

SOP: IC 701 Version No.: 06 Effective Date: 12/7/10	INFORMED CONSENT	Supersedes Document Dated: 07/01/08
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Steering Committee approved 1/31/11

Note: The Aurora RSPP generally uses a combined informed consent / HIPAA authorization document (IC 701-A). Policy HI 1201 sets forth the requirements for the HIPAA authorization and for requests for waiver or alteration of authorization.

1. POLICY

No investigator may involve a human being as a research subject unless the investigator has obtained legally effective informed consent of the subject or the subject’s legally authorized representative or a waiver was granted by the IRB. An investigator shall seek consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to consider whether or not the subject will participate and that minimize the possibility of coercion or undue influence.

Specific Policies

The following are definitions of key terms used in this policy. Terms not defined herein shall have the meanings set forth in the Glossary.

“Impartial Third Party Witness” means someone who does not have an interest in the outcome of the research study or whether the subject enrolls. It is not a family member or an individual who is part of the research of the study. The witness must sign the informed consent document in the “witness” section.

1.1. Informed Consent as a Process

Since the central requirement for ethical human subject research is that people participate voluntarily, the consent process is one of the most important parts of research study. Informed consent is more than just a signature on a form; it is a process of information exchange that may include, in addition to reading and signing the informed consent document, subject recruitment materials, verbal instructions, question/answer sessions and a measurement of subject understanding. The process must assure that the potential subject understands the study and its risks and benefits, and can certify his or her willingness to participate. The IRB, the investigator, and the research sponsors all share responsibility for ensuring that the informed consent process is adequate. The informed consent process must occur throughout the subject’s participation in the research study. Thus, rather than an endpoint, the consent document should be the basis for a meaningful on-going exchange between the investigator and the subject.

1.2. The Consent Document

Investigators must use the Aurora IRB consent template (IC 701-A) when submitting an informed consent to the Aurora IRB for review. In studies where children are to be involved in

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research, the Aurora IRB parental permission template (IC 701-C) and age appropriate assent templates (IC 701-D, IC 701-E and IC 701-F) must be used.

For review by the convened IRB, the Primary Reviewer takes the IRB though the determinations in RR 402-A to determine whether the consent process and consent document, or waiver or alteration, meet all regulatory and organizational requirements.

For review using the expedited procedure, the reviewer uses RR 402-A to determine whether the consent process and consent document, or waiver or alteration, meet all regulatory and organizational requirements.

1.3. Mailing, Faxing, or the Sending of an Electronic File Of Consent Documents To Subjects

1.3.1. The IRB may approve a consent process by means other than an in person discussion provided the request is included in the submission application or made via the modification process.

1.3.2. When the potential subject cannot give consent but the legally authorized representative (LAR) is available by telephone, the IRB may prospectively approve a process via expedited review that allows the consent document to be delivered by fax or a protected copy of the consent document sent by electronic file to the potential subject's LAR. The consent interview may be conducted by telephone when the LAR can read the consent document as it is discussed. Witnessing consent obtained over the telephone should comply with the applicable Aurora Facility's policy on telephone consent. The informed consent document should be signed and dated by the LAR and faxed back to the investigator. The original, signed informed consent document should be mailed to the investigator as soon as possible. It is the investigator's obligation to send a summary of events to the IRB office for the RSPB study file.

1.3.3. Significant new findings and consent addenda communicated by telephone. The IRB may prospectively approve a process via expedited review that allows significant new findings or consent addenda to be delivered by mail, fax or electronic file to the subject or the subject's LAR (if appropriate). The new information contained in the document should be discussed with the subject or their LAR by telephone when they have had an opportunity to read the document. The informed consent document should be signed and dated by the subject (or the LAR) and mailed back to the investigator as soon as possible.

1.3.4. Survey studies involving no more than minimal risk to the subject where a waiver of documentation of informed consent has been granted. The IRB may approve a process that allows a consent information sheet to be delivered by mail, fax or electronic file to the potential subject. The subject can participate in the study if he/she chooses.

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1.4. Enrolling Subjects With Impaired Reading Or Writing Skills (e.g. Illiterate Subjects, Blind Subjects, Etc.)

A person who speaks and understands English, but does not read or write, can be enrolled in a study by "making their mark" on the consent document, when consistent with applicable state law and Facility policy.

A person who can understand and comprehend spoken English, but is physically unable to talk or write, can be entered into a study if he/she is competent and able to indicate approval or disapproval by other means. If, in the opinion of the investigator, (1) the person retains the ability to understand the concepts of the study and evaluate the risks and benefits of being in the study when it is explained verbally (still competent) and (2) is able to indicate approval or disapproval to study entry, such person may be entered into the study.

In any of these cases, the investigator must document the method used for communication with the prospective subject and the specific means by which the prospective subject communicated agreement to participate in the study. An Impartial Third Party Witness must witness the entire consent process and sign the consent document.

