

COLUMBIA UNIVERSITY INSTITUTIONAL REVIEW BOARD GUIDANCE ON ELECTRONIC INFORMED CONSENT

I. BACKGROUND

Electronic consenting (“e-Consenting”) is the use of electronic systems and processes, whether in person or remotely, that employ multiple electronic media (e.g., text, graphics, audio, video, podcasts, websites, etc.) to convey information relating to a research study and to document informed consent of subjects who wish to participate in such study. E-Consenting is becoming increasingly common and has been sanctioned by both the Department of Health and Human Services (“HHS”) Office of Human Research Protections (“OHRP”) and the Food and Drug Administration (“FDA”). Although many of the details remain to be finalized, it is the view of the Columbia University (“Columbia” or the “University”) Human Research Protection Office (“HRPO”) that when e-Consenting is to be used in a research study, a description of e-Consenting procedures should be included in the applicable Institutional Review Board (“IRB”) protocol and such procedures will be subject to IRB approval. As there are a variety of software packages and systems that can be used in connection with e-Consenting, the HRPO does not wish to limit the use of such software or systems; however, a description of the applicable software or system should be included in the IRB protocol and will be subject to IRB approval.

This Guidance is being provided to the research community to describe the requirements for the use of e-Consenting for research studies at the University. Although compliance with applicable laws and regulations is necessary, such requirements should not be arbitrarily more stringent than those for obtaining informed consent in a traditional face-to-face interaction with documentation by signature on a paper consent document.

II. SCOPE

This Guidance covers all e-Consenting, whether In Person e-Consenting or Remote e-Consenting (as such terms and certain other terms are defined in Section IV) in non-exempt human subjects research. At this time, as a general matter, Remote e-Consenting is recommended only for research studies that do not involve greater than minimal risk. Proposals for use of Remote e-Consenting for greater than minimal risk studies or, for example, for those studies that require multiple signatures on a consent document or involve assessment of capacity, should be discussed with the HRPO staff in advance.

The Columbia University Electronic Signature Policy, dated January 1, 2017, is not applicable to research e-Consenting.

III. EFFECTIVE DATE: May 1, 2017

IV. DEFINITIONS

Certain terms used in this Guidance are defined as follows:

Common Rule: The HHS regulations regarding the protection of human subjects as codified in 45 CFR 46, Subpart A and in effect prior to January 18, 2017.

Electronic Signature: an electronic sound, symbol or process, attached to or logically associated with an electronic record and used by a person with the intent to sign such record.

FDA Human Research Regulations: the FDA regulations codified at 21 CFR 50 and 56.

In Person e-Consenting: as defined in Section V(A).

Remote e-Consenting: as defined in Section V(A).

Revised Common Rule: the HHS regulations regarding the protection of human subjects as codified in 45 CFR 46, Subpart A and in effect after January 18, 2017.

Subject: the person who is giving consent to participation in a research study or his/her legally authorized representative.

V. GUIDANCE

A. Types of e-Consenting

E-Consenting can take place at the research study site where both the investigator (or other authorized member of the research team) and the Subject are at the same location (“In Person e-Consenting”) or remotely where the Subject reviews the consent information in the absence of the investigator (or other member of the research team) (“Remote e-Consenting”). For instance, In Person e-Consenting may make use of an electronic tablet to present the required information about the study with the subject signing the consent form with an Electronic Signature. Remote e-Consenting typically involves web-based software or a mobile phone to convey the text and to document consent.

E-Consenting may be used to either supplement or replace paper-based informed consent processes in order to best address the Subject’s needs and/or preferences. Unless not permitted by the sponsor of the research study, if a Subject does not wish or is unable to use e-Consenting, he/she should have the option to use paper-based informed consent methods completely or partially except when use of the electronic format is an integral part of the study (e.g., when the use of an e-consenting application is being studied or the ability to use an electronic device or application is an inclusion criterion).

B. E-Consenting Information

E-Consenting mechanisms must contain all of the elements of informed consent required by the Common Rule or the Revised Common Rule and/or, if applicable, the FDA Human Research Regulations, unless the IRB has appropriately waived one or more of the elements. The information must be appropriate for the intended audience, taking into consideration the Subjects' age, language and comprehension level. Additional considerations may have to be assessed depending on the nature of the study, the level of risk involved in the study and the study's potential subject population.

