Glossary of eConsent Terms

General Information

In the dynamic landscape of eConsent, forging a common understanding of various aspects of eConsent through harmonized terms represents the foundational stride toward clarity and consensus.

Widespread misunderstandings result in conflicting messages on acceptance and non-acceptance of eConsent, lack of clarity regarding study document requirements, and incomplete insights into benefits and challenges posed to stakeholders.

To enable a common understanding and facilitate adoption of eConsent, the multi-stakeholder, nonprofit European Forum for Good Clinical Practice (EFGCP) eConsent Initiative developed a Glossary of eConsent Terms to standardize the nomenclature and terminology used to describe eConsent.

Firstly , and most important, "eConsent" is an overarching term and there are multiple different eConsent models – there is no-one-size-fits-all. The main point of commonality between all models is "*the use of one or more digital features to support the overall consent process*", reflecting the essence and definition of eConsent.

Secondly, as there is no one-size-fits all eConsent model, it is important to understand and describe the underlying platform and operational aspects underpinning each eConsent model, which are described in this glossary in the following 2 sections:

- **eConsent Platform Aspects terminologies** describing key aspects related to the eConsent platform and underlying data and technology. Digital features terminologies - one of the fundamental eConsent platform aspects – were defined by clustering individual examples based on their characteristics and commonalities.
- **eConsent Operational Aspects terminologies** describing key aspects related to operational management. These aspects are often also applicable in the traditional paper consent process and examples include terminologies on different stakeholders, locations, and device deployment.

These aspects should not be looked at in isolation, as there is often an interplay between the eConsent platform and operational aspects. Each term defined also includes a description and some examples.

The focus of this glossary was not to repeat what is already available, but to focus on the gaps and disconnects. Hence, where applicable, terminologies of existing guidelines[1-12] are incorporated.

Of note, this glossary might also be used as a comprehensive list of various platform and operational aspects to consider when developing and deploying eConsent.

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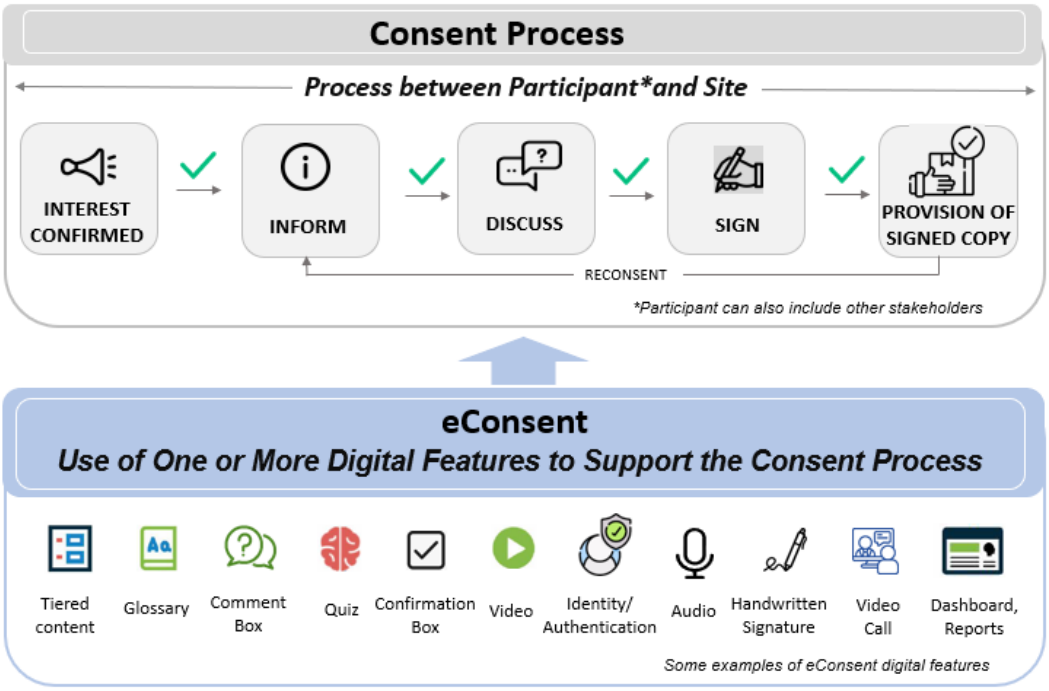
OVERVIEW OF ECONSENT TERMS

