



Human Research Protection
Program Policy

**OBTAINING INFORMED CONSENT IN
HUMAN SUBJECTS RESEARCH**

POLICY

No investigator at the University of Cincinnati (UC) may involve a human being as a participant in research unless the investigator has first secured the participant's informed consent or the Institutional Review Board (IRB) has waived the requirement that informed consent be obtained.

THE INFORMED CONSENT PROCESS

GENERAL

The process of obtaining informed consent from research participants, or rationale for not obtaining informed consent, must be described in the research protocol and approved by the IRB.

The location and circumstances involved in the consent discussion must minimize the possibility of coercing or unduly influencing an individual to participate. The investigator and other study personnel who conduct the consent discussion must present information objectively so as to minimize the possibility of coercing or unduly influencing an individual to participate.

Potential participants must be given sufficient time to consider whether or not to agree to be in the study and must have the opportunity to have all their questions answered. The IRB, Institutional Official (IO) and their designees have authority to observe the consent process for any approved study.

Researchers must continue to provide information to participants throughout the study so participants can continue to assess their willingness to remain in the study. If new information becomes available during the course of the study that could influence a participant's choice to remain in the study, the investigator must inform the IRB. The IRB may require the investigator to obtain the participant's signature on a revised informed consent document (ICD) to affirm their decision to remain in the study.

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LEGALLY AUTHORIZED REPRESENTATIVE

If the participant is not competent to give informed consent, the investigator may get permission (surrogate consent) from a legally authorized representative (LAR) of the participant. The LAR is determined by the law of the state where the research is being conducted. In many jurisdictions, the representative who can give consent for medical procedures is not the same as the representative who can give consent for research procedures. In Ohio the following are the only surrogate entities who are allowed to provide consent for research purposes:

1. Health care agent appointed by the potential participant in a Durable Power of Attorney for Healthcare (DPAHC) or similar document that gives authority to give informed consent,
2. Court-appointed guardian for the potential participant, and
3. Next of kin, if the potential participant does not have a DPAHC or a legally appointed guardian.

WAIVER OR ALTERATION OF THE INFORMED CONSENT PROCESS

For waivers of consent the following criteria are considered:

- The research involves no more than minimal risk to the participants;
- The waiver or alteration does not adversely affect the rights and welfare of the participants;
- The research cannot practicably be carried out without the waiver or alteration;
- When appropriate, the participants will be provided with additional pertinent information after participation; and
- The research is not FDA-regulated.

The IRB may alter or waive the requirement to obtain informed consent from participants if all criteria defined in 45CFR46.116 have been met, as described in Human Research Protection (HRP) Procedure 201 *Writing an Informed Consent Document for Human Subject Research*. Requirements found in other federal regulations may still apply.

The IRB may find for some or all participants that the criteria for exception from informed consent (EFIC) for emergency research are met, as defined in 21CFR50.24, HRP Policy III.05 *Emergency Use of an Investigational Drug, Biological Product or Device in Human*

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Subject Research and HRP Procedure 202 Exception from Informed Consent in Clinical Research.

For public demonstration projects the following criteria must be met when waiving consent and/or parental permission the following requirements apply:

- The research is conducted by or subject to the approval of state or local government officials.
- The research or demonstration protocol is designed to study, evaluate, or otherwise examine:
 - Public benefit or service programs.
 - Procedures for obtaining benefits or services under those programs.
 - Possible changes in or alternatives to those programs or procedures.
 - Possible changes in methods or levels of payment for benefits or services under those programs.
- The research cannot practicably be carried out without the waiver or alteration.
- The research is not FDA-regulated.

When using a waiver of documentation for the consent process due to harm the following requirements apply:

- The only record linking the participant and the research is the consent document.
- The principal risk is potential harm resulting from a breach of confidentiality.
- Each participant will be asked whether he or she wants documentation linking the participant with the research, and the participant's wishes will govern.
- The research is not FDA-regulated.

When using a waiver of documentation for the consent process for minimal risk:

- The research presents no more than minimal risk of harm to participants.
- The research involves no procedures for which written document of the consent process is normally required outside of the research context.

