



Monthly IRB-Investigator Meeting (MIM)

Electronic Consent and Remote Consent

June 17, 2021

Agenda

- Review federal informed consent regulations
- Review other requirements
- Present e-consenting guidance
- Discuss remote consent guidelines

Presenters:

- Brenda Ruotolo, AVP for Human Research Protection
- Kimberly Bazylewicz, Asst. Director for IRB Management



Federal regulatory consent requirements

45 CFR 46.116(a) *General*. General requirements for informed consent, whether written or oral...

- (1) Before involving a human subject in research covered by this policy, an investigator shall obtain the **legally effective informed consent** of the subject or the subject's legally authorized representative.
- (2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative **sufficient opportunity to discuss and consider** whether or not to participate and that **minimize the possibility of coercion or undue influence**.



45 CFR 46.116

- (3) The information that is given to the subject or the legally authorized representative shall be in **language understandable to the subject** or the legally authorized representative.
- (4) The prospective subject or the legally authorized representative must be provided with **the information that a reasonable person would want to have** in order to make an informed decision about whether to participate, and an opportunity to discuss that information.



45 CFR 46.116

- (5)(i) Informed consent must begin with a **concise and focused presentation of the key information** that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
- (ii) 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 legally authorized representative's understanding** of the reasons why one might or might not want to participate.



45 CFR 46.116

- (6) No informed consent may include any **exculpatory language** through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
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Definition of “waive” (Merriam Webster)

“- the act of intentionally relinquishing or abandoning a known right, claim, or privilege”

Statements such as “If a commercial product is developed, we do not intend to share profits with you” are not exculpatory



Federal regulatory consent requirements

FDA 21 CFR 50, General requirements for informed consent

Except as provided in §§ 50.23 and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the **legally effective informed consent** of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative **sufficient opportunity to consider** whether or not to participate and that **minimize the possibility of coercion or undue influence**. The information that is given to the subject or the representative shall be in **language understandable to the subject** or the representative. No informed consent, whether oral or written, may include any **exculpatory language** through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.



Consider other federal regulations

- If applicable (e.g., based on funding, or collaboration)
- Examples:
 - DOD Directive 3216.02: Consent documents must include:
 - o A statement that the DoD or a DoD organization is funding the study.
 - o A statement that representatives of the DoD are authorized to review research records.
 - National Institute of Justice (28 CFR 46): The confidentiality statement on the consent form must state that confidentiality can only be broken if the subject reports immediate harm to subjects or others.
 - Dept. of Justice, Bureau of Prisons (28 CFR 512): A statement that participation in the research project will have no effect on the inmate subject's release date or parole eligibility.
- <https://research.columbia.edu/sites/default/files/content/HRPO/AdditionalRequirementsforProtocolsFundedbySpecificFederalAgencies356.4.4.18.pdf>



General points to remember

The informed consent process begins with recruitment and continues throughout the study

The responsibility for obtaining informed consent remains with the investigator and the study personnel to which responsibility has been appropriately delegated.

Regulations require consideration of privacy and confidentiality, the elements of which apply to the consent process

Potential participants should be advised in advance how long the consent process may take, so they can plan accordingly and the process will not be rushed



E-Consent Guidance, eff. 6/11/21

- Effective June 11, 2021
- Provides guidance to researchers at Columbia University on the use of electronic systems and processes to obtain and document informed consent for research. It also describes several systems available for researchers to facilitate electronic informed consent and their pros and cons.
- Replaces the Columbia University Institutional Review Board Guidance on Electronic Informed Consent, dated May 1, 2017.
- Includes definitions of Electronic Consent, In Person e-Consent, Remote Consent, Electronic Signature
- https://research.columbia.edu/human-research-policy-guide#/cu_accordion_item-3656



Remote Consent

“The purpose of Remote Consent is to allow the investigator/designee and potential participant to engage in the informed consent process in a way that is similar to what would be conducted in-person under normal circumstances. These conversations may occur via telephone, conference call, video conferencing, telemedicine, or other methods used by your organization.” (NCI CIRB)



Remote consent guidelines

- Guidance document in development
- General requirements if discussion is part of the process
 - Discussion can be by phone or video conference
 - Consent document must be provided in advance
 - Data security must be considered
 - POC must consider privacy of location
 - Remind potential participant to consider privacy of location
 - Confirm identity if necessary (copy not usually required)
 - After enrollment, participant will provide the original signed form or a copy of it, POC will sign and a copy of the fully executed form must be made available to the participant



Remote consent guidelines (cont.)