1. What is eConsent?



2. eConsent Platform Aspects

eConsent Platform Aspects			

Digital Features	• Interest Confirmation
	• Educational Content
	• Comprehension Content
	• Consent Document Copy
	• Identity/Authentication
	• Comprehension Confirmation
	• Documentation/Log
	• Signed Consent Upload
	• Paper Consent Tracking
	• Communication Channels
	• Notifications
	• Confirmation of Participation:
	  • Electronic Acknowledgement
	  • (Simple) Electronic Signature
	  • Advanced Electronic Signature
	  • Qualified Electronic Signature
	• eConsent Platform Training Content
	• Non-Study, Non-Consent Related Content
	• Metadata Insights and Metrics
	• Business Intelligence
	• Artificial Intelligence
		Identifiers	• Consent Document Identifier
			• Consent Document Version Identifier
			• Participant Identification Code
			• Participant Token

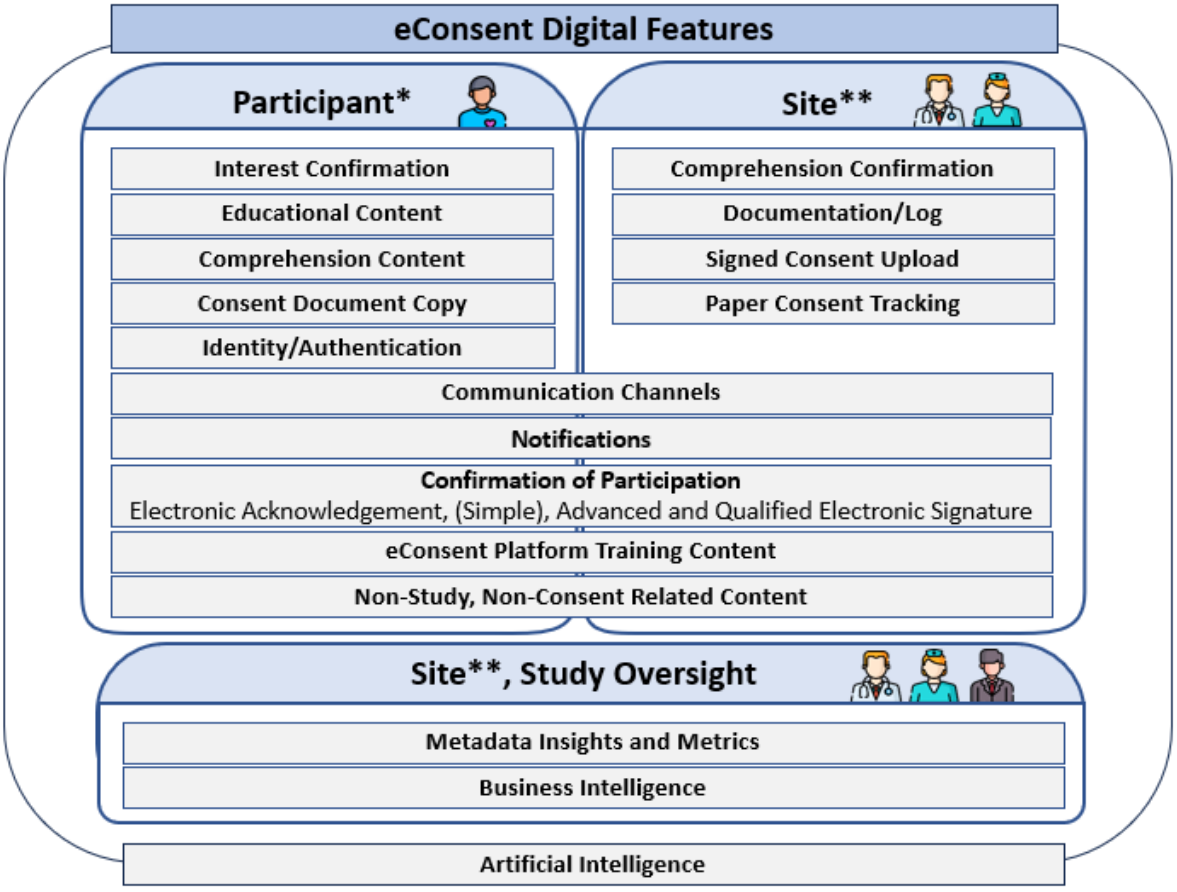
		Consent Account	• Participant Account • Stakeholder Account
		Data Types	• Personal Data • Non-Personal Data • Aggregated Metadata
		Data Privacy Clause/Agreement	
		Compliance Documentation	
		Validation Documentation	
		Integrations	
		Environments	

