Title	Guidance for Obtaining Electronic Informed Consent
Contact	researchcompliance@luriechildrens.org
Scope	This guidance applies to Investigators and research personnel who will obtain electronic informed consent.
Definitions	**Please see Glossary of Terms**
Policy	This guidance is in compliance with Code of Federal Regulations (CFR), International Council for Harmonization (ICH), Good Clinical Practice (GCP) (E6), and guidelines that apply to the involvement of human research participants.
Procedure	*In this guidance, the use of the term 'consent' includes parent permission, adolescent assent, adult consent, and/or Information Sheet.* • Prior to implementation of electronic consent/obtaining electronic signatures: a. Electronic consent (e-consent) may be obtained for research after obtaining Institutional Review Board (IRB) approval of the consent process, form(s), and the electronic application that will be utilized. b. In principle, the procedures for obtaining e-consent via an electronic application are the same as obtaining consent in person. Refer to the IRB Policies and Procedures Manual Section 11 for Informed Consent requirements. c. The participant/Legally Authorized Representative (LAR) must be presented with the IRB approved e-consent information, and voluntary agreement must be secured without coercion or undue influence. d. The Lurie Children's IRB consent templates must be used, and all elements of consent must be included; unless appropriately waived by the IRB. e. There must be adequate measures to protect privacy and confidentiality and obtain valid HIPAA Authorization when collecting any Protected Health Information (PHI) (if applicable). f. If obtaining adolescent assent is required, the methods for obtaining this assent via the electronic application must also be IRB approved. g. The IRB will stamp and return the IRB approved consent form or information sheet(s) in Cayuse IRB. h. All subsequent changes to the e-consent content and/or process require IRB approval prior to implementation by submitting a Modification submission in Cayuse IRB. The method and process for re-consent via an electronic application must be included in the Modification submission. • If the study requires an electronic signature (e-signature) on an e-consent form: a. The entirety of the approved, stamped IRB consent form must be presented to the participant/LAR, with the IRB stamp visible. Ensure

that the correct, and current version of the consent form is presented.

b. The e-consent process (i.e., discussion) and the application in which this process will be conducted (e.g., in-person with a tablet, via a virtual discussion on Microsoft Teams, over the phone, etc.) is to be included in the e-consent process submitted to the IRB. The phone consent procedures for obtaining e-consent may be followed. Refer to IRB Policies and Procedures Manual Section 11.

c. This e-signature must be able to be validated and the process of this validation is to be included in the consent process submitted in the IRB application.

- If the study has an IRB-approved Information Sheet and a waiver of obtaining a signed consent form (this is different than a waiver of consent), then the approved Information Sheet is to be presented in its entirety to the participant/LAR. A check box response that says "I agree and would like to participate" should be used to verify/confirm consent for participation.

- If a study includes an FDA-regulated drug, biologic, or device, the electronic application to obtain e-consent must comply with the regulations outlined in 21 CFR Part 11.
    a. Those studies that require adherence to 21 CFR Part 11 and intend to utilize Northwestern's REDCap e-consent framework must follow training and attestation requirements provided by Northwestern's REDCap team. Study teams must work with Northwestern's REDCap team to ensure the correct e-consent framework is built into their project.
    b. If the electronic application to be utilized for e-consent is <u>not</u> hosted by Lurie Children's (nor Northwestern University), documentation of the application's compliance with 21 CFR Part 11 is required to be submitted to the IRB for review and confirmation.

- Obtaining e-consent from Non-English-Speaking Participants/LAR:
    a. Study teams are to describe the process for incorporating an interpreter in the e-consent process in the IRB submission, when applicable. Refer to IRB Policies and Procedures Manual Section 11 for Guidance on how to obtain consent from Non-English-Speaking Participants.
    b. If translated documents will be utilized, the principles for obtaining e-consent remain the same as if this consent were obtained in person.
    c. Special attention is required when there is a need for a short-form in an e-consent process. This may apply when the consent process is conducted in-person, by phone, or virtually through a video platform (e.g., Microsoft Teams). At the time of e-consent, the person obtaining e-consent must be aware of the need to add a translated short form to the e-consent platform and include an interpreter for the non-English speaking participant/LAR.

- Documentation of the consent process:
    a. When an e-consent form is electronically signed, the study team is to appropriately document the e-consent process. Refer to the Guidance:

	"Consent Documentation" for more information. b. The documentation of the process should be made in real-time while obtaining the e-signature, or in a timely manner after consent, with sign-off by the person obtaining consent. c. The documentation should be in the most appropriate place for the study and follow other Institutional policies (e.g., documentation in the medical record if required). d. All other Institutional requirements for enrollment are also to be followed (e.g., sponsor requirements (internal logs), creation of the research record in EPIC, completing internal enrollment tracking logs, etc.). e. Documentation must be stored securely and follow all Institutional rules for storing PHI. If the consent process is not documented in EPIC, the documentation must only be saved on the Institutional internal servers/drives. f. Documentation must include all the required elements outlined in the IRB Policies and Procedures Manual Section 11. g. A checklist for documentation of the consent process may be utilized. • Presentation of the e-consent documents: a. The e-consent process must include a way for the participant to be able to print and/or save a copy or receive an emailed copy of the e-consent form. b. If HIPAA Authorization is obtained within the e-consent form, the participant must be provided with a signed copy of the e-consent document. • Document Retention and Access: a. Study teams are required to securely store and retain completed e-consent forms. E-consent files are to be stored only on secure Institutional servers, unless the documents are stored on applications that are maintained and under the authority of a Sponsor, Lead Site, or Data Coordinating Center and a local copy is not made/saved. b. If required per policy, the signed copy of the e-consent is to be uploaded into EPIC. c. E-consent forms and documentation of the consent process are to be accessible for inspection, monitoring, and/or auditing. d. E-Consent records are to be retained according to Lurie Children's Record Retention policies.
References	• Lurie Children's IRB Policies and Procedures Manual Section 11: Informed Consent Process • Guidance: Consent Documentation • Add reference to e-consent Packet
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