



MINIMAL RISK RESEARCH

For minimal risk research, the consent process may be altered in four ways:

1. A short form may be signed to document an oral consent process (see below), or
2. The requirement to document informed consent may be waived, or
3. Some required elements may be altered or waived, or
4. The requirement to obtain consent may be totally waived.

WAIVER OF REQUIREMENT TO DOCUMENT CONSENT:

For minimal risk research, if the research involves no procedures for which written consent is normally required outside of the research context, then the requirement to document informed consent may be waived. [46.117(c)] The IRB may require an information sheet, however it does not require an optional signature line. When the requirement to document consent is waived, there is still a consent process, the only change is that no signature is obtained.

For research subject to FDA regulations, except as allowed by the emergency use of a test article provision, the requirement for a written, signed informed consent document may only be waived if:

1. The research presents no more than minimal risk of harm to subjects; and
2. Involves no procedures for which written consent is normally required outside the research context.

WAIVER OR ALTERATION OF CONSENT:

For minimal risk research, the IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent. When an alteration is approved, there will still a modified consent process. The IRB may also entirely waive the requirement to obtain consent. [46.116(d)] In order for the IRB to approve waiver or alteration of the elements of consent, the following conditions must be true:

Condition	Yes?	No?
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.		

Whenever appropriate, the IRB will require that subjects be provided with additional pertinent information after participation. This may be in the form of an information sheet or other appropriate sources of information and may include references for services or counseling.

NOTE: The OHSU IRB may not waive informed consent for any FDA regulated studies involving human subjects. The FDA will exercise “enforcement discretion” regarding the requirement for informed consent for certain in vitro diagnostic (IVD) studies which use de-identified tissue samples or specimens.

MORE THAN MINIMAL RISK RESEARCH

For research that is greater than minimal risk, there are three modifications that may be made to the mandated consent process.

1. Waiver of requirement to document consent
2. Oral consent process with use of a short form to document consent.
3. Exception from informed consent requirements for emergency research

WAIVER OF REQUIREMENT TO DOCUMENT CONSENT:

When the requirement to document consent is waived, there is still a consent process, the only change is that no signature or other documentation is obtained. In order for the IRB to be able to approve a waiver of the requirement for the investigator to obtain a signed consent form for some or all subjects, the following two conditions must be met:

Condition	Yes?	No?
Only record linking the subject and the research would be the consent document		
The Principal risk is harm from breach of confidentiality		

If those two conditions are met, then the requirement to document consent can be waived. The IRB will require that an information sheet be made available to subjects. The information sheet will have an optional signature line. The investigator is required to ask each subject whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

SHORT FORM

Using a short form is an alteration of the standard documentation of consent process (a subject signing the full consent form). A short form is a written consent document stating that the required elements of informed consent have been presented orally to the subject or the subject's legally authorized representative (LAR). Instances when oral consent is appropriate include consenting subjects who are unable to understand the written form due to language barriers, disability or other impediments to comprehension. The IRB must approve a written summary of what is to be said to the subject or the representative and the short form.

When this method is used, there shall be a witness (other than the LAR and the investigator) to the oral presentation. A copy of the summary and a copy of the short form shall be given to the subject or the representative. The following signatures are required:

1. The subject or the LAR signs: the short form
2. The person obtaining consent signs: the summary
3. The witness signs: the short form and the summary

EXCEPTION FROM INFORMED CONSENT REQUIREMENTS FOR EMERGENCY RESEARCH

The regulations allow for an exception to the requirement to obtain informed consent from each subject, or the subject's legally authorized representative, prior to enrollment in a clinical investigation. [Note: this is not a waiver of consent, but a full exception from any consent requirements] The exception applies to emergency research involving human subjects who cannot give informed consent because of their emerging, life-threatening medical condition, for which available treatments are unproven or unsatisfactory, and where the intervention must be administered before informed consent from the subjects' legally authorized representative is feasible. Studies involving an exception from informed consent requirements may proceed only after a sponsor has received prior written permission from FDA or OHRP, and the IRB has found and documented that specific conditions have been met.

The emergency research permitted, under 21 CFR 50.24 and per Secretarial Order under Section 46.101(i) of the Common Rule, involves a particularly vulnerable population: persons with life-threatening conditions who can neither give informed consent nor actively refuse enrollment. This lack of autonomy creates a special need for the government, study sponsors, IRBs, and clinical investigators to work closely together to ensure that the interests of this vulnerable population of subjects are protected to the maximum extent possible. The regulations for emergency research therefore contain specific human subject protection requirements to account for these concerns. These include specific requirements that representatives of the community(ies) in which the research will take place and from which the subjects will be drawn be consulted about the study and that information about a study be publicly disclosed before the study may proceed. This is often referred to as the community consultation and disclosure process which must be approved by the IRB.

Please consult with the IRB Chair or the Associate Director of ORIO early if you will be requesting an exception from informed consent. This process can be very time-consuming.