



Informed Consent

Informed Consent Guidelines:

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What is Informed Consent?

Informed consent is one of the primary ethical considerations in research involving human participants. The principle of respect for persons requires that people be given the opportunity to choose what will or will not happen to them. This opportunity is provided when standards for informed consent are satisfied.

The Belmont Report describes the purpose of

consent as the mechanism to ensure participants understand the research study and voluntarily agree to participate. Freely given informed consent must be obtained from every decisionally capable, potential study participant before any research procedures begin.

Consent should be considered as a process, and not just a form that

participants must sign. Dr. Ruth Faden, Executive Director of the John Hopkins University Bioethics Institute stated:

"...The idea of informed consent suggests that a patient or subject does more than express agreement with, acquiesce in, yield to, or comply with an arrangement or a proposal. He or she actively authorizes the proposal in the act of consent."

Regulatory Requirements for Obtaining Consent

There are federal requirements that mandate the form of consent that must be obtained, elements that should be present in a consent explanation, and who may obtain and give consent for research purposes.

Federal Requirements:

Informed consent must meet regulatory requirements of the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA). Under these regulations, there are four general

requirements for informed consent.

Consent Documentation

Unless the requirement for consent is waived, investigators may involve human participants in research only with the consent of the participant or his/her authorized representative.

Voluntary Participation

The potential study participant must be given enough time to consider whether or not to participate in the study, and the possibility of

coercion or undue influence should be minimized.

Understandable Language

Written or oral consent explanations must be in language understandable to the potential study participant or his or her authorized representative.

Waiver of Rights Prohibited

The consent (written or oral) may not include language through which the participant or their representative is made to waive the participant's legal rights or releases the investigator, the sponsor, the institution or its agents from liability.

What is the Consent Process?

There are two possible processes: Consent obtained using a written IRB approved consent document, or an oral consent process approved by the St. Vincent IRB.

Written informed consent document process: Generally, the IRB requires consent to be documented by a written consent form approved by them prior to use. Unless waived by the

IRB, the written consent form must be reviewed with the participant (or the representative), and signed and dated by the participant or the representative before any research procedures (including screening) or research data collection begins.

Oral consent process: Oral consent may be obtained under very limited circumstances and it must be IRB approved.

The IRB may approve the request under two circumstances: a) 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 in confidentiality; **or** b) the research presents no more than minimal risk and involves no procedure for which written consent is normally required outside the research context.



“The principal investigator must ensure that informed consent from each potential research participant is obtained...”

Who May Obtain Informed Consent?

The principal investigator (PI) for an IRB-approved project is ultimately responsible for conducting the study. The PI must ensure that informed consent from each potential research participant is obtained and documented using the method approved by the IRB. Informed consent must be obtained before an individual participates in any aspect of the study.

The PI does not have to obtain the consent personally. Any co-investigator listed on the IRB application form may obtain consent. In addition, the IRB application may include consent designees who are part of the research study team and are authorized to obtain consent. All individuals authorized to obtain informed consent from

study participants must be knowledgeable about the study.

The prospective participants or their representatives must be given sufficient information to make an informed decision whether or not they want to participate and must have the opportunity to have their questions answered.



Who May Give Informed Consent?

Adults: In the U.S., adults (as defined by state law) may provide consent for themselves. In Indiana adults are defined as age 18 or older.

An exception is adults judged to be incompetent to give consent. In this case, federal regulations

require that the participant’s legally authorized representative give consent.

Children: In Indiana, anyone under 18 years of age, with few exceptions, is considered a child. The federal regulations require that any person including

a child, who participates in research must do so voluntarily.

Generally speaking, the investigator must ask for the assent of the child and from the child’s parent(s) or legal representative.

Special Considerations

Pregnant Women:

Under federal regulations, there are special considerations if pregnant women, fetuses or neonates will be involved in research. The federal regulations provide a list of conditions that must be met for this research. Investigators should consult the regulations prior to conducting research with this population.

