# SageBionetworks

# CD2H eConsent Needs Assessment Tool

Prepared by Sage Bionetworks

Version 1.0
May 2022

# eConsent Needs Assessment Tool

March 2022

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

**Pilot: eConsent Needs Assessment**

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 eConsent 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 understand your considerations and requirements for selecting an eConsent platform. We greatly appreciate your participation.

Please note: This assessment includes questions that apply to eConsent needs across different domain areas (e.g. operations and implementation features, IT/security considerations, regulatory requirements, etc.) for a particular study facilitated by your organization. *As eConsent considerations are anticipated to vary across study protocols within your organization, we encourage you to complete this assessment in close consultation with and on behalf of relevant study team members and stakeholders that can evaluate the specific eConsent needs and requirements with a particular study (or set of related studies) in mind.*

**Start of Block: General info about you/your org**

Please fill out the requested information below:

Your name (First Last): _____

Your email: _____

Name of your organization: _____

Job title / organizational role: _____


How familiar are you with **general study participant consent processes** (i.e. previous involvement in facilitating and/or completing consent for a research study)?

☐ Not familiar at all

☐ Slightly familiar

☐ Moderately familiar

☐ Very familiar

☐ Extremely familiar


*If How familiar are you with general study participant consent processes… = Slightly familiar, Moderately familiar, Very familiar, or Extremely familiar*

How familiar are you with **eConsent processes** (i.e. previous involvement in facilitating and/or completing eConsent for a research study)?

☐ Not familiar at all

☐ Slightly familiar

☐ Moderately familiar

☐ Very familiar

☐ Extremely familiar

Over the next 5 years, approximately how many **studies** do you anticipate to require eConsent facilitation?

- ☐ none
- ☐ 1-2 studies
- ☐ 3-5 studies
- ☐ 5-10 studies
- ☐ more than 10 studies

Over the next 5 years, approximately how many **consenting individuals** do you anticipate to facilitate completion of eConsent?

- ☐ none
- ☐ 1-10 consenting individuals
- ☐ 11-500 consenting individuals
- ☐ 501-1000 consenting individuals
- ☐ more than 1000 consenting individuals

**End of Block: General info about you/your org**

**Start of Block: General feature questions**

Do you need an eConsent platform that is compliant with 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

How important is it for an eConsent platform to collect and export data in accordance with CDISC standards?

☐ Not important

☐ Preferred

☐ Required

☐ Unsure

How would you rank the importance of the following features when selecting an eConsent platform? **Please rank the answer choices; 1=most important; 7= least important**

_____Ease of use by consenting individuals

_____Ease of use by study team members

_____Cost of implementation and use

_____Amount of technical support / other assistance provided by the eConsent platform for implementation and use

_____Scope of customization and breadth of available features

_____Established compliance with 21 Code of Federal Regulations (CFR) Part 11. For more information on CFR Title 21, refer here.

_____Compatibility and integration with other tools and software

What are your budgetary considerations when selecting an eConsent platform?

☐ A freely available eConsent platform is required

☐ A freely available eConsent platform is preferred, but not required

☐ Unsure

What other factor(s) regarding budgeting and cost do you consider when selecting an eConsent platform?

_____

Do you have **internal** support (e.g. research staff or IT support) allocated to develop, customize, implement, and maintain the eConsent platform?

☐ No

☐ Yes

☐ Unsure

Do you need an eConsent platform that can be utilized across multiple studies?

☐ No

☐ Yes

☐ Unsure

Do you need an eConsent platform that is capable of collecting age-appropriate child assent?

☐ No

☐ Yes

☐ Unsure

To what extent do you need an eConsent platform that allows for customization of eConsent templates?

☐ **No Customization Needed**: eConsent templates do not need to provide room for formatting, added text, or custom code

☐ **Moderate Customization Needed**: eConsent templates should 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 Needed**: eConsent templates should provide many formatting options and widespread ability to add text & custom code

☐ Unsure

How important are the following eConsent **implementation features** when selecting an eConsent platform?

| | Not important | Preferred | Required | Unsure |
|---|---|---|---|---|
| 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) | ☐ | ☐ | ☐ | ☐ |

How important are the following eConsent **reporting metrics** in the selection of an eConsent platform?

| | Not important | Preferred | Required | Unsure |
|---|---|---|---|---|
| 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 | ☐ | ☐ | ☐ | ☐ |

How would you prefer to generate / view reports related to eConsent metrics? **Select all that apply.**

☐ Automated and/or scheduled report / query system

☐ On-demand report / query system

☐ Performance dashboard

☐ Other (please specify) _____

☐ Unsure

How important are the following eConsent **notification features** when selecting an eConsent platform?

| | Not important | Preferred | Required | Unsure |
|---|---|---|---|---|
| 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 | ☐ | ☐ | ☐ | ☐ |

How important are the following eConsent **accessibility features** when selecting an eConsent platform to accommodate consenting individuals with visual, auditory, physical and/or cognitive impairment?

| | Not important | Preferred | Required | Unsure |
|---|---|---|---|---|
| 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) | ☐ | ☐ | ☐ | ☐ |
| Video integration (e.g. instructional video pop-ups) | ☐ | ☐ | ☐ | ☐ |
| 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 or 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) | ☐ | ☐ | ☐ | ☐ |
| Submission preview (e.g. ability to update, correct, and confirm responses prior to submission) | ☐ | ☐ | ☐ | ☐ |