*eConsent "Platform" terminology has been used within this glossary and includes web-based applications, mobile Apps , etc. Other terms used within the industry are eConsent systems or eConsent tools.

3. eConsent Operational Aspects

eConsent Operational Aspects			
Stakeholders	• Participant • Participant Related Stakeholder • Non-Participant Related Stakeholder • Miscellaneous Study Stakeholder • Site Investigator/ Delegate • Site Coordinator • Study Oversight Stakeholder	**Consent Categorization**	• Main Consent Document • Optional Consent Document • Assent Document
Participant/ Site Location	• In the Same Location • Not in the Same Location • Mixed Location	**Consent workflow**	• Initial Consent • Declined • Reconsent • Withdrawal • Dynamic Consent
Timing of Signature	• Discuss/Sign At the Same Time • Discuss/Sign Not at the Same Time	**Health Authority & Ethics Committee Submission**	
Device Deployment	• Own Electronic Device • Provisioned Electronic Device	**Monitoring**	
Data Access	• Personal Data Access • Non-Personal Data Access • Edit Access • Read Access	**Auditing/Inspecting**	
		Training	
		Support	
		Archiving/ Permanent Records	• Site Consent Archiving • Sponsor Consent Archiving • Participant Consent Permanent records

4. eConsent Digital Features per Stakeholder



* Participant includes Participant Related, Non-Participant Related and Miscellaneous Study Stakeholder

** Site includes Site Investigator/Delegate and Site Coordinator

TERMS AND DEFINITIONS

Throughout the glossary, when the term:

- "Participant" is used, it may include other stakeholders such as Participant Related, Non-Participant Related and Miscellaneous Study Stakeholders, unless explicitly specified.
- "Site" is used, it includes the Site Investigator/Delegate and Site Coordinator, unless explicitly specified.

A. ECONSENT PLATFORM ASPECTS

1. DIGITAL FEATURES

1.1. INTEREST CONFIRMATION

Definition:
Digital confirmation/agreement from the participant that study consent information can be shared. This is predominantly applicable when the consent process is started when participant and site investigator/delegate are not in the same location.

Digital confirmation/agreement might include the collection and use of participant personal data (e.g., email, phone number) for sharing the study consent information.

Examples:
Digital confirmation/agreement collected via e.g. digital recruitment portals, or study registration website.

Primary stakeholders involved:
Participants.

1.2. EDUCATIONAL CONTENT

Definition:
Digital educational consent content that participant can read, watch, hear, etc but that does not allow an interaction from the participant beyond consuming the content.

Examples:
Video, audio, visuals, dictionary/glossary, Frequently Asked Questions, tiered content (organized into sections, drill downs), etc.

Primary stakeholders involved:
Participants.

