Where Science, Quality & Ethics Meet

EFGCP eConsent Initiative

eConsent Study Documents Recommendations

5 July 2024

Table of Contents

1. INTRODUCTION

To date, there are still many uncertainties regarding the level and type of information, and in which documents such information needs to be reflected for eConsent.

The two surveys conducted in 2023, focusing on industry's perspectives of Ethics Committees' (ECs) and Health Authorities' (HAs) study documentation needs of various eConsent Platform and Operational Aspects made that very clear. Not one of the 28 eConsent questions about what ECs or HAs should be informed about had 100% consensus among the 63 organizations that completed the EC survey or the 58 organizations that responded to the HA survey. Even with the same organization type, there were often different opinions. For more details about the surveys, consult the supporting article "Navigating eConsent Submissions: Who, What, Where and Why?"[1]

The purpose of the eConsent Study Documents Recommendations is to provide overall guidance on which eConsent platform and operational aspects should be documented in various study documents. In total, we evaluated 50 different eConsent aspects and the following nine different study documents:

- Protocol
- Health Authority Submission Cover Letter
- Ethics Committee Submission Cover Letter
- Participant-related eConsent Documents
- Informed Consent Document
- Site eConsent Documents
- Monitoring Plan
- Data Management Plan
- Platform/Vendor Due Diligence Documents

For detailed information about the different eConsent platform and operational aspects, please refer to the **Glossary of eConsent Terms** developed by the EFGCP eConsent Initiative (Appendix A).

The eConsent recommendations are presented in a table format for each study document. Many eConsent platform and operational aspects were evaluated at different levels: e.g. "High level" (a short description is presented) versus more detailed descriptions such as "Details/Types", "Usability Details", "Reimbursement of Data Usage". In the tables, we indicate all that apply, for ease of readability and consistency (e.g. tables can contain both high and detailed level). A total overview of all eConsent aspects related to all nine study documents is provided in Appendix B.

Important to note - there is no one-size-fits-all study documentation recommendation. Depending on the study (e.g. single-site study versus multiple site/country study), the number of eConsent aspects that could be included (e.g. one versus multiple eConsent digital features) may vary, and in other cases, another documentation approach might be more appropriate.

2. WHAT IS ECONSENT

Informed consent is a process between the participant and site personnel – the two key players – but the sponsor and other parties also have important roles to drive, support, and verify accuracy of the process.

The term 'eConsent' is the overarching terminology for the traditional informed consent process supported by one or more digital features[1]. It is important to understand that the consent process does not change; the same consent process steps are still applicable, as shown in Figure 1.

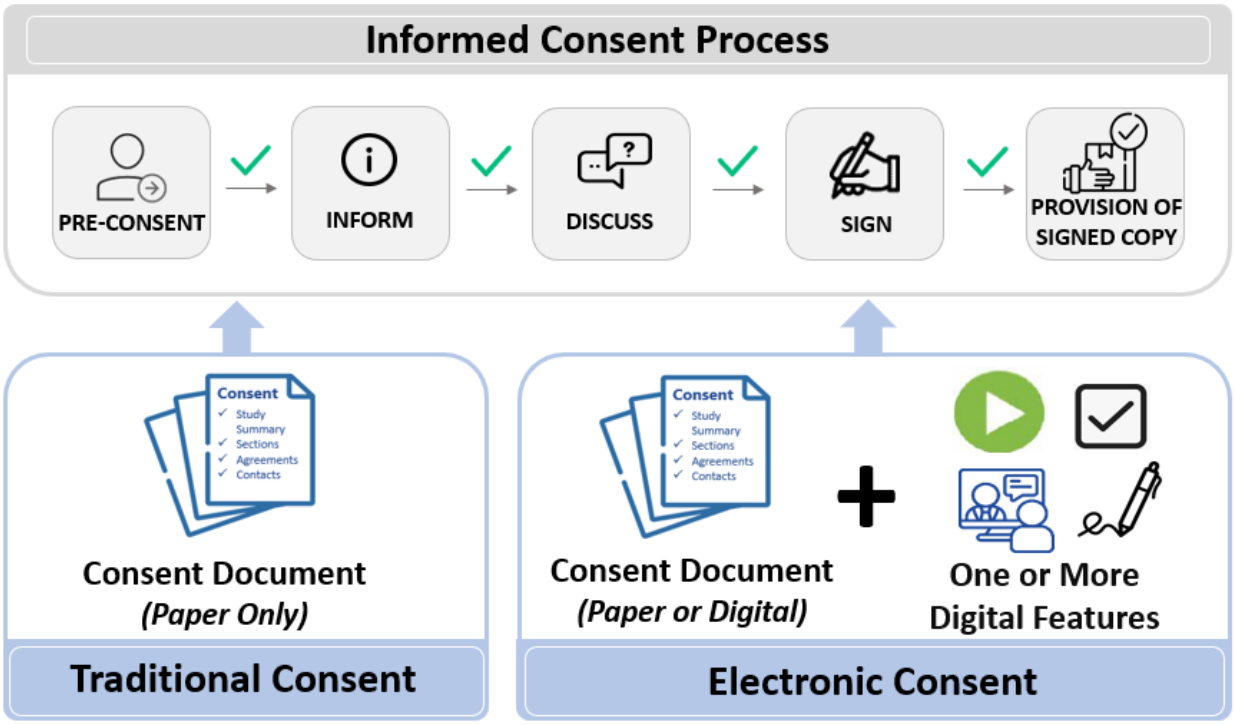

Figure 1: eConsent Definition and Some Examples of eConsent Digital Features

There are many disconnects regarding eConsent with some misconceptions as outlined in Figure 2. For example, eConsent is often confused with remote consent but they are two different concepts.-Remote consent refers to the location of the participant and investigator during the consent process and that they are not in the same physical location. A remote consent process could be conducted entirely on paper (not eConsent) or by using digital features (eConsent).

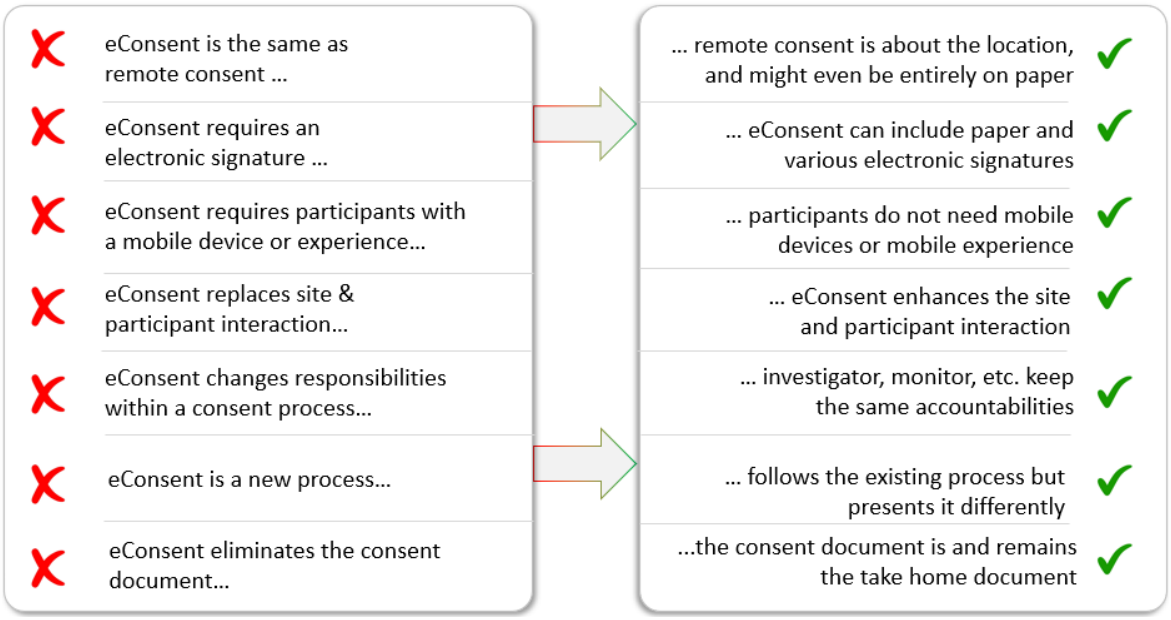

Figure 2: Some Common eConsent Misunderstandings

3. PROTOCOL

3.1. Description

A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents (Definition from ICH GCP E6 R3)[2].

