
Yale University Institutional Review Boards

IRB Policy 200 Informed Consent for Human Research

Responsible Office	Office of Research Administration	Effective Date	04/01/2009
Responsible Official	Institutional Review Board Executive Chair	Last Revision	02/07/2017

Policy Sections	2
200.1 Informed Consent Requirements	2
200.2 Documentation of Informed Consent	4
200.3 Waiver of Informed Consent	4
200.4 Waiver of Documentation of Informed Consent	5
200.5 Non-English Speaking and/or Illiterate Participants	5
200.6 Studies involving Deception	5
200.7 Ongoing Consent Requirements	6
200.8 Separate Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) Required	6
200.9 Emergency Research with Exception From Informed Consent	6

Scope

This policy describes the requirements for legally effective informed consent for research involving human research participants. Additional requirements for obtaining informed consent in research involving children, decisionally impaired adults, and for HIPAA authorization are not described here but may be found in the applicable policies. See the Related Information section for links information.

Policy Statement

Prior to a participant becoming involved in research, investigators must obtain either 1) the legally effective informed consent of the participant or the participant's legally authorized representative or 2) Institutional Review Board (IRB) approval for a waiver of informed consent in accordance with 45 CFR §46.116 and 21 CFR §50. Consent is an ongoing process throughout the research study. Researchers are responsible for ensuring continuing participant consent, particularly when the study involves multiple interventions.

The IRB reviews the informed consent processes in all human research and will only approve those processes that provide informed consent in accordance with this policy or that meet the criteria for waiver of consent or waiver of documentation of consent as described below.

Reason for the Policy

Obtaining truly informed and voluntary consent to participate in research is a hallmark of research ethics. The ethical principle of respect for persons requires that prior to involving human participants in any aspects of a research study such as enrollment screenings, study interventions, or any other human data collection, the investigator obtain the informed consent of the individual who wishes to participate, or justify why it cannot be obtained and receive IRB approval for a waiver of consent. Consent for participation in research is a process, often extending beyond the initial agreement to participate in the study.

Definitions

Community Consultation

Providing the opportunity for discussion with, and soliciting opinions from, the community(ies) in which the study will take place and from which the study subjects will be drawn. These communities may not always be the same; when they are not the same, both communities should be consulted.

Demonstration Project

Implementation of a method, technology, policy or idea to assess feasibility prior to full implementation. For example, proof of concept studies or the initiation of a benefit or service program or modification of such program for the purpose of assessing its ability to improve the provision of government programs.

Exculpatory Language

Language that waives or appears to waive any of an individual's legal rights or which releases or appears to release the investigator, sponsor, the institution or its agents from liability for negligence.

Family Member

For purposes of this policy, any one of the following legally competent persons: spouse; parents; grandparents; children (including adopted children); brothers, sisters, and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the participant is the equivalent of a family relationship. [21 CFR. § 50.3(m)]

Data and Safety Monitoring Board or Committee (DSMB/DSMC)

A group charged by the sponsor, investigator, or steering committee of a study with protecting participant safety by examining the accruing data for indications of benefit or harm. The DSMB/DSMC makes a judgment as to whether the trial should continue. The DSMB/DSMC usually looks at global data, as investigators forward all adverse event reports and safety data to a data coordinating center, which compiles the data for the DSMB/DSMC to review at predefined intervals. Data presented to the DSMB/DSMC is either completely unblinded, or categorized by treatment arm. As such, the DSMB/DSMC is able to determine whether a clear effect exists in one arm of the study versus the other(s).

Legally Authorized Representative (LAR)

An individual, or judicial or other body, authorized under applicable law to consent on behalf of a prospective participant to the participant's participation in the procedure(s) involved in the research (45 CFR §46.102(c) and 21 CFR §50.3(l))

Public Benefit or Service Program

A federal, state, or local government initiated or endorsed program to deliver financial or medical benefits such as those provided under the Social Security Act or services to improve public welfare such as social, supportive, or nutrition services as provided under the Older Americans Act.

Public Disclosure

(a) Before a planned exception from informed consent (EFIC) research protocol begins, the dissemination of information in the community(ies) in which the study will take place and from which the subjects will be drawn sufficient to allow a reasonable assumption that the communities are aware that the study will be conducted, and its risks and benefits; and (b) after the study has been conducted, the dissemination of information to the community(ies) in which the study was conducted and to scientific researchers sufficient to describe the study's demographic characteristics and the study's results.

Surrogate Permission

Permission for an individual to participate in research given by an appropriate surrogate (e.g., next of kin – spouse, parent, child, sibling) when an individual is assessed as not capable of providing fully informed and legally effective consent and state law does not define the appropriate LAR for research purposes.

Test Article

Any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under 42 U.S.C. §§ 262 and 263b-263n.

