



Procedure Number: 201

**Writing an Informed Consent Document for
Human Subject Research**

Adopted: 3/2005

Revised: 6/2014

Page 1 of 11

Human Research Protection Program

WRITING AN INFORMED CONSENT DOCUMENT FOR HUMAN SUBJECT RESEARCH

DESCRIPTION

At the University of Cincinnati (UC), every person who participates in human subjects research must give their informed consent before their participation begins unless the requirement is waived by the Institutional Review Board (IRB). Their consent must be documented using a signed informed consent document (ICD) unless the requirement is waived by the IRB.

RESPONSIBILITY

The Principal Investigator (PI) of a research study is responsible for obtaining IRB approval of all consent procedures and ICDs needed to adequately inform research participants about the study and their rights as participants. The PI may delegate preparation of ICDs, but remains responsible for the content and use of all ICDs in the study.

PROCESS

REQUIRED BASIC ELEMENTS OF AN INFORMED CONSENT DOCUMENT

The following information will be provided to each participant, as described in 21 CFR 50.25 and 45 CFR 46.116. These elements are included in the template consent versions posted on the Human Research Protection Program (HRPP) website.

1. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the participant's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
2. A description of any reasonably foreseeable risks or discomforts to the participant.
3. A description of any benefits to the participant or to others that may reasonably be expected from the research.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the participant. Alternative procedures or treatment must include their important potential benefits and risks.

Human Research Protection Program

5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. In the case of Food and Drug Administration (FDA)-related research, the ICD must disclose a statement noting the possibility that the FDA may inspect the records. The ICD will include all individuals and organization that have access to a participant's original medical record, including the sponsor, funding entities, agents of UC, and any other federal agencies, as appropriate. By signing the ICD, the participant or their legally authorized representative (LAR) authorizes such access.
6. For research involving more than minimal risk, an explanation as to whether any compensation or medical treatments are available if injury occurs, and, if so, what they consist of, or where further information may be obtained.
7. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant.
8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
9. ICDs and consent processes for applicable drug, biological products and device clinical trials shall include a specific statement that clinical trial information will be submitted to the National Institutes of Health/National Library of Medicine (NIH/NLM) for inclusion in the clinical trial registry databank (ClinicalTrials.gov).

No informed consent, whether oral or written, may include any exculpatory language through which the subject or their LAR is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

ADDITIONAL ELEMENTS OF AN INFORMED CONSENT DOCUMENT

When appropriate, one or more of the following elements of information will also be provided to each participant, as described in 21 CFR 50.25 and 45 CFR 46.116: These elements are included in the template consent documents available online.



Procedure Number: 201

**Writing an Informed Consent Document for
Human Subject Research**

Adopted: 3/2005

Revised: 6/2014

Page 3 of 11

Human Research Protection Program

1. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus if the participant is or may become pregnant) that are currently unforeseeable.
2. Circumstances under which participation may be terminated by the investigator without the subject's consent.
3. Any additional costs to the participant that may result from participation in the research.
4. The amount and schedule of payments.
5. The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant.
6. A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant.
7. The approximate number of participants involved in the study.
8. Any additional information that, in the judgment of the IRB, would add meaningfully to the protection of the rights, safety, and well-being of the participants.

REQUIRED ELEMENTS OF A CINCINNATI VETERANS AFFAIRS MEDICAL CENTER INFORMED CONSENT DOCUMENT

Cincinnati Veterans Administration Medical Center (CVAMC) research is defined as research that uses CVAMC facilities, employees, resources or patients, regardless of funding source.

Any ICD for CVAMC research must include the following information in addition to the required and additional elements that are listed above. These CVAMC elements are included in the CVAMC template consent posted on the CVAMC SharePoint site. Assistance with accessing the SharePoint site may be obtained by contacting the Research Services office at CVAMC.

1. Include "Department of Veterans Affairs" in the header information on page one and the signature page, and in the "How Many People Will Take Part in the Research" section.

Human Research Protection Program

2. Include the name of the investigator who will be in charge at CVAMC in the “Who Is Conducting the Research” section.
3. Include that representatives of CVAMC may inspect records in the “How Will Information be Kept Private and Confidential” section.
4. Include verbatim CVAMC language in the “What Are the Costs to Be in the Study” section.
5. Include a statement detailing how participants will be treated for injuries that may result from the research.
6. Include verbatim CVAMC language in the “Who Do You Call if You Have Questions or Problems” section.
7. The ICD must be written on CVAMC form 10-1086 and follow all posted instructions.
8. A copy of the signed ICD must be provided to the participant or the participant’s LAR.

ENHANCING COMPREHENSION OF THE INFORMED CONSENT DOCUMENT

Guidance regarding ICD layout, font, reading level, and other considerations is available online. ICDs must conform to the IRB's current templates and guidance.

