

## Guidelines for Obtaining Consent from Human Subjects

With the desire for many human subjects research protocols to “go remote”, the Catholic University IRB is providing these guidelines to help researchers navigate the regulatory and compliance requirements set forth in 45 CFR 46.

The default condition for human subject research is that “informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject, or the subject’s legally authorized representative.” (45 CFR 46.117(a))

### Exempt Studies

Exempt studies (approved by the IRB) do not require documented written informed consent. If the study meets any of the Exemption criteria found in 45 CFR 46.104, as determined by the IRB, there are no informed consent requirements. It is always desirable for remote studies to be designed in a way that they can be granted an Exemption, alleviating the need for obtaining consent.

With changes made to the Common Rule in 2018, studies that include “benign” interventions now can qualify for exemptions under category (3) (b) (3). Please read the Exemption Certificate found on the IRB web site carefully to determine if the study can be proposed as Exempt.

### Waivers of Informed Consent and Documentation of Informed Consent

There are two alternatives (waivers) of the documented informed consent process that are allowable under 45 CFR 46.

1. Informed consent can be waived (or altered from the requirements of 45 CRFR 46 (b) and (c) only if all of the following criteria are met and confirmed by an IRB:

- The research involves no more than minimal risk;
- The research could not practicably be carried out without the waiver or alteration
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation

It is extremely rare that a project meets all five of the criteria.

2. A researcher can also propose a waiver of *documentation* of informed consent (use of a non-signed, but otherwise acknowledged understanding of the project and informed consent materials). There are two specific criteria (only one needs to be met) as determined by the IRB that will allow the protocol to be approved without a signed informed consent form.

- The signature on the informed consent document would be the only record linking the subject to the research and the principal risk of harm to the subject would be a breach of confidentiality. For example, for research on sensitive topics, such as domestic violence or illegal activities; **OR**
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. For example, minimal risk research that involves surveys/interviews conducted via telephone or online.

It is important to note that a granted waiver of documentation of informed consent *does not change* the requirements for informing subjects. The protocol should include some method for the subject to indicate they have read and understood the informed consent information. The IRB must also be convinced that, in addition to the normal review requirements:

- There is an adequate process that facilitates the subject’s comprehension of the information, and allows adequate opportunity for the subject to ask questions and consider whether or not to participate.
- This process must continue beyond obtaining the subject’s initial consent at the time of enrollment.
- If consent and administration of the protocol are done entirely remotely, it must be described in the protocol how any amendments to the protocol that might alter the consent decision will be distributed to the subjects.
- The information should be presented in a way that the subject cannot indicate their consent without reviewing all of the consent materials.
- Any indication of informed consent must include a method to ensure that the person “electronically” signing the informed consent is the subject who will be participating or is the subject’s legally authorized representative (LAR). There is some leeway in this requirement based on risk. Minimal risk social and behavioral research would not typically warrant such verification.

Approved methods for documenting written informed consent from remote subjects

1. By mail:

- Mail or email study materials and consent form to subject.
- Describe how subject can contact researcher to obtain additional information or have questions answered.
- Subject signs consent form and mails back to researcher.

2. By email (1):

- Mail or email study materials and consent form to subject.
- Describe how subject can contact researcher to obtain additional information or have questions answered.
- Subject signs consent form, scans the form, and emails the scan back to the researcher.

3. By email (2):

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- Email study materials and “electronically signable” consent form to subject.
- Describe how subject can contact researcher to obtain additional information or have questions answered.
- Subject electronically signs consent form, and returns to researcher.