

HAC Policies and Procedures

Informed Consent Process and Documentation

What Is The Informed Consent Process?

The informed consent process is a continual process of communication between the subject, the investigator (s) and the research team. It is not merely the written documentation of the subject's willingness to participate. Open communication of any information that may influence the subject's decision to participate or continue participation in the study must be available and documented.

Who Is Responsible For Assuring That No Research Begins Prior To Informed Consent Being Obtained?

Federal and institutional regulations specify that the investigator is responsible for *personally* assuring that no research begins before obtaining consent, unless the Human Assurance Committee (HAC) has waived the requirement for written informed consent.

Can The Informed Consent Document (ICD)/Childrens Assent Document (CAD) Include Exculpatory Language?

The Informed Consent Document (ICD) and/or Children's Assent Document (CAD) shall not include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights or release or appear to release the research investigator, the sponsor, or the institution or its agents from liability for negligence, except for the extent specifically allowed by law.

When Is It Appropriate To Use The Minimal Risk Informed Consent Document Template?

Studies that meet the expedited review criteria of minimal risk may utilize the minimal risk template for the informed consent document.

How Do You Properly Obtain and Document The Informed Consent Process?

To obtain informed consent from a subject, a Human Assurance Committee (HAC) approved investigator must fully explain the study to the subject and/or their parents, or legally authorized representative. Legally authorized representatives are the following individuals and are listed in their order of priority:

- Health-care agent
- Legal guardian or special guardian
- Next-of-kin: a close relative of the subject eighteen years of age or older, in the following priority:
 - Spouse
 - Child
 - Parent

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- Sibling
- Grandparent
- Grandchild
- Close friend

Consent is to be obtained from the subject or his/her legally authorized representative in circumstances that encourage and preserve the subject's free choice to participate; and the investigator communicates in language that is understandable to the subject.

Legally authorized representatives are to be well informed regarding their roles and obligations to protect incompetent participants or persons with impaired decision making capacity. They must also be told their obligation is to try to determine what the prospective participant would do if competent, or if the prospective participant's wishes cannot be determined, what they think is in the incompetent person's best interest.

This process must be documented in the source documents including the medical record. Refer to the OHRP Clinical Research Standard Operating Procedure (SOP) at http://www.mcg.edu/research/ohrp/training/SOP02_Informed_Consent.pdf

How Do You Obtain Informed Consent From Children?

For children under 18, assent of the child, as well as the consent of the parents must be obtained under Department of Health and Human Services (DHHS) regulations. In determining the capability of the child to give assent for research, the child's age (e.g., typically above 6 years), maturity and emotional state should be considered.

What Are The Readability Requirements For The ICD And CAD?

The ICD should be presented at the eighth grade reading level and the CAD must be presented at the second grade reading level. Most word processing software allows a readability check. The HAC recommends giving the draft document to a non-medical person for their review since another medical professional reviewing the draft does not allow for true comprehension by a layperson. The ICD and/or CAD must be written in language that the subject and/or legal representative can be expected to understand and must clearly present all the information regarding the study in order that the subject and/or legal representative can make a reasonable decision concerning participation.

Can We Just Use The Sponsor Or CRO's Sample ICD And/Or CAD?

No. Each ICD and/or CAD should be customized using our templates and the sponsors.

Should I Run The Draft ICD And/Or CAD By The Sponsor Or The Contract Research Organization Before I Submit It To The HAC?

Yes. Please forward the draft to the sponsor or Contract Research Organization (CRO) prior to HAC submission if the protocol is industry sponsored.

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Where Can We Find Laymen's Terms?

For easily understood laymen's terms in a glossary format, paste the following address into your web browser: <http://www.centerwatch.com/patient/glossary.html>. The following is included for reference:

15 ml = 1 Tablespoon

5 ml = 1 Teaspoonful

30 ml = 1 Ounce

What Person Usage Should Be In The Research Informed Consent Document?

General:

1. First or second person usage must be consistent throughout the document and the length of the study. Please review the document carefully as this is a common area for mistakes to occur.
2. Any consent document written in the second person must have the first person statement of agreement to participate at the end of the document, using the standard wording, set off by a heading "Consent to Participate."
3. Do not rely on the spell check feature of the word processing document to catch all errors.

Adult Research Subject Informed Consent Document:

1. Second or first person is acceptable although the FDA recommends second person.
2. Second person is occasionally clearer for complex consent documents that present a large amount of information.