3.2. eConsent Recommendations for Protocol

Aspects	Categories	Sub-Categories	Category Detail	Description
eConsent Platform Aspects	**Digital Features**	**Participants' Digital Features**	**High Level**	High level description/reference of the digital features that a participant may have/use to support the consent process (eConsent).
		Participants'/ sites' Confirmation of Participation	**High Level**	High level description/reference of the digital features that a participant/site may have/use to confirm his/her participation in the consent process: e.g. an eIDAS eSignature will/can be used to confirm participant's participation in the consent process.
		Participants' Remote Identity/Authentication		Description of methods used to remotely identify/authenticate the participant during the consent process: e.g. locally approved/certified identity devices/systems, digital sharing of participant's identity card, two-factor authentication, etc.
eConsent Operational Aspects	**Participant/Site Location**	**Full Remote Consent Process**	**High Level**	High level reference in case of absence of any physical interaction between the participant and site investigator for the consent process.
	Consent Workflow	**Participants' Remote Withdrawal Process**		Description that a participant can remotely revoke his/her decision to participate in a clinical study via the eConsent platform.
The term "Participant" may also apply to other stakeholders involved (e.g. legal authorized representatives, witness, translator).				

There might be cases where sites are using their own eConsent platform, the sponsor will need to consider whether this detail should be part of the protocol or be documented somewhere else.

4. HEALTH AUTHORITY SUBMISSION COVER LETTER

4.1. Description

A document that supports the Health Authority (HA) clinical trial submission and provides a short description of the study submitted, highlighting relevant points that may be of interest to the HA, and listing the documents submitted.

Under the EU CTR 536/2014, the cover letter is part of the "Part I of the Clinical Trial Application (CTA)".

4.2. eConsent Recommendations for Health Authority Submission Cover Letter

None of the eConsent platform or operational aspects were considered to be documented in the HA Submission Cover Letter. However, in case no EC submission cover letter exist, and the HA and EC submission is done via the same system, some elements might be included on the EC cover submission letter (see Section 5).

5. ETHICS COMMITTEE SUBMISSION COVER LETTER

5.1. Description

A document that supports the Ethics Committee clinical trial submission and provides a short description of the study submitted, highlighting relevant points that may be of interested to the EC, where and by whom the trial will be conducted, and listing the documents submitted. Under the EU CTR 536/2014, there is no cover letter for the Part II of the CTA.

5.2. eConsent Recommendations for Ethics Committee Submission Cover Letter

Aspects	Categories	Sub-Categories	Category Detail	Description
eConsent Platform Aspects	Digital Features	Participants' Digital Features	High level	High level description/reference of the digital features that a participant may have/use to support the consent process (eConsent).
			Details/Types	Description/details of the different types of digital features that participants may use/ have access to support the consent process, e.g. educational material like audio, or comprehension content like quiz, etc.
		Participants'/ Sites' Confirmation of Participation	High level	High level description/reference of the digital features that a participant/site may have/use to confirm his/her participation in the consent process: e.g. an eIDAS eSignature will/can be used to confirm participant's participation in the consent process.
			Details/Types	Description/details of the type of the digital feature that the participant/site may use to confirm his/her participation in the consent process: e.g. handwritten signature on an electronic device, or more general like eIDAS advanced eSignature will be used.
		Participants' Remote Identity/Authentication		Description of methods used to remotely identify/authenticate the participant during the consent process: e.g. locally approved/certified identity devices/systems, digital sharing of participant's identity card, two-factor authentication, etc.
eConsent Operational Aspects	Participant/Site Location	Full Remote Consent Process	High Level	High level reference in case of absence of any physical interaction between the participant and site investigator for the consent process.
			Details/Types	Details/type of remote/not in the same location interaction between participant and site investigator: e.g. phone call, video call.
	Data Access	Participants' Access to eSigned Consent Document		Description of how the participant can access eSigned Consent Documents: e.g. provided by site, download from website, sent via email.
	Device Deployment	Participants'/Sites' Provisioned Electronic Device	High Level	High level description that the site or participant receives an electronic device that can be used for the consent process.
			Usability Details	Description of access rights of the provisioned devices: e.g. access might be restricted to the consent information only or have access to other websites.
		Participants' Own Electronic Device	Participant's Own Electronic Device	Description of participant using their own electronic device.
			Reimbursement of Data Usage	Description of participant's reimbursement linked with using their own electronic device for the consenting process.
The term "Participant" may also apply to other stakeholders involved (e.g. legal authorized representatives, witness, translator).				

There might be cases where sites are using their own eConsent platform, depending on the site and whether the site is doing the EC submission and using an EC cover letter, this detail might be included in the EC cover letter.

The level of detail that needs to be included (details/types of digital features) might vary depending on the Ethics Committee (e.g. related to their experience and/or known expectations within the country).

6. PARTICIPANT RELATED eCONSENT DOCUMENTS

6.1. Description

Documents describing all interactions, instructions and activities of participants related to eConsent. Documents might be provided directly to the participant (e.g. participant's eConsent user manual) and/or only to other stakeholders (e.g. ECs) to give insight and oversight of participants' interactions and activities related to eConsent (e.g. screenshots of eConsent platform/multimedia). Documents can only cover eConsent and/or part of another document (e.g. participant manual).

Note - Some participant-related eConsent aspects might be referenced in the recruitment/pre-screening material.

Note – The Informed Consent Document has also been listed as a separate document (See Paragraph 7).

6.2. eConsent Recommendations for Participant Related eConsent Documents

Aspects	Categories	Sub-Categories	Category Detail	Description
eConsent Platform Aspects	Digital Features	Participants' Digital Features	High Level	High level description/reference of the digital features that a participant may have/use to support the consent process (eConsent).
			Details/Types	Description/details of the different types of digital features that participants may use/ have access to support the consent process, e.g. educational material like audio, or comprehension content like quiz, etc.
		Participants'/Sites' Confirmation of Participation	High Level	High level description/reference of the digital features that a participant/site may have/use to confirm his/her participation in the consent process: e.g. an eIDAS eSignature will/can be used to confirm participant's participation in the consent process.
			Details/Types	Description/details of the type of the digital feature that the participant/site may use to confirm his/her participation in the consent process: e.g. handwritten signature on an electronic device, or more general like eIDAS advanced eSignature will be used.
			Participants/Sites' Wet-ink Signature	Description that the consent process involved several digital features (e.g. digital educational material) but that the signing is done on paper (wet-ink signature).
		Participants' Remote Identity/Authentication		Description of methods used to remotely identify/authenticate the participant during the consent process: e.g. locally approved/certified identity devices/systems, digital sharing of participant's identity card, two-factor authentication, etc.
		Participants' eConsent Platform Training		Digital content or guidance for participants to help with navigating and using the eConsent platform.
	Data Storage	Participants' Personal Data Storage	Electronic Storage of Personal Data	Description of which personal data is stored in eConsent platform.
			Electronic Storage of Wet-ink Signed Consent Document	Description that the paper signed document (including all personal data) will be stored electronically.
	Identifiers	Participants' Token		Description of use of a participant token for the consenting process.
	Data Privacy Clause/Agreement	eConsent Platform Data Privacy Clause/Agreement		Description of the legal disclaimer or privacy clause/agreement of the participant that their personal data can be collected and/or used in the eConsent platform.
	Platform Owner	eConsent Platform Vendor Selected		Description of eConsent platform vendor selected.

