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Cook County Health Remote Consent Guidance

While the required elements of consent are consistent for research, the setting in which consent is obtained can vary depending upon the nature of the study. There are times when an in-person consent process with a prospective subject or legally authorized representative (LAR) is not feasible, for example, during a health pandemic such as COVID-19. Electronic and remote informed consent procedures are permitted by the Cook County Health IRB and must meet the same regulatory and institutional requirements of an in-person paper-based informed consent process.

The following guidance is intended for research studies that require signed informed consent but do not have an electronic informed consent process in place.

1. There must be a process detailing how the prospective subject or LAR will receive a copy of the informed consent form. Acceptable methods include, but are not limited to:
 - A paper copy may be mailed to the subject or LAR
 - An electronic copy of the consent may be e-mailed and then printed by the subject or LAR
 - The consent may be faxed to the subject or LAR
 - Research/clinical staff may deliver a paper consent directly to the subject or LAR
2. Once the subject or LAR receives the consent document, there must be process detailing how a consent discussion will occur. The Principal Investigator/research staff will review the study and consent document with each participant, asking questions to gauge comprehension, and answering subject's questions and concerns. If child assent is required, the discussion must occur with both the parent/legal guardian and the child. Acceptable methods include but are not limited to:
 - A conversation over the phone
 - A conversation utilizing videoconferencing technology such as Webex
3. After all questions have been answered and the PI/research staff is confident in the subject or LAR's understanding of the study, the subject or LAR will initial on the HIPAA page (if applicable), and sign and date the consent form. If there is a separate child assent, the child will sign and date the assent form.
4. There must be a process detailing how the subject or LAR will return the signed consent form to the study team. Whenever possible, the signed consent/assent should be returned to the researcher before any research procedures take place. Acceptable methods include but are not limited to:
 - The signed consent may be scanned and e-mailed back to the study team.
 - The signed consent may be faxed back to the study team.
 - The signed consent may be mailed back to the study team.

- If the signed consent cannot be faxed, e-mailed, or mailed back, the subject may take a picture of the initialed HIPAA page (if applicable) and full study consent signature page with their cell phone or tablet and send via email or text back to the study team.
5. The study team will ensure:
- Upon receipt of the signed consent form, the PI/research staff who conducted the consent discussion will sign and date the consent. The date should be the current date, NOT the date on which the discussion occurred. A consent note should be added to the study documents explaining the difference in signature dates between the subject/LAR and the person obtaining consent. This can also be noted directly on the consent form itself.
 - Ensure the signed consent document (or printed images of patient's HIPAA and consent signature page) are placed in patient's study source document.
 - Provide documentation of the informed consent process by completing consenting progress note and place in patient's study source document.
 - Ensure the subject/LAR receives a copy of the signed consent form



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Betty Anna Donoval, JD, MS
Interim Director Research & Regulatory Affairs

Date