All ICDs must be written in language that is understandable to the targeted population. Medical terminology must be defined in lay terms. Formatting that may be used to improve readability includes, but is not limited to, bulleted lists, paragraph breaks, font type and size, page margins, tables of information, diagrams and graphs.

When the IRB believes it to be appropriate, the investigator may be required to assess and confirm a participant’s understanding of the information presented in the ICD. Methods for doing this include, but are not limited to, using a written comprehension tool (quiz), requiring a friend or family member to be present during the consent discussion, requiring a waiting period before study visits begin, and approval of the research by a community review board. The investigator may be required to document the results of the comprehension assessment activity. If such documentation is required, it may be attached to individual ICDs or filed with other documents in the study file, as appropriate.



Procedure Number: 201

**Writing an Informed Consent Document for
Human Subject Research**

Adopted: 3/2005

Revised: 6/2014

Page 5 of 11

Human Research Protection Program

WAIVER OR ALTERATION OF ELEMENTS OF THE INFORMED CONSENT DOCUMENT

The IRB may approve a consent process or an ICD which does not include, or which alters, some or all of the elements of the informed consent, as described in 45 CFR 46.116. The investigator must show, and the IRB must document, that all of the following are true.

1. The research involves no more than minimal risk to the participants,
2. The waiver or alteration will not adversely affect the rights and welfare of the participants,
3. The research could not practicably be carried out without the waiver or alteration, and
4. When appropriate, the participants will be provided with additional pertinent information after participation.

WAIVER OF INFORMED CONSENT DOCUMENTATION (SIGNATURE)

For research that does not involve FDA oversight

The IRB may waive the requirement for the investigator to obtain a signed ICD for some or all participants as described in 45 CFR 46.117. The investigator must show, and the IRB must document, that either of the following is true.

1. The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Participants will be given the opportunity to say whether they want documentation linking them to the research and their wishes will govern.
2. The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context.

The IRB may require that a written summary of the research be provided to participants instead of a traditional ICD. If so, the IRB must approve the summary before it may be used with participants.



Procedure Number: 201

**Writing an Informed Consent Document for
Human Subject Research**

Adopted: 3/2005

Revised: 6/2014

Page 6 of 11

Human Research Protection Program

For research that involves FDA oversight

The IRB may waive the requirement for the investigator to obtain a signed ICD for some or all participants as described in 21 CFR 56.109. The investigator must show, and the IRB must document, that both of the following are true.

1. The research presents no more than minimal risk of harm to subjects, and
2. The research involves no procedures for which written consent is normally required outside the research context or exception from informed consent for emergency research.

The IRB may require that a written summary of the research be provided to participants instead of a traditional ICD. If so, the IRB must approve the summary before it may be used with participants.

For CVAMC research

The investigator must maintain a master list of all subjects from whom informed consent has been obtained, whether or not the requirement for consent documentation has been waived. The IRB may waive the requirement for a master list if both of the following conditions are met.

1. There is a waiver of documentation of informed consent, and
2. The IRB determines that a breach of confidentiality poses a potential risk to the subjects.

If the IRB waives the requirement to maintain such a master list, the IRB must provide written documentation in the IRB minutes or IRB protocol file justifying the waiver. See *VA Handbook 1200.05 §9.u (2)(b)* and *1200.05 §9.u(3)*.



Procedure Number: 201

**Writing an Informed Consent Document for
Human Subject Research**

Adopted: 3/2005

Revised: 6/2014

Page 7 of 11

Human Research Protection Program

WAIVER OF THE INFORMED CONSENT PROCESS

For research that does not involve FDA oversight

The IRB may waive the requirement for the investigator to obtain informed consent for some or all participants as described in 45 CFR 46.116-117. The investigator must show, and the IRB must document, that all of the following are true.

1. The research involves no more than minimal risk to the subjects,
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects,
3. The research could not practicably be carried out without the waiver or alteration, and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

For research that involves FDA oversight

Informed consent, with or without signature, must be obtained unless the test article must be used in an emergency situation as described in 21 CFR 50.23. To enroll the participant without first obtaining informed consent the following conditions must be met:

1. The investigator and a physician who is not otherwise participating in the research must both certify in writing that all of the following are true.
 - a. The subject is confronted by a life-threatening situation that necessitates the use of the test article,
 - b. Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject,
 - c. There is not sufficient time to obtain consent from the subject's LAR, and
 - d. There is no alternative therapy available that is approved or generally accepted that provides an equal or greater likelihood of saving the life of the subject.