Aspects	Categories	Sub-Categories	Category Detail	Description
eConsent Operational Aspects	Stakeholders	Stakeholders Linked with Participants		Description of the stakeholders, that are directly or indirectly linked with the participant during the consent process: e.g. participant-related stakeholders (e.g. parent), non-participant related stakeholders (e.g. impartial witness) and miscellaneous study stakeholders (e.g. pregnant female partner of a male participant).
	Participant/Site Location	Full Remote Consent Process	High Level	High level reference in case of absence of any physical interaction between the participant and site investigator for the consent process.
			Details/Types	Details/type of remote/not in the same location interaction between participant and site investigator: e.g. phone call, video call.
	Data Access	Participants' Access to eSigned Consent Document		Description of how the participant can access eSigned consent documents: e.g. provided by site, download from website, sent via email.
		Remote Inspector/Auditor Access	Personal Data	Description that inspectors/auditors have remote access to personal data.
		Remote Monitor Access		Description that monitors have remote access to consent personal data.
	Device Deployment	Participants'/Sites' Provisioned Electronic Device	High Level	High level description that the site or participant receives an electronic device that can be used for the consent process.
			Usability Details	Description of access rights of the provisioned devices: e.g. access might be restricted to the consent information only or have access to other websites.
		Participants' Own Electronic Device	Participants' Own Electronic Device	Description of participant using its own electronic device.
			Reimbursement of Data Usage	Description of participant's reimbursement linked with using their own electronic device for the consenting process.
	Support/ Helpdesk	Participants' eConsent Support/Helpdesk	Overall Process	Description of process to support participants with the use of the eConsent platform (e.g. helpdesk).
			Measures Related to Privacy Data	Description of measures that of the support/helpdesk related to privacy data of the participant.
	Consent Workflow	Participants' Remote Withdrawal Process		Description of how a participant can remotely revoke his/her decision to participate in a clinical study via the eConsent platform.
		eConsent End-to-End Workflow		Description of the entire eConsent stakeholders' workflow (from interest confirmed that information can be shared to the provision of signed document) and post-eConsent workflows (e.g. reconsent, withdrawal, addition of participant EDC ID), and applicability for different consents (main, optional, assent).
	Risk Management	eConsent Risk Instructions		General instructions on aspects to take into account (e.g. making sure that electronic device is charged).

- The term "Participant" may also apply to other stakeholders involved (e.g. legal authorized representatives, witness, translator).
- Participants/Sites' Wet-Ink Signature has been added together within the digital feature 'Participants/Sites' Confirmation of Participation" for a better flow, however, it is not a digital feature.

In case of sites using their own eConsent platform, the site is responsible for creating the participant-related eConsent documents.

7. INFORMED CONSENT DOCUMENT

7.1. Description

A document (paper or digital) that the study participant receives after confirming their participation in a clinical trial and which is signed by the participant, investigator, and related stakeholders, if applicable. This document describes the rights of a study participant and provides details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document (part of definition from the National Institute of Aging (NIA))[3].

7.2. eConsent Recommendations for Informed Consent Document

Aspects	Categories	Sub-Categories	Category Detail	Description
eConsent Platform Aspects	Digital Features	Participants'/sites' Confirmation of Participation	High Level	High level description/reference of the digital features that a participant/site may have/use to confirm his/her participation in the consent process: e.g. an eIDAS eSignature will/can be used to confirm participant's participation in the consent process.
			Details/Types	Description/details of the type of the digital feature that the participant/site may use to confirm his/her participation in the consent process: e.g. handwritten signature on an electronic device, or more general like eIDAS advanced eSignature will be used.
			Participants/Sites' Wet-ink Signature	Description that the consent process involved several digital features (e.g. digital educational material) but that the signing is done on paper (wet-ink signature).
	Data Storage	Participants' Personal Data Storage	Electronic Storage of Personal Data	Description of which personal data is stored in eConsent platform.
			Electronic Storage of Wet-ink Signed Consent Document	Description that the paper signed document (including all personal data) will be stored electronically.
	Identifiers	Participants' Token		Description of use of a participant token for the consenting process.
	Data Privacy Clause/Agreement	eConsent Platform Data Privacy Clause/Agreement		Description of the legal disclaimer or privacy clause/agreement of the participant that their personal data can be collected and/or used in the eConsent platform.
eConsent Operational Aspects	Stakeholders	Stakeholders Linked with Participants		Description of the stakeholders, that are directly or indirectly linked with the participant during the consent process: e.g. participant-related stakeholders (e.g. parent), non-participant related stakeholders (e.g. impartial witness) and miscellaneous study stakeholders (e.g. pregnant female partner of a male participant).
	Data Access	Participants' Access to eSigned Consent Document		Description of how the participant can access eSigned consent documents: e.g. provided by site, download from website, sent via email.
		Remote Inspector/Auditor Access	Personal Data	Description that inspectors/auditors have remote access to personal data.
		Remote Monitor Access		Description that monitors have remote access to consent personal data.
	Device Deployment	Participants'/Sites' Provisioned Electronic Device	High Level	High level description that the site or participant receives an electronic device that can be used for the consent process.
			Usability Details	Description of access rights of the provisioned devices: e.g. access might be restricted to the consent information only or have access to other websites.
		Participants' Own Electronic Device	High Level	Description of participant using its own electronic device.
			Reimbursement of Data Usage	Description of participant's reimbursement linked with using their own electronic device for the consenting process.
	Consent Workflow	Participants' Remote Withdrawal Process		Description of how a participant can remotely revoke his/her decision to participate in a clinical study via the eConsent platform.

- The term "Participant" may also apply to other stakeholders involved (e.g. legal authorized representatives, witness, translator)
- Participants/Sites' Wet-Ink Signature has been added together within the digital feature 'Participants/Sites' Confirmation of Participation" for a better flow, however, it is not a digital feature

In case of sites using their own eConsent platform, the site is responsible to include the above information in the informed consent document.

8. SITE eCONSENT DOCUMENTS

8.1. Description

Documents which provide the sites information and specifications of how the eConsent will be used in a particular study. Note: Site eConsent Documents can be standalone documents and/or part of another document such as site manual.

8.2. eConsent Recommendations for Site eConsent Documents

Aspects	Categories	Sub-Categories	Category Detail	Description
eConsent Platform Aspects	Digital Features	Participants' Digital Features	High Level	High level description/reference of the digital features that a participant may have/use to support the consent process (eConsent).
			Details/Types	Description/details of the different types of digital features that participants may use/ have access to support the consent process, e.g. educational material like audio, or comprehension content like quiz, etc.
		Sites' Digital Features	High Level	High level description/reference of the digital features that sites may use/have access to support the consent process (eConsent).
			Details/Types	Description/details of the different types of digital features that sites may use/ have access to support the consent process, e.g. comprehension confirmation, documentation/log, etc.
		Participants'/sites' Confirmation of Participation	High Level	High level description/reference of the digital features that a participant/site may have/use to confirm his/her participation in the consent process: e.g. an eIDAS eSignature will/can be used to confirm participant's participation in the consent process.
			Details/Types	Description/details of the type of the digital feature that the participant/site may use to confirm his/her participation in the consent process: e.g. handwritten signature on an electronic device, or more general like eIDAS advanced eSignature will be used.
			Participants/Sites' Wet-ink Signature	Description that the consent process involved several digital features (e.g. digital educational material) but that the signing is done on paper (wet-ink signature).
		Participants' Remote Identity/Authentication		Description of methods used to remotely identify/authenticate the participant during the consent process: e.g. locally approved/certified identity devices/systems, digital sharing of participant's identity card, two-factor authentication, etc.
		Sites' eConsent platform Training		Digital content or guidance for sites to help with navigating and using the eConsent platform.
	Data Storage	Participants' Personal Data Storage	Electronic Storage of Personal Data	Description of which personal data is stored in eConsent platform.
			Electronic Storage of Wet-ink Signed Consent Document	Description that the paper signed document (including all personal data) will be stored electronically.
		Non-Personal Data	Electronic Storage of Non-Personal Data	Description of non-personal data storage (e.g. time spent reviewing, questions asked).
		Aggregated Metadata	Electronic Storage of Aggregated Metadata	Description of metadata storage (e.g. % of questions incorrectly answered).
	Platform Specifications	Linkage of Wet-ink Signed Document with Electronic Consent Record		Description of how the wet-ink signed document is linked with the electronic consent record.
	Consent Accounts	Participants/Stakeholders' Accounts		Provision or creation of participant/stakeholder credentials to access their respective accounts.
	Identifiers	Participants' Token		Description of use of a participant token for the consenting process.
	Integration	eConsent platform Integration with Other Study Systems		Description of eConsent platform integration with other study systems.
		eConsent Platform Integration with Site Systems		Description of eConsent platform integration with the site systems.
	Platform Owner	eConsent platform Vendor Selected		Description of eConsent platform vendor selected.

