CD2H eConsent Evaluation Tool

Prepared by Sage Bionetworks

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eConsent Evaluation Tool

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Please contact sage-cd2h-econsent@sagebase.org with any questions.

Start of Block: Intro

Pilot: eConsent Evaluation Tool

The COVID-19 pandemic has changed how academic medical centers engage with study participants, sparking a need for tools to collect study participant consent in a virtual environment. CD2H, NCATS, and Sage Bionetworks have partnered to develop an assessment framework to help organizations evaluate, select, or build an eConsent tool or platform.

Please complete the assessment below to help us pilot this framework to evaluate existing eConsent tools. We greatly appreciate your participation.

End of Block: Intro

Start of Block: Who are you

Please fill out the requested information below:

Name of eConsent platform being evaluated: _____

Your name (First Last): _____

Your email: _____

Name of your organization: _____

End of Block: Who are you

Start of Block: Survey triage/general info gathering

Please select the option(s) that **best describe** your role at your organization and/or which area you are best suited to answer questions.

Note that your selection(s) will impact the questions you are asked throughout the rest of the assessment. If you would like to evaluate all aspects of [NAME OF SPECIFIED PLATFORM] as an eConsent platform, please select all of the options below.

- ☐ Investigator / Research Staff
- ☐ IT / Business Partner
- ☐ Regulatory / Compliance Officer

FYI for this document:

Please note this assessment has been designed in Qualtrics to support the assignment and completion of specific questions relevant to the evaluation of eConsent platforms by individuals with specific organizational role(s). The set of questions to be completed will be determined by selection of the role(s) above. For the purposes of review, please feel free to jump to:

- Questions for Investigator/Research Staff
- Questions for IT/Business Partner
- Questions for Regulatory/Compliance Officer

How familiar are you with [NAME OF SPECIFIED PLATFORM]?

- ☐ Not familiar at all
- ☐ Slightly familiar
- ☐ Moderately familiar
- ☐ Very familiar
- ☐ Extremely familiar

How familiar are you with [NAME OF SPECIFIED PLATFORM], specifically for use as an eConsent platform?

- ☐ Not familiar at all
- ☐ Slightly familiar
- ☐ Moderately familiar
- ☐ Very familiar
- ☐ Extremely familiar

If How familiar are you with [NAME OF SPECIFIED PLATFORM], specifically for use as an eConsent platform? = Moderately familiar, Very familiar, Extremely familiar

Based on your level of familiarity with using [NAME OF SPECIFIED PLATFORM] as an eConsent platform, please share any **positive** user feedback you have experienced or received (i.e. from the perspective of study team members and/or consenting individuals):

_____

If How familiar are you with [NAME OF SPECIFIED PLATFORM], specifically for use as an eConsent platform? = Moderately familiar, Very familiar, or Extremely familiar

Based on your level of familiarity with using [NAME OF SPECIFIED PLATFORM] as an eConsent platform, please share any **negative** user feedback you have experienced or received (i.e. from the perspective of study team members and/or consenting individuals):

_____

End of Block: Survey triage/general info gathering

Start of Block: Questions for Investigator/Research Staff

How can [NAME OF SPECIFIED PLATFORM] be implemented as an eConsent platform within an organization? **Select all that apply.**

- ☐ Across multiple organizational units (e.g. across research divisions, departments, schools)
- ☐ Only for a particular organizational unit (e.g. a particular division, department, or school)
- ☐ Across multiple research groups or studies
- ☐ Only for a particular research group or study
- ☐ Other _____
- ☐ Unsure

Does [NAME OF SPECIFIED PLATFORM] offer support to develop, customize, and maintain the system?

- ☐ None at all
- ☐ A little (e.g. up to 1 hour access to support team per year)
- ☐ A moderate amount (e.g. up to 5 hours of access to support team per year)
- ☐ A lot (e.g. up to 20 hours of access to support team per year)
- ☐ A great deal (unlimited access to support)
- ☐ Various support packages available depending on license
- ☐ Unsure

Is [NAME OF SPECIFIED PLATFORM] free to use?

