**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.
* 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.

**Instructions:** Keep the form title(s) that apply to your study. Fill in the assent age if applicable. And fill in the Header Information and Principal Researcher’s Name.

**PARental Permission Form**

**Consent Form: Ages 18 and up**

**Assent Form: Ages 14-**

**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.
* Emergency Contact: Include a 24-hour emergency number if participants may experience adverse events as a result of the research activities. Indicate who families should contact, e.g., principal researcher, on-call specialist etc. If researchers are named as first contact, include back up for when researchers cannot be reached right away.
* Include Clinical Research Center (CRC) phone number IF APPLICABLE.

**The Research Team:**

| **Name/Degree** | **Phone Number** | **E-mail** |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |

|  |
| --- |
| Clinical Research Center: (206) 987-3897[if applicable] |

If you have questions about your rights as a research study participant, you can call the Institutional Review Board at (206) 987-7804.

|  |
| --- |
| **24 hour Emergency Contact Number(s)**: |

**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.**

**Instructions:**

* Ensure that a clean IRB-stamped approved copy of the consent form is used when signing.
* Select the participant population that applies to your study from the list below.
* Please note that if parents alone (and NOT participants) will be reading

this form the term “your child” can be used throughout the form instead of the term “you”. There is also a Parental Permission Only Template that you can use.

[When adult participants are anticipated include the following]

**Potential Participants 18 years and older:** This is a consent form. It provides a summary of the information the research team will discuss with you. If you decide that you would like to take part in this research study, you would sign this form to confirm your decision. If you sign this form, you will receive a signed copy of this form for your records.

[When written assent is needed include the following]

**Potential Teen Participants:** This form also serves as an assent form. That means that if you choose to take part in this research study, you would sign this form to confirm your choice. Your parent or guardian would also need to give their permission and sign this form for you to join the study.

**Parents/Guardians**: You have the option of having your child or teen join a research study. This is a parental permission form. It provides a summary of the information the research team will discuss with you. If you decide that your child can take part in this study, you would sign this form to confirm your decision. If you sign this form, you will receive a signed copy for your records.

The word **“you”** in this form refers to your child/teen.

**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?**

**Instructions:**

This should include the MAIN goals of the study. Language in this section should be consistent with the AIMS section of your IRB-ITHS Application, but expressed in lay language.

The goal of any research study is to answer questions. We (the research team listed on the front of this form and our staff) are doing this research study to answer       questions:

* [First question]
* [Second question]
* Etc…

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

You have the option to take part in this research study because you have      .[List condition, disease or explain the reason.]

**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.

**Include the following statement if applicable:** A total of      people will take part at hospitals and clinics around the country.

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

If you join the study, you would have some tests and exams. All the visits you would need to make, are listed in the chart below.

These tests and exams help us find out if being in this study causes any effects that are important to know about. We use them to check on the safety of people in the study. We also use them to learn if an experimental treatment is helping or not.

**Instructions:**

* See [LRT](http://www.seattlechildrens.org/doc/language-resource-text.doc) for examples of language that is available for this section.
* If applicable, describe how study visits compare to standard of care so families understand what is extra for the research study.
* Research Study Visits:
* Describe the tests that will be done to monitor participants during the study. Be sure that families understand how the testing compares to standard of care. If the tests are done more often than standard of care, explain this.
* **Any experimental procedures need to be described in detail and listed as experimental.**
* If medical records will be used in this research: For example, if the results of tests done for standard of care will be used. Explain if the results of tests and procedures done in this study will be included in the child’s medical records.
* Study Visit Charts:
* See examples of Visits and Procedures charts in the [LRT](http://www.seattlechildrens.org/doc/language-resource-text.doc). The use of a chart is not required but is preferred.

**Explanation of Research Tests or Procedures:**

The tests that would be done include:



**Research Study Visits:**

| **Visit #** | **Procedures** | **Location**  [if all procedures take place at Seattle Children’s, explain where they will take place e.g.) the CRC, the Radiology Department, etc.] | **How much time the visit will take** |
| --- | --- | --- | --- |
| **Visit 1** | **Sample Examples:**   * An exam by the research doctor * Blood tests (*how much blood will be taken - use only tablespoons or teaspoons rather than ml, cc or oz)* * Urine test * Pregnancy test |  |  |
| **Visit 2** |  |  |  |
| **Visit 3** |  |  |  |

**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      .

If you join the study, you can decide to stop **at anytime for any reason**. If you decided to stop, you would need to talk with       so you leave the study in a safe way.