Aspects	Categories	Sub-Categories	Category Detail	Description
eConsent Operational Aspects	Stakeholders	Stakeholders Linked with Participants		Description of the stakeholders, that are directly or indirectly linked with the participant during the consent process: e.g. participant-related stakeholders (e.g. parent), non-participant related stakeholders (e.g. impartial witness) and miscellaneous study stakeholders (e.g. pregnant female partner of a male participant).
	Participant/Site Location	Full Remote Consent Process	High Level	High level reference in case of absence of any physical interaction between the participant and site investigator for the consent process.
			Details/Types	Details/type of remote/not in the same location interaction between participant and site investigator: e.g. phone call, video call.
	Data Access	Participants' Access to eSigned Consent Document		Description of how the participant can access eSigned consent documents: e.g. provided by site, download from website, sent via email.
	Device Deployment	Participants'/Sites' Provisioned Electronic Device	High Level	High level description that the site or participant receives an electronic device that can be used for the consent process.
			Usability Details	Description of access rights of the provisioned devices: e.g. access might be restricted to the consent information only or have access to other websites.
	Support/ Helpdesk	Sites' eConsent Support/Helpdesk	Overall Process	Description of process to support sites with the use of the eConsent platform (e.g. helpdesk).
	Consent Workflow	Participants' Remote Withdrawal Process		Description of how a participant can remotely revoke his/her decision to participate in a clinical study via the eConsent platform.
		EConsent End-to-End Workflow		Description of the entire eConsent stakeholders' workflow (from interest confirmed that information can be shared to the provision of signed document) and post-eConsent workflows (e.g. reconsent, withdrawal, addition of participant EDC ID), and applicability for different consents (main, optional, assent).
	Archiving/ Permanent Records	eConsent Archiving Process		Description of archiving of eConsent material respectively by the site or sponsor, or the retention of a permanent record by the participant. This can include blank eConsent material/templates and eConsent material completed by participants/other stakeholders.
	Risk Management	eConsent Risk Instructions		General instructions on aspects to take into account (e.g. making sure that electronic device is charged).

- The term "Participant" may also apply to other stakeholders involved (e.g. legal authorized representatives, witness, translator).
- Participants'/Sites' Wet-Ink Signature has been added together within the digital feature 'Participants/Sites' Confirmation of Participation" for a better flow, however, it is not a digital feature.

In case of site using its own eConsent platform, at least a site attestation form or a form that confirms that the site is accountable and confirms that the platform used is in compliant with all regulations is required.

Some platform and operational aspects listed in the table above are also covered in the participant eConsent material and hence might not be detailed in the site documents. In the list above the most important ones are mentioned to consider to document in the site eConsent documents (e.g. participant's digital features), but for aspects as participant helpdesk or participant training, this is often documented only in the participant eConsent documents.

9. MONITORING PLAN

9.1. Description

A document that describes the strategy, methods, responsibilities, and requirements for monitoring the trial. It generally includes the following monitoring activities, as applicable: 1) communication with parties conducting the trial, 2) investigator site selection, initiation, management and close out, 3) monitoring of investigational product management, 4) monitoring of clinical trial data and 5) monitoring report. (part of ICH E6 R3 definition)[2].

9.2. eConsent Recommendations for Monitoring Plan

Aspects	Categories	Sub-Categories	Category Detail	Description
eConsent Platform Aspects	Digital Features	Participants' Digital Features	High Level	High level description/reference of the digital features that a participant may have/use to support the consent process (eConsent).
		Study Oversight Stakeholders' Digital Features	High Level	High level description/reference of the digital features that study oversight stakeholders (e.g. monitors) may use/have access to support the consent process (eConsent).
			Details/Types	Description/details of the different types of digital features that the study oversight stakeholders (e.g. monitors) may use/ have access to support the consent process, e.g. metadata insights and metrics, business intelligence, etc.
		Participants'/sites' Confirmation of Participation	High Level	High level description/reference of the digital features that a participant/site may have/use to confirm his/her participation in the consent process: e.g. an eIDAS eSignature will/can be used to confirm participant's participation in the consent process.
			Details/Types	Description/details of the type of the digital feature that the participant/site may use to confirm his/her participation in the consent process: e.g. handwritten signature on an electronic device, or more general like eIDAS advanced eSignature will be used.
			Participants/Sites' Wet-ink Signature	Description that the consent process involved several digital features (e.g. digital educational material) but that the signing is done on paper (wet-ink signature).
		Participants' Remote Identity/Authentication		Description of methods used to remotely identify/authenticate the participant during the consent process: e.g. locally approved/certified identity devices/systems, digital sharing of participant's identity card, two-factor authentication, etc.
	Data Storage	Participants' Personal Data Storage	Electronic Storage of Personal Data	Description of which personal data is stored in eConsent platform.
		Non-Personal Data	Electronic Storage of Non-Personal Data	Description of non-personal data storage (e.g. time spent reviewing, questions asked).
		Aggregated Metadata	Electronic Storage of Aggregated Metadata	Description of metadata storage (e.g. % of questions incorrectly answered).
	Platform Specifications	Linkage of Wet-ink Signed Document with Electronic Consent Record		Description of how the wet-ink signed document is linked with the electronic consent record.
	Consent Accounts	Participants/Stakeholders' Accounts		Provision or creation of participant/stakeholders' credentials to access their respective accounts.
	Platform Owner	eConsent Platform Vendor Selected		Description of eConsent platform vendor selected.
		Sites' Own eConsent platform		Description/reference that site's own eConsent systems is used. Certificates might be included, if applicable.
eConsent Operational Aspects	Data Access	Participants' Access to eSigned Consent Document		Description of how the participant can access eSigned consent documents: e.g. provided by site, download from website, sent via email.
	Data Access	Remote Monitor Access	Personal Data	Description that monitors have remote access to consent personal data.
			Non-Personal Data	Description that monitors have remote access to consent non- personal data.
	Consent Workflow	Participants' Remote Withdrawal Process		Description of how a participant can remotely revoke his/her decision to participate in a clinical study via the eConsent platform.
	Monitoring	eConsent Monitoring Process		Description and instructions of how monitors will proceed with the monitoring activities for eConsent.
	Risk Management	eConsent Risk Management Plans		Description of risks, estimated impacts and responses to risks related to eConsent.

- The term "Participant" may also apply to other stakeholders involved (e.g. legal authorized representatives, witness, translator).
- Participants/Sites' Wet-Ink Signature has been added together within the digital feature 'Participants/Sites' Confirmation of Participation" for a better flow, however, it is not a digital feature.

In case of sites using their own eConsent platform, we recommend that a short description is present in the monitoring plan for how the monitoring for eConsent will be done for those sites.

