

Forms for Documentation of Informed Consent

- **Written informed Consent (Long Form):** paper, written consent document used to present all required elements information (45 CFR 46.116) as approved by IRB and document informed consent (may be obtained in-person or remote).
- **eConsent:** use of electronic systems and processes that may employ multiple electronic media (e.g. text, graphics, audio, video, podcasts) to convey information related to the study and to obtain and document informed consent (may be obtained in-person or remote).

Methods for of conducting the consent discussion

- **In-person:** Process which consent discussion is conducted in-person, face-to-face (e.g. clinic visit).
- **Remote:** Process equivalent to obtaining in-person written informed consent, except that the subject/legal guardian is at a different physical location and the consent discussion is conducted by phone or video-conferencing. This typically includes the following:
 1. Provide subject/legal guardian with a copy of the consent form to review by mail or email
 2. Conduct consent discussion with subject/legal guardian by phone or video-conferencing (e.g. Zoom)
 3. Instruct subject/legal guardian to sign their copy of consent (in handwritten wet signature) and return by mail, scan, email or photo of signed consent.

When feasible, the consent discussion should be conducted remotely. However, when remote consent procedures are not reasonable, the consent discussion may be conducted at the visit and the subject may sign the form following BCH required infection control procedures.

Types of consent signature

- **Wet signature:** Handwritten signature
- **Digital signature:** Process by which a subject provides an electronic signature by using their finger or stylus to actually sign a form on an ipad, computer or phone (e.g. REDCap application developed by BCH IT).

Please note for FDA regulated studies, any digital signature must be 21 part 11 compliant. Currently, BCH does not provide any 21 part 11 compliant systems)

		Method of conducting consent discussion	
		In-person	Remote
Type of Signature	Wet signature (handwritten)	No	No
	Digital signature (electronic)	Yes	Yes