CASE WESTERN RESERVE UNIVERSITY

CWRU HRPP Guidance for the Informed Consent Checklist

November 2024

This document serves as a reference point for Investigators and Study Teams utilizing an Informed Consent Checklist or Narrative Note as an element of the informed consent process. Note that this is intended for CWRU IRB-approved protocols. For UH IRB-approved protocols see informed-consent-tip-sheet.pdf

Utilizing an Informed Consent Narrative Note or Checklist can be a valuable tool to ensure that the informed consent process was conducted according to both the federal regulations and the approved study protocol. Additionally, a checklist or note can act as a space for Principal Investigator signoff/confirmation that the participant meets eligibility criteria and has been enrolled according to study procedures.

Either method used should include the following information:

- The date of the informed consent
- The name of the person obtaining consent
- A description of the consenting process including consent version, privacy, and time
- If witnesses or others were present and/or if other's were involved in the participant's decision making process
- The subject (or legally authorized representative) had an opportunity to ask questions about the research and, if applicable, what questions were asked and answered
- A statement that the subject (or legally authorized representative) received a signed and dated copy of the informed consent document.

Be sure not to include any identifying information such as participant or family members names, specific addresses, URLs, email addresses, etc. Narrative notes or checklists should be stored with de-identified data.

Example Narrative Note

On [date] at [time], I met with the participant at [the study team office/by Zoom/their home/etc.] Others present were [i.e., participant's spouse, friend, other study team member, etc.] The participant received a copy of the consent, version [version number or approval date] to review, and we discussed the purpose of the study, why they are/might be eligible to participate, the detailed study procedures, potential risks/discomforts and benefits, compensation, that the study is voluntary, confidentiality, and who to contact if they have any additional questions or concerns.

The participant was asked to describe the study in their own words. They correctly identified the study purpose, procedures, risks, compensation, and voluntary nature. After confirming that the participant was willing to proceed, they signed and dated the consent form. I also signed and dated the consent form. A copy of the signed form was given to them. The informed consent document was signed before any research procedures were performed.

[Name and signature of the person who obtained consent]
[Date the narrative note was written]

Example Informed Consent Checklist

Below is an example of an Informed Consent Checklist. This can be adapted to suit a study's specific needs, used as a guide for creating an electronic form, or used as is.

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Informed Consent Checklist

Study IRB Number: _____

Principal/Site Investigator(s): _____

Participant/Subject ID: _____

Consent Form CWRU IRB Stamp Approval and Expiration Dates: _____

Date of Informed Consent: _____ Time Consent Started and Ended: _____

Name of Person Obtaining Consent: _____

Individuals Present During Consent*: _____
**No participant identifiers, e.g., "Participant and Consenter," or "Consenter, Participant, and Participant's Spouse," etc.*

Person who obtained consent should complete the table, including signature and date checklist completed:

COMPONENT	YES or NO	COMMENTS
1. Does the participant meet all eligibility criteria?		
2. Was the participant consented in a private location?		
3. Was the participant given adequate time to review the ICF and ask questions?		
4. Were the participant's questions answered to their satisfaction?		Questions asked and answered:
5. Did the participant verbalize an understanding of the study procedures?		□ Talk back method □ Q&A □ Other
6. Were others involved in the participant's decision-making process?		If "Yes," who?
7. Did the participant sign and date the ICF before study procedures were performed?		
8. Was the participant given a copy of the signed ICF?		

Additional Notes/Comments: _____

_____

_____

Completed By (Sig.): _____ Date Completed: _____

PI Signature: _____ PI Signature Date: _____