10. DATA MANAGEMENT PLAN

10.1.Description

A plan that documents the processes for handling the flow of data from collection through analysis. Software and hardware systems along with quality control and validation of these systems, as relevant are described (Definition from National Institute of Aging (NIA))[3]

10.2.eConsent Recommendations for Data Management Plan

Aspects	Categories	Sub-Categories	Category Detail	Description
eConsent Platform Aspects	Digital Features	Participants' Digital Features	High Level	High level description/reference of the digital features that a participant may have/use to support the consent process (eConsent).
		Study Oversight Stakeholders' Digital Features	High Level	High level description/reference of the digital features that study oversight stakeholders (e.g. monitors) may use/have access to support the consent process (eConsent).
			Details/Types	Description/details of the different types of digital features that the study oversight stakeholders (e.g. monitors) may use/ have access to support the consent process, e.g. metadata insights and metrics, business intelligence, etc.
		Participants'/sites' Confirmation of Participation	High Level	High level description/reference of the digital features that a participant/site may have/use to confirm his/her participation in the consent process: e.g. an eIDAS eSignature will/can be used to confirm participant's participation in the consent process.
	Data Storage	Participants' Personal Data Storage	Electronic Storage of Personal Data	Description of which personal data is stored in eConsent platform.
		Aggregated Metadata	Electronic Storage of Aggregated Metadata	Description of metadata storage (e.g. % of questions incorrectly answered).
	Platform Specifications	Linkage of Wet-ink Signed Document with Electronic Consent Record		Description of how the wet-ink signed document is linked with the electronic consent record.
	Integration	eConsent Platform Integration with Other Study Systems		Description of eConsent platform integration with other study systems.
		eConsent Platform Integration with Site Systems		Description of eConsent platform integration with the site systems.
	Environment	eConsent Platform Environments		Description of unique instance(s) of the eConsent platform that facilitate different intended uses. Instances can be live or production environments containing actual participant data, or pre-production environments containing test or demonstration data.
	Platform Owner	eConsent Platform Vendor Selected		Description of eConsent platform vendor selected.
	Platform Owner	Sites' Own eConsent platform		Description/reference that site's own eConsent systems is used. Certificates might be included, if applicable.
eConsent Operational Aspects	Consent Workflow	Participants' Remote Withdrawal Process		Description of how a participant can remotely revoke his/her decision to participate in a clinical study via the eConsent platform.
The Term "Participant" may also apply to other stakeholders involved (e.g. legal authorized representatives, witness, translator).				

In case of sites using their own eConsent platform, we recommend that a short description is present in the data management plan about which consent data, if any, is transferred to a sponsor platform.

11. PLATFORM/VENDOR DUE DILIGENCE DOCUMENTS

11.1.Description

Documents pertaining to the specific platform/software used for managing eConsent whether it's a vendor, or site platform. Documents are often non-study specific.

11.2.eConsent Recommendations for Platform/Vendor Due Diligence Documents

Aspects	Categories	Sub-Categories	Category Detail	Description
eConsent Platform Aspects	Data Storage	Participants' Personal Data Storage	Electronic Storage of Personal Data	Description of which personal data is stored in eConsent platform.
			Electronic Storage of Wet-ink Signed Consent Document	Description that the paper signed document (including all personal data) will be stored electronically.
		Non-Personal Data	Electronic Storage of Non-Personal Data	Description of non-personal data storage (e.g. time spent reviewing, questions asked).
		Aggregated Metadata	Electronic Storage of Aggregated Metadata	Description of metadata storage (e.g. % of questions incorrectly answered).
	Platform Specifications	Linkage of Wet-ink Signed Document with Electronic Consent Record		Description of how the wet-ink signed document is linked with the electronic consent record.
	Consent Accounts	Participants'/Stakeholders' Accounts		Provision or creation of participant/stakeholder's credentials to access their respective accounts.
	Identifiers	Participants' Identification Code		Provision of a unique identifier assigned to each study participant to protect the participant's identity.
		Participants' Token		Description of use of a participant token for the consenting process.
		Consent Document Identifiers		Provision of unique identifier (e.g., code, number) assigned to a particular consent document.
	Data Privacy Clause/ Agreement	eConsent Platform Data Privacy Clause/Agreement		Description of the legal disclaimer or privacy clause/agreement of the participant that their personal data can be collected and/or used in the eConsent platform.
	Validation	eConsent Platform Validation		Description of eConsent platform validation: e.g. package with documents such as testing scripts, traceability matrix, software development lifecycle.
	Compliance Documentation	eConsent Platform Compliance Documentation		Description that the eConsent platform complies with regulatory requirements related to security, privacy, electronic signatures, and other requirements of electronic platforms used in clinical studies: e.g. Data integrity, privacy, and compliance certificates and/or documentation related to various regulations.
	Integration	eConsent Platform Integration with Other Study Systems		Description of eConsent platform integration with other study systems.
		eConsent Platform Integration with Site Systems		Description of eConsent platform integration with the site systems.
	Environment	eConsent Platform Environments		Description of unique instance(s) of the eConsent platform that facilitate different intended uses. Instances can be live or production environments containing actual participant data, or pre-production environments containing test or demonstration data.

Aspects	Categories	Sub-Categories	Category Detail	Description
eConsent Operational Aspects	Stakeholders	Stakeholders Linked with Participants		Description of the stakeholders, that are directly or indirectly linked with the participant during the consent process: e.g. participant-related stakeholders (e.g. parent), non-participant related stakeholders (e.g. impartial witness) and miscellaneous study stakeholders (e.g. pregnant female partner of a male participant).
	Device Deployment	Participants'/Sites' Provisioned Electronic Device	High Level	High level description that the site or participant receives an electronic device that can be used for the consent process.
			Usability Details	Description of access rights of the provisioned devices: e.g. access might be restricted to the consent information only or have access to other websites.
	Support/ Helpdesk	Participants' eConsent Support/Helpdesk	Overall Process	Description of process to support participants with the use of the eConsent platform (e.g. helpdesk).
			Measures Related to Privacy Data	Description of measures that of the support/helpdesk related to privacy data of the participant.
		Sites' eConsent Support/Helpdesk	Overall Process	Description of process to support sites with the use of the eConsent platform (e.g. helpdesk).
	Consent Workflow	Participants' Remote Withdrawal Process		Description of how a participant can remotely revoke his/her decision to participate in a clinical study via the eConsent platform.
	Archiving/ Permanent Records	eConsent Archiving Process		Description of archiving of eConsent material respectively by the site, sponsor, and participant. This can include blank eConsent material/templates and eConsent material completed by participant/other stakeholders.
	Risk Management	eConsent Risk Management Plans		Description of risks, estimated impacts and responses to risks related to eConsent.
The term "Participant" may also apply to other stakeholders involved (e.g. legal authorized representatives, witness, translator).				

In case of site using its own eConsent platform, at least a site attestation form or a form that confirms that the site is accountable and confirms that the platform used is compliant with all regulations is required.

12. ADDITIONAL CONSIDERATIONS

Additional recommendations for the study documents are:

- Use flexible language for global documents to cover local, site or cultural differences.
- Create separate eConsent sections in existing documents (e.g. monitoring plan) to enable easy extraction, in case requested.

You might also consider the following additional (new) documents:

- eConsent Study-Specific Documents Overview
    - Starting from the study docs recommendation overview maintain only what is applicable for your study and in which study documents it is described. Such a study-specific overview might be useful to share upfront with Ethics Committees/Health Authorities to check if they want to receive any other documents.
- eConsent Study-Specific Country Site Implementation Overview
    - Use the platform/operational/aspects overview of your study to indicate how it was implemented at a country or site level for that study. For country/site deviations compared to the global set up, also indicate the rationale (e.g. too expensive or time-intensive to set up a local hosting center and hence used wet-ink signature).
- An All-In-One Study-Specific eConsent Manual
    - Combines all eConsent-related paragraphs/documents in one overarching eConsent Manual, and with reference in the other documents to this manual (no duplication of content).
    - Manual can be divided in sections such as “participant-related documents”, “site documents”, “sponsor documents”, “platform documents”, etc and also include the eConsent study docs overview and eConsent country site implementation overview.