Therapeutic Window

The time period, based on available scientific evidence, during which the intervention under investigation in the planned emergency research might reasonably produce a demonstrable clinical effect.

Policy Sections

200.1 Informed Consent Requirements

The consent process must be conducted in a manner and language which is understandable to the prospective participant or his/her legally authorized representative (LAR) and which provides the prospective participant or LAR with sufficient opportunity to consider whether or not to participate. The informed consent process must be designed to minimize any potential for coercion or undue influence. No informed consent process may contain any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor the institution or its agents from liability for negligence. (45 CFR §46 116; 21 CFR §50.20)

The following eight basic elements of informed consent are required to be provided in the course of the consent process (45 CFR §46 116). The investigator must ensure that these elements and any others required by the IRB are presented in such a manner as to facilitate the prospective participant's ability to understand involvement in the research study. In some cases, the investigator may need to proactively query the participant's understanding of the consent materials.

1. A statement that the study involves research, an explanation of the purpose of the research, the expected duration of participation, a description of the procedures, and identification of the experimental procedures.
2. A description of any reasonably foreseeable risks or discomforts.
3. A description of any benefits to the participant or to others that might be reasonably expected from the research.
4. Disclosure of appropriate alternative procedures or courses of treatment, if any, that may be advantageous to the participant.
5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained including as appropriate: (a) what records may be examined by the sponsor, the IRB, other University personnel, the Food and Drug Administration (FDA), or other regulatory agencies, (b) whether or not the data collected will be retained, and, if so, for what purpose and for what period of time, or when the data will be de-identified and/or destroyed, (c) what procedures will be put in place to ensure that unauthorized individuals will not have access to this information, and (d) the limitations (if any) to these confidentiality procedures such as legal reporting requirements for specific diseases and in the case of suspected child or elder abuse.
6. For research involving more than minimal risk, an explanation as to whether or not any compensation and medical treatment are available if injury occurs to the participant and if so, what they consist of or where further information may be obtained. The explanation contained in the informed consent document must be consistent with the terms of the applicable clinical trial agreement for the research, if any. *(Note: The consent form language is often more general than what is written in the clinical trial agreement in order to ensure that the language is understandable to subject.)*
 - a. For research funded by certain funding agencies (e.g., the Department of Defense or its components), stricter requirements for research related injuries may apply.)
7. Identification of whom to contact for answers to questions about the research and the research participants' rights including whom to contact when the investigator may be unavailable or to discuss any other questions, complaints or concerns and whom to contact if the participant sustains a research-related injury.
8. A statement that research participation is voluntary, that the participant may discontinue participation at any time, and that the participant's refusal to take part or withdrawal will not involve a penalty or loss of benefits to which the participant is otherwise entitled.

When appropriate, the following additional elements of informed consent must also be adequately provided to the participant or representative:

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) which are unknown or currently unforeseeable.
2. Anticipated circumstances under which the volunteer's participation may be terminated by the investigator without regard to the participant's consent or willingness to continue to participate.
3. Any additional costs to the participant that may result from taking part in the research, including whether or not such costs may be billed to a third party payor. Such information must be consistent with the terms of the applicable clinical trial agreement for the research, if any. *(Note: The consent form language is often more general than what is written in the clinical trial agreement in order to ensure that the language is understandable to subject.)*
4. The amount and schedule of payments for participating in the research. Such information must be consistent with the terms of the applicable clinical trial agreement for the research, if any. *(As noted above, the consent form language is often more general than what is written in the clinical trial agreement in order to ensure that the language is understandable to subject.)*
5. The consequences of the participant's decision to withdraw from the research and procedures for safe and orderly termination of participation, if applicable.
6. A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue to participate will be provided to the participant.

7. The approximate number of participants involved in the study.
8. *If the study is registered on [clinicaltrials.gov](http://www.ClinicalTrials.gov):* A description of this clinical trial will be available on <http://www.ClinicalTrials.gov> as required by U.S. law. This web site will not include information that can identify you. A most, the web site will include a summary of the results. You can search this web site at any time.

Note: The IRB has the authority and reserves the right to determine whether the information contained in informed consent documents is adequate to meet any of the above listed elements.

200.2 Documentation of Informed Consent

Unless waived by the IRB in accordance with sections 200.3, 200.4 and 200.5 below, the consent information will be provided to the participant in writing and will be signed by the participant or their legally authorized representative (LAR) or surrogate. For a research project that is also under the purview of the Food and Drug Administration (FDA) regulations (21 CFR §50), the individual obtaining informed consent must also sign and date the form. Such informed consent forms must be marked with the approval and expiration date as determined by the IRB. Participants must be provided with a copy of the consent document.

