What is the "key information" requirement in the 2018 Common Rule?

The Department of Health and Human Services issued revisions to the existing Common Rule, the regulations governing human subjects research including consent process and documentation, in 2018. **The effective date for the revised Common Rule was January 21, 2019**.

As it is recognized that research consent forms are often lengthy and complex, under the revised Common Rule consent forms for regulated research are now required to begin with a "concise and focused" presentation of the key information that will likely help someone considering research participation to make a decision about whether or not to participate in a study. As a result of this and other additional requirements, the IRB office prepared a new consent form template. This template was available as of December 2018 and most recently updated in July April 2025.

The requirement for a concise and focused presentation of key information is mandatory for any federally funded research newly reviewed by the IRB. New submissions to the IRB should use the new template.

What is the 2018 Common Rule requirement to post consent forms?

The revised Common Rule requires at 45CFR 46.116(h) that for any clinical trial conducted or supported by a Common Rule department or agency, one consent form must be posted on a publicly available federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit (as required by the protocol) by any subject. The consent form must have been used in enrolling participants in order to satisfy this new provision.

"Clinical Trial" is defined in the revised Common Rule as "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes."

Currently, two publicly available federal websites will satisfy the clinical trial consent form posting requirement:

- ClinicalTrials.gov and
- a docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021).

Please see OHRP's website for specific instructions as to how documents are posted on those two sites.
https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/index.html

What are the required consent form elements?

DHHS regulations require certain elements be present in a consent form. Additional elements are required for more than minimal risk research and FDA-regulated research.

General requirements for informed consent [from 45 CFR 46.116]

- Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
- An investigator shall seek consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
- The information that is given to the subject or the representative shall be in language understandable to the subject or representative.
- The prospective subject or representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
- The informed consent (and associated documentation) must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
- Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or representative' understanding of the reasons why one might or might not want to participate.
- No consent may include any exculpatory language through which the subject or the representative 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.
- Any applicable federal, state, or local laws which require additional information to be disclosed to a subject in order for the consent to be legally effective should be followed.
- In addition, the following information should be provided to the subject:
    - statement that the study involves research
    - explanation of the purposes of the research
    - explanation of the expected duration of the subject's participation
    - description of the procedures to be followed
    - identification of any procedures which are experimental
    - description of any reasonably foreseeable risks or discomforts to the subject
    - description of any benefits to the subjects or to others which may reasonably be expected from the research
    - disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
    - statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
    - explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights
    - explanation of whom to contact in the event of a research-related injury to the subject

  - statement that participation is voluntary
  - statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled
  - statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled
  - for research of more than minimal risk, an explanation as to whether any compensation and any medical treatments are available if injury occurs and if so, what they consist of, or where further information may be obtained
  - for research involving identifiable private information or identifiable biospecimens:
    - statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies without additional informed consent, if this might be a possibility
      -or-
    - statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

If you have not requested a waiver or alteration of consent, the above conditions must be upheld.

- When appropriate, the following elements should also be provided to the subject:*
  - statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable
  - anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or representative's consent
  - any additional costs to that subject that may result from participation in the research
  - consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
  - statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject
  - approximate number of subjects involved in the study
  - statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in the commercial profit
  - statement regarding whether any clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
  - for research involving biospecimens, whether the research will (if known) or might include whole genome sequencing

** Note that the IRB Committee makes the decision regarding appropriateness of the information to be included in the consent form, and in most cases asks that many or all of these "additional" elements be included.*

In addition to the above required elements, FDA additionally requires:

- Investigator will inform any potential subjects that (if applicable) the drugs are being used for unapproved purposes [21CFR312.53]
- For applicable clinical trials, the following text must be included:
  "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. At most, the Web site will include a summary of the results. You can search this Web site at any time." [21CFR50.25(c)]
- Consent form notes the possibility that the Food and Drug Administration may inspect the records [21CFR50.25(a)]
- Date and time for signature lines [21CFR50.27]

Is there a Consent Form Template I can use?

BSD/UCMC consent/authorization form template (November 2025 version)

Previous version:
BSD/UCMC consent/authorization form template (November 2023 version)

Can I use a template consent form prepared by an external sponsor?

In efforts to streamline the IRB submission process, we are now offering a guidance document that may be utilized to customize sponsor or cooperative group consent forms to ensure that all local requirements are met. We recognize that significant effort is exerted into the creation of these documents and that use of a University of Chicago specific template is not necessary. The goal is to ensure that a consent form is presented to potential research participants that embodies all of the elements of informed consent while ensuring UChicago specific criteria are met. In working with our research partners, we have developed a document that provides instruction for customizing sponsor or cooperative group consent forms to include all UChicago required elements.

Guidance - Customizing Research Consent Forms for BSD/UCMC IRB review

Is there an Assent Form Template I can use?

The regulations at 45CFR46 do not define required elements for an assent process or assent form. It is expected that pertinent information will be presented to child subjects. The following form has been prepared as an example of simplified language that can be used when documenting assent of a child subject.

Assent form template

What are the HIPAA authorization required elements?

Under the HIPAA regulations, the following elements must be included and/or described in an authorization form in language understandable to a subject.

