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Guidance on Conducting Informed Consent during the COVID-19 Outbreak

Since the advent of the COVID-19 outbreak in the United States, the IRBO has been fielding many questions about investigators' ability to obtain IRB approval to conduct a modified consent process as part of NIH IRB-approved research. Per 45 CFR 46, in general, investigators conducting IRB-approved research are expected to conduct an informed consent process which includes 1) providing the prospective subject with a written version of the consent form that meets all the requirements of *legally effective informed consent* (see definitions below); 2) going over the consent form with the subjects orally; and 3) obtaining a written signature from the subject (i.e. *documentation of informed consent*). Investigators may request a *waiver of consent*, an *alteration of consent*, or a *waiver of documentation of informed consent*, but they must provide written justification that the research and circumstances meet the criteria for a waiver or alteration as described in the regulations (see criteria below).

The IRB will likely approve a remote informed consent process, i.e. over the telephone or using videoconferencing technology, when appropriate in the context of the research. An example of research in which a remote consent process would be appropriate would be a study which involves only the collection and shipping of biospecimens, medical records or images from outside of the NIH. If the consent process is occurring by telephone or videoconference, the subject should still receive a consent form and return a signed consent form to the investigator. **If the protocol involves staff interacting with subjects to conduct research procedures on site, the protocol should include an in person informed consent process with collection of a written signature.**

The IRB will consider approving a waiver of documentation of informed consent for minimal risk, in person, research in which the subject is known or is likely to be infected with SARS-CoV–2. When research will be conducted remotely and entirely online, e.g. completion of an online survey only, it is likely that an electronic consent process could be approved with a waiver of documentation of informed consent. When documentation of consent is waived, the IRB may still require that a written copy of the consent information, e.g. a complete consent form, a verbal script or an information sheet, be provided to the subject for ethical or policy reasons. In addition, the investigator will need to establish a reliable procedure to document that consent was obtained. (*For specific information about the requirements for conducting informed consent under NIH policy, please review NIH HRPP SOP 12.*)

Definitions and Regulatory* Criteria:

Legally Effective Informed Consent: A written or oral process with a prospective subject or his or her legally authorized representative (LAR) which meets the general requirements as described under 45 CFR 46.116 a-c

Waiver of Consent (45 CFR 46.116(f)(1)): Waiver of the requirement to obtain informed consent for research

**The regulatory citations are from the revised Common Rule (the 2018 Requirements) which applies to new protocols approved on or after January 21, 2019. To review the regulations included as part of the pre-2018 Common Rule, please see pre-2018 Common Rule.*

Alteration of Consent (45 CFR 46.116(f)(2)): IRB approval of a consent procedure that omits or alters some or all of the elements of informed consent as described in 45 CFR 46.116(b)-(c)

In order for an IRB to approve a **waiver or alteration of consent**, the PI must address and provide justification for the following in the protocol:

(i) The research involves no more than minimal risk to the subjects;

(ii) **The research could not practicably be carried out without the requested waiver or alteration;**

(iii) 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;

(iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; **and**

(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Documentation of Informed Consent (45 CFR 46.117(a)-(b)): Use of a written informed consent form that meets the requirements of 46.116 (or a short form written informed consent and a written summary) approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative.

Waiver of Documentation of Informed Consent (45 CFR 45.117(c))**:** Waiver of the requirement for a written signature on a consent document for some or all of the subjects

In order for an IRB to approve a **waiver of documentation of informed consent**, the PI must address and provide justification for one of the following in the protocol:

(i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

(ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or

(iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

For research that is FDA-regulated, i. & iii. above are not applicable.

Electronic Informed Consent (eConsent): Electronic informed consent uses an electronic format to provide information about a study to a potential subject and to document the consent of the subject or their LAR with an electronic signature and timestamp. NIH is actively working towards being able to conduct Part 11 compliant electronic informed consent and data management (as required under FDA regulations) but does not currently have this capability. **Accordingly, the use of eConsent will not be approved by the NIH IRB at this time.** The **use of a finger or stylus/mouse** to create a signature on an electronic informed consent document is not considered eConsent and can be approved by the IRB, when appropriate. Please note that even when the subjects are creating their signature using these methods; in most cases, there is still an expectation that protocol will include an oral consent process.

For studies which involve only certain types of minimal risk procedures occurring in a remote setting, e.g. on-line surveys or tasks, the IRB may approve the use of a web-based consent form along with a waiver of documentation of informed consent (and no required oral consent process). This process is not what is meant by the term, eConsent.

In addition to the regulations, NIH research is also subject to other regulations and policies. Accordingly, information about these requirements and protections, when applicable, must always be communicated to prospective subjects as part of the consent process. These policies include:

NIH Genomic Data Sharing Policy
FDAAA 801 and the Final Rule (ClinicalTrials.gov)
NIH Policy for Issuing Certificates of Confidentiality (CoCs)
The Privacy Act of 1974
Public Readiness and Emergency Preparedness Act (PREP Act)

When a research study is subject to the Privacy Act, i.e. collects identifiable private information about a subject, the prospective subject must be provided with written notification about the Privacy Act. When an investigator wishes to conduct an oral consent process and receive a waiver of documentation of consent, he or she must still have a way to provide this information in writing. A description of the plan should be included in the consent section of the protocol. When the subjects will not go through registration as Clinical Center patients for a given protocol, the PI must consult with his or her IC's Privacy Officer to obtain a copy of the appropriate information that must be provided.

Please note that any protocol which involves the administration or use of an antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID–19, or the transmission of SARS-CoV–2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product, must include the required PREP Act language in the consent form.