COMPARISON OF DIFFERENT METHODS OF OBTAINING CONSENT SIGNATURES

	PHYSICAL SIGNATURE	WAIVER OF DOCUMENTATION OF CONSENT	DOCUSIGN SIGNATURE	DOCUSIGN PART 11 SIGNATURE	REDCAP E-CONSENT
Applicability	All studies	Minimal risk research only	Non-FDA-regulated research only	FDA-regulated research only	Exempt research only (for now)
Method of consent discussion	Remote discussion prior to signing	Remote discussion prior to signing	Remote discussion prior to signing	Remote discussion prior to signing	Remote discussion whenever there is an opportunity
Contact information required to send consent document	Varies	Varies	Name & E-mail address	Name & E-mail address + access code provided by study team	Varies
How the consent document is provided to the participant	In-person, mailed, e-mailed, or faxed prior to the consent discussion	In-person, mailed, e-mailed, or faxed prior to the consent discussion	In-person, mailed, e-mailed, or faxed prior to the consent discussion	In-person, mailed, e-mailed, or faxed prior to the consent discussion	In-person, mailed, e-mailed, or faxed prior to the consent discussion
Used for in-person consent signatures	YES	YES - Consent is signaled verbally, by clicking a button, or in some other manner	YES – only if the in-person signing feature is used	NO - In-person use is not permitted	N/A – not usually signed for exempt studies
Used for remote consent signatures	YES - The signed copy is mailed, scanned & emailed, faxed, or brought to 1st visit	YES - Consent is signaled verbally, by clicking a button, or in some other manner	YES	YES	N/A – not usually signed for exempt studies
May be used for child assent signatures	YES	NO - Verbal assent process must be IRB approved	NO - Verbal assent process must be IRB approved	NO - Verbal assent process must be IRB approved	NO
May be used for HIPAA authorization signatures	YES	N/A – Request a Partial Waiver of the signature element of authorization	YES	YES	NO – Request a Partial Waiver of the signature element of authorization

Remote Consent Process Example 1: A greater-than-minimal-risk, interventional study (e.g. a clinical trial) that is not FDA-regulated

Option 1: Remote consent discussion with **physically signed consent** document	Study team sends the consent document to the participant by mail (2 copies), email, fax, etc. to refer to during the consent discussion.	A remote consent discussion is held via phone, Zoom, etc. and the participant's questions are answered.	The participant signs the consent document. They mail, scan and email (using a secure email account), or fax the signed copy back to the study team. Or they bring it with them to the 1st study visit.			Once the signed consent form is received, the person obtaining consent and Principal Investigator sign the form. Research activities proceed.
Option 2: Remote consent discussion with **DocuSign signatures**	Study team sends the consent document to the participant by, email, fax, etc. to refer to during the consent discussion.	A remote consent discussion is held via phone, Zoom, etc. and the participant's questions are answered. If the person indicates they are willing, the study team member collects the person's name and email address.	The study team member goes into their regular DocuSign account, creates an envelope, and sends it to the participant.	The participant clicks the DocuSign email and creates an account password to log in. They review and sign the consent document electronically.	The DocuSign envelope is routed to the person obtaining consent for signature and then to the Principal Investigator.	Once all signatures are obtained, all persons receive an email and can download a copy of the signed form. Research activities proceed.

Remote Consent Process Example 2: An FDA-regulated, greater-than-minimal-risk, interventional study (e.g. a clinical trial of a drug, device, or supplement)

Option 1: Remote consent discussion with **physically signed consent** document	Study team sends the consent document to the participant by mail (2 copies), email, fax, etc. to refer to during the consent discussion.	A remote consent discussion is held via phone, Zoom, etc. and the participant's questions are answered.	The participant signs the consent document. They mail, scan and email (using a secure email account), or fax the signed copy back to the study team. Or they bring it with them to the 1st study visit.			Once the signed consent form is received, the person obtaining consent and Principal Investigator sign the form. Research activities proceed.
Option 2: Remote consent discussion with **DocuSign Part 11 signatures**	The study team member who will obtain consent completes DocuSign Part 11 training and contacts a designated DocuSign Part 11 Administrator who sets up a user account. Study team sends the consent document to the participant by, email, fax, etc. to refer to during the consent discussion.	A remote consent discussion is held via phone, Zoom, etc. and questions are answered. If the person indicates they are willing to be in the study, the study team member collects the person's name and email address.	The study team member goes into their DocuSign Part 11 account, creates an envelope, sets an access code for the participant to use, and sends it. They communicate the access code to the participant.	The participant clicks the DocuSign email, creates an account password to log in, and enters the access code. They review and sign the consent document electronically.	The DocuSign envelope is routed to the person obtaining consent for signature and then to the Principal Investigator.	Once all signatures are obtained, all persons receive an email and can download a copy of the signed form. Research activities proceed.

Remote Consent Process Example 3: A minimal risk study with direct participant interactions

Option 1: Remote consent discussion with **physically signed consent** document	Study team sends the consent document to the participant by mail (2 copies), email, fax, etc. to refer to during the consent discussion.	A remote consent discussion is held via phone, Zoom, etc. and the participant's questions are answered.	The participant signs the consent document. They mail, scan and email (using a secure email account), or fax the signed copy back to the study team. Or they bring it with them to the 1st study visit.			Once the signed consent form is received, the person obtaining consent and Principal Investigator sign the form. Research activities proceed.
Option 2: Remote consent discussion with **DocuSign signatures**	Study team sends the consent document to the participant by, email, fax, etc. to refer to during the consent discussion.	A remote consent discussion is held via phone, Zoom, etc. and the participant's questions are answered. If the person indicates they are willing, the study team member collects the person's name and email address.	The study team member goes into their regular DocuSign account, creates an envelope, and sends it to the participant.	The participant clicks the DocuSign email, creates an account password to log in, and enters the access code. They review and sign the consent document electronically.	The DocuSign envelope is routed to the person obtaining consent for signature and then to the Principal Investigator.	Once all signatures are obtained, all persons receive an email and can download the signed copy of the signed form. Research activities proceed.
Option 3 (easiest): Remote consent discussion with an IRB approved **waiver of documentation of consent**/partial waiver of HIPAA	Study team sends the consent document to the participant by mail, email, fax, etc. to refer to during the consent discussion.	A remote consent discussion is held via phone, Zoom, etc. and the participant's questions are answered.	The study team asks if the person consents to participate, and they verbally indicate agreement. The study team records in a study log the participant's name, whether they agreed or not, the date consent was obtained, the method by which the participant indicated agreement, and the name and signature of the person who obtained the consent.			Research activities proceed.

Remote Consent Process Example 4: A minimal risk study with no direct participant interactions (e.g. an exempt online survey study)

Exempt Research: Online information is provided; **consent signature not expected** or a partial waiver of HIPAA signature	Consent information sheet is presented as the landing page for the survey	Participants are instructed to call the study team if they have any questions prior to moving forward with the survey.	The participant clicks an Agree button to signal that they are willing to participate. They have an option to download a copy of the information sheet for their records.	Research activities proceed.
Expedited Research: Consent form is provided online with an IRB-approved **waiver of documentation of consent**/partial waiver of HIPAA signature	Consent information sheet is presented as the landing page for the survey	Participants are instructed to call the study team if they have any questions prior to moving forward with the survey.	The participant clicks an Agree button to signal that they are willing to participate. They have an option to download a copy of the information sheet for their records.	Research activities proceed.