THE INFORMED CONSENT DOCUMENT

GENERAL

The IRB must approve the ICD that will be used by the researcher to explain the research study to potential participants. Guidelines and template ICDs are posted on the website. Research



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involving Veterans Administration Medical Center (VAMC) facilities, employees, resources or patients, regardless of funding, must use the posted VAMC ICD templates.

The participant's consent to take part in the study must be documented by signatures on the ICD of the participant and the researcher who conducted the consent discussion. The researcher must give a copy of the signed ICD to the participant and maintain the original in the research record. The IRB, IO, sponsor of the research, regulatory and accrediting agencies, and designees of any of these entities are authorized to randomly review protocols and ICDs.

ALTERATION OR WAIVER OF THE INFORMED CONSENT DOCUMENT

The IRB may approve an ICD which does not include, or which alters, some or all of the required elements of an ICD, as described in 21CFR50.25 and 27, 45CFR46.116-117 and HRPP Procedure 201 *Writing an Informed Consent Document for Human Subject Research*.

ALTERATION OR WAIVER OF INFORMED CONSENT SIGNATURES

The IRB may alter or waive the requirement for a researcher to obtain signatures on an ICD for some or all participants as described in 21CFR50.27, 21CFR56.109, 45CFR46.109 and 117 and HRPP Procedure 201 *Writing an Informed Consent Document for Human Subject Research*. The IRB may require that additional information be given to participants when the information would meaningfully add to the protection of the rights and welfare of participants.

Investigators conducting VAMC research must maintain a master list of all subjects from whom informed consent has been obtained, whether or not the requirement for consent documentation (signature) 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 including the subjects on such a master list poses a potential risk to the subjects from a breach of confidentiality.

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, as described in the VA Handbook 1200.05 §9.u(2)(b) and 1200.05 §9.u(3).



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OBTAINING CONSENT FROM THOSE WHO DO NOT UNDERSTAND ENGLISH OR ARE ILLITERATE

Individuals who do not understand English or are illiterate may not be excluded from participating in a study without justification. Alternate methods of presenting information and documenting consent may be used as described in 21 CFR 50.23, 45 CFR 46.116-117 and HRPP Procedure 201 *Writing an Informed Consent Document for Human Subjects Research* and HRPP Procedure 204 *Obtaining Informed Consent in Human Subjects Research*.

Applicable Regulations and Documents:

- 21 CFR 50.20-27
- 21 CFR 56.109
- 45 CFR 46.109, 116-117
- Policy I.06 *Participant Outreach Program*
- Policy III.05 *Emergency Use of Investigational Drug, Biologic, or Device in Human Subjects Research*
- Procedure 201 *Writing an Informed Consent Document for Human Subjects Research*
- Procedure 202 *Exception from Informed Consent in Clinical Research*
- Procedure 204 *Obtaining Informed Consent in Human Subjects Research*
- 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)

Adoption Date:	Created by:	Date of Revision:	Revised By:	Summary of Revision:
11/2005	M. Belskis	07/2007	C. Jake	Revision has been made to the definition of Next of Kin in the State of Ohio.
		07/2009	J. Gerlach	Removed website links. Referenced either institutional policy or federal regulation. Rearranged language in Waiver of Informed Consent Documentation.
		10/2009	J. Gerlach per AAHRPP	Added text to Additional Elements of Informed Consent section: The amount and schedule of payments; Added additional text for required elements of informed consent regarding alternative procedures and access to participants medical records for auditing purposes. ICH-GCP (E-6)



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				guidelines
		03/2011	J. Gerlach	Added text regarding FDA required element - Informed consent documents and processes for applicable drug, biological products and device clinical trials 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 a databank.
		5-31-12	C. Norman	Add section about VA master list of subjects. Update formatting, remove unnecessary wording.
		8-22-12	C. Norman	Revise format and wording for clarification and to conform to other HRP policies. Remove language that more appropriately belongs in other documents. Replace Compliance Officer with IO. Add reference to 21CFR56.109, HRP Policy I.06, HRP Procedure 202.
		09/2014	A.Braggs-Brown	Revised to reflect AAHRPP recommendations
3/2015		3/2015	J. Strasser	Revisions for clarification

Date Adopted March 2015 Signature signed copy on file