13. REFERENCES

1. Navigating eConsent Submissions: Who What, Where and Why? Applied Clinical Trials, 10 November 2023. https://efgcp.eu/public/Navigating%20eConsent%20Submissions%20-%20ACT%2010%20Nov%202023%20v2.pdf
2. ICH Harmonized Guideline Good Clinical Practice (GCP) E6 (R3), 19 May 2023 (DRAFT). https://database.ich.org/sites/default/files/ICH_E6%28R3%29_DraftGuideline_2023_0519.pdf
3. National Institute of Aging (NIA) Glossary of Clinical Research Terms, assessed on 1 July 2024. https://www.nia.nih.gov/research/dgcg/nia-glossary-clinical-research-terms
4. Glossary of eConsent Terms, 5 July 2024 . https://efgcp.eu/public/EFGCP%20Glossary%20of%20eConsent%20Terms.pdf
5. eConsent: Why Language Matters! Applied Clinical Trials, 20 December 2023. https://efgcp.eu/public/eConsent%20-%20Why%20Language%20Matters%20-%20ACT%2020%20Dec%202023.pdf

APPENDIX A:
GLOSSARY OF eCONSENT TERMS

The Glossary of eConsent Terms developed by the EFGCP eConsent initiative contains over 60 different terminologies to describe various eConsent platform aspects and eConsent operational aspects. The below figures represent the eConsent platform operational aspects including digital features terminologies (See Figure A.1), the eConsent operational aspects terminologies (See Figure A.2), the digital features terminologies categorized per stakeholder group (See Figure A.3) and the descriptions and some examples of each digital feature term (See Figure A.4).

More details (e.g. descriptions and examples of other aspects) can be found in the "Glossary of eConsent Terms"[4], and the supporting article "eConsent: Why Language Matters"[5].

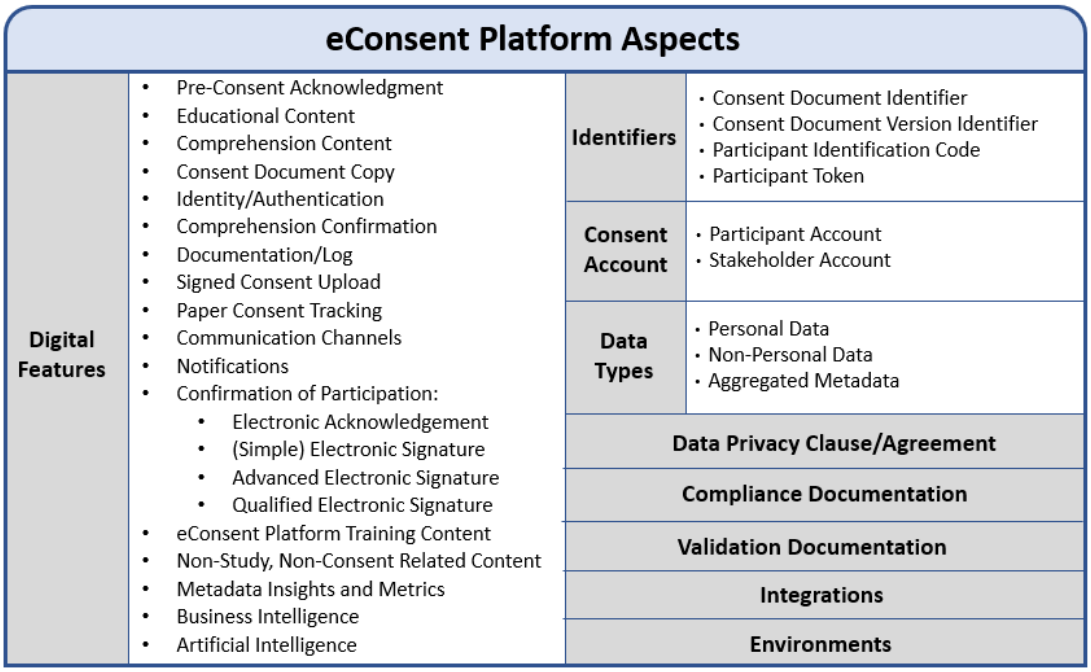

Figure A.1. eConsent Platform Aspects (including Digital Features)