- ☐ [NAME OF SPECIFIED PLATFORM] is free to use by any type of organization
- ☐ [NAME OF SPECIFIED PLATFORM] is free to use only by certain types of organizations (e.g. nonprofit organizations)
- ☐ [NAME OF SPECIFIED PLATFORM] is NOT free to use, regardless of organization type
- ☐ Unsure

If not available for free, which of the following billing options does [NAME OF SPECIFIED PLATFORM] offer? *If you are unsure, please leave the row blank, or indicate "unsure" in the comments section.*

	No	Yes	Comments (optional)
Billed on a per user (i.e. per individual study team member) basis	☐	☐	
Billed on a per license basis	☐	☐	
Billed on a per study basis	☐	☐	
Billed based on number of completed participant consent forms	☐	☐	
Billed based on utility (i.e. amount of data stored, number of interactions with the platform, etc.)	☐	☐	
Flat billing fee regardless of platform utilization	☐	☐	
Billed based on the types of e-consent features included in a package	☐	☐	

Other (please check "yes" if applicable & specify in comments box)	☐	☐	

Which of the following eConsent features does [NAME OF SPECIFIED PLATFORM] offer?
If you are unsure, please leave the row blank, or indicate "unsure" in the comments section.

	No	Yes	Comments (optional)
Ability for consenting individuals to interact with the platform/tool to support comprehension checks throughout eConsent (e.g. add notes, comments, questions, or feedback)	☐	☐	
Ability for consenting individuals to preview, update, correct, and confirm their responses before completing and signing the eConsent?	☐	☐	
Ability for consenting individuals to provide feedback on usability and/or user burden following completion and signing of the eConsent (e.g. post-completion user surveys)	☐	☐	
Ability for study team members to provide feedback on usability and/or user	☐	☐	

burden throughout use (e.g. user satisfaction surveys)			
Ability to integrate videos (e.g. instructional video pop-ups) into the eConsent	☐	☐	
Ability to integrate graphics and/or animations into the eConsent	☐	☐	
Automated notification capability (e.g. email when eConsent has been completed)	☐	☐	
Ability to generate a certificate of completion to be shared with study participants and/or coordinators	☐	☐	
Ability to generate an exportable PDF of completed eConsent forms	☐	☐	
Ability to accommodate and manage a library of eConsent templates	☐	☐	
Ability to accommodate and manage linkage of consent to studies	☐	☐	

Automatic version history and change logs	☐	☐	
Reporting capability (e.g. eConsent completion status, number of eConsents distributed, etc)	☐	☐	
Other (please check "yes" if applicable & specify in comments box)	☐	☐	

If Which of the following eConsent features does [NAME OF SPECIFIED PLATFORM] offer? If you are unsure, pleas... : = Reporting capability (e.g. eConsent completion status, number of eConsents distributed, etc) [Yes]

Which of the following metrics can [NAME OF SPECIFIED PLATFORM] report on? *If you are unsure, please leave the row blank, or indicate "unsure" in the comments section.*

	No	Yes	Comments (optional)
A consenting individual's eConsent completion status	☐	☐	
A consenting individual's eConsent signature date	☐	☐	
Number of completed eConsents for a study	☐	☐	
Number of initiated eConsents for a study	☐	☐	
eConsent metrics within a specified date range	☐	☐	
Other (please check "yes" if applicable & specify in comments box)	☐	☐	

If Which of the following eConsent features does [NAME OF SPECIFIED PLATFORM] offer? If you are unsure, pleas... : = Reporting capability (e.g. eConsent completion status, number of eConsents distributed, etc) [Yes]

How does [NAME OF SPECIFIED PLATFORM] report on these metrics? **Select all that apply.**

- ☐ Automated and/or scheduled report / query system
- ☐ On-demand report / query system
- ☐ Performance dashboard
- ☐ Other _____
- ☐ Unsure

If Which of the following eConsent features does [NAME OF SPECIFIED PLATFORM] offer? If you are unsure, please... : = Automated notification capability (e.g. email when eConsent has been completed) [Yes]

Which of the below automated notification features exist within [NAME OF SPECIFIED PLATFORM]? **Select all that apply.**

- ☐ Notification to study team member(s) when eConsent documents are signed
- ☐ Notification to consenting individuals when they sign and complete eConsent documents
- ☐ Notification to study participants when they need to re-consent on a new version of the consented document
- ☐ Other _____
- ☐ Unsure

Does [NAME OF SPECIFIED PLATFORM] include the following features to accommodate consenting individuals with visual, auditory, physical and/or cognitive impairment? *If you are unsure, please leave the row blank, or indicate "unsure" in the comments section.*

	No	Yes, via the eConsent platform itself	Yes, via the device used for eConsent or integration with other software	Comments (optional)
Color vision deficiency features (e.g. contrast and color blindness settings)	☐	☐	☐	
Text adjustment (e.g. settings for font style and size)	☐	☐	☐	
Resolution adjustment and requirements (e.g. minimum resolution requirements for video or images)	☐	☐	☐	
Responsive content display (e.g. accommodates portrait or landscape display)	☐	☐	☐	
Keyboard-only navigation (e.g. can be used without a computer mouse)	☐	☐	☐	
Captions for video and audio content (e.g. options to display captions)	☐	☐	☐	

