Methods of Obtaining Written Informed Consent

The main difference between obtaining informed consent in-person vs. remotely are the logistics of ensuring and documenting the actual consent discussion and process are not compromised.

The following are methods of obtaining written informed consent ('long form'). While the logistics of conducting and documenting this consent process differ, the basics process itself is the same (blank copy of approved consent given to all parties, thorough review the consent form to ensure

	Method		
Informed Consent Process	**In-person**	**Remote**	**RCS eConsent *** (remote and in-person)
1. Provide copy of the consent document to all required parties with adequate time for each to review the document prior to the consent discussion ▪ Subject/legal guardian: main consent form ▪ Child subject: if a separate assent form is required, the child must receive a copy of the assent form ▪ Interpreter: if English is not the primary language of the subject and/or legal guardian, an interpreter should be identified prior to consent discussion note: if the short form is used, the interpreter will sign as witness on long form (see short form consent checklist) ▪ if a witness is required (e.g. subject/guardian is capable but cannot read, write, speak or is blind), an impartial witness should be identified and receive a copy of the consent.	Copy can be given directly (in-person) as long as subject/legal guardian is given enough time to review the document. A copy can also be sent prior to consent discussion by: ▪ Postal mail ▪ Scan and email ▪ Fax	Copy sent prior to consent discussion by: ▪ Postal mail ▪ Scan and email ▪ Fax	Copy sent prior to consent discussion: ▪ Upload consent ▪ Emailing link
2. Schedule consent discussion	Schedule date and time with all required parties to conduct a real-time ('face-to-face') discussion.		
3. Consent discussion (real-time) ▪ PI/authorized staff provides an overview of the study and reviews the consent document with subject/guardian ▪ Subject/guardian able to ask questions	Face-to-face	Telephone HIPAA compliant: Video conferencing, e.g. Zoom	Telephone HIPAA compliant: Video conferencing, e.g. Zoom

*RCS eConsent is service provided through Research Computing.

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	Method		
Informed Consent Process	**In-person**	**Remote**	**RCS eConsent *** (remote and in-person)
Signatures Subject/legal guardian PI/authorized staff Witness, if applicable	Original wet signature 1. Subject/legal guardian sign/date when they decide to participate 2. If applicable, witness sign and date, attesting to the consent process and subject/participant consent is voluntary 3. PI/authorized staff sign/date attesting to the consent process (never should sign before subject/guardian)	Copy of wet signature 1. Subject/legal guardian sign/date when they decide to participate 2. If applicable, witness sign and date, attesting to the consent process and subject/participant consent is voluntary 3. PI/authorized staff sign/date attesting to the consent process (never should sign before subject/guardian)	Digital signature 1. Subject/legal guardian sign/date when they decide to participate 2. If applicable, witness sign and date, attesting to the consent process and subject/participant consent is voluntary 3. PI/authorized staff sign/date attesting to the consent process (never should sign before subject/guardian
Complete consent process	Everyone signs same document. ▪ Original is kept by PI for study record ▪ A photocopy is given to subject/legal guardian to take home	▪ Subject/guardian sign/dates and send back to PI by: - mail, - scan and email - photo and email ▪ If Witness is required, PI/authorized staff should send copy signed by subject to the witness. Witness should sign that copy and return. Witness could also sign their own copy and return and PI can merge all signatures into one complete document. ▪ PI/authorized staff (person who obtained consent), should sign and date copy when received.	Everyone provides digital signature and can be done at the same time (e.g. during phone call or video conferencing.
Document process as it occurred - Specify method, date and time each step completed. - Verify subject received signed copy of consent and that consent/assent was obtained prior to any study participation.	In-person consent checklist (EQuIP template) Study/clinic visit notes Memo-to file	Remote consent checklist (EQuIP template) Study/clinic visit notes Memo-to file	RCS eConsent checklist Study/clinic visit notes Memo-to file