Non English-Speaking Subjects:

The DHHS regulations require that informed consent be presented “in language understandable to the subject.” Subjects that do

not speak English should be presented with a consent document written in a language understandable to them.

Alternatively, federal regulations permit oral presentation of informed consent in conjunction with a written short form document (stating the elements of consent have been presented orally) and a written summary of what is presented orally. A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary.

When this procedure is used, a) oral presentation

and written short form document should be in a language understandable to the subject; b) the IRB-approved English language informed consent document may serve as the summary; and c) the witness should be fluent in both English and the language of the subject.

Illiterate English Speakers and Those With Physical Disabilities:

A person who can understand and comprehend spoken English, but is physically unable to talk or write, can be entered into a study if they are competent and able to indicate approval or disapproval by other means.



There are special considerations for pregnant women participating in a research study.

How Does HIPAA Affect Consent?

The Health Insurance Portability and Accountability Act (HIPAA) affects the research consent process by giving the participant more rights and protections about the use a disclosure of protected health information (PHI).

The investigator must inform participants of these new rights. The participant needs to understand these rights so that he or she can willingly give permission for the researcher to proceed. Without that permission, the participant cannot be enrolled in the study, and the investigator

cannot use the subject’s protected health information.

HIPAA gives each participant these rights, which must be included in the IRB approved Privacy Authorization and signed by each participant:

- The right to know what types of protected health information the research plans to use or disclose,
- The right to know how the researcher will use or disclose that information,

- The right to know who may have access to that information for study purposes,
- The right to know to whom that information might be disclosed outside of the research study,
- The right to know the expiration date, if any, of the authorization,
- The right to revoke the authorization at any time.

If the participant decides later to withdraw from the study data obtained up until that withdrawal may be used in the study.

“Basic research is what I am doing when I don’t know what I am doing.”

Wernher von Braun

Can Informed Consent Be Waived?

An investigator may submit, as part of the initial application to the IRB, a request to waive the requirement to obtain consent from participants. Waiver of consent is allowed under DHHS and FDA regulations.

Under the federal regulations, the IRB may approve a consent

procedure which does not include, or which alters, some or all of the elements of informed consent, or waives the requirements to obtain informed consent.

The IRB must find and document that: a) the research involves not more than minimal risk to the participants; b) the

waiver or alteration will not adversely affect the rights and welfare of the participants; c) the research could not practicably be carried out without the waiver or alteration; and d) whenever appropriate, participants will be provided with additional pertinent information after participation.

“The idea of informed consent suggests that a patient or subject does more than express agreement... He or she actively authorizes the proposal in the act of consent.”

Ruth Faden

How To Know If Participant Understands

For participation in a study to be truly voluntary, the participant must understand what he or she is agreeing to do. The investigator must present the information to the participant in an understandable way, and then assess whether the participant did understand the information.

Readability: The St. Vincent IRB believes that the reading level of the informed consent document should be no higher than an 8th grade level. If the study’s technical nature makes this difficult, the investigator can discuss this problem with the IRB.

To test the level and clarity of the consent form: a) read the form out loud to colleagues/staff and test it on a target audience; b) use the word processing tool available to check the grade level (see page 6 for directions.)

When and Where Should Consent Be Obtained?

Participants should have adequate time to review the consent form, ask questions about the research, and consult with family, friends or others (if desired) before signing the form. The application submitted to the IRB must include details of where and when consent will be obtained. For projects approved by the St. Vincent IRB, the consent form should be signed by both the participant and the PI at the time consent is obtained.

Although information about the research study may be given in groups or individually, the decision to participate should be an individual, private decision. In addition, the consent interview should be held in a private, neutral setting, such as a private office or room.

Web Based Studies: The agreement button must contain a message, or there must be a separate statement right above the button in which clicking on it confirms the participant

has read the statement, printed a copy for their file, agrees to participate in the study, and accepts that personal information will be electronically supplied to the researcher to document their participation. Also there must be a mechanism by which information is returned to the researcher that identifies the person who is participating. This document must be kept by the researcher, for at least the standard three years beyond the end of the study.