Controls for video and audio content (e.g. volume, play/pause, stop controls)	☐	☐	☐	
Alternative text for non-text content (e.g. descriptive content for graphics)	☐	☐	☐	
Icons (e.g. supports integration of suggested or custom icons and graphics to assist content navigation)	☐	☐	☐	
Compatibility with assistive technologies (e.g. screen readers)	☐	☐	☐	
Adjustable time-out (e.g. sessions do not expire or time-out after a short period, and can be extended to longer durations)	☐	☐	☐	
Other (please check "yes" if applicable & specify in comments box)	☐	☐	☐	

What languages does [NAME OF SPECIFIED PLATFORM] support for eConsent? **Select all that apply.**

- ☐ English
- ☐ Spanish
- ☐ Chinese (including Mandarin and Cantonese)
- ☐ Vietnamese
- ☐ Korean
- ☐ Russian
- ☐ Arabic ☐
- Tagalog ☐
- Polish ☐
- French
- ☐ Haitian Creole
- ☐ Portuguese
- ☐ Japanese
- ☐ Other _____
- ☐ Unsure

To what extent does [NAME OF SPECIFIED PLATFORM] include features to support consenting individuals with different language reading and comprehension abilities? *If you are unsure, please leave the row blank, or indicate "unsure" in the comments section.*

	No support	Moderate support	Extensive support	Comments (optional)
Evaluation and/or adjustment of text / content to different education levels	☐	☐	☐	
Evaluation and/or adjustment of text / content to different comprehension levels	☐	☐	☐	
Suggested simplified text / content	☐	☐	☐	
Inclusion and/or integration with language interpretation services	☐	☐	☐	
Other (please specify in comments box)	☐	☐	☐	

From an **accessibility perspective**, is a study team member required to be physically present in the same room or connected virtually to support the use of [NAME OF SPECIFIED PLATFORM] by a consenting individual?

Note: Individuals that selected the "IT / Business Partner" role at the start of this assessment are also asked this question from a technology perspective.

- ☐ No, a study team member is not required to be physically present in the same room or connected virtually for a consenting individual to use [NAME OF SPECIFIED PLATFORM]
- ☐ Yes, a study team member must be physically present in the same room or connected virtually for a consenting individual to use [NAME OF SPECIFIED PLATFORM]
- ☐ Unsure

[NAME OF SPECIFIED PLATFORM] allows for data collection and export in accordance with (**select all that apply**):

- ☐ CDSIC standards
- ☐ Non-CDISC standards (please specify) _____
- ☐ Unsure

Does [NAME OF SPECIFIED PLATFORM] include data de-identification options/features for data export (e.g. removal of identifiers, hashing, date shifting)?

- ☐ No
- ☐ Yes
- ☐ Unsure

Please list any additional eConsent features or considerations from an Investigator / Research Staff perspective. Specifically, are there any eConsent features and/or requirements relevant to your organization that were not evaluated through this assessment?

_____

_____

_____

End of Block: Questions for Investigator/Research Staff

Start of Block: Questions for IT

Please select **all options** that apply to the design of [NAME OF SPECIFIED PLATFORM]:

- ☐ Web-based, accessed through a browser
- ☐ Uses a native client
- ☐ Uses a mobile client
- ☐ Unsure

Do the following actions require a special purpose client, either a native or mobile client, to be downloaded and configured? *If you are unsure, please leave the row blank, or indicate "unsure" in the comments section.*

	No	Yes	Comments (optional)
Set up and distribution of the eConsent by study team members	☐	☐	
Completion of the eConsent by consenting individuals	☐	☐	

The backend (e.g. API and server) for [NAME OF SPECIFIED PLATFORM] are hosted (**select all that apply**):

- ☐ In a public cloud (e.g. AWS)
- ☐ In a private data center (e.g. institutional data center)
- ☐ Unsure

Services (e.g. server) for [NAME OF SPECIFIED PLATFORM] are hosted (**select all that apply**):

- ☐ In the US
- ☐ Outside of the US
- ☐ Unsure

If Please select all options that apply to the design of [NAME OF SPECIFIED PLATFORM]: = Uses a native client, or Uses a mobile client

If [NAME OF SPECIFIED PLATFORM] requires a native or mobile client to access, which platforms are supported? *If you are unsure, please leave the row blank, or write "unsure" in the comments section.*

