AAH RSPP GUIDANCE
Informed Consent

PURPOSE
No investigator may involve a human being as a research subject in a non-exempt study 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.

NOTE while the ethical tenets of informed consent noted in this document are applicable to all human subject research, the operation parts of the guidance should only be applied to research oversee by the AAH IRB. For instance, it is the purview of the IRB of Record to decide what language is included in the IRB approved consent document. While the AAH RSPP has created boilerplate consent/authorization language that should be included in the consent documents for studies conducted at AAH but rely on an External IRB, it is up to the External IRB if they wish to include this language in the IRB-approved consent document. If the IRB of Record does not wish to include the AAH boilerplate language (also includes research authorization language), the RSPP Office must be contacted for authorization prior to elimination of this language.

Definitions of Italicized words can be found in the AAH RSPP Glossary.

GUIDANCE
Is the Informed Consent just a document to be signed by the prospective subject?
No, it is not only a form, it is 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 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.

How should I write a consent document?
Investigators are encouraged to use the RSPP consent templates when submitting an informed consent. The RSPP templates include the required and additional elements of informed consent.
per the federal regulations, as well as the requirements for informed consent under the revised Common Rule. Should you opt to not use the RSPP consent/authorization template in your submission to the AAH IRB, it is your responsibility to ensure that all requirements of the federal regulations are met.

Note that the RSPP consent templates are a combined informed consent form and HIPAA authorization. References to “consent document” in this document assumes the inclusion of the HIPAA authorization (if necessary for the research study).

In studies where children are to be involved in research, the RSPP parental permission template and age appropriate assent templates should be referenced.

The RSPP also provides guidance on enrollment of adult subjects who are unable to consent for themselves (decisionally incapacitated) [See RSPP Guidance: Surrogate Decision Makers/ Legally Authorized Representatives (LAR) in Human Subject Research.] If approved by the IRB, the use of a legally authorized representative (LAR) to enroll decisionally incapacitated subjects requires the addition of an LAR signature line to the consent document.

**How is Informed Consent documented by the research team?**
The AAH IRB consent templates include a section where the research team member obtaining consent from the subject attests to the process used for obtaining consent. The signature of the individual obtaining consent is required.

It is recommended that, when applicable, the research team also include notation in the patient’s medical and/or research record regarding the process of consent and documentation of informed consent.

**Are there special considerations if my study follows ICH GCP regulations?**
If the investigator has agreed to conduct the research in compliance with ICH GCP E6 regulations, there are requirements that affect the informed consent document and process. The RSPP informed consent templates are compliant with the ICH GCP E6 consent requirements. [More information on ICH GCP regulations/requirements for human subject research conducted under ICH GCP E6 regulations may be found in the RSPP Guidance: ICH GCP Compliance for Researchers or the regulations themselves.]

**Will there be consideration to waivers or alterations to informed consent or waivers of documentation of informed consent?**
DHHS regulations at 45 CFR 46.116 allow the IRB to waive the requirement for obtaining informed consent or parental permission or to approve a consent procedure that leaves out or alters some or all of the elements of informed consent otherwise required under the regulations.
The FDA does not allow a waiver or alteration of the requirements for obtaining informed consent except in limited circumstances (21 CFR 50.23 and 21 CFR 50.24). See the FDA Guidance on Informed Consent for more information.

Per DHHS regulations found at 45 CFR 46.117(c), with IRB approval of a waiver of documentation of informed consent potential subjects, or the parents of children who are subjects, are presented (either verbally or in writing) with the same information required in a written consent document, but documentation of the process (signing of the consent form) has been waived by the IRB.

In cases where the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement regarding the research.

Per FDA regulations, informed consent must be documented by a signed and dated written consent form except under two specific circumstances, as described in FDA's regulations at 21 CFR 56.109(c).

**Do I need to provide the subject with a copy of the signed consent?**
Yes, the subject must be provided with a copy of the signed consent document. In addition, a copy of the signed and dated consent document should be placed in the subject’s medical record, unless a request is made to the IRB to waive this requirement.

Whenever possible, the original signed consent document should be retained the investigator’s research records. Electronic consent signatures will be allowable in situations approved by the IRB. [See RSPP Guidance: Use Of Electronic Informed Consent.]

**Will the IRB approve a consent process by means other than an in-person discussion?**
Yes. 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.