The research study doctor could also decide to take you out of this study. This might happen if we find out that it is not safe for you to stay in the study. Or it might happen if you cannot come to enough of the study visits. If we ask you to leave the study, we would always explain why.

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

**Instructions:**

Potential Harms and Discomforts:

**This section should include all physical, psychological, financial and social risks etc. in lay terms**

**When appropriate include a statement about risk to the participant or fetus of the participant is or becomes pregnant. See the** [**LRT**](http://www.seattlechildrens.org/doc/language-resource-text.doc)**.**

If your study involves a drug, device, or biologic,Chart A is preferred. Depending on the study, it may be helpful to split out potential physical harms from social or psychological harms.

If your study does not include a drug, device or biologic, select Chart B or C.

If quantification of risks is not possible use Chart D. (This should be used only in rare circumstances)

Use two or more charts if randomization is involved to distinguish between different groups the participant could be assigned.

Other Potential Harms and Discomforts:

Select the most appropriate chart. Chart D may be most appropriate.

There are potential harms or risks if you take part in this study. [if applicable, The drugs you would take can cause side effects.] Some are common and some are rare. These are described in the chart below.

**Potential Harms and Discomforts:**

**Chart A**

|  | **Likely**  (Likely to happen to 21-100 out of every 100 people) | **Less Likely**  (Likely to happen to 5-20 out of every 100 people) | **Rare**  (Likely to happen to 1-4 out of every 100 people) |
| --- | --- | --- | --- |
| **Immediate**  Within 1-2 days | **Sample Examples:**   * Vomiting * Diarrhea |  |  |
| **Prompt**  Within weeks |  |  |  |
| **Delayed**  Anytime during the study |  |  |  |
| **Late**  Anytime after the study |  |  |  |

**Chart B**

[Study teams may change the parameters of “Likely,” Less Likely,” and “Rare” but should establish a quantitative way for the reader to understand the category.]

**Likely:** Likely to happen to 21-100 out of every 100 people

* Potential harm
* Potential harm

**Less Likely:** Likely to happen to 5-20 out of every 100 people

* Potential harm
* Potential harm

**Rare:** Likely to happen to 1-4 out of every 100 people

* Potential harm
* Potential harm

**Chart C**

| **Likely**  **(**Likely to happen to 21-100 out of every 100 people) | **Less Likely**  (Likely to happen to 5-20 out of every 100 people) | **Rare**  (Likely to happen to 1-4 out of every 100 people) |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**Chart D**

* Risk 1
* Risk 2

[If the drug, device, or biologic is experimental include the following]

Because this research study involves an experimental      , we do not know all of the possible harms or risks.

[If a Data Safety Monitoring Board is connected with the study include the following]

A Data Safety Monitoring Board will review the information from this research study. This board is made of a group of experts. They are responsible for looking at how people in the research study are doing. If you take part, we would tell you about any new information we learn that might affect your health or your willingness to stay in the study.

**Other Potential Harms:**

**Likely:** Likely to happen to 21-100 out of every 100 people

* Potential harm
* Potential harm

**Less Likely:** Likely to happen to 5-20 out of every 100 people

* Potential harm
* Potential harm

**Rare:** Likely to happen to 1-4 out of every 100 people

* Potential harm
* Potential harm

[f there is a risk of breach of confidentiality or privacy include the following]

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. However, we will take every precaution to make sure that this does not happen.

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

**Instructions**:

* If there are multiple study groups list the potential benefits for each study group. Choose the statement that is most applicable to your study.

**Potential Benefits for You:**

We do not expect this study to benefit you.

Being in this study might benefit you in the following ways:



**Potential Benefits for Others:**

We hope to use information we get from this study to benefit others who have      .

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

If you choose not to be in this study, you can:

* List alternatives

Please talk to your doctor or the research team about these options.

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

**Instructions:**

* If you have obtained a Certificate of Confidentiality, see the [LRT](http://www.seattlechildrens.org/doc/language-resource-text.doc) for assistance.
* If banking of data or specimens is involved, then see the [LRT](http://www.seattlechildrens.org/doc/language-resource-text.doc) for language to include here.

**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.

[If research information will become part of the medical record, then include the statement below. Please note that if the research information could place the participant or families at risk of stigmatization, loss of insurance, etc, then it should NOT be placed into the medical record.]

If you join this study, we would put information about this study in your medical record. We do this because the research study involves patient care.