1.3. COMPREHENSION CONTENT

Definition:

Digital interactive consent content where an interaction of the participant might be, or is required, to check comprehension.

Examples:
Quiz, content flags, comment/free text boxes, section/chapter-based confirmation/attestation of understanding.

Primary stakeholders involved:
Participants.

1.4. CONSENT DOCUMENT COPY

Definition:
A paper or electronic copy of the consent document(s). This can include the informed consent form (unsigned or signed) and any other accompanying consent documents. The information about the clinical trial should be a physical hard copy or electronic copy in a format that can be downloaded. The copy should be available immediately to the trial participant[2,3,4].

Examples:
Printed or downloadable participant fully signed informed consent form

Primary stakeholder involved:
Participants.

1.5. IDENTIFICATION / AUTHENTICATION

Definition:
Digital methodologies that are used to identify/authenticate the participant during the consent process. Different methods might be required depending on the study, country, etc.

Note – several guidances give more details on authentication methods, remote authentication, etc[2, 5]

Examples:
Locally approved/certified identity devices/systems, digital sharing of participant's identity card, two-factor authentication, etc.

Primary stakeholders involved:
Participants, Sites.

1.6. COMPREHENSION CONFIRMATION

Definition:
Digital interactive consent content for the site investigator/delegate to close the loop on any questions, concerns, or knowledge gaps from the participant. This feature is closely linked with the participant's comprehension content features and is meant to address and document actions taken.

Example:
Site confirmation box or site comments box linked with participant's comprehension content digital feature (e.g., quiz, content flags).

Primary stakeholders involved:
Sites.

1.7. DOCUMENTATION / LOG

Definition:
Digital log for the site to capture specific information about the participant's consent process.

Examples:
Site note logs, site comment fields/boxes.

Primary stakeholders involved:
Sites.

1.8. SIGNED CONSENT UPLOAD

Definition:
Capability for the site to upload a fully signed, paper consent document (wet ink signature management). This might include confirmation that it is an exact copy of the original document.

Examples:
Upload signed paper consent capability.

Primary stakeholders involved:
Sites.

1.9. PAPER CONSENT TRACKING

Definition:
Capability for the site to document or confirm one or more steps of the paper consent process (e.g., discuss, sign, provision of signed copy), and create digital transparency for the overall consent process.

For example, for countries where the fully signed paper consent cannot be uploaded, this can be useful to document that the signature process has been finalized, optional consents agreed/not agreed, etc.

Examples:
Site data fields to capture the paper consent process.

Primary stakeholders involved:
Sites.

1.10. COMMUNICATION CHANNELS

Definition:
Digital communication channel between the participant and site to share consent information, to ask questions, to discuss, to sign, etc. These communication channels may be incorporated within the eConsent platform or reside outside of it.

Examples:
Email, web portal, video call, using electronic devices such as PC, smartphones, tablets.

Primary stakeholders involved:
Participants, Sites.

1.11. NOTIFICATIONS

Definition:
Digital consent notifications/messages for the participant and/or site related to the consent process.

Examples:
Notifications on remote consent activities, notifications on availability of reconsent.

Primary stakeholders involved:
Participants, Sites.

1.12. CONFIRMATION OF PARTICIPATION

1.12.1. ELECTRONIC ACKNOWLEDGEMENT

Definition:
Digital methods used by the participant and site investigator/delegate, other than a signature or equivalent, to confirm participation in the study.

Examples:
Recording of names and tick boxes to confirm participation (no real signature), implicit consent unless opted out.

Primary stakeholders involved:
Participants, Sites.

1.12.2. (SIMPLE) ELECTRONIC SIGNATURE

Definition:
Any data in electronic form which is attached to or logically associated with other data in electronic form, and which is used by the signatory to sign (~ European eIDAS regulation definition[5]).

No biometric data are used. Additional identity verification/authentication might be required in line with local regulations and study type.

Other countries and regions might use other categorization, hence it is important to not simply use the term "Simple eSignature" but to describe the actual implementation of the eSignature (see examples below).

