**INFORMATION SHEET**

Instructions: This information sheet is for research teams who are asking for a waiver of documentation of consent where study participation is limited to completing surveys.

**Using this template….**

* The goal of this template is to provide a skeleton for a consent, assent (age 14 and up) and/or parental permission form for your study where the IRB has waived the requirement to obtain a signature.
* This form should be consistent with your IRB-ITHS application and Local Implementation Plan.
* The form should be written for the average person, which means it should be written below an 8th-grade reading level.
* The current template is below 8th-grade reading level along with recommended and required language.
* **All section headings of this template are required.**
* **Required text is in purple.** All other text should be edited according to the needs of your study. If you choose not to use required text your study will require full board review.
* Please avoid the use of medical terms and jargon when possible.
* The form is written to keep the voluntary nature of research at the forefront of the potential participant’s mind. Thus using, “We **would** do X, Y and Z if you chose to take part.”
* The [Language Resource Text](http://www.seattlechildrens.org/doc/language-resource-text.doc) (LRT) contains study specific text below an 8th grade reading level. The LRT is meant to be a resource for teams providing created language for common procedures or issues that arise in the research setting. The LRT will be updated regularly in hopes of best meeting researchers needs. The Institutional Review Board (IRB) expects study teams to use available language that is applicable to their study.
* Please note that the gray, shaded areas should be filled in with text; when the form is printed these sections will NOT be shaded.

**Before submitting the form to the IRB….**

* Please delete the instructional text/green highlights throughout the document.
* Please delete all sample examples/turquoise highlights throughout the document.
* Please change the **required purple text** to black**.** You can do this by selecting all the text and choosing “automatic” or “black” as the font color.
* Please ensure careful spacing in the final version. A new section should start on a new page, if possible.

**Study Title:**

**Principal Researcher:**

**Instructions:**

* List Principal Researcher first.
* Fill in the table below AS APPROPRIATE (e.g., you do not need to include e-mails if this is not an effective means of reaching a research team member). This information is used for families to contact researchers. Be sure to include information for families to contact researchers after hours and on weekends.

**The Research Team:**

| **Name/Degree** | **Phone Number** | **E-mail** |
| --- | --- | --- |
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|  |  |  |
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**1. Researchers’ Statement:**

**You have the option to take part in a research study. The goals of this form are to give you information about what would happen in the study if you choose to take part and to help you decide if you want to be in the study. Feel free to take notes, write questions or highlight any part of this form.**

**2. What you should know about this study:**

* This form explains what would happen if you join this research study.
* Please read it carefully. Take as much time as you need.
* Please ask the research team questions about anything that is not clear.
* You can ask questions about the study any time.
* If you choose not to be in the study, it will not affect your care at Seattle Children’s.
* If you say ‘Yes’ now, you can still change your mind later.
* You can quit the study at anytime.
* You would not lose benefits or be penalized if you decide not to take part in the study or to quit the study later.

**3. What is the goal of this study?**

The goal of any research study is to answer questions. We are doing this research study to answer the following questions:

**4. Why do I have the option of joining the study?**

You have the option to take part in this research study because you      .

**5. How many people will take part in the study?**

We think that about       people will take part in this research study at Seattle Children’s.

**6. If I agree to join this study, what would I need to do?**

If you decide to take part in this study, we would ask you to      . We would ask you to do this       times. We expect this research will take       [specify amount of time].

**7. How long would I be in the study?**

If you choose to take part in all the study visits, you would be in the study for      .

**8. What are the potential harms or risks if I join this study?**

You might feel uncomfortable answering some questions on the survey. You could skip any questions you did not want to answer.

There is a risk that your confidentiality or privacy could be breached.  This would mean that someone other the research team or our collaborators may find out that you were in the research or see your answers or medical information.

**9. What are the potential benefits if I join this study?**

We do not expect this study to benefit you. We hope to use information we get from this study to benefit others who have      .

**10. What other options do I have?**

You can choose not to participate in this study.

**11. How would you keep my information confidential?**

**If you take part, we will make every effort to keep your information confidential.** We will store all of your research records in locked cabinets and secure computer files. We will not put your name on any research data. Instead, we will label your information with a study number. The master list that links a person’s name to their study number is stored in a locked cabinet or on a secure computer file. If results of this research are published, we would not use information that identifies you.

We would only use your information for research. These are some reasons that we may need to share the information you give us with others:

* If it’s required by law.
* If we think you or someone else could be harmed.
* Sponsors, government agencies or research staff sometimes look at forms like this and other study records. They do this to make sure the research is done safely and legally. Anyone who reviews study records would keep your information confidential.
  + Agencies or sponsors that may look at study records include:
    - Example 1
    - **Sample Examples:** FDA; Study Sponsor; Hospital Auditors; Government Agencies; others responsible for watching over the safety, effectiveness, and conduct of the research.

We would keep your results      . [Specify a period of time.]

**12. Would it cost me money to be in the study?**

**Would it cost me money to be in the study?**

**If you take part in this study, there would be no cost to you and no cost to your insurance company.**

**13. Would I be paid if I join this study?**

**Instructions if no payment is involved**

You will not be paid to take part in this study.

**Instructions if payment is involved:**

Note you need to follow Office of Research Finance Policy 004 (ORF-004) for participant payments. This policy is available on CHILD. See also HRP-316 Payments.

State the following:

* Amount of payment that will be given,
* The method for providing payment (ClinCard/check/egift card),
* When the payment will be given

Example if you are providing ClinCards:

To thank you for taking part in the study we would give you $X after each study visit you complete. You would receive the payment on a Seattle Children’s reloadable debit/gift card called a ClinCard. The study staff will provide you with additional information about how the ClinCard works. It is important that you do not lose the ClinCard. Costs for replacing a lost or stolen ClinCard will be your responsibility. The cost to replace the ClinCard is $7.

**Note:** You may be able to get an exception to the requirement to collect names, addresses, and social security. See ORF-004 for more information. If you do not have an exception, then the next section is required.

**The IRS has certain rules about paying people who take part in research studies.  If you took part in this study, we would ask you to provide your name, mailing address, and social security number so we could pay you.**

**You can be in this study even if you do not give us this information. If you decide not to give us this information, you could receive a gift card or no payment.**

**The payments you would receive for being in this study might be taxable. Seattle Children’s is required to report to the IRS study payments of $600 or more made to anyone in any year.**

**Instructions:**

* Be sure to keep all identifying information collected solely for payment reasons, including social security number, separate from the research records. It is suggested that you destroy such information after sending it to the Finance Department or after the family has received payment. Be sure to add identifying information collected for payment purposes to your HIPAA form even if you are not collecting it for research purposes, if applicable.

**14. Who do I contact if I have problems, questions or want more information?**

**Questions?**

**If you think you have been harmed from this study, please call      . For questions about your rights as a research participant, please contact the Institutional Review Board at (206) 987-7804.**

**Do I have to take part in this research?**

No. Your participation is voluntary and your choice will not affect your care at Seattle Children’s. **If you choose to leave the study, it will not affect your care at Seattle Children’s. You will not lose any benefits or be penalized if you choose to leave the study.**

**If you join the study, you can decide to stop at anytime for any reason. You will not lose any benefits or be penalized if you choose to leave the study.**  If you decide to stop, please contact Dr.       at      .