Consent documentation may be provided through an Informed Consent Form (ICF) that includes all the required elements of consent and is signed by the participant, or through the use of a short form consent document, or documented through audio or video recording. Short form consent documents must include an IRB approved written summary (typically the English version of the full consent document) which includes all of the required elements of consent, as well as a short form document (written in a language understood by the participant) which indicates that the elements of consent were provided orally to the participant or his/her LAR/surrogate. The summary document is to be reviewed with the participant or his/her LAR/surrogate in the language understood by the participant, using an interpreter, if needed. The short form must be signed by both the participant or his/her LAR/surrogate and by a witness to the oral presentation. The interpreter may serve as witness for the short form. If the study requires a witness signature, the witness and the individual providing consent must sign the IRB approved summary. A copy of both the short form and summary must be provided to the participant or his/her LAR/surrogate (see template consent forms at [Yale HRPP website](#)). The informed consent document may serve as the written summary.

200.3 Waiver of Informed Consent

The IRB may approve a consent procedure that omits or alters some or all of the elements of informed consent. The IRB may alter or waive the requirement to obtain informed consent only if the IRB finds and documents that:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine (45 CFR §46.116(c)):
 - public benefit or service programs;
 - procedures for obtaining benefits or services under those programs;
 - possible changes in or alternatives to those programs or procedures; or
 - possible changes in methods or levels of payment for benefits or services under those programs;
 AND
 - the research could not practicably be carried out without the waiver or alteration;
 - the research is not FDA-regulated

OR

2. The research meets the following criteria (45 CFR §46.116(d)):
 - involves no more than minimal risk to the participants;
 - the waiver or alteration will not adversely affect the rights and welfare of the participants;
 - the research could not practicably be carried out without the waiver or alteration; and
 - whenever appropriate, the participants will be provided with additional pertinent information after participation, and
 - The research is not FDA-regulated (21 CFR §56.109)

OR

3. Exceptions from the informed consent requirements are justified for emergency research pursuant to 21 CFR §50.23 and §50.24.

NOTE: When following FDA regulations, the IRB is prohibited from waiving or altering the consent process.

200.4 Waiver of Documentation of Informed Consent

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants (45 CFR §46.117(c)) if it finds and documents the following:

1. That the research (or a specific part of the research, such as recruitment) presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. This condition also applies to FDA regulated research (21 CFR § 56.109(c)(1)). OR
2. That 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. In such a case, each participant will be asked whether the participant wants documentation linking the participant to the research, and the participant's wishes will govern. This condition is not applicable to FDA regulated research.

In situations in which the documentation requirement is waived, the IRB reviews a written description of the information that will be provided to participants to ensure that the information provided to participants includes all required and appropriate additional elements of consent disclosure, and may require the investigator to provide participants with a written statement or information sheet regarding the research.

Other restrictions may apply to research funded by the Department of Defense or its components (See 100 PR 4, Department of Defense Supported Research).

200.5 Non-English Speaking and/or Illiterate Participants

When some or all of the prospective participants do not speak English, the participant must be provided information throughout the study in their own language. This includes both documentation and ongoing dialogue. Documentation must take the form of a written consent document drafted in language understandable to the participant that embodies all the elements necessary for legally effective informed consent.

Alternatively, oral presentation of informed consent information may be used with persons who do not speak (or cannot read) English. In such cases, the oral presentation and the short form written document must be in a language readily understandable to the participant and the English language informed consent document approved by the IRB may serve as the basis for the oral presentation. When using the short form consent:

1. The short form consent must state that the elements of disclosure required by regulation have been presented orally to the participant or his/her Legally Authorized Representative (LAR).
2. The form must embody the basic and appropriate additional elements of disclosure.
3. There must be a witness to the oral presentation. The interpreter may serve as a witness.
4. For participants who do not speak English, the interpreter presenting the consent information must be conversant in both English and the language of the participant.
5. The participant or his/her LAR must sign the short form consent. If the study is FDA-regulated, the participant or LAR must also date the short form consent (21 CFR §50.27(a)).
6. The interpreter obtaining consent and the witness (who may be the same person) must sign the short form consent and the summary (full consent document in English).
7. The researcher must sign the summary (full consent document in English).
8. Copies of the short form and the summary (full consent document) must be given to the participant or his/her LAR, as appropriate.

The IRB must receive and approve prior to their use, all foreign language versions of the short form document and any other translated documents presented to the participants.

See also 200 GD2: Inclusion of Non-English Speaking Participants in Human Research.

200.6 Studies Involving Deception

Studies which will not fully disclose the purpose, nature or other aspects of the study to potential participants at the time of informed consent may do so only when the deception is deemed necessary by the IRB for the conduct of the research (see also 200 GD 1: Guidance on Deception in Human Research).

The IRB may approve a consent process involving incomplete disclosure of the eight basic elements of consent if the requirements for a waiver of consent described in section 200.3 above are met.