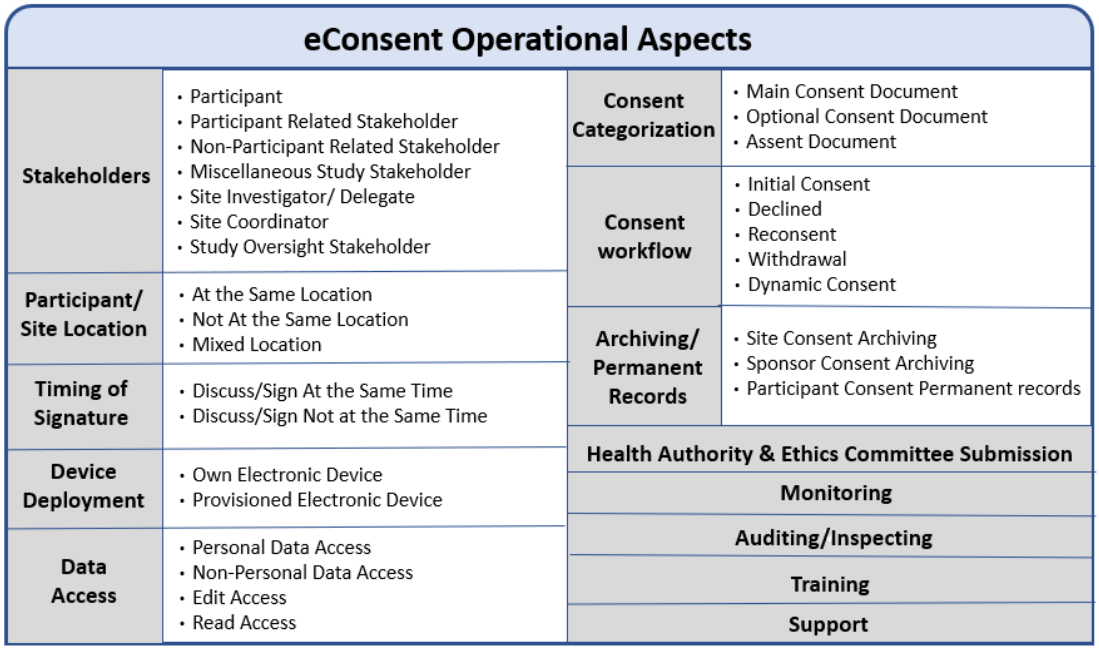

Figure A.2. eConsent Operational Aspects

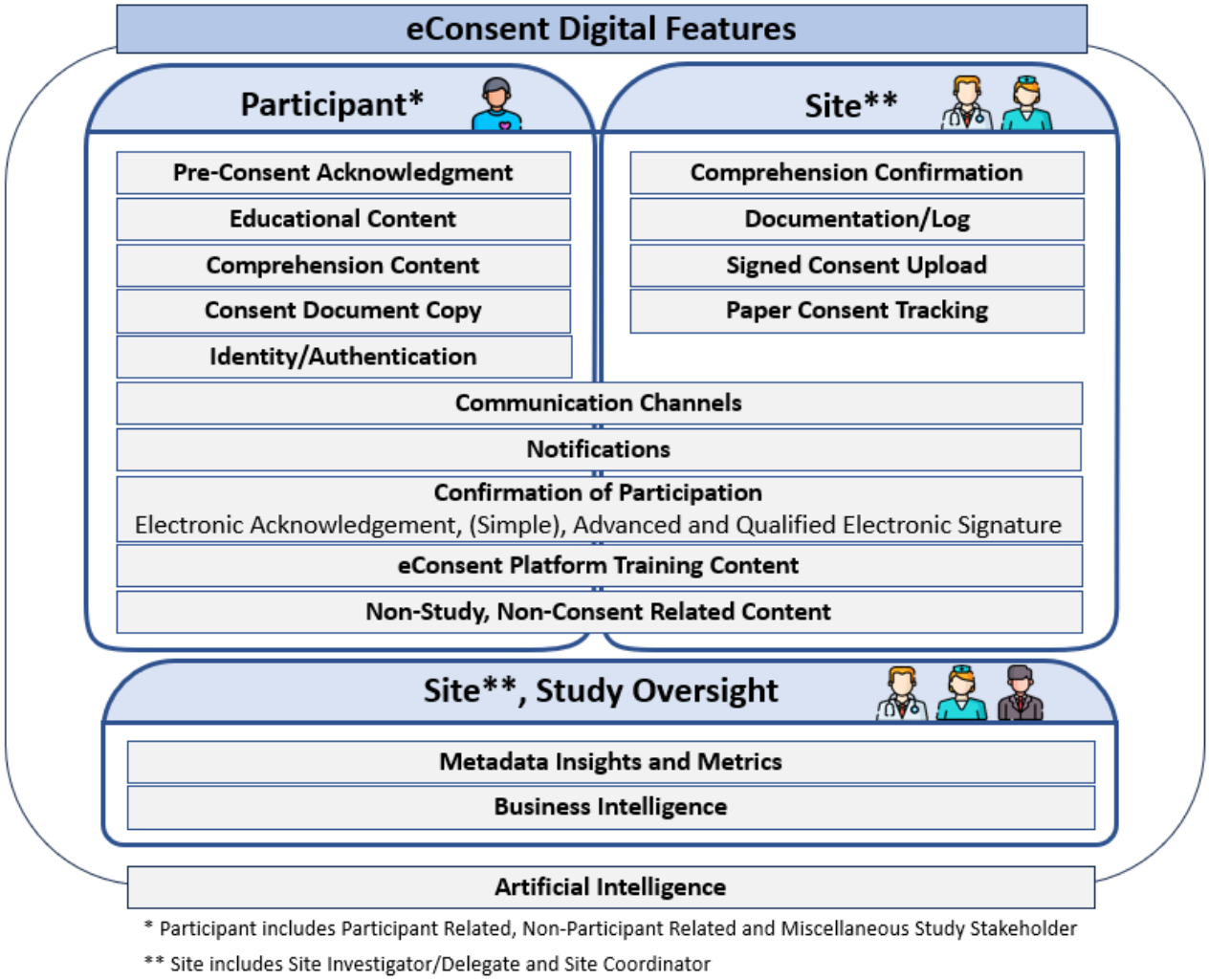

Figure A.3: eConsent Digital Features Per Stakeholder Group.

APPENDIX B:
eCONSENT ASPECTS STUDY DOCUMENTS RECOMMENDATIONS OVERVIEW

Aspects	Categories	Sub-Categories	Category Detail	Description	Applicable Study Document(s)
eConsent platform Aspects	Digital Features	Participants' Digital Features	High Level	High level description/reference of the digital features that a participant may have/use to support the consent process (eConsent).	• Protocol • EC Submission Cover Letter • Participant Related eConsent Documents • Site eConsent Documents • Monitoring Plan • Data Management Plan
			Details/Types	Description/details of the different types of digital features that participants may use/ have access to support the consent process, e.g. educational material like audio, or comprehension content like quiz, etc.	• EC Submission Cover Letter • Participant Related eConsent Documents • Site eConsent Documents
		Sites' Digital Features	High Level	High level description/reference of the digital features that sites may use/have access to support the consent process (eConsent).	• Site eConsent Documents
			Details/Types	Description/details of the different types of digital features that sites may use/ have access to support the consent process, e.g. comprehension confirmation, documentation/log, etc.	• Site eConsent Documents
		Study Oversight Stakeholders' Digital Features	High Level	High level description/reference of the digital features that study oversight stakeholders (e.g. monitors) may use/have access to support the consent process (eConsent).	• Monitoring Plan • Data Management Plan
			Details/Types	Description/details of the different types of digital features that the study oversight stakeholders (e.g. monitors) may use/ have access to support the consent process, e.g. metadata insights and metrics, business intelligence, etc.	• Monitoring plan • Data Management Plan
		Participants'/ sites' Confirmation of Participation	High Level	High level description/reference of the digital features that a participant/site may have/use to confirm his/her participation in the consent process: e.g. an eIDAS eSignature will/can be used to confirm participant's participation in the consent process.	• Protocol • EC Submission Cover Letter • Participant Related eConsent Documents • Informed Consent Document • Site eConsent Documents • Monitoring plan • Data Management Plan • Platform/Vendor Due Diligence Documents
			Details/Types	Description/details of the type of the digital feature/s that the participant/site may use to confirm his/her participation in the consent process: e.g. handwritten signature on an electronic device, or more general like eIDAS advanced eSignature will be used.	• EC Submission Cover Letter • Participant Related eConsent Documents • Informed Consent Document • Site eConsent Documents • Monitoring Plan • Data Management Plan
			Participants/ Sites' Wet-ink Signature	Description that the consent process involved several digital features (e.g. digital educational material) but that the signing is done on paper (wet-ink signature).	• Participant Related eConsent Documents • Informed Consent Document • Site eConsent Documents • Monitoring Plan
		Participants' Remote Identity/Authentication		Description of methods used to remotely identify/authenticate the participant during the consent process: e.g. locally approved/certified identity devices/systems, digital sharing of participant's identity card, two-factor authentication, etc.	• Protocol • EC Submission Cover Letter • Participant Related eConsent Documents • Site eConsent Documents • Monitoring Plan

Aspects	Categories	Sub-Categories	Category Detail	Description	Applicable Study Document(s)
eConsent Platform Aspects	Digital Features	Participants' eConsent platform Training		Digital content or guidance for participants to help with navigating and using the eConsent platform.	• Participant Related eConsent Documents
		Sites' eConsent platform Training		Digital content or guidance for sites to help with navigating and using the eConsent platform.	• Site eConsent Documents
	Data Storage	Participants' Personal Data Storage	Electronic Storage of Personal Data	Description of which personal data is stored in eConsent platform.	• Participant Related eConsent Documents • Informed Consent Document • Site eConsent Documents • Monitoring Plan • Data Management Plan • Platform/vendor Due Diligence Documents
			Electronic Storage of Wet-ink Signed Consent Document	Description that the paper signed document (including all personal data) will be stored electronically.	• Participant Related eConsent Documents • Informed Consent Document • Site eConsent Documents • Platform/vendor Due Diligence Documents
		Non-Personal Data	Electronic Storage of Non-Personal Data	Description of non-personal data storage (e.g. time spent reviewing, questions asked).	• Site eConsent Documents • Monitoring Plan • Platform/vendor Due Diligence Documents
		Aggregated Metadata	Electronic Storage of Aggregated Metadata	Description of metadata storage (e.g. % of questions incorrectly answered).	• Site eConsent Documents • Monitoring Plan • Data Management Plan • Platform/vendor Due Diligence Documents
	Platform Specifications	Linkage of Wet-ink Signed Document with Electronic Consent Record		Description of how the wet-ink signed document is linked with the electronic consent record.	• Site eConsent Documents • Monitoring Plan • Data Management Plan • Platform/vendor Due Diligence Documents
	Consent Accounts	Participants/Stakeholders' Accounts		Provision or creation of participant/stakeholder's credentials to access their respective accounts.	• Site eConsent documents • Monitoring Plan • Platform/vendor Due Diligence Documents
	Identifiers	Participants' Identification Code		Provision of a unique identifier assigned to each study participant to protect the participant's identity.	• Platform/Vendor Due Diligence Documents
		Participants' Token		Description of use of a participant token for the consenting process.	• Participant Related eConsent Documents • Informed Consent Document • Site eConsent Documents • Platform/vendor Due Diligence Documents
		Consent Document Identifiers		Provision of unique identifier (e.g., code, number) assigned to a particular consent document.	• Platform/Vendor Due Diligence Documents
	Data Privacy Clause/ Agreement	eConsent Platform Data Privacy Clause/Agreement		Description of the legal disclaimer or privacy clause/agreement of the participant that their personal data can be collected and/or used in the eConsent platform.	• Participant Related eConsent Documents • Informed Consent Document • Platform/vendor Due Diligence Documents
	Validation	eConsent Platform Validation		Description of eConsent platform validation: e.g. package with documents such as testing scripts, traceability matrix, software development lifecycle.	• Platform/Vendor Due Diligence Documents