Which language(s) would you like an eConsent platform to support? **Please drag each language option into its respective category to the right.**

| Required | Preferred | Unsure / Likely Not Needed |
|---|---|---|
| ☐English | ☐English | ☐English |
| ☐Spanish | ☐Spanish | ☐Spanish |
| ☐Chinese (including Mandarin and Cantonese) | ☐Chinese (including Mandarin and Cantonese) | ☐Chinese (including Mandarin and Cantonese) |
| ☐Vietnamese | ☐Vietnamese | ☐Vietnamese |
| ☐Korean | ☐Korean | ☐Korean |
| ☐Russian | ☐Russian | ☐Russian |
| ☐Arabic | ☐Arabic | ☐Arabic |
| ☐Tagalog | ☐Tagalog | ☐Tagalog |
| ☐Polish | ☐Polish | ☐Polish |
| ☐French | ☐French | ☐French |
| ☐Haitian Creole | ☐Haitian Creole | ☐Haitian Creole |
| ☐Portuguese | ☐Portuguese | ☐Portuguese |
| ☐Japanese | ☐Japanese | ☐Japanese |

Are there any additional languages that you would like an eConsent platform to support?

_____

How important are the following eConsent **interpretation/comprehension features** when selecting an eConsent platform to accommodate consenting individuals with different language reading and comprehension abilities?

| | Not important | Preferred | Required | Unsure |
|---|---|---|---|---|
| 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 | ☐ | ☐ | ☐ | ☐ |

How important are the following eConsent **feedback features** when selecting an eConsent platform?

| | Not important | Preferred | Required | Unsure |
|---|---|---|---|---|
| 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 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) | ☐ | ☐ | ☐ | ☐ |

How important is it for an eConsent platform to include data de-identification options/features (e.g. removal of identifiers, hashing, date shifting) for data export?

☐ Not important

☐ Preferred

☐ Required

☐ Unsure

Are you interested in an eConsent platform that can be integrated with any of the following systems? **Select all that apply.**

☐ 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)

☐ Unsure

☐ Other (please specify) _____

Are you or others at your organization interested in an eConsent platform that can be used for functions outside of consent for a research study (e.g. data capture)?

☐ No

☐ Yes

☐ Unsure

*If Are you or others at your organization interested in an eConsent platform that can be used for fu... = Yes*

Please list these additional functions:

_____

**End of Block: General feature questions**

**Start of Block: Technical questions**

Which of the following devices can be used by consenting individuals to complete their eConsents (this may be informed by study-specific protocol and/or institutional policy)? **Select all that apply.**

☐ Desktops

☐ Laptops

☐ Mobile devices: Tablets

☐ Mobile devices: Cell Phones

☐ Other (please specify) _____

☐ Unsure


Will all consenting individuals have access to the internet and/or a stable data connection to complete their eConsent?

☐ No

☐ Yes

☐ Unsure


*If Will all consenting individuals have access to the internet and/or a stable data connection to co... = No or Unsure*


If internet access and/or a stable data connection are not available, will consenting individuals have access to a device whereby they can complete their eConsent offline?

☐ No

☐ Yes

☐ Unsure

Please indicate your preferences for the following **design features** when selecting an eConsent platform:

| | Not needed | Preferred | Required | No preference / unsure |
|---|---|---|---|---|
| **Web-based**, accessed through a browser | ☐ | ☐ | ☐ | ☐ |
| Operated via a **native client** for study team members to set up & distribute the eConsent | ☐ | ☐ | ☐ | ☐ |
| Operated via a **native client** for consenting individuals to complete the eConsent | ☐ | ☐ | ☐ | ☐ |
| Operated via a **mobile client** for study team members to set up & distribute the eConsent | ☐ | ☐ | ☐ | ☐ |
| Operated via a **mobile client** for consenting individuals to complete the eConsent | ☐ | ☐ | ☐ | ☐ |

*If Please indicate your preferences for the following design features when selecting an eConsent pla... = <strong>Web-based</strong>, accessed through a browser [ Preferred ], or <strong>Web-based</strong>, accessed through a browser [ Required ]*

If web-based, which of the following browsers are preferred for implementation of the eConsent platform? **Select all that apply.**

☐ Internet Explorer

☐ Edge

☐ Firefox

☐ Chrome

☐ Safari

☐ No preference

☐ Unsure

Where can the eConsent take place? **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

How important is it for consenting individuals to be able to use an eConsent platform independently (i.e. without a study team member physically present in the same room or connected virtually)?

☐ Not important

☐ Preferred

☐ Required

☐ Unsure

How important are the following **security features** when selecting an eConsent platform?

|  | Not important | Preferred | Required | Unsure |
|---|---|---|---|---|
| Audit logs and / or activity logs | ☐ | ☐ | ☐ | ☐ |
| Verification of electronic signature dates | ☐ | ☐ | ☐ | ☐ |
| Verification of electronic signature times | ☐ | ☐ | ☐ | ☐ |
| File encryption and storage | ☐ | ☐ | ☐ | ☐ |

When selecting an eConsent platform, which of the following **security features** are required for Study Team Members and / or 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 | ☐ | ☐ | |

**End of Block: Technical questions**

**Start of Block: Do you want to evaluate eConsent tool?**

**Please note**: In addition to this eConsent Needs Assessment, we have also developed a complementary eConsent Evaluation Tool to help researchers evaluate the features and functionality of existing eConsent platforms. Have you already completed the eConsent Evaluation Tool?

☐ No

☐ Yes

*If Please note: In addition to this eConsent Needs Assessment, we have also developed a complementar... = No*

Would you like to complete the eConsent Evaluation Tool?

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

☐ No

☐ Yes

**End of Block: Do you want to evaluate eConsent tool**