottom of each page for a parent/guardian to initial to show they have read each page.

Then include a statement from the investigator(s):

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

Signature of Investigator(s): _____ Date and Time: _____

**Authorized Study Personnel.** Identify all personnel authorized and CITI-certified to document consent as listed in the IRB application. Use the following subheadings: Principal Investigator, Co-Investigator, and Participating Personnel. Include daytime phone numbers and emails for all listed individuals.

Principal Investigator: _____ Phone: _____ Email: _____

Co-Investigator: _____ Phone: _____ Email: _____

Participating Personnel: _____ Phone: _____ Email: _____