1.5. Copies of Signed Informed Consent Document

A copy of the signed and dated consent document should be placed in the subject's medical record, if applicable. This requirement may be waived in certain circumstances when a request is reviewed and approved by the IRB.

In all cases, the original signed consent document should be retained the investigator's research records.

1.6. Enrolling Subjects into a Research Study When They Do not Speak English

Investigators should consider ethical/legal implications of enrolling subjects when a language barrier exists.

1.6.1. If investigators wish to target Non-English speaking subjects in their research, they will need to document this action in the Aurora IRB submission form (FO 301-A) or via the modification process (RR 403) if added after the research study is approved by the Aurora IRB. It is expected that a translated version of the consent document (or other consent materials) will be used to enroll potential subjects into such research. The translated version of the consent document (or consent materials) should be included in the initial submission or with the modification request. The translated consent document (or other consent materials) and the English version of the informed consent will be will be provided to the Aurora Interpreter/Translation Services department who will verify that the translation is accurate, unless a certified translation is provided.

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1.6.2. In addition to the consent form, other materials provided to the subject (e.g., diary cards, study questionnaires, or other written study instructions) should be translated into a language the subject can readily understand. These translated materials also require IRB review and approval before they are given to the subject. The translated and English versions of the subject materials will be provided to the Aurora Interpreter/Translation Services department who will verify that the translation is accurate, unless a certified translation is provided.

1.6.3. Process For Oral Presentation Of Translated Short Form Consent for Non-English Speaking Subjects

When enrolling subjects who do not speak English, routine ad hoc translation of the consent document should not be substituted for a written translation. The Aurora RSPP office has the short form consent translated into several commonly used languages at Aurora Health Care. These are version are on the RSPP website. If a investigator (or study representative) unexpectedly encounters a potential subject for a research study that does not speak or understand English, a translated version of the short form consent may be used to enroll such subjects. The investigator (or study representative) must contact the RSPP office to obtain clearance for use of the translated short form consent in the research study **prior** to its use. The investigator (or study representative) must inform the IRB of use of the translated version of the short form consent on the next Continuing Review report

All of the following conditions must be met in order for the use of the short form consent to be used:.

- A. There is an oral presentation (using an interpreter who speaks the language of the subject or LAR) of all information contained in the complete informed consent document.
- B. The subject must be provided with an IRB-approved short form written informed consent document (in a language understandable to the subject or the subject’s LAR) [Short Form Consent Template IC 701-B]. This document shall provide the elements of informed consent. It may be presented orally to the subject or the subject’s legally authorized representative.
- C. The subject must be provided with an IRB-approved written summary (the English version of the informed consent documents may serve as the summary) of the study information that is presented orally to the subject.
- D. An Impartial Third Party Witness (who is able to understand the language of the subject or LAR and English) to the oral presentation is required. The witness must sign and date both the translated short form written informed consent document and the copy of the written summary. The person obtaining

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consent may not be the witness to the consent process.

E. The subject or the legally authorized representative must sign and date the short form written consent document. The subject or legally authorized representative must be given a copy of the signed and dated short form consent form and the signed and dated summary

F. The person obtaining consent (e.g., the investigator) must sign and date a copy of the written summary of the information that is presented orally.

1.6.4. Ongoing Informed Consent Process

A. If an Investigator enrolls a Non-English speaking subject into a research study, he/she is required to have an impartial individual that speaks and understands the subject's native language conduct the translation at all subsequent study visits.

If the investigator unexpectedly encounters a non-English speaking subject for which a translated version of short form consent that is not already available on the RSPP web site, he/she may submit a translated version to the Aurora RSPP office with a modification to the approved study (RR 403). Expedited review of a translated short form consent version is acceptable. The translated version of the short form consent and the English version will be provided to the Aurora Interpreter/Translation Services department who will verify that the translation is accurate.

2. SCOPE

This policy applies to all research submitted to the IRB in which prospective subject informed consent is required.

3. APPLICABLE REGULATIONS, GUIDELINES AND STANDARDS

Belmont Report

Wis. Stat. § 448.30

Wis.Admin Code Med 18

21 CFR 50

45 CFR 46.116, 46.117

FDA Information Sheets, 1998

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Joint Commission Comprehensive Accreditation Manual for Hospitals, RI.01.03.01 and RI.01.03.05

Guidance for Industry (E6) Good Clinical Practice Consolidated Guidance (ICH)

42 CFR 482.13(b)(2), 482.24(c)(2), 482.51(b)(2)

Wis. Stat. § 51.30(2)

Wis. Stat. § 146.81(2)

Wis. Stat. § 252.15

Wis. Admin Code § DHS 92

AAHRPP Elements II.3.F. and II.3.G.

4. REFERENCES TO OTHER APPLICABLE SOPS

SOP 1201