	No	Yes	Comments (optional)
Windows	☐	☐	
Linux	☐	☐	
Android	☐	☐	
ChromeOS	☐	☐	
MacOS	☐	☐	
iOS	☐	☐	
Other (please check "yes" if applicable & specify in comments box)	☐	☐	

If Please select all options that apply to the design of [NAME OF SPECIFIED PLATFORM]: = Web-based, accessed through a browser

If [NAME OF SPECIFIED PLATFORM] is accessed through a web browser, which of the following browsers are supported? *If you are unsure, please leave the row blank, or write "unsure" in the comments section.*

	No	Yes	Comments (optional)
Internet Explorer	☐	☐	
Edge	☐	☐	
Firefox	☐	☐	
Chrome	☐	☐	
Safari	☐	☐	
Other (please check "yes" if applicable & specify in comments box)	☐	☐	

Is an internet and/or stable data connection required for consenting individuals to access and sign eConsent forms using [NAME OF SPECIFIED PLATFORM]?

- ☐ No (i.e. the forms can be accessed offline)
- ☐ Yes
- ☐ Unsure

If Is an internet and/or stable data connection required for consenting individuals to access and si... = Yes

Does [NAME OF SPECIFIED PLATFORM] save a consenting individual's completion progress, if disconnected?

- ☐ No
- ☐ Yes
- ☐ Unsure

Where can [NAME OF SPECIFIED PLATFORM] be utilized? **Select all that apply.**

- ☐ On-site setting where both the consenting individual and study team member are physically present on premises, with eConsent device(s) connected to a specific on-premises network (e.g. the consenting individual and study team member meet and complete the eConsent at a study clinic)
- ☐ In-person setting where both the consenting individual and study team member are physically present at the same location, independent of the location (e.g. the consenting individual and study team member meet and complete the eConsent at location that is not the study clinic, such as the consenting individual's home)
- ☐ Remote setting where the consenting individual and a study team member are NOT physically present at the same location (e.g. the consenting individual and study team member connect via videoconference to complete the eConsent)
- ☐ Unsure

From a **technology perspective**, is a study team member required to be physically present in the same room or connected virtually to support the use of [NAME OF SPECIFIED PLATFORM] by a consenting individual?

Note: Individuals that selected the "Investigator / Research Staff" role at the start of this assessment are also asked this question from an accessibility perspective.

- ☐ No, a study team member is not required to be physically present in the same room or connected virtually for a consenting individual to use [NAME OF SPECIFIED PLATFORM]
- ☐ Yes, a study team member must be physically present in the same room or connected virtually for a consenting individual to use [NAME OF SPECIFIED PLATFORM]
- ☐ Unsure

Which of the following types of devices can consenting individuals use to access and sign eConsent forms using [NAME OF SPECIFIED PLATFORM]? *If you are unsure, please leave the row blank, or write "unsure" in the comments section.*

	No	Yes	Comments (optional)
Desktops	☐	☐	
Laptops	☐	☐	
Mobile devices: Tablets	☐	☐	
Mobile devices: Cell Phones	☐	☐	
Other (please check "yes" if applicable & specify in comments box)	☐	☐	

To what extent does [NAME OF SPECIFIED PLATFORM] allow for eConsent content and design to be customized?

- ☐ **No Customization**: eConsent templates provide no room for formatting, added text, or custom code
- ☐ **Moderate Customization**: eConsent templates allow users to format certain sections (e.g. add a logo to the top of the document) or add text to specific areas
- ☐ **Extensive Customization**: eConsent templates provide many formatting options and widespread ability to add text & custom code
- ☐ Unsure

Which of the following types of systems can [NAME OF SPECIFIED PLATFORM] be integrated with? *If you are unsure, please leave the row blank, or write "unsure" in the comments section.*

	No	Yes	Comments (optional)
Electronic Health Record (EHR) Systems [e.g. Epic, Millenium (Cerner)]	☐	☐	
Electronic Data Capture (EDC) Systems (e.g. MediData Rave, REDCap)	☐	☐	
Electronic Institutional Review Board (e-IRB) Application Systems (e.g. IRBNet)	☐	☐	
Other (please check "yes" if applicable & specify in comments box)	☐	☐	

Which of the following types of **security features** does [NAME OF SPECIFIED PLATFORM] offer? *If you are unsure, please leave the row blank, or write "unsure" in the comments section.*

	No	Yes	Comments (optional)
Audit logs and / or activity logs	☐	☐	
Verification of electronic signature dates	☐	☐	
Verification of electronic signature times	☐	☐	
File encryption and storage	☐	☐	
Other (please check "yes" if applicable & specify in comments box)	☐	☐	