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

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

**Instructions:**

* For all research studies, you must describe any additional costs to the participant or their insurance that may result from participation in the study. To accomplish this, choose the language below that is most appropriate to your study. **Inclusion of one of these statements is required.**

1) For a study (except a clinical trial as defined below) in which there are no costs to the participant that may result from involvement in the study, use the following language:

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

2) For a study (except a clinical trial as defined below) in which there are costs to the participant that may result from participation in the study, use the following language:

**If you take part in this study, you or your insurance company may be charged for:** [Describe the services that the participant or their insurance provider may be charged for as a result of study participation. Some information from the Clinical Trial section below may be appropriate.]

3) For a clinical trial include:

**This study is a clinical trial that involves two types of services. Some services are related to the research. Other services are related to your usual medical care.**

**Services related to the research are done only for the purpose of the study. These include:**

[Clearly identify these services by referencing when they take place (e.g., 1st visit).]

* Research Service
* Research Service

[Choose the appropriate statement below about who will be charged for these research services.]

**There would be no cost to you and no cost to your insurance company for these research services.**

**You or your insurance company may be charged for these research services.**

[Include an explicit statement about who is financially responsible for the experimental components of the study (drug, administration of drug, device, implantation of device).]

**Services related to your usual medical care are part of your routine care. You or your insurance company would be charged for these services. If you join the study, costs to you would include your usual insurance deductibles and co-payments. All of your insurance company’s usual rules would apply.**

[When applicable, include a statement about when pre-approval will be required from insurance companies (likely for inpatient stays, surgery, devices, and any other high-cost items).]

**13. What if I were injured because I joined the study?**

**Instructions:**

* One of the statements below is required.
* Select the appropriate required phrase based on your study.
* See the Information Sheet “[Who Pays for Research Related Injuries](http://www.seattlechildrens.org/doc/irb-who-pays-for-research-related-injuries.doc)” for specific guidance about what language to include in this section for studies that are greater than minimal risk (45 CFR 46.405 & 46.406). Who pays for research related injuries depends on risk, who is sponsoring the study, and whether the study provides a potential for direct benefit (e.g., treatment, diagnosis) to the participant.

1) For minimal risk (45 CFR 46.404) studies, please use the following language:

**If you think you have been harmed from this study, please call \_\_\_\_\_\_\_\_.**

2)For studies where Seattle Children’s compensation program applies (this usually applies if the study does not have an industry sponsor and does not provide the potential for direct benefit):

**If you were injured as the direct result of this research study, Seattle Children's Hospital would provide treatment. We would refer you for treatment if needed.**

**You would NOT need to pay for this treatment and neither would your insurance company. This is the only compensation offered for study-related injuries. It is important that y****ou tell the Principal Researcher** **, if you think that you have been injured as a result of taking part in this study. You can call him/her at** **.**

3) For studies where families or third party payers are responsible (usually when the study offers the prospect of direct benefit):

**If you were injured as the direct result of this research study, Seattle Children's Hospital would provide treatment. We would refer you for treatment if needed. No funds have been set aside for this treatment.  You or your insurance company would be billed for the treatment.**

**It is important that you tell the Principal Researcher** **, if you think that you have been injured as a result of taking part in this study. You can call him/her at** **.**

4) For industry-sponsored studies involving Category B devices:

**If you were injured as the direct result of this research study, Seattle Children's Hospital would provide treatment. We would refer you for treatment if needed.**

**You or your insurance company MAY need to pay for this treatment.  Neither you nor your insurance company would need to pay for the cost of treatment needed because the study device failed or malfunctioned. This is the only compensation offered for study-related injuries. It is important that you tell the Principal Researcher** **, if you think that you have been injured as a result of taking part in this study. You can call him/her at**      **.**

5) For all other industry-sponsored studies:

**If you were injured as the direct result of this research study, Seattle Children's Hospital would provide treatment. We would refer you for treatment if needed.**

**You would NOT need to pay for this treatment and neither would your insurance company. This is the only compensation offered for study-related injuries. It is important that you tell the Principal Researcher** **, if you think that you have been injured as a result of taking part in this study. You can call him/her at** **.**

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

[If no payment is involved]

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

[If reimbursement is involved, then include]

The study will reimburse you for out-of-pocket costs to you or your parent/guardian. This would include: [include all that apply and/or add as appropriate]

* Transportation costs to the hospital or clinic for study tests and visits.
* Cost of meals during the time of your study visits.
* Cost of child care during the time of your study visits.