When the potential subject cannot give consent but the legally authorized representative (LAR) is available by telephone or telepresence technology, 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 or telepresence technology when the LAR can read the consent document as it is discussed. Witnessing consent obtained over the telephone should comply with Institution’s policy on telephone consent.

The informed consent document should be signed and dated by the LAR and a copy sent back to the investigator/study team as soon as possible via email/fax/mail. The investigator/study team must receive a copy of the signed consent document prior to implementation of research operations. 
interventions. The original, signed informed consent document should be mailed to the study team as soon as possible. If a witness is used in the consent discussion, the witness must sign and date a copy of the informed consent on the line provided within the document. A copy must be returned by email/fax/mail prior to implementation of research interventions.

Significant new information and consent addenda may be communicated by telephone/telepresence upon IRB approval. The IRB may also 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/video 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. It is recommended that the study team document the discussion of the significant new information or consent addenda in the subject’s medical and/or research record.

In 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 they choose.

Are there ways of enrolling subjects with impaired reading or writing skills (e.g. Illiterate Subjects, Blind Subjects, Etc.)?
Yes. 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 institutional 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.

What should I consider if my research study is targeting non-English speaking subjects?
When a researcher anticipates enrolling non-English speakers in a research study, it is required that the English language consent form and written subject materials be translated into the
language that the subject understands. This translated document must be prospectively approved by the IRB in advance. The inclusion of this ‘targeted’ non-english speaking/understanding population must be included in the IRB submission application or via the modification process if added after the research study is approved by the IRB. It is recommended that the consent document not be translated until the research team has received an IRB approved version of the consent document (or consent materials). These translated documents may be provided using the modification process after study approval.

The translated consent document (or other consent materials) and the English version of the informed consent should be provided to the IRB with a Certificate of Accuracy. If the Certificate of Accuracy/Translation is not provided with the translated consent document, the translated consent will be provided to an institution-approved Interpreter/Translation Services company who will ‘back-translate’ the document. This may cause extra review time – plan accordingly.

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. A Certificate of Accuracy/Translation must be provided with the translated documents. If a Certificate is not provided, a ‘back-translation’ will be requested by the RSPP Office.

If the person obtaining informed consent is not a qualified interpreter (as outlined by the AAH System Policy) in the potential subject’s language, a qualified interpreter must facilitate the informed consent discussion, either in person, by phone or telepresence technology. An impartial witness must be present for the discussion. If the person obtaining informed consent is a qualified interpreter in the language understood by the prospective subject, this individual may conduct the consent discussion, and a witness is not required.

**Who can serve as the Impartial Witness?**
The individual serving as the impartial witness must be someone who understands both English and the subject’s language, not a member of the immediate family of the potential subjects and not a member of the research team. The role of the witness in the consent process is to attest to the adequacy of the consent process and to the subject’s voluntary consent. The interpreter may serve as the witness if s/he is willing to do so. This must be clarified with the interpreter before beginning the informed consent discussion.

The witness will sign the witness signature line of the consent form. By signing, s/he attests to the adequacy of the consent process and to the subject’s voluntary consent.

**What if I unexpectedly encounter a Non-English-speaking prospective subject?**
In most cases, the AAH IRB will agree to the inclusion of an unexpectedly encountered Non-English-speaking individual into the study even if the study is not targeting such a population.
Most often in these situations, there is not time to get the IRB approved consent document translated into the language that the potential subject understands. Therefore a ‘short form consent process’ is used. The AAH RSPP office has the “short form consent” translated into several commonly used languages (available on the RSPP website). See more about the short form consent process in the RSPP Guidance: Enrollment Of Subjects With Limited English Proficiency.

If the investigator unexpectedly encounters a non-English speaking subject for which a translated version of short form consent is not already available on the RSPP web site, he/she may submit a translated version of the RSPP English short form consent document along with a Certificate of Accuracy/Translation to the RSPP office via the modification process.

REQUIREMENTS

- Common Rule Regulations 45 CFR 46.116, 46.117, 42 CFR 482.13(b)(2), 482.24(c)(2), 482.51(b)(2)
- FDA Regulations: 21 CFR 50
- FDA Information Sheets, 1998
- Guidance for Industry (E6) Good Clinical Practice Consolidated Guidance (ICH)
- State Law: § 448.30, § 51.30(2), § 146.81(2), § 252.15
- Wis. Admin Code Med 18; § DHS 92