|  |  |
| --- | --- |
| **Point Addressed** | **Comment** |
| Who was present during the consent process? (e.g., subject, spouse, CRC, investigator)2 |  |
| Was an adequate opportunity provided for the subject/family to read the consent document? |  |
| Who reviewed the consent document with the subject/family and explained the details of the study? (e.g., investigator, CRC)2  |  |
| Were all risks and benefits of study participation presented to the subject/family? |  |
| Were all questions of the subject/family answered? |  |
| Does the subject/family appear to understand all terms of participation and agree to enrollment? |  |
| How was comprehension assessed? |  |
| Who obtained consent? (e.g., investigator, CRC)2, 3 |  |
| Who provided consent? (e.g., subject, parent, spouse, POA)4 |  |
| Was the consent document signed by all parties prior to the performance of any study related procedure?   |  |
| Was a copy of the consent document provided to the subject?  |  |
| Was assent obtained? (if applicable)5 |  |
| Was consent provided by LAR? (if applicable)6 |  |

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**Signature of Person Completing this Form Date**

**Documentation of the Informed Consent Process1**

1 In addition to obtaining the signed, written informed consent document, the University of Pittsburgh IRB recommends that a narrative note be written in the subject’s research records documenting the informed consent process. This documentation may depend on the risk of the study and could include information such as:

* Who was present during the informed consent discussion;
* The fact that risks were presented;
* A notation, if applicable, that significant issues of concern to the subject were addressed;
* A statement that all questions were answered to the satisfaction of the subject.

The narrative note should also indicate the date and time that the subject signed the informed consent document and be signed by individual responsible for the documentation. Noting the time of consent, in addition to the date, is especially important if any research procedures will be performed on the same day that informed consent was obtained. The narrative note of consent process should be recorded by someone who was involved with or witnessed the consent process.

 **Note that this is a requirement for any research study involving the evaluation of a research intervention which falls under the jurisdiction of the FDA (21 CFR 312.62).**

2 Document the name of the study team members.

3 Studies Involving Drug, Device, or Surgical Procedures: The University of Pittsburgh IRB requires that the PI or a Sub-Investigator who is a licensed physician obtain informed consent. This does not mean the study coordinator cannot introduce the study and answer preliminary questions about the research. The final process of obtaining the written informed consent must be conducted by a physician investigator who must sign the Investigator’s Certification statement at the time of this involvement.

4 The IRB Policies and Procedures, Chapter 14, provides additional safeguards and considerations for the following special subject populations:

* Children
* Decisionally impaired individuals
* Employees as research participants
* Pregnant women, neonates and fetuses
* Prisoners
* Students as research participants

5 Assent – is the affirmative agreement of the child to participate in the research. Assent may be obtained with child’s written signature or verbally. The investigator must document any procedures and/or forms that were used to assess the child’s ability to give assent.

6 Legal Authorized Reprehensive (LAR) – An individual or judicial or other body authorized under applicable law to consent on behalf of prospective subject to the subject’s participation in the procedure(s) involved in the research.