**Important:** You will need to give us receipts that clearly show your costs.

**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.**

**If there is potential for product development/commercialization from the research:**

Your data and/or samples may be used to make new products, tests or findings. These may have value and may be developed and owned by the research team and/or others. If this happens, there are no plans to pay you.

**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.

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

**Instructions:**

* This section is required. Please fill in as appropriate. After you add the text, change the font to black.

| **❓ If I have questions or would like to know about …** | 🚹 **You can call …** | **🕾** **At …** |
| --- | --- | --- |
| * **Emergencies** * **General study questions** * **Research-related injuries** * **Any research concerns or complaints** | **[Insert Principal Researcher’s Name]** | **Phone:**  **Pager**: |
| * **Emergencies** * **General study questions** * **Research-related injuries** * **Any research concerns or complaints** | **[Research Team Member]** | **Phone:**  **Pager:** |
| * **Your rights as a research participant** | **Institutional Review Board**  **This is a group of scientists and community members who make sure research meet legal and ethical standards**. | **Phone: (206) 987-7804** |

**Instructions: If your clinical trial falls within certain parameters and requires registration at clinical trials.gov the text box below is required and must be included in the consent form:**

**More Information:**

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**16. If I join the study, can I stop?**

Yes. Taking part in research is always a choice. If you decide to be in the study, you can change your mind at any time. We ask that you tell [List appropriate person]      . You can contact this person by [List appropriate means of contact]       (e.g. phone number, address, etc.).

**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 the research study is FDA regulated, then include the statement below.]

If you decide to stop participation in the study, the data collected until the time you withdraw will remain part of the study database and may not be removed. In addition, we will ask you if you want to provide further data collection from routine medical care.

**17. What would my signature on this form mean?**

Your signature on this form would mean:

* The research study was explained to you.
* You had a chance to ask all the questions you have at this time. All your questions have been answered in a way that is clear.
* You understand that the persons listed on this form will answer any other questions you may have about the study or your rights as a research study participant.
* **You have rights as a research participant. We will tell you about new information or changes to the study that may affect your health or your willingness to stay in the study.**
* By signing this consent form, you do not give up any of your legal rights. The researcher(s) or sponsor(s) are not relieved of any liability they may have.

[Choose appropriate bulleted statement(s) below]

* You agree to take part in the research study.
* If the person reading this form is a parent/guardian, you agree to have your child take part in this research study.

**Please Note:** If the person taking part in this research study is a foster child or a ward of the state, then please tell the researcher or their staff.

**Instructions:**

* Choose appropriate signature lines

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Printed Name of Research Participant*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Signature of Research Participant (required if 14 years or older)*

*\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_*

*Date Time*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Printed Name of Parent or Legal Guardian*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Signature of Parent or Legal Guardian*

*\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_*

*Date Time*

**18. Researcher’s Signature**

I have fully explained the research study described by this form. I have answered the participant and/or parent/guardians questions and will answer any future questions to the best of my ability. I will tell the family and/or the person taking part in this research of any changes in the procedures or in the possible harms/possible benefits of the study that may affect their health or their willingness to stay in the study.

**Instructions**: The preference is to obtain all of the required signatures on the same form. If approved to obtain consent via telephone, the researcher should make note of the date of the consent conference. When the participant/parent-signed form is returned the researcher can then sign and date it with the current date. He/she should add a notation that the actual consent conference took place on the date noted via telephone.

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Printed Name of Researcher Obtaining Parental Permission or Consent*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Signature of Researcher Obtaining Parental Permission or Consent*

*\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_*

*Date Time*

**19. Interpreter Information**

**Instructions:** The interpreter name is only recorded here if 1) the consent/assent or parental permission is documented with a corresponding translated form; or 2) the study meets the criteria for short form use and the consent/assent/parental permission is documented with a Short Form Consent in the appropriate language for those taking part. See the Investigator Manual (HRP-103, Appendix A-10) and HRP-001 for more information.

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Printed Name of Interpreter during initial presentation of study Date*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Printed Name of Interpreter when translated form is presented (if applicable) Date*

**20. Witness Information for Short Form Use**

**Instructions:** A witness signature is required when using the Short Form Consent to document consent/assent/parental permission or as otherwise required by the IRB.

## Witness Statement

**I have been present during the verbal presentation of this research study.**

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Printed Name of Witness*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Signature of Witness*

*\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_*

*Date Time*

**Original form to:**

Research Team File

**Copies to:**

Participant

Parents/Guardians (if applicable)

Medical Records (if applicable)