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# Yale University Institutional Review Boards

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## IRB Policy 200 Informed Consent for Human Research

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### 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.

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### Policy Statement

Investigators must obtain either 1) the legally effective informed consent of the participant or the participant's legally authorized representative or 2) IRB approval for a waiver of informed consent prior to a participant becoming involved in research in accordance with 45 CFR 46.116 and 21 CFR 50.

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### 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 can not be obtained and receive IRB approval for a waiver of consent. The IRB is responsible for reviewing the planned informed consent process to ensure that it meets the ethical and regulatory requirements for fully informed and voluntary consent to participate in research.

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### Definitions

#### 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 subject is the equivalent of a family relationship. [21 C.F.R. § 50.3(m)]

### **Independent Data Monitoring Committee (DMC)**

An independent group of experts without Yale affiliation, established by the sponsor of a research protocol to assess periodically the progress of a study (the safety data and the critical efficacy endpoints), and to recommend to the sponsor whether to continue, modify, or stop a trial. In some instances, the IRB may permit people with Yale affiliations to be members of a DMC so long as the majority of the membership is not affiliated with Yale. Also known as a data and safety monitoring board (DSMB).

### **Legally Authorized Representative (LAR)**

An individual, or judicial or other body, authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

### **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.

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## **Policy Sections**

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

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### **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.

The following eight basic elements of informed consent are required to be provided in the course of the consent process. 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 subject 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 subject.
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. (Note that for research funded by 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.
4. The amount and schedule of payments for participating in the research.
5. The consequences of the participant's decision to withdraw from the research and procedures for safe and orderly termination of participation.
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

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## **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. For a research project that is also under the purview of the Food and Drug Administration (FDA) regulations, 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) including all the required elements of consent which is signed by the participant or through the use of a short form consent. Short form consent documents must include an IRB approved written summary to

be read to the participant or his/her LAR which includes all of the required elements of consent as well as a short form (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. The short form must be signed by both the participant or his/her LAR and by a witness to the oral presentation. 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 (see template consent forms at <http://info.med.yale.edu/hic/forms/index.html>).

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### **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;

OR

2. The research meets the following criteria (45 CFR 116(d)):
  - involves no more than minimal risk to the subjects;
  - the waiver or alteration will not adversely affect the rights and welfare of the subjects;
  - 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.

OR

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

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### **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 if it finds and documents the following:

1. That the research 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. 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 subjects 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.

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### **200.5 Non-English Speaking and/or Illiterate Participants**

When some or all of the prospective participants do not speak English, 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 summary.

The IRB must receive all foreign language versions of the short form document and any other translated documents presented to the participants as a condition of approval.

See also Guidance on Inclusion of Non-English Speaking Participants in Human Research.

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### **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 Guidance on Deception in 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.

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### **200.7 Ongoing Consent Requirements**

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.

Investigators conducting studies which involve multiple interactions with participants should consider confirming 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.

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### **200.8 Record Keeping and Notification Requirements**

The signed informed consent forms will be kept in a secure location for a minimum of three (3) years (or more if required by the FDA or a sponsor) following completion of the research.

Studies which are reviewed in accordance with section 0000.4 above and which are not deemed to meet the requirements for exception to informed consent must be reported by the IRB to the PI and to the sponsor. The sponsor is required to notify the FDA as well as other investigators and IRBs involved in this or other substantially equivalent studies by this sponsor.

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## 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.

Exception to the consent requirements described herein may be granted for planned emergency research as described in IRB Policy 620: Planned Emergency Research.

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## Related Information

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

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

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.

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## Contacts

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

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**Roles and Responsibilities**

Human Investigation Committee:

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

Human Subjects Committee

The HSC is responsible for the review and oversight of social and behavioral research involving human subjects.

**Revision History**

Modified 04/01/2009, 05/04/2010, 05/06/2010