Please select all **security measures** that [NAME OF SPECIFIED PLATFORM] offers for Study Team Members and for Consenting Individuals. *If you are unsure, please leave the row blank, or write "unsure" in the comments section.*

	Study Team Members	Consenting Individuals	Comments (optional)
Single sign on	☐	☐	
Two-factor authentication	☐	☐	
Two-factor electronic signatures	☐	☐	
Identity verification via background checks	☐	☐	
Certificate-based identification	☐	☐	
Biometric identification	☐	☐	
Token-based identification	☐	☐	
Password protected accounts	☐	☐	

Personal security questions for account protection	☐	☐	
System logs user activity, associated with single user	☐	☐	
System captures IP address	☐	☐	
System captures session ID	☐	☐	
Bot detection	☐	☐	
Other (please check "yes" if applicable & specify in comments box)	☐	☐	

What level of support does [NAME OF SPECIFIED PLATFORM] provide for system validation? **Select all that apply.**

System validation involves proving that a 'system' or service does what you expect it to (and how to set it up to do what you expect it to) before you start using it. Validation starts by defining system requirements, mapping how a service meets those requirements, then testing and confirming that it meets specification(s) when configured in the right way. It is a process that documents how a tenant should be configured and makes it difficult to change after it gets validated.

- ☐ Full-service support
- ☐ Collaborative support (i.e. [NAME OF SPECIFIED PLATFORM] will work with [NAME OF YOUR ORGANIZATION] to provide support)
- ☐ Limited or no support (i.e. [NAME OF SPECIFIED PLATFORM] will need to set up system validation independently)
- ☐ Various support packages available depending on license
- ☐ Unsure

What level of technical support does [NAME OF SPECIFIED PLATFORM] provide *following* implementation? **Select all that apply.**

- ☐ Full-service support
- ☐ Collaborative support (i.e. [NAME OF SPECIFIED PLATFORM] will work with [NAME OF YOUR ORGANIZATION] to provide support)
- ☐ Limited or no support
- ☐ Various support packages available depending on license
- ☐ Unsure

Does [NAME OF SPECIFIED PLATFORM] provide information or resources related to prior user feedback or user experience assessments?

- ☐ No
- ☐ Yes
- ☐ Unsure

Please list any additional eConsent features or considerations from an IT / Business Partner perspective. Specifically, are there any eConsent features and/or requirements relevant to your organization that were not evaluated through this assessment?

_____

_____

_____

End of Block: Questions for IT

Start of Block: Questions for Regulatory/Compliance Officer

By default, does [NAME OF SPECIFIED PLATFORM] meet requirements for FDA-regulated studies?

FDA-regulated studies must be compliant with electronic record and electronic signature standards, as outlined in 21 Code of Federal Regulations (CFR) Part 11. For more information on CFR Title 21, refer here.

- ☐ No
- ☐ Yes
- ☐ Unsure

If By default, does [NAME OF SPECIFIED PLATFORM] meet requirements for FDA-regulated studies? FDA-regulated s... = No, or Unsure

Can [NAME OF SPECIFIED PLATFORM] be configured to meet requirements for FDA-regulated studies?

FDA-regulated studies must be compliant with electronic record and electronic signature standards, as outlined in 21 Code of Federal Regulations (CFR) Part 11. For more information on CFR Title 21, refer here.

- ☐ No
- ☐ Yes
- ☐ Unsure

Is [NAME OF SPECIFIED PLATFORM] capable of collecting age-appropriate child assent for a study?

- ☐ No
- ☐ Yes
- ☐ Unsure

Please list any additional eConsent features or considerations from a Regulatory / Compliance Officer perspective. Specifically, are there any eConsent features and/or requirements relevant to your organization that were not evaluated through this assessment?

_____

_____

_____

End of Block: Questions for Regulatory/Compliance Officer

Start of Block: Do you want to take the needs assessment?

Please note: In addition to this eConsent Evaluation Tool, we have also developed a complementary eConsent Needs Assessment to help researchers consider their specific feature and functionality requirements in the selection of an eConsent platform.

Have you already completed the eConsent Needs Assessment?

- ○ No (1)
- ○ Yes (2)

Display This Question:

If Please note: In addition to this eConsent Evaluation Tool, we have also developed a complementary... = No

Do you want to complete the eConsent Needs Assessment?

Please note that you will automatically be redirected to the eConsent Needs Assessment if you select "yes." However, you will also receive a link to the eConsent Needs Assessment via email. Please close out of the survey and instead access the eConsent Needs Assessment link from your email if you would prefer to complete the evaluation at a later time.

- ○ No (1)
- ○ Yes (2)

End of Block: Do you want to take the needs assessment