Any e-Consenting system should be easy to navigate, allowing the user to proceed forward or backward within the system and to stop and continue at a later time. Hyperlinks may be provided where helpful. Interactive electronic-based technology, such as diagrams, images, graphics, videos or narration can also be used. The system may incorporate electronic strategies to encourage a Subject to access all of the consent material before documenting his/her consent.

Any Remote e-Consenting system must include information as to how questions from Subjects may be asked and answered from a remote location. This may be accomplished by scheduling in-person discussions with study personnel or through a combination of electronic messaging, telephone calls, video conferencing or electronic chatting. The person answering questions should be either the Principal Investigator of the study or a member of the research team to whom such responsibility has been appropriately delegated and who has been properly trained in obtaining e-Consents.

The e-Consenting mechanism may contain various methods to help an investigator assess the Subject's understanding of the information being presented. For example, the mechanism may include questions at various points that can be used to educate the Subject about the information presented, as well as assess the Subject's understanding of the informed consent materials. Such questions and other methods may be used as tools to gauge subject comprehension of key study elements and highlight areas where the Subject might need further explanation and discussion before consenting to participate in the study.

C. Electronic Signatures

E-Consents may capture the signature of the Subject through use of an Electronic Signature. Applicable regulations permit a wide variety of methods to create Electronic Signatures, including using computer-readable ID cards, biometrics, digital signatures and user name and password combinations. Clicking an "I Agree" icon, hyperlink or other similar method to consent to participate in a study, when an identifier is not linked to that action, is not considered to be an acceptable Electronic Signature. For such mechanisms, waiver of written documentation of informed consent by the IRB may be appropriate.

If a research study involves a FDA-regulated product and is subject to FDA regulations (a "FDA Study"), compliance with the requirements of 21 CFR 11, including verification of the identity of the signing individual is required prior to the e-Consent being signed. FDA regulations do not specify any particular method for such verification. The date that the e-Consent was signed should be recorded in the applicable system for FDA Studies.

Unless the research study is a FDA Study or the sponsor requires it, no verification of an Electronic Signature is required for any research study if none would be required for a signature on a paper consent document.

For FDA Studies, the date that the e-Consent was signed should be recorded in the applicable system.

D. Copies of e-Consents

Each e-Consenting mechanism should provide for the generation of a copy of the informed consent form signed by the Subject. The copy provided to the Subject can be paper or electronic and may be provided on an electronic storage device or via email. If the copy provided includes one or more hyperlinks to information on the Internet, the hyperlinks should be maintained and the information should be accessible until study completion.

E. Confidentiality and Privacy

The electronic system that supports e-Consenting must be secure with restricted access and should include methods to ensure confidentiality of the Subject's identity, study participation and personal information. It must comply with the [Columbia University Information Security Charter](#) and the other Information Security Policies referred to in such Charter to the extent applicable.

HIPAA authorization may be obtained electronically, either separately or as part of the e-Consent. If separate, a copy of the HIPAA Authorization Form must be provided to the Subject.

F. Archiving and Accessibility of e-Consent Forms

The e-Consenting process should incorporate procedures to ensure that electronic documents can be archived appropriately and that all versions of the IRB-approved e-Consent Form and all signed e-Consent Forms can be accessed and retrieved easily. If an electronic system is used exclusively for storage of e-Consent Forms, proper data backup should be maintained.

G. Oversight

The Principal Investigator of a research study should designate a member of the study team to be responsible for overseeing Remote e-Consenting and ensuring that adequate procedures are in place to provide each potential Subject with adequate information about the research study to allow for an informed decision about the Subject's voluntary participation in the study. Procedures should be in place to regularly assess that the components of the e-Consent process are functioning properly. It is the responsibility of the Principal Investigator to ensure that the IRB-approved e-Consenting information is appropriately converted into the e-Consenting format.

H. IRB Review

A request to use e-Consenting in a study must be submitted and approved by the IRB prior to its implementation. The e-Consenting information must be submitted to the IRB in a format that facilitates review and includes a description of the e-Consenting process, the applicable e-Consenting system or software and all ancillary information that will be provided to a Subject through links or branching options. When a research study will involve a vulnerable population, the manner in which the e-Consenting process will address the specific characteristics of such population should be described.