



Scope: This document is intended to guide researchers when considering informed consent requirements.

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I. Requirements for Informed Consent

The requirements for informed consent differ for exempt and non-exempt (Expedited or Full Board) research.

A. For non-exempt research

Before involving a human subject in non-exempt research, an investigator shall obtain the legally effective informed consent of the participant or the participant's legally authorized representative (LAR). Informed consent is to be obtained under circumstances that minimize the possibility of coercion or undue influence and that provide sufficient opportunity for the person to review, discuss and consider whether to participate.

Information given must be in a language understandable to the participant and/or LAR. Potential participant's must be provided the information that a reasonable person would want to have in order to make an informed decision about whether to participate.



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 LAR's understanding of the reasons why one might or might not want to participate.

The informed consent process and forms may not include exculpatory language through which an individual is made to waive or appear to waive any legal rights or release the investigators, institutions or study sponsors from liability for negligence.

B. For exempt research

Before involving a human subject in exempt research, it is ethically important in the responsible conduct of research to obtain the informed consent of potential participants. While the informed consent process for exempt research does not need to include all elements of informed consent in the Common Rule regulations (as noted below), researchers should employ a consent process when interacting with participants even when conducting exempt research.

Researchers are strongly encouraged to continue using the guidance information below and the RCS Informed Consent Form Template. At minimum, the informed consent process for exempt research should include disclosure of the following to participants:

- That the activity involves research.
- A description of the procedures.
- That participation is voluntary.
- Name and contact information for the Researcher.

II. Key Information Summary

The informed consent process must begin with a concise and focused presentation of key information that is most likely to assist a prospective participant or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the consent process must be organized and presented in a way that facilitates comprehension. To accomplish this, a section is added to the beginning of the informed consent form or script that is used to facilitate this process.

How each Principal Investigator applies the key information requirement, and to what level of detail, will depend on the complexity of the research. The preamble to the revised 2018 Common Rule suggests the following five elements be included as the Key Information Summary:

- A statement that the project is research and participation is voluntary
- A summary of the research, including:



- Purpose
- Duration
- List of procedures
- Reasonable, foreseeable risks or discomforts
- Reasonable, expected benefits
- Alternative procedures or course of treatment, if any
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III. Elements of Informed Consent

In addition to the Key Information Summary, the informed consent process/form must contain basic elements of informed consent and additional elements, when applicable, to allow participants to make an informed decision about whether to participate.

A. Basic Elements

In seeking informed consent, basic elements must be included in the information provided to participants unless elements are waived by the IRB under specific conditions. A list of the [basic elements of informed consent](#) can be found on the RCS website. These have been incorporated into RCS' template informed consent guidance and form. In some circumstances, some basic elements of informed consent will be provided in sufficient detail within the Key Summary Information and may not need to be reiterated in the body of the consent form.

B. Additional Elements

When appropriate, additional elements of informed consent must be provided to participants and/or LAR's. A list of the [additional elements of informed consent](#) can be found on the RCS website. Please refer to the template informed consent guidance and form to determine when these are appropriate for inclusion.

C. Alterations

In some circumstances, the IRB may approve a consent procedure that omits some or alters some or all of the elements of informed consent. The specific conditions for a consent alteration can be found in our [waiver or alteration of informed consent guidance](#).



D. UO Specific Requirement for Compensation

If participants will be compensated for participation in the research, there are institution-specific requirements and template language to include that are outlined in our [guidance for compensation for participation in research](#).

IV. Documentation Requirements

A. Documentation (Signature)

Informed consent must be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's LAR. A written copy shall be given to the person signing the form and sufficient time allowed to read or have the form read to them.

B. Waiver of Documentation

Under specific conditions, the IRB may waive the requirement to obtain documentation of informed consent. If documentation is waived, the IRB may require that the investigator provide a written statement about the research to the subject and/or LAR. The specific conditions for a waiver of documentation can be found in our [waiver or alteration of informed consent guidance](#).

V. Other Waivers and Exceptions to Informed Consent

A. Complete Waiver of Informed Consent

In some circumstances, the IRB may waive the requirement to obtain informed consent for research all together. The IRB will need to find and document that specific conditions have been met in order to grant a full waiver. More information on these conditions can be found in our [waiver or alteration of informed consent guidance](#).

B. Exception for Screening, Recruiting, or Determining Eligibility

In some circumstances, the IRB may waive the requirement to obtain informed consent for research all together. The IRB will need to find and document that specific conditions have been met in order to grant a full waiver. More information on these conditions can be found in our [waiver or alteration of informed consent guidance](#).

C. Waiver/Alteration for Public Benefit and Service Programs

The IRB may approve a waive the requirement to obtain informed consent or approve a consent procedure that omits or alters some or all of the elements of informed consent for public benefit and service programs conducted by or subject to the approval of State



or local officials. More information on these conditions can be found in our [waiver or alteration of informed consent guidance](#).

VI. Broad Consent

In the revised 2018 Common Rule, "broad consent" is an alternative consent process only for the storage, maintenance, and secondary use of identifiable private information or identifiable biospecimens for future, yet-to-be-specified research. The use of broad consent requires that the investigator maintain a sophisticated tracking system. For this reason, and because the regulations permit the secondary research use of identifiable data/biospecimens through study-specific consent, IRB waiver of consent, or removal of identifiers, the UO IRB does not plan to implement the broad consent option at this time. Please contact Research Compliance Services if you have any questions.

For full details about broad consent including the requirements (in addition to tracking), limitations, and considerations for use, see [SACHRP's Recommendations for Broad Consent Guidance](#).

VII. Sample Consent Materials

Research Compliance Services has developed a UO informed consent form template and template guidance for use with adult participants. This template and guidance incorporates the 2018 Common Rule required and additional elements of informed consent.

RCS will be developing additional consent and assent templates as well as make available sample forms for specific methodologies and subject populations. These will be announced on the website as they are released.

VIII. Clinical Trials

For federally-sponsored clinical trials, investigators are required to post a copy of an IRB approved consent form to a "publicly available, federal website" post-recruitment and no later than 60 days after the last study visit by any subject. This is a new requirement under the revised 2018 Common Rule. The Office for the Protection of Human Subjects (OHRP) has posted detailed information and guidance on the [Revised Common Rule's clinical trial informed consent form posting requirement](#). In addition, federal departments or agencies may have exceptions and/or additional stipulations related to this requirement. Investigators will need to work with federal sponsors to determine whether this requirement applies and where to publicly post the approved consent form.