200.7 Ongoing Consent Requirements

As part of the consent process, investigators conducting studies which involve multiple interactions with participants should confirm the participant's willingness to continue throughout the course of the study and offer participants the opportunity to ask questions and/or voice concerns at any time during the study.

Investigators are required to modify consent documents or create addenda to consent forms whenever the Investigator becomes aware of new information which may impact a participant's willingness to continue involvement in the research. Investigators may become aware of new information arising from the study itself or from publications related to the research or from the study sponsor. Revised consent information must be approved by the IRB prior to presenting the materials to participants.

200.8 Separate Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) Required

Protocols under FDA oversight will not be approved by the IRB without a separate IND or IDE (as applicable) as required by the FDA. Products that have current INDs or IDEs must also provide a separate IND/IDE for the purpose of the planned emergency research, because of the exception to the informed consent requirement. Hence the IND/IDE submission may not be an amendment to an existing IND/IDE, and must clearly identify the study as including subjects who are unable to consent. Investigators should provide a copy of the separate IND/IDE to the IRB.

200.9 Emergency Research with Exception From Informed Consent

Federal regulations recognize a very narrow exception under which an IRB may approve a study which is greater than minimal risk or which involves FDA regulated products for which informed consent will not be obtained. This exception is limited to planned research in emergency situations where subjects cannot give informed consent due to a life-threatening medical condition and for which the legally authorized representative or other appropriate surrogate cannot be reached within the therapeutic window. Investigators should be aware that such planned emergency research involves an extensive application process that involves prior community consultation and, when applicable, submission of a separate protocol to the FDA under a new IND or IDE number before the research can be approved.

The Institutional Review Board (IRB) will only approve planned emergency research at Yale in accordance with the applicable regulatory requirements of the Food and Drug Administration (FDA) at [21 CFR §50.24](#) and the Department of Health and Human Services (DHHS) Emergency Research Consent Waiver effective November 1, 1996 pursuant to [45 CFR §46.101\(i\)](#). Research that is subject to FDA regulations will be carried out under an FDA Investigational New Drug (IND) application or an FDA Investigational Device Exemption (IDE), and will be reviewed by the IRB in accordance with FDA regulations. Research that is not subject to FDA regulations but is federally funded or supported will be reviewed under the DHHS Waiver provisions.

See also 200 PR 2: Exception From Informed Consent (EFIC) Research

Special Situations/Exceptions

The informed consent requirements described here are not applicable to and do not limit the ability of a physician to provide treatment or emergency medical care.

Related Information

HIPAA Policy 5039: Policy On Use And Disclosure Of Protected Health Information For Research Purposes

100 PR 4, Department of Defense Supported Research

200 PR 1: Informed Consent for Research Participation: Competent Adult Participants

[200 PR 2: Exception From Informed Consent \(EFIC\) Research](#)

200 GD 1: Deception in Human Research

200 GD 2: Guidance on the Inclusion of Non-English Speaking Participants in Human Research

200 FR 1: Consent Template – Biomedical Research

200 FR 2: Consent Template – Social/Behavioral/Educational Research

- 200 FR 3: Sample Short Form Consent
- 200 CH 1: Human Investigation Committee Informed Consent Checklist
- 200 CH 2: Human Subjects Committee Informed Consent Checklist
- 200 CH 3: Human Subjects Committee Waivers of Consent and Authorization Checklist
- 310 PR.1 Informed Consent in Research Involving Children
- 310 FR.1: Assent Template
- Policy 340: Participation of Individuals with Impaired Consent Capacity
- 340 PR 1: Assessment of Capacity to Consent
- Policy 600 Use of Investigational New Drugs and Devices In Human Research
- 600 PR 1: Emergency Use of an Investigational New Drug (IND) or Device (IDE)
- 600 FR 2: Informed Consent Document for Emergency Use Investigational Drug or Device.

Contacts

Subject	Contact	Phone/e-mail
Informed Consent Policy and Procedures	Human Investigation Committee and Human Subjects Committee	203-785-4688 hrpp@yale.edu human.subjects@yale.edu

Roles and Responsibilities

[Human Research Protection Program](#) (HRPP)

The Human Research Protection Program is responsible for oversight of human research protection through ongoing education, monitoring, and evaluation of all parties involved in the conduct of human research.

Human Investigation Committee (HIC)

The HIC I, HIC II, HIC III and HIC IV serve as the four Institutional Review Boards or IRBs for biomedical human research conducted at Yale University.

Human Subjects Committee (HSC)

The HSC serves as the Institutional Review Board for social, behavioral and educational human research at Yale University.

Revision History

Modified: 04/01/2009; 05/04/2010; 05/06/2010; 05/23/2012; 11/8/2012; 01/27/2013; 05/22/2013; 01/09/2017; 02/07/2017