Child Research Subject Parental Informed Consent Document

1. Because the consent is usually addressed to the parent/guardian as the consenting party in reference to a third party (the child), second person is generally preferred.
2. Do not use the term "you/your child." "You" can be used to include both the parents and the child. When necessary to specify the child alone, state "your child." If necessary, the locutions "he/she" may be used to refer to the child, but for clarity avoid excessive use.
3. Do not use "your child/ward." In the body of the consent, parents or guardians should be referred to simply as "parents." In the signature block, the standard "parent/guardian" wording should be retained.

Children's Assent Document:

1. First person is strongly preferred because it more accurately conveys to the child the nature of the assent process (the child is saying, "I agree"). The child may perceive an

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assent document written in the second person as a demand. The HAC may, at its discretion, request that assents not written in first person be revised.

2. If second person is chosen, avoid coercive language such as "you must" or "you will have to. State, "you will be asked to."
3. Language should be very simple and direct (no more than a second or third grade receptive vocabulary). This is true even for consents intended for teenagers.
4. A consent document does not substitute for an assent document, which should be simpler and shorter. This document is primarily used for children age seven (7) to twelve (12).
5. Keep sentence length short.

Who Does the HAC Authorize to Obtain Informed Consent?

Only a named Principal Investigator (PI) or Sub-Investigator (sub-I), proposed to and approved by the HAC, may obtain consent or assent. The specific investigators authorized to obtain informed consent must be proposed to and approved by the Committee prior to obtaining informed consent. Only an approved investigator is allowed to conduct the interview and obtain consent.

Are Clinicians the Only Individuals Authorized to Obtain Informed Consent for Investigational Studies?

It depends on the type of study. The HAC is aware that multiple people play an integral role in the conduct of an investigational study. Some of these individuals may be Registered Nurses (RN), Advanced Practice Registered Nurses (APRN), Physician Assistants (PA), and Pharmacists. Regardless of the professional education of the individual, it is critical that the role and activities of all investigators involved in clinical research studies be defined. The rationale for the following recommendations is based upon the fact that non-physician investigators play a critical role in the initiation of a study and answering subject's questions in non-medical terms. A higher level of specialty expertise would be expected if the protocol involves decision-making about alternative treatment, particularly if an experimental drug/device is involved than if the study involves more common and/or standard treatments.

What Are The Risk Levels?

Defining the risk level of a protocol ultimately rests with the HAC at the time the protocol is reviewed. Experimental procedures, therapies, drugs or devices that carry a high risk of permanent injury or death should be considered High Risk. Examples may include significantly invasive procedures, emergency procedures or the use of medications or procedures that may affect a fetus. Examples of lower risk protocols may include the comparison of standard treatments or the use of approved medications in an appropriate manner.

Who Is Eligible to Obtain Informed Consent for Investigational Studies Using an Investigational Drug or Device?

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For High Risk protocols, the investigator with expertise in the topic/protocol and approved by the HAC must obtain informed consent. If requested by the PI and approved by the HAC, an individual in this area of expertise may explain the study/informed consent document (ICD), if the knowledge for such explanation is within their practice. A designated clinician investigator must be present to answer questions. The Sub-I who initially explained the protocol/study must also sign the ICD.

Who Is Eligible To Obtain Informed Consent for Non-Investigational Drug or Device Studies?

The PI and approved Sub-I(s) generally obtain consent for Low Risk protocols. These individuals must be knowledgeable, by education and/or experience about the topic and study protocol and must be approved for this role by the HAC prior to obtaining consent. The approval for investigators to obtain consent is accomplished during the initial application and HAC review process or can occur through an amendment request after the protocol is initially approved. Upon request, an approved investigator with appropriate expertise and knowledge must be available to answer questions from the potential study subject before the ICD is signed.

How Do You Determine Which Children's Assent Document To Use?

In Georgia, studies that involve children aged seven (7) to seventeen (17) years must include a separate assent document for the children to sign. This is a simplified version of the consent, written at a level that the youngest subject can understand. If possible, children under age seven (7) should give verbal agreement. It may be appropriate to have more than one CAD for different age levels (e.g., 7-12 and 13-17 years of age).

Is It Possible To Use The Adult Informed Consent Document For Subjects That Are Minors But In The Age Range Of Sixteen (16) To Eighteen (18)?

If research subjects are minors, but in the age range from sixteen (16) to eighteen (18), and the standard consent for the parents' signature is written at a level they can understand, it may be acceptable to use the single document with both child and parent signing the ICD. The HAC will determine the appropriateness of this use.