- The Protected Health Information (PHI) to be used or disclosed, described in a specific or meaningful way
- Who will use or disclose the PHI
- To whom the PHI will be disclosed
- A description of each purpose of the requested use or disclosure
- An expiration date/expiration event that relates to the purpose of the use or disclosure
- A statement of the individual's right to revoke the authorization in writing and the exceptions to the right to revoke, together with a description of how the individual may revoke the authorization
- A statement that information used may be subject to re-disclosure by the recipient and no longer be protected by this rule [HIPAA]
- Signature of the individual and date, and if the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual
- Statement of the consequences to the individual of a refusal to sign

The authorization must be written in plain language.

A signed copy must go to the individual.

An authorization may be combined with a research consent form.

Does our site have a policy on research-related injury?

For studies that involve more than minimal risk, federal regulations (45CFR46.116/ 21CFR50.25) require that the consent process include "an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs, and, if so, what they consist of, or where further information may be obtained." As the wording in consent forms is intended to inform subjects about studies, not to limit liability, the University of Chicago Biological Sciences Division has set the following policy to ensure that all compensation for injury statements meet both Federal and Institutional standards.

A. Commercial Sponsor Statements

   It is the policy of the University of Chicago and the Medical Center that commercial sponsors of clinical research at the Medical Center must agree to pay for treatment of injuries that are the direct result of the administration of a study drug or device, or any

study procedure required to be performed in the study. This obligation of commercial sponsors is limited to research protocols designed or supplied by the commercial sponsor. The University and the Medical Center's obligations for treatment of research injuries, as expressed in the language below and in Medical Center's Policy on Research-Related Injuries, will be secondary to the commercial sponsor's obligations under the clinical trial or other sponsored research agreement. University Research Administration is responsible for implementation of this requirement in commercially-sponsored research agreements.

The obligations of commercial sponsors to subjects who suffer a research-related injury must be expressed in the written consent form using the following language, which should immediately precede the applicable statement concerning the Medical Center's obligations discussed below:

The sponsor of the study, [insert sponsor name], has agreed to pay for the care of certain injuries directly resulting from this research. If you think that you have suffered a research-related injury, you must contact [insert PI/study doctor name] right away. The study doctor can help you obtain more information about the sponsor's agreement to pay for research-related injuries.

Exceptions to this consent form language may be considered by the IRB, in consultation with legal counsel, on a case by case basis if requested by the commercial sponsor, but are not looked on favorably, and must satisfy the requirements of the Medical Center's Policy on Research-Related Injuries.

B. University/Medical Center Statements

One of the following University of Chicago BSD/ University of Chicago Mecical Center statements must be included (without any modifications) in the written consent form, immediately following the commercial sponsor statement described above (if applicable). The appropriate statement should be chosen based upon the subject population being recruited. The IRB recognizes that for studies that recruit both individuals with a disorder and condition and healthy controls, the use of both statements may be required. However, a separate consent form should be drafted for each of the populations with the appropriate costs statement included.

1. For studies with therapeutic intent for the subject (including Phase I and II trials):

If you suffer an unanticipated injury as a direct result of this research and require emergency medical treatment, you may receive such emergency medical treatment at the University of Chicago Medical Center, UChicago Medicine Ingalls Memorial Hospital, UChicago Medicine Northwest Indiana, UChicago Medicine AdventHealth Bolingbrook, UChicago Medicine AdventHealth Glen Oaks, UChicago Medicine Advent Health Hinsdale, or UChicago AdventHealth LaGrange at no cost to you. You must notify _____ [insert PI/study doctor name] as promptly as possible after your injury in order to receive this care. An injury is "unanticipated" if it is not one of the known

effects of a study drug, medical device or procedure, and is not the result of your disease or condition. The costs of any non-emergency care for such an injury will be billed to you, your insurance [or the study sponsor] in the ordinary manner. If you think that you have suffered a research-related injury, you must let _____ [insert PI/study doctor name] know right away.*

In the event of an emergency, you should seek care at the nearest emergency room or call 911.

* Include only if study is commercially sponsored and the sponsor designed or supplied the protocol.

2. For studies involving healthy volunteers:

If you suffer an unanticipated injury as a direct result of this research and require emergency medical treatment, you may receive such emergency medical treatment at the University of Chicago Medical Center, UChicago Medicine Ingalls Memorial Hospital, UChicago Medicine Northwest Indiana, UChicago Medicine AdventHealth Bolingbrook, UChicago Medicine AdventHealth Glen Oaks, UChicago Medicine Advent Health Hinsdale, or UChicago AdventHealth LaGrange at no cost to you. Costs of related non-emergency care for an unanticipated research injury will be covered if that care is provided at the University of Chicago Medical Center. You must notify _____ [insert PI/study doctor name] as promptly as possible after your injury in order to receive this care. An injury is "unanticipated" if it is not one of the known effects of a study drug, medical device or procedure. If you think that you have suffered a research related injury, you must let _____ [insert PI/study doctor name] know right away.

In the event of an emergency, you should seek care at the nearest emergency room or call 911.

How do I consent someone using Proxy Consent?

