

Options for Storing Electronic Consent

	Option	Strengths	Challenges
1	Representation of Consent transmitted by requesting clinician in body of Direct message (or similar tool)	<ul style="list-style-type: none"> ◆ Relative simple to implement ◆ Requires little central infrastructure to implement 	<ul style="list-style-type: none"> ◆ Requires use of Direct or a similar tool ◆ Only valid in states where representation of consent is legal
2	Representation of Consent entered by requesting clinician in a web-based application and accessed by sending clinician	<ul style="list-style-type: none"> ◆ Allows broad-based access to consent data by authorized users in any state ◆ Users only require a web browser 	<ul style="list-style-type: none"> ◆ Application must be created and maintained ◆ Users must be authorized and maintained ◆ Only valid in states where representation of consent is legal
3	Image of patient-signed consent document transmitted by requesting clinician attached to a Direct message (or similar tool)	<ul style="list-style-type: none"> ◆ Relative simple to implement ◆ Requires little central infrastructure to implement ◆ Enables transmission when full consent document is required 	<ul style="list-style-type: none"> ◆ Requires use of Direct or a similar tool ◆ Clinician must be capable of scanning consent documents
4	Consent entered with digitally-captured patient signature into a web-based application by requesting clinician and accessed by sending clinician	<ul style="list-style-type: none"> ◆ Allows broad-based access to consent data by authorized users in any state ◆ Users only require a web browser ◆ Enables access when full consent document is required 	<ul style="list-style-type: none"> ◆ Application must be created ◆ Users must be authorized and maintained ◆ Clinical sites must have signature capture pads
5	Consent document submitted and stored in an IHE-compliant document repository	<ul style="list-style-type: none"> ◆ Standards-based way to represent consent ◆ More limited use of IHE which can expand into broader use once participants can support it ◆ Since use of IHE transactions is limited, alternate access to consent document repository could be provided (Direct is 	<ul style="list-style-type: none"> ◆ Requires limited IHE transaction support to store and retrieve consent documents ◆ May requires additional work to develop alternate access methods to document repository

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		one possible alternative)	
6	<p>Consent received by requesting clinician within an IHE-compliant transaction using BPPC as a result of query</p> <p>Consent attached to clinical documents deposited in a document repository</p>	<ul style="list-style-type: none"> ◆ Standards-based way to represent consent ◆ Allows for consent to be managed within the work flow of the clinical site through integration with the EHR-S ◆ Allows for more granular consent rules to be implemented by articulating explicit rules or attaching consent to specific clinical documents ◆ Allows clinicians to register patient consent documents with an HIE ◆ Can support many styles of consent documentation, including image of a consent document (or just a signature) deposited in the document repository 	<ul style="list-style-type: none"> ◆ Requires support for IHE XDS transactions both within the EHR-S and the HIE ◆ Requires support for BPPC both within the EHR-S and HIE ◆ Enforcement based on trust between HIE participants and agreement on policies ◆ Granular consent rules difficult to implement and manage