Procedure Number: 201

**Writing an Informed Consent Document for
Human Subject Research**

Adopted: 3/2005

Revised: 6/2014

Page 8 of 11

Human Research Protection Program

2. If, in the investigator's opinion, immediate use of the test article is required to preserve the life of the subject and time is not sufficient to obtain the independent determination required in paragraph 1 above, the four required determinations shall be made by the investigator and, within 5 working days after the use of the article, shall be reviewed and evaluated in writing by a physician who is not participating in the research study.
3. The documentation required in paragraph 1 or 2 above shall be submitted to the IRB within 5 working days after the use of the test article.

EXCEPTION FROM INFORMED CONSENT IN CLINICAL TRIALS

The IRB may find for some or all participants that the requirements for an exception from informed consent (EFIC) for emergency research are met as described in 21 CFR 50.24. See Human Research Protection Program (HRPP) Policy III.05 *Emergency Use of an Investigational Drug, Biological Product or Device in Human Subject Research* and HRPP Procedure 202 *Exception from Informed Consent in Clinical Research*. Although documentation of consent (signature on an ICD) is not required prior to use of the test article when EFIC is approved, the researcher is still required to seek documented consent from the subject or their LAR as soon as possible.

SHORT FORM CONSENT DOCUMENT

45 CFR 46.117 permits oral presentation of consent information in conjunction with a short form written consent document.

1. The short form must state that all the elements of informed consent required by 45 CFR 46.116 have been presented orally to the subject or their LAR.
2. The IRB shall approve a written summary of what is to be said to the subject or their LAR. The standard ICD may be the summary.
3. When this method is used, there shall be a witness to the oral presentation who will verify that the summary accurately describes the information given to the subject orally. The witness may be a family member of the subject. The witness may not be a researcher associated with the study.
4. The short form shall be signed by the subject or their LAR. The witness shall sign both the short form and the summary. The person conducting the consent discussion shall sign the summary.



Procedure Number: 201

**Writing an Informed Consent Document for
Human Subject Research**

Adopted: 3/2005

Revised: 6/2014

Page 9 of 11

Human Research Protection Program

5. Signed copies of the short form and summary shall be given to the subject or their LAR.

OBTAINING CONSENT FROM THOSE WHO CANNOT SPEAK ENGLISH OR ARE ILLITERATE

Non-English Speaking Participants

Individuals who are unable to speak English may not be excluded from participating in a research study without justification. Prospective participants must be given an approved translation of the ICD in their preferred language unless an alternative procedure has been approved by the IRB.

A short form consent document and oral presentation may be used with subjects who do not speak English, with the following additional provisions.

1. The oral consent presentation and the short form written document must be in a language understandable to the subject.
2. The witness to the oral presentation must be fluent in both English and the language of the subject.
3. Unless the researcher is fluent in the participant's language, a qualified translator must be included in the consent discussion and must sign the summary as a witness.

The IRB must receive all foreign language versions of an ICD or short form that will be used. Expedited review of these versions is acceptable if the protocol, the full English language ICD, and the English version of the short form have already been approved by the IRB.

Illiterate Participants or Otherwise Unable to Read the ICD

The consent presentation may be done orally if the subject is not able to read the ICD, with the following conditions.

1. There shall be a witness to the oral presentation who will verify that the oral presentation was consistent with the written ICD. The witness may be a family



Human Research Protection Program

member of the subject. The witness may not be a researcher associated with the study.

2. A subject who is illiterate shall "make their mark" on the ICD's signature line.
3. The witness and the person conducting the consent discussion will sign the ICD.
4. A signed copy of the ICD will be given to the subject.

Applicable Regulations and Documents:

21 CFR 50.20-27

21 CFR 56.109

45 CFR 46.116-117

Policy II.01 *Obtaining Informed Consent in Human Subject Research*

Policy III.01 *Authority of the IRB*

Procedure 202 *Exception from Informed Consent in Clinical Trials*

Guidance for Industry Good Clinical Practice: Consolidated Guidance (ICH E-6) 4.8.10

VA Handbook 1200.05 §9.u(2)(b) and 1200.05 §9.u(3)

Informed Consent Template - Medical

Informed Consent Template – Social/Behavioral

Information Sheet Template – Medical and Social/Behavioral

Assent Template – Medical

Child Assent Template – Social/Behavioral

Youth Assent Template – Social/Behavioral

Parent Permission Template – Social/Behavioral

Genetics Consent Template – Medical

Humanitarian Use Device Consent Template – Medical

Shriners Consent Template – Medical and Social/Behavioral

CVAMC Consent Template – Medical and Social/Behavioral

Short Form – English

Short Form – Spanish

Waiver of Consent Process Form

Waiver of Consent Documentation/Signature Form

Adoption Date:	Created by:	Date of Revision:	Revised By:	Summary of Revision:
03/2005	M. Belskis	07/2007	C. Jake	Revision has been made to delete the emergency