Examples:
A handwritten signature drawn by finger or stylus on an electronic device, a username and password, an uploaded picture of a handwritten signature on a paper form. These are all examples without biometric data included.

To illustrate different local/regional categorizations: “a handwritten signature drawn by finger or stylus on an electronic device” is a (simple) Electronic Signature according to European eIDAS regulations[5], but not considered an electronic signature by FDA regulations[6].

Primary stakeholders involved:
Participants, Sites.

1.12.3. ADVANCED ELECTRONIC SIGNATURE

Definition:
An electronic signature that is uniquely linked to the signatory, is capable of identifying the signatory, is created using electronic signature creation data that the signatory can, with a high-level of confidence, use under his sole control, and is linked to the data signed therewith in such a way that any subsequent change in the data is detectable (~ European eIDAS regulation definition[5]).

Other countries and regions might use other categorization, hence it is important to not simply use the term "Advanced eSignature" but to describe the actual implementation of the eSignature (see examples below).

Examples:

Simple electronic signatures (see 1.12.2) combined with multi-factor authentication (e.g., registration code, security questions) or biometric data collection (e.g., fingerprints, facial recognition, retina scan, voice recognition).

Primary stakeholders involved:
Participants, Sites.

1.12.4. QUALIFIED ELECTRONIC SIGNATURE

Definition:
An advanced electronic signature that is created by a qualified electronic signature creation device, and which is based on a qualified certificate for electronic signatures. (~ European eIDAS regulation definition[5]).

Other countries and regions might use other categorization, hence it is important to not simply use the term "Qualified eSignature" but to describe the actual implementation of the eSignature (see examples below).

Examples:
Locally approved/certified identity/signature applications and software, e.g., Belgian eID software/Itsme with linked electronic signature.

Primary stakeholders involved:

Participants, Sites.

1.13. ECONSENT PLATFORM TRAINING CONTENT

Definition:
Supporting digital content or guidance for participant or site to help with navigating and using the eConsent platform.

Examples:
How-to-use eConsent App instructions for participants, mock eConsent app for sites where they can consent a mock participant, digital consent training content.

Primary stakeholders involved:
Participants, Sites.

1.14. NON-STUDY, NON-CONSENT RELATED CONTENT

Definition:
Non-study, non-consent related content that is part of the eConsent platform and visible to the participant and/or site.

It is important to decide how to handle updates related to non-study, non-consent related content. For example, will changes to the name of an icon (e.g., “Help” icon of participant’s app is renamed to “Questions”) result in updates to study documents and/or trigger a submission?

Examples:
Platform/Application user interface content, profile information, general settings (e.g., language), privacy policies, terms & conditions.

Primary stakeholders involved:
Participants, Sites.

1.15. METADATA INSIGHTS AND METRICS

Definition:
Generated insights regarding usage of the eConsent platform on various aspects of an individual participant or group of participants. Generation of information may be passive or active.

Examples:
Time registrations/insights (e.g., per section, overall review time, reconsent), use of functionalities (e.g., video, Frequently Asked Questions), repeating questions that appear across various participants, etc.

Primary stakeholders involved:
Sites, Study oversight stakeholders.

1.16. BUSINESS INTELLIGENCE

Definition:
Overviews of eConsent status for an individual participant or across participants at a site, country, regional and global level. Access level depends on the role (e.g., global roles will have access at a global level).

Examples:
Dashboard, reports, alerts triggered e.g., by consent status thresholds.

Primary stakeholders involved:
Sites, Study oversight stakeholders.

1.17. ARTIFICIAL INTELLIGENCE

Definition:
Artificial Intelligence refers to systems that display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals (definition of EMA Reflection Paper on the use of Artificial Intelligence (AI) in the Medicinal Product Lifecycle[7]).

AI can impact various eConsent aspects and the overall consent process. It can cover a broad set of algorithms, which enable computers to mimic human intelligence, and range from simple if-then rules and decision trees, to more advanced subsets of AI like Machine Learning (ML) and deep learning.