When Should The Subject, Witness And Investigator Sign The ICD And/Or CAD?

The subject must sign and date the ICD and/or CAD in the presence of an approved investigator. The approved investigator must also sign and date the ICD and/or CAD, during this interaction with the subject. In cases where a witness signature is used or required, MCG requires the witness to be present during the entire consent presentation to attest to the accuracy of the presentation and the apparent understanding by the subject.

Why Is A Witness Required?

Witnesses are not required on every protocol. The HAC makes the decision on a case by case basis. A witness is generally defined as an individual who is not affiliated with the protocol and verifies that they witnessed the **informed consent process**, not simply the signature of the

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subject and/or the authorized representative. It is recommended that the witness be a family member or friend of the potential subject, not the SC.

How Do We Document That The Initial Informed Consent Was Obtained Prior To Participation In The Study?

All studies must include a statement in the research chart or medical record that informed consent was obtained prior to participation in the study. The investigator must sign and date the statement. No screening procedures or answers to study specific questions may be obtained prior to the subject signing the informed consent document. The Joint Commission on Accreditation of Healthcare Organizations [TJC; previously known as The Joint Committee on Accreditation of Healthcare Organizations (JCAHO)] requires the information to be placed in the subject's medical record, also.

How Is The Informed Consent Process Documented?

Each subject or his/her legally authorized representative must sign and date a copy of the current HAC stamped approved informed consent document (ICD) prior to enrollment or prior to any participation in any phase of the study, unless the written consent requirement is waived by the HAC. For additional institutional requirements, please see http://www.mcg.edu/research/ohrp/training/SOP02_Informed_Consent.pdf

How Is Informed Consent Obtained From A Cognitively Impaired Subject?

A research subject must be legally and autonomously competent to give informed consent. For subjects that are cognitively impaired, a surrogate whose primary interest is the subject's welfare may give informed consent. The guidelines for consent by individuals other than the subject are defined in Code 31-9-2 of the Official Code of Georgia, and in VHA Handbook 1200.5, as appropriate to the site of study conduct.

Competency is commonly judged by the subject showing a choice with regard to research participation through his/her understanding of the issues, information, and nature of the research project. If competency is an issue, it must be acknowledged in the research proposal and the procedures used to evaluate competency must be described in detail. It is recommended that a physician, not affiliated with the conduct of the study, document the competency of the subject prior to participation.

What Is A Legally Authorized Representative?

A legally authorized representative is an individual or body authorized under applicable law to provide permission on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. For the purposes of this policy and procedure, a legally authorized representative includes not only a person appointed as a health care agent under a Durable Power of Attorney for Health Care (DPAHC), a court appointed guardian of the person, but also next-of-kin in the following order of priority unless otherwise specified by applicable

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state law: spouse, adult child (18 years of age or older), parent, adult sibling (18 years of age or older), grandparent, or adult grandchild (18 years of age or older)

Legally authorized representatives are to be well informed regarding their roles and obligations to protect incompetent participants or persons with impaired decision making capacity. They must also be told their obligation is to try to determine what the prospective participant would do if competent, or if the prospective participant's wishes cannot be determined, what they think is in the incompetent person's best interest.

Can A Subject Be Forced To Give Up Their Property Rights To Their Body Fluids, Substances Or Tissues?

No. If the investigator believes that body fluids, substances or tissues of a research subject could be part of or lead to the development of a commercially valuable product, the consent document should contain the language as specified for MCG or MCGHI subjects.

Does The HAC Stamp Each Page Of The ICD And/Or CAD With An Approval Stamp?

Yes. Each page of the ICD and/or CAD must display the HAC stamp of approval that indicates the approval and expiration dates of the study. This is for all sites (MCG, MCGHI and the Augusta VAMC to include the VA Form 10-1086.) The approval date is from the initial period of review but may change as amendments are submitted and approved as well as at the time of continuing review.

Does The HAC Allow Remote Informed Consent?

HAC approval for obtaining informed consent from a remote site is considered on a case-by-case basis. Only those studies that qualify for, and obtain prior written HAC approval for remote informed consent, are eligible for this policy.

What Is The Appropriate Procedure If Remote Informed Consent Is Prospectively Approved By The HAC?

Send the HAC approved informed consent document (ICD) to the site via facsimile or scanned email attachment. The subject must have possession of the HAC approved ICD before the informed consent process is initiated. If duplicating facilities are not available, send multiple documents to ensure that the subject retains a copy.

