SOP		
Department	**Title**	**Dates**
Research Integrity and Protection	Documentation of Informed Consent	Effective: 12/22/2017
		Approved: 12/18/2017
SOP ID		Last Revised: n/a
IRB-SOP-902		Expiration: n/a

PURPOSE:
This document establishes the procedures and requirements for documenting the research informed consent process.

SCOPE
This procedure applies to all non-exempt human subject research conducted at any Ascension Wisconsin Facility.

DEFINITIONS
Investigator Principal investigator or an individual authorized by the principal investigator and approved by the IRB to obtain consent for the specific protocol, such as a co-investigator, research assistant, or coordinator.

Subject/representative For the purposes of this procedure, subject/representative means the following:
- The subject when the subject is an adult capable of providing consent.
- Legally authorized representative when the subject is an adult unable to give consent.
- One or both biologic or adoptive parents when the subject is a child or in the absence of a parent, a person authorized under applicable law to consent on behalf of the child to the child's general medical care.

PROCESS:
1. The Principal Investigator is responsible for ensuring appropriate documentation of informed consent. This includes, when applicable, signatures on the consent document and a progress type note written to explain the entire consenting process and any discrepancies.

2. If the consent process will be documented in writing with the long form of consent documentation:
2.1. Verify that the consent form is in language understandable to the subject/representative.
2.2. Ensure that the consent documentation includes the Ascension Wisconsin Research HIPAA Authorization form (a Notice of Privacy Practices cannot be used as a substitute for the Research HIPAA Authorization)
2.3. Print or otherwise legibly affix the name of the following individuals:
- Subject/representative
- Person obtaining consent (for the consent only; not required for the HIPAA Authorization)

2.4. Have the following individuals personally sign and date the documents:
- Subject/representative
- Person obtaining consent (for the consent only; not required for the HIPAA Authorization),

2.5. If an impartial witness was part of the consent process, print the name of the impartial witness on the consent document. Have the impartial witness personally sign and date the consent document to attest that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject, and that consent was freely given.

3. If the consent process will be documented in writing with the short form of consent documentation:
3.1. Verify that the short consent form is in language understandable to the subject/representative.
3.2. Print or otherwise legibly affix the name of the following individuals on the short form consent document and the summary:
- Subject/Representative

- Person obtaining consent
- Impartial witness

3.3. Have the following individuals personally sign and date the short form consent document and the summary:
- Subject/Representative
- Person obtaining consent
- Impartial witness

4. If the IRB required written documentation of assent, note on the signature block if assent of the child was obtained or if assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

5. If the requirement for written documentation of the consent process has been waived by the IRB and the IRB determined that the subject/representative had to be offered the opportunity to document his or her consent in writing, offer the subject/representative the option to document his or her consent in writing.
- If the subject/representative declines, take no further action.
- If the subject/representative accepts, follow the process to document consent in writing with the long or short form of consent documentation.

6. Signed consent forms should be filed as follows:

6.1. Provide copies of the signed and dated consent document(s) and Research HIPAA Authorization to the subject/representative.

6.2. Place the original signed and dated documents in the research site subject file.

6.3. If the research includes clinical procedures or interventions, or if participation in research could reasonably impact other care or treatment patients receive from healthcare providers other than the study doctor, a signed copy of the consent document must be placed in the subject's medical record. Examples of clinical intervention include the use of a drug or device, surgery, psychotherapy or any physical interaction that is more than minimal risk and is done specifically as part of the research study. Follow local process to ensure that a signed copy of the consent document is placed in the subject's medical record, when applicable.

6.4. Follow local process to ensure that a signed copy of the Research HIPAA Authorization is placed in the subject's medical record.

REFERENCES:

- 21 CFR §50.27
- 45 CFR §46.117

RELATED MATERIALS

- SOP: Use of PHI in Research (SOP-701)
- SOP: Informed Consent for Research (SOP-902)
- SOP: Informed Consent Process for Research: Legally Authorized Representative (LAR) (SOP-904)
- SOP: Research Involving Adults with Decreased Decision Making Ability (SOP-907)
- SOP: Research Invovling Children (SOP-908)
- SOP: Research Involving Subjects with Limited English Proficiency (SOP-909)

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	11/08/2017	New- Initial Integration Update	J. Blundon