Examples:
AI-powered chatbots for consent questions, ML-algorithms for consent personalization and optimization.

Primary stakeholders involved:
Participants, Sites, Study oversight stakeholders.

2. IDENTIFIERS

2.1. CONSENT DOCUMENT IDENTIFIER

Definition:
Unique identifier (e.g., code, number) assigned to a particular consent document.

Consent documents include the traditional informed consent form (ICF) but can also cover documents linked to Educational Content Digital Features (e.g., video scripts, Frequently Asked Questions) or Comprehension Content Digital Features (e.g., Quiz).

Examples:
ICF Study ABCD, Glossary ICF Study 1234

2.2. CONSENT DOCUMENT VERSION IDENTIFIER

Definition:
Identifiers (numbers and/or date) to manage ordered iterations of various consent documents.

Examples:
ICF Study ABCD Version 1, Glossary ICF Study 1234 version 1, date DD-MM-YYYY

2.3. PARTICIPANT IDENTIFICATION CODE

Definition:
A unique identifier assigned to each study participant to protect the participant's identity and used in lieu of the participant's name when the investigator reports adverse events and/or other study-related data (ICH GCP E6(R3) definition[5]).

The Participant Identification Code can be generated by the eConsent platform and/or entered by the participant/site in the eConsent platform when the consent process is started/activated for a specific participant.

Examples:
Participant ID ABCD, Participant@xx.com.

2.4. PARTICIPANT TOKEN

Definition:
Unique, de-identified and encrypted participant identifier originating from healthcare data that might be used to connect the consent of the participant with medical records/real world data. If a participant token is introduced, this concept would be covered in the consent document and the consent/agreement of the participant obtained prior to deploying.

Of note, not every stakeholder needs to be introduced to the term "Participant Token". For example, in a participant informed consent document, the focus should be on what are the benefits and risks on the participant, why is it introduced, etc.

Examples:
PTS6789 (code originated from health care data)

3. CONSENT ACCOUNT

3.1. PARTICIPANT ACCOUNT

Definition:
Unique credentials linked with the Participant Identification Code enabling the participant to access the eConsent platform.

These credentials can be generated by the participant but are often generated by the eConsent platform and required to be changed by the participant upon first login.

Accounts are closely linked with the digital feature "Identification/Authentication" (see 1.5), which are implemented to validate that the person attempting to access an account is the legitimate owner of that account.

Examples:
Participant username and password, participant email address and password, platform generated QR code, PIN, multifactor authentication.

3.2. STAKEHOLDER ACCOUNT

Definition:
Unique credentials for other stakeholders directly or indirectly involved or supporting the participant in the consent process (for more details see section B1 "Stakeholders") so they can access the eConsent platform and document their activities, in line with their assigned role.

Stakeholders' accounts should be linked with the participant and/or Participant Identification Code.

Accounts are closely linked with the digital feature "Identification/Authentication" (see 1.5), which are implemented to validate that the person attempting to access an account is the legitimate owner of that account.

Examples:
Stakeholder username and password, stakeholder email address and password, eConsent platform generated QR code, PIN, multifactor authentication.

4. DATA TYPE

4.1. PERSONAL DATA

Definition:
Any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person (EU General Data Protection Regulation (GDPR) definition[8])

Other countries might have other privacy regulations and terms. As an example, a commonly used term is "Personal(ly) Identifiable Information (PII)" introduced by the US Department of Labor[9] , or "Protected Health Information (PHI)" which is used by the US "Health Insurance Portability and Accountability Act (HIPAA)"[10].

Examples:
Name, signature, email address, phone number, etc

4.2. NON-PERSONAL DATA

Definition:
Any information (data) linked to an individual participant but that does not reveal the identity of the individual.