Subject and/or subject's legally authorized representative (LAR) such as a parent/guardian or other reads and receives explanation of the ICD and the study over the telephone line. The potential for loss of confidentiality must be addressed if using a cellular phone.

What About Illiterate Subjects and Remote Informed Consent?

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If a written informed consent document [21 CFR 50(b) (1)] is used, then the PI or authorized Sub-I to obtain informed consent reads the consent to the subject in the presence of an identified witness (with the subject).

What About Non-English Speakers and Remote Informed Consent?

Subjects who do not speak English must have a HAC approved ICD translated into the subject's language which can be sent to the subject by facsimile or scanned email attachment. The subject is given a copy of the translated ICD. An interpreter may assist with the discussion; but ad hoc translation may not replace the written document. Subject discusses consent with investigator authorized to obtain consent via the telephone, with an identified witness present while the subject is on line. The subject and the witness sign consent document with the subject retaining a copy of the informed consent document.

How Are The Signed ICDs Used During the Remote Informed Consent Process Sent To The PI?

The signed ICD(s) should be sent to PI by facsimile or scanned and sent by email. The original signed and dated ICD must be sent to the PI by mail. Upon receipt, the person obtaining consent signs both copies. A copy of the ICD, signed by the investigator authorized to obtain consent, is sent to the subject with a self-addressed, stamped receipt acknowledgement card for the subject to return to the PI. The study may proceed upon receipt of the (faxed or scanned email copy, when applicable) consent.

Can Telemedicine Be Used for Remote Informed Consent?

The research subject discusses consent with the investigator authorized to obtain consent via telephone or bi-directional visual contact. With bi-directional visual contact, the witness can be on either end. "Home house call" - written consent is obtained before the equipment is installed in the subject's house.

For research activities beyond those included in the initial consent, the subject must be re-consented to ensure accurate differentiation between research and practice of medicine. Consult the HAC before starting new activities. All other applicable institutional regulations apply in regards to the copies being given to the Investigational Pharmacy, copy in the medical record and /or source document, etc.

Does The Informed Consent Process Have To Occur At Each Visit Or Interaction?

Yes. Remember that the informed consent process should take place at each protocol visit to ensure that the subject is aware of the research and that they want to continue to participate. This verbal confirmation of continuation of consent should be documented in the research chart and medical record.

Are We Required To Notify Subjects Of Any New Significant Findings During The Course Of The Study?

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Subjects must be informed of any significant new findings that develop during the course of the study, which may relate to their continued willingness to participate. This may require revisions to the ICD and may also require re-consenting of previously enrolled subjects. **NOTE: If a subject is unable to read or write, it must be documented on the informed consent document and in the medical record or visit note.**

How Long Do We Keep Signed Informed Consent Documents For MCG And MCGHI?

Signed consent documents must be retained by the investigator for at least three years past the completion of the research activity or at least three years after termination of the last HAC approved period for research activity, whichever is later. The sponsor or cooperative group should also be contacted for their storage requirements.

What Do We Do If We Consent A Subject Using An Expired Informed Consent Document?

Notify the HAC via a completed HAC Form 120 PDV, Protocol Deviation/Violation, and re-consent the subject at their next visit. Document in the research progress notes exactly what occurred and create a preventive action plan if one is not in place. This may also demonstrate a need for a standard operating procedure (SOP) to address future recurrences of this issue. At times, a note to file may be appropriate. Please contact the HAC Administrative Office for additional guidance.

What if the Protocol Changes After a Subject Has Been Consented?

Please see the amendments section for additional guidance on ICD addendums or revised ICD and/or CAD.

Are There Any Tips for Consenting Research Subjects?

Always confirm that the research subject is signing the most recently HAC approved consent document. Double-check the approval stamp to determine if the approval is still valid.

Be certain that the subject has adequate time to review the document. Ask the research subject questions about the study that requires more than a yes/no answer.

After the research subject signs the consent document, review it to make certain that the research subject has:

- Initialed all pages
- Printed and signed their name in the correct area
- Recorded the correct date

After the investigator signs the consent document, review it to make certain that the investigator has:

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- Printed and signed their name in the correct area
- Recorded the correct date

After the above has been confirmed:

- Provide a copy to the subject
- Store the original in the research record
- Provide a copy for the medical record
- Write the enrollment note
- Update the enrollment/screening log

What If We See An Error In The Date Or Name?

Correct the error with a single-line strikethrough, initial and date the correction.