Aspects	Categories	Sub-Categories	Category Detail	Description	Applicable Study Document(s)
eConsent Platform Aspects	Compliance Documentation	eConsent Platform Compliance Documentation		Description that the eConsent platform complies with regulatory requirements related to security, privacy, electronic signatures, and other requirements of electronic platforms used in clinical studies: e.g. Data integrity, privacy, and compliance certificates and/or documentation related to various regulations.	• Platform/Vendor Due Diligence Documents
	Integration	eConsent Platform Integration with Other Study Systems		Description of how eConsent platform integration with other study systems.	• Site eConsent Documents • Data Management Plan • Platform/vendor Due Diligence Documents
		eConsent Platform Integration with Site Systems		Description of how eConsent platform integration with the site systems.	• Site eConsent Documents • Data Management Plan • Platform/vendor Due Diligence Documents
	Environment	eConsent Platform Environments		Description of unique instance(s) of the eConsent platform that facilitate different intended uses. Instances can be live or production environments containing actual participant data, or pre-production environments containing test or demonstration data.	• Data Management Plan • Platform/vendor Due Diligence Documents
	Platform Owner	eConsent Platform Vendor Selected		Description of eConsent platform vendor selected.	• Participant Related eConsent Documents • Site eConsent Documents • Monitoring Plan • Data Management Plan
		Sites' Own eConsent Platform		Description/reference that site's own eConsent systems is used. Certificates might be included, if applicable.	• Monitoring Plan • Data Management Plan
eConsent Operational Aspects	Stakeholders	Stakeholders Linked with Participants		Description of the stakeholders, that are directly or indirectly linked with the participant during the consent process: e.g. participant-related stakeholders (e.g. parent), non-participant related stakeholders (e.g. impartial witness) and miscellaneous study stakeholders (e.g. pregnant female partner of a male participant).	• Participant Related eConsent Documents • Informed Consent Document • Site eConsent Documents • Platform/vendor Due Diligence Documents
	Participant/ Site Location	Full Remote Consent Process	High Level	High level reference in case of absence of any physical interaction between the participant and site investigator for the consent process.	• Protocol • EC Submission Cover Letter • Participant Related eConsent Documents • Site eConsent Documents
			Details/ Types	Details/type of remote/not in the same location interaction between participant and site investigator: e.g. phone call, video call.	• EC Submission Cover Letter • Participant Related eConsent Documents • Site eConsent Documents
	Timing of Confirmation to Participate vs Discussion		At The Same Time/Not at The Same Time	Description of timing of confirmation to participate between participant and site and whether the confirmation to participate is given at the same time of the discussion or not.	Not it in study document but site needs to have a documentation as to why the dates are different. Recommended that the tool provides the option for the site to make this comment directly in the system.
	Data Access	Participants' Access to eSigned Consent Document		Description of how the participant can access eSigned consent documents: e.g. provided by site, download from website, sent via email.	• EC Submission Cover Letter • Participant Related eConsent Documents • Informed Consent Document • Site eConsent Documents • Monitoring Plan

Aspects	Categories	Sub-Categories	Category Detail	Description	Applicable Study Document(s)
eConsent Operational Aspects	Data Access	Remote Inspector/ Auditor Access	Personal Data	Description that inspectors/auditors have remote access to personal data.	• Participant Related eConsent Documents • Informed Consent Document
			Non-Personal Data	Description that inspectors/auditors have remote access to non-personal data.	Part of internal SOP on inspections/audits
		Remote Monitor Access	Personal Data	Description that monitors have remote access to consent personal data.	• Participant Related eConsent Documents • Informed Consent Document • Monitoring Plan
			Non-Personal Data	Description that monitors have remote access to consent non- personal data.	• Monitoring Plan
	Device Deployment	Participants'/ Sites' Provisioned Electronic Device	High Level	High level description that the site or participant receives an electronic device that can be used for the consent process.	• EC Submission Cover Letter • Participant Related eConsent Documents • Platform/vendor Due Diligence Documents
			Usability Details	Description of access rights of the provisioned devices: e.g. access might be restricted to the consent information only or have access to other websites.	• EC Submission Cover Letter • Participant Related eConsent Documents • Informed Consent Document • Platform/vendor Due Diligence Documents
		Participants' Own Electronic Device	High Level	Description of participant using its own electronic device.	• EC Submission Cover Letter • Participant Related eConsent Documents
			Reimbursement of Data Usage	Description of participant's reimbursement linked with using their own electronic device for the consenting process.	• EC Submission Cover Letter • Participant Related eConsent Documents • Informed Consent Document
	Support/ Helpdesk	Participants' eConsent Support/ Helpdesk	Overall Process	Description of process to support participants with the use of the eConsent platform (e.g. helpdesk).	• Participant Related eConsent Documents • Platform/vendor Due Diligence Documents
			Measures Related to Privacy Data	Description of measures that of the support/helpdesk related to privacy data of the participant.	• Participant Related eConsent Documents • Platform/vendor Due Diligence Documents
		Sites' eConsent Support/ Helpdesk	Overall Process	Description of process to support sites with the use of the eConsent platform (e.g. helpdesk).	• Site eConsent Documents • Platform/vendor Due Diligence Documents
	Consent Workflow	Participants' Remote Withdrawal Process		Description of how a participant can remotely revoke his/her decision to participate in a clinical study via the eConsent platform.	• Protocol • Participant Related eConsent Documents • Informed Consent Document • Site eConsent Documents • Monitoring Plan • Data Management Plan • Platform/vendor Due Diligence Documents

Aspects	Categories	Sub-Categories	Category Detail	Description	Applicable Study Document(s)
eConsent Operational Aspects	**Consent Workflow**	**EConsent End-to-End Workflow**		Description of the entire eConsent stakeholders' workflow (from interest confirmed that information can be shared to the provision of signed document) and post-eConsent workflows (e.g. reconsent, withdrawal, addition of participant EDC ID), and applicability for different consents (main, optional, assent).	• Participant Related eConsent Documents • Site eConsent Documents
	Monitoring	**eConsent Monitoring Process**		Description and instructions of how monitors will proceed the monitoring activities for eConsent.	• Monitoring Plan
	Archiving/ Permanent Records	**eConsent Archiving Process**		Description of archiving of eConsent material respectively by the site, sponsor, and participant. This can include blank eConsent material/templates and eConsent material completed by participant/other stakeholders.	• Site eConsent documents • Platform/vendor Due Diligence Documents
	Risk Management	**eConsent Risk Instructions**		General instructions on aspects to take into account (e.g. making sure that the electronic device is charged).	• Participant Related eConsent Documents • Site eConsent Documents
		eConsent Risk Management Plans		Description of risks, estimated impacts and responses to risks related to eConsent.	• Site eConsent Documents • Monitoring plan • Platform/vendor Due Diligence Documents

- The term "Participant" may also apply to other stakeholders involved (e.g. legal authorized representatives, witness, translator).
- Participants/Sites' Wet-Ink Signature has been added together within the digital feature 'Participants/Sites' Confirmation of Participation" for a better flow, however, it is not a digital feature" (footnote is part of table)