Institutional Review Board

Parent-Guardian Consent Form Instructions and Template

Informed consent from a parent/guardian for his/her child is required to provide potential subjects or their legally authorized representatives with the information necessary for them to decide about participating in research. For children 8-17 years of age, the use of a Children's Assent Form is generally expected.

Consent documents should be written in plain language, generally at the 8th grade reading level. The reading level can be higher if the target population tends to have a higher literacy rate than the general population.

We recommend the use of this template to create the informed consent document(s) for your study. <u>Carefully read the following important directions</u>:

- CarefBllyeptexfrieadby your final document. Use the same font and type size throughout. The finished document should reflect what you will give to the subject.
 - 4. You and the parent/guardian should sign a copy of the consent form. Keep it with your research records. Give an unsigned copy to the subject.
 - 5. Use a file name for each consent document that clearly identifies type of consent and for which subjects it is intended (e.g. child assent, parental permission, adult consent, etc.). Include the last name of the principal investigator (e.g., Smith Adult Consent.docx).

For questions about informed consent, please contact the CU-IRB at 262-243-2721 or janessa.doucette@cuw.edu. For more information about plain language go to

http://www.plainlanguage.gov/

Parent-Guardian Consent Form

[Title of the project.]

Your consent is being sought for your child's participation in this research study. His/her participation in this study is voluntary.

Who is conducting this study?

[Give the name of the principal investigator (PI), credentials, and institutional affiliation. Give the name of any co-investigators, credentials, and institutional affiliation. If you are a student PI,

What will you/your child be expected to do?

If your child agrees to take part in this study, your child will be asked to [If your consent form is more than three pages and you included the research summary (see box above), use this section to provide a more comprehensive description about the research procedures. Describe what the subject will be asked to do in chronological order (what, when, where, how). Use short sentences and easy words.]. We expect this to take about [indicate duration and number of interactions].

Add this wording if parents are also being asked to be research subjects.

If you agree to take part in this study, you will be asked to [If the parent/guardian is also being asked to complete any testing components such as a parent questionnaire or other research activity, please include the details.

Does your child have to participate?

It is totally up to you and your child to decide to be in this research study. Participating in this study is voluntary. Even if you or your child decide to be part of the study now, you or your child may change your minds and stop at any time. You and your child do not have to answer any questions you do not want to answer.

What are your options if your child does not participate in this study?

[State other possible activities, procedures, or courses of treatment which the subject might take part. If there are no alternatives, just state "none."]

How will we protect your and your child's personal information?

The records of this study will be kept private. In any sort of published report, we will not include information that will make it possible to identify you or your child. Your record for the study may, however, be reviewed by a member of the research team, the Institutional Review Board, [the study sponsor, if any], or the federal Office of Human Research Protections (OHRP), and to that extent, confidentiality is not absolute.

Will your or your child's personal information be used for future research?

Yes____ No ____

"Because this study pays more than \$100, Concordia University will collect your name, address, social security number, and payment amount. This information