“The time to stop talking is when the other person nods his head affirmatively but says nothing.”
Anon.

Basic Elements for a Written Informed Consent

The St. Vincent Hospitals and Health Services Institutional Review Board requires investigators to include the consent requirements established by DHHS and FDA regulations.

Required Elements:

- Statement that the study involves research
- Reason for selection as possible participant
- Purpose of study
- Description of procedures
- Duration of participation
- Identification of experimental procedures
- Description of risks
- Benefits statement
- Alternative procedures
- Confidentiality statement
- Compensation statement
- PI information
- IRB statement and telephone number.
- Withdrawal statement
- No prejudice statement
- Cost to subject
- Incentive
- Statement that subject given a copy of form
- Simple, lay language
- Pregnancy statement
- Significant new findings statement
- Circumstances under which participation may be terminated
- Consequences of patient's withdrawal
- Signature of person other than investigator enrolling participants
- Signature of parent or legal representative; minor assent (if age ≥ 7 years)

Possible Additional Elements:

- The approximate number of participants

Additional Documentation:

- St. Vincent Hospital requires all study participants or their legal representative sign a **Patient's Bill of Rights**



Confused? Don't worry, help is available.

Drafting Tips

- Use words familiar to the non-medical reader
- Check to see that terminology is consistent throughout the form.
- Write short, simple, and direct sentences.
- Keep paragraphs short and limited to one idea.
- Use active verbs.
- Use the second person (you) not third person (the participant) to increase personal identification.
- Check the text to see if each idea is clear and logically sequential.
- Highlight important points; use underline, bold, boxes rather than italics or all caps.
- Avoid repetition.
- Avoid abbreviations and acronyms.
- Avoid large blocks of printed text.
- If at all possible, keep words to 3 syllables or fewer.
- Use graphics or tables if they will help clarify procedures.

"Informed consent is not just a form or a signature, but a process of information exchange that takes place between the prospective participant and investigator before, during, and sometimes after the study."

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We're on the G Drive!

See us at:

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Word Processing Readability Statistics

Microsoft Word:

1. On **Tools** menu, click **Options**, then click **Spelling & Grammar** tab.
2. Select **Check grammar with spelling** check box.

3. Select the **Show readability statistics** check box then click **OK**.
4. Click **Spelling and Grammar** on the **Standard** toolbar.

Word Perfect:

Block the text, click **Tools>Grammatik>Option>Analysis>Readability**.

St. Vincent Informed Consent Templates

Individual Informed Consent Document

This template is required for:

- Adults (aged ≥ 18 years), capable of understanding.
- Family members or legal guardians for instances in which the subject lacks the capacity to consent.
- The template applies to both 'minimal risk' and 'more than minimal risk' research.
- For non English-speaking participants and those unable to read English, use this form and the *Short Form Consent Document*.

Simplified Informed Consent Document

This template is required for participants with an altered mental status, or who are not capable of understanding the *Individual Informed Consent Document*. Depending on the nature of the study, an *Informed Consent Document* signed by a family member may also be required.

Consent Forms for Minors

Depending on age of the subject, the following consent documents must be used:

- Ages 1-12 years old: *Parental Consent Template*

- Ages 7-12 years old, capable of assenting:

- *Parental Consent Template and*
- *Child Assent Template*

- Ages 13-17 years old: *Parental and Young Adult Template*.

Consent Form for Research Involving Illiterate English Speakers and Those With Physical Disabilities

Modify the appropriate form by including the method used for communication and the means by which the participant communicated agreement.

About Our Division...

As the Division of Health Services Research and Development, our mission is to provide and support clinical research that focuses

on patient-centered care and is consistent with the core values of St. Vincent Hospitals and Health Services.

We are dedicated to offering technical

assistance, in proposal development and writing, grant acquisition, and in the execution of research to residents and faculty at St. Vincent Hospital.