- The proposed remote consent process must be described in the consent process section of the Rascal IRB submission and approved prospectively by the IRB
 - Describe whether remote consent procedures are temporary/permanent, and for all/some participants
- If the study offers the prospect of direct benefit, there must be consideration as to how to accommodate all potential participants, if applicable
- Research records should document the manner in which consent was obtained and who was present



Confirming identity (OHRP)

OHRP recognizes that it may not be possible or necessary for all types of research covered by 45 CFR part 46 to verify that the person signing the informed consent is the subject or the subject's LAR who will be participating in the research study. OHRP encourages investigators to apply a risk-based approach to the consideration of subject identity. For example, social behavioral minimal risk research will not typically warrant such verification. In addition, informed consent may be waived for minimal risk research meeting the requirements at 45 CFR 46.116(d).

<https://www.fda.gov/media/116850/download>



Confirming identity (FDA)

“If any or all of the consent process takes place remotely and is not personally witnessed by study personnel, the electronic system must include a method to ensure that the person electronically signing the informed consent is the subject who will be participating in the research study or is the subject’s LAR (see 21 CFR 11.100(b)). Examples of various methods that could be used include verification of a state-issued identification or other identifying documents or use of personal questions, biometric methods, or visual methods (see Q7).”

<https://www.fda.gov/media/116850/download>



Consider COVID-19 requirements

Example: NCI CIRB, 04.22.2020

Remote Consent Procedures: Revised FAQs Due To COVID-19

*“The NCI has directed that the Remote Consent Procedure **must include a witness**. While this may differ from your normal procedures, the NCI stipulated this requirement for all NCI-sponsored clinical trials under CIRB oversight. The rationale for this requirement is to ensure that another party has observed the informed consent conversation and has observed the participant consenting to research participation. The CIRB does not require that this witness be impartial, only that the witness be able to hear both sides of the conversation. The intent is to protect both parties if there is a dispute about the consent. Requirements for social distancing may dictate that the witness is in a different location than the investigator. Any arrangement is acceptable providing the witness can listen to both parties in the informed consent discussion.”*

<https://www.ncicirb.org/announcements/remote-consent-procedures-revised-faqs-due-covid-19>



Federal guidance

- OHRP: Informed Consent FAQs.
 - <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html>
- OHRP: Use of Electronic Informed Consent: Questions and Answers (Dec. 2016)
 - <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/use-electronic-informed-consent-questions-and-answers/index.html>
- NCI CIRB: Remote Consent Procedures: Revised FAQs Due To COVID-1 (April 22, 2020)
 - <https://www.ncicirb.org/announcements/remote-consent-procedures-revised-faqs-due-covid-19>



FDA guidance

- FDA: Use of Electronic Informed Consent Questions and Answers Guidance for Institutional Review Boards, Investigators, and Sponsors (December 2016).
 - <https://www.fda.gov/media/116850/download>
- FDA: Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency (updated Jan. 27, 2021)
 - <https://www.fda.gov/media/136238/download>
- FDA: Part 11, Electronic Records; Electronic Signatures - Scope and Application, *Guidance for Industry*, (Sept. 2003)
 - <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application>



Columbia consent policies/guidance

Informed Consent:

https://research.columbia.edu/sites/default/files/content/HRPO/10%20Informed_Consent_Policy102610RYlinks%20updated.pdf

Enrollment of Non-English Subjects:

https://research.columbia.edu/sites/default/files/content/HRPO/None_englishspeakingsubjects.Revised.FINAL%20111909.pdf

Same Day Consent:

https://research.columbia.edu/sites/default/files/content/HRPO/Same_DayConsentPolicy.FINAL_.092910.pdf



Columbia consent policies/guidance (cont.)

Children in Research:

<https://research.columbia.edu/sites/default/files/content/HRPO/107ResearchInvolvingChildrenPolicy2005.pdf>

Radiation exposure consent language:

[https://research.columbia.edu/sites/default/files/content/HRPO/399Radiation Risk Calculator and ICF%20Language 9.18.2019.pdf](https://research.columbia.edu/sites/default/files/content/HRPO/399RadiationRiskCalculatorandICF%20Language9.18.2019.pdf)

Templates/resources: <https://research.columbia.edu/irb-protocol-and-consent-form-resources>



Questions?



Contact the HRPO

If you have a question about a submitted protocol:

- Identify the IRB to which it is assigned
- Contact the designated HRPO staff:
 - <https://research.columbia.edu/sites/default/files/content/HRPO/Directories/HRPOStaffDirectory%2011.30.2020.pdf>

General questions only:

- irboffice@columbia.edu
- 212-305-5883