Conducting studies in situations where the patient is unable to consent to participation in a research project present challenges to the traditional consent process. Such situations include many protocols in the Intensive Care Unit, the Emergency Department, the Psychiatry Department, and those involving patients with dementia. Amendments to the Health Care Surrogate Act and the Medical Patient Rights Act provide a legal basis in the State of Illinois for the use of proxy consent in research.

The University of Chicago believes in the importance of the informed consent process and believes that subjects should be given every opportunity to provide their consent. Understanding, however, that medical circumstances may preclude a subject from participating in the consent process, the following procedures are in place to consider requests for surrogate consent in keeping with the Medical Patient Right Act and the Health Care Surrogate Act.

The federal regulations require that informed consent be provided by the subject or the subject's legally authorized representative, except 1) in cases where the IRB has altered or waived some of the requirements for informed consent and the research presents no more than minimal risk or 2) in cases which meet the criteria for waiver of consent in emergency situations (45 CFR 46 and 21 CFR 50). It is State law that defines who can act as a subject's "legally authorized representative" to make treatment and /or research-related decisions on the subject's behalf. The State of Illinois has two pieces of legislation which provide family members or others with legal authority to provide consent in situations where the patient is unable to provide consent. The Medical Patient Rights Act indicates that consent to participate in a research program or experimental procedure may be given by "the patient or, if the patient is unable to consent, the patient's guardian, spouse, parent, or authorized agent." In 1997, the State of Illinois amended the Medical Patient Rights Act to align state law with the recently enacted federal (DHHS and FDA) regulations on the waiver of consent in emergency situations.

The Illinois Health Care Surrogate Act also provides authority for a surrogate decision maker to act on behalf of patients (minor or adult) who lack decisional capacity. This statute initially applied only in situations concerning withdrawal of life sustaining treatment. Amendments to the statute extend the surrogate's authority to general medical treatment decisions, which can include research-related decisions.

For copies of The Medical Patient Rights Act and The Health Care Surrogate Act, please contact the Office of Medical Legal Affairs.

Proxy consent should involve all the same considerations that informed consent from a competent patient involves. It also involves identifying the proper surrogate and ensuring that the research decision reflects the wishes of the subject, if known or, if not known, the best interests of the subject. In addition, the IRB will consider whether the research could be accomplished in situations involving the consent of a competent patient and will consider whether the intervention is likely to offer therapeutic benefit to the subject of the study.

Researchers wishing to utilize surrogate consent should answer the questions concerning subjects who are not able to make decisions for themselves on the protocol submission form and submit a consent form suitable for proxy consent.

Illinois law requires that the following process be followed when obtaining consent from a surrogate decision-maker.

1) The attending physician must determine that the subject lacks decisional capacity.

2) An attempt should be made to determine whether there is an operable and unrevoked living will, durable power of attorney for health care, or declaration for mental health treatment ("Advance Directive") which is applicable to the subject's decision about whether to participate in the research. Surrogate consent should be invoked only in cases when, after reasonable inquiry, no Advance Directive applies or, despite efforts to contact the person authorized in an Advance Directive, that person is unavailable.

3) The researcher must attempt to identify a surrogate of the highest priority. (Note: If there is more than one surrogate of the highest priority and there is a disagreement between them, majority rules. If there is disagreement and no majority, consult with the Ethics Consult Service or the Office of Medical Legal Affairs.)

For the purposes of this law, relevant surrogates in order of priority are as follows:

1) patient's guardian of the person;
2) patient's spouse;
3) any adult son or daughter of the patients;
4) either parent of the patient;
5) any adult brother or sister of the patient;
6) any adult grandchild of the patient;
7) a close friend of the patient;
8) the patient's guardian of the estate.

4) The consent process with the surrogate should include a discussion with the attending physician and an inquiry into the extent to which the surrogate is able to speak for the subject. Following the requirements of the Health Care Surrogate Act, this discussion should emphasize the surrogate's ability to make a decision that would conform as closely as possible to what the subject would have done or intended under the circumstances. The surrogate should take into account evidence that includes the subject's personal, philosophical, religious, and moral beliefs and ethical values relative to the purpose of life, sickness, medical procedures, suffering and death.

5) In circumstances in which the subject's wishes are unknown after reasonable efforts to discern them, the decision shall be made on the basis of the subject's best interests as determined by the surrogate decision maker. In determining the subject's best interests, the surrogate shall weigh the burdens and benefits of the proposed research and shall take into account any other information, including the views of family and friends, that the surrogate decision maker believes the patient would have considered if able to act for self.

6) The surrogate should express a decision to the researcher in the presence of an adult witness (at least 18 years of age).

7) The subject should be made aware of the research and the identity of the surrogate as soon as feasible. If the subject objects and the surrogate is not a court-appointed guardian, the subject should be withdrawn from the research.

8) The surrogate will have the same rights as the subject to receive information on the research, to withdraw consent for further participation, etc.

The IRB requires that the research team maintain documentation that each of the required elements in the surrogate process set forth above has been satisfied, including, but not limited to: a determination by the attending physician that the subject lacks decisional capacity, the identity of the surrogate, and the relationship of the surrogate to the subject.