Examples:
Participant Identification Code, anonymized data such as questions raised, knowledge results, time spent on a certain activity in the eConsent platform, reason for not participating, optional consent agreed/not agreed, etc. All data is solely linked with the Participant Identification Code, no personal data are included.

4.3. AGGREGATED METADATA

Definition:
Any information (data) represented in an aggregated/combined/summary format, and that cannot be represented or accessed at the individual participant level.

Examples:
Summary reports of questions raised, time spent in the eConsent platform, quiz results, etc.

5. DATA PRIVACY CLAUSE / AGREEMENT

Definition:
Legal disclaimer or privacy clause/agreement of the participant that their personal data can be collected and/or used in the eConsent platform. This agreement/clause can be part of the consent content and/or is collected prior to the usage of the eConsent platform itself.

Examples:
Company and/or eConsent platform specific legal disclaimer or privacy language that personal data of the participant can be collected and/or used in the eConsent platform.

6. COMPLIANCE DOCUMENTATION

Definition:
Documentation that ensures the eConsent platform complies with regulatory requirements related to security, privacy, electronic signatures, and other requirements of electronic platforms used in clinical studies.

Examples:
Data integrity, privacy, and compliance certificates and/or documentation related to various regulations[2, 3, 5, 6, 7].

7. VALIDATION DOCUMENTATION

Definition:
Documentation that the specified requirements of the eConsent platform are consistently fulfilled, and that the system is fit for purpose. Validation should ensure accuracy, reliability, and consistent intended performance, from the design until the decommissioning of the system or transition to a new system (definition from EMA guideline[2]).

Examples:
Validation package with documents such as testing scripts, traceability matrix, software development lifecycle documentation, etc.

8. INTEGRATIONS

Definition:
Connecting diverse software, hardware, or data platforms with the eConsent platform to ensure seamless communication, interoperability, and functionality, enabling them to share information, or work together as a unified platform.

Integrations can be with other clinical study platforms, site-based platforms, or other platforms.

Examples:
Integrations with recruitment platforms, EDC, IRT/RTSM, medication courier platforms, home nurse platforms, video call platforms are examples of clinical study platform integrations. Integrations with site EMR/EHR, site authentication platforms, site eConsent platforms are examples of site-based platform integrations. Integration with governmental platforms is an example of another platform integration.

9. ENVIRONMENTS

Definition:
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.

Examples:
Demo, Sandbox, Development, User Acceptance Testing, Production/Live environments.

B. OPERATIONAL ASPECTS

1. STAKEHOLDERS

1.1. PARTICIPANT

Definition:
An individual who participates in a clinical study, either as a recipient of the investigational product(s) or as a control (Trial Participant definition of ICH GCP E6(R3)[5]).

Other terms used are e.g., subject, trial participant.

Examples:
Patient, healthy volunteer, minor, etc.

1.2. PARTICIPANT RELATED STAKEHOLDER

Definition:
An individual related to the participant who is involved in the consent process and can confirm the participant's participation in the clinical trial, either on behalf of the participant and/or next to the participant's confirmation to participate.

Examples:
Legally authorized/acceptable representative, caregiver, partner, parent, guardian, next of kin, etc.

1.3. NON-PARTICIPANT RELATED STAKEHOLDER

Definition:
An individual that is not related to the participant but has a supporting and/or witnessing role in the consent process. They may confirm the participant's participation on the consent document and/or their participation in the consent process is separately documented.

Examples:
Translator, impartial witness

1.4. MISCELLANEOUS STUDY STAKEHOLDER

Definition:
An individual that is directly or indirectly linked with the participant and may sign off on a separate document and/or their involvement is separately documented next to the consent process. They might not be part of the overall consent process.

Examples:
Pregnant female partner of a male participant, nursing care staff in retirement house not acting as a caregiver.

1.5. SITE INVESTIGATOR / DELEGATE

Definition:
Site personnel responsible for the informed consent discussion and countersigning the consent document together with the participant and involved stakeholders.

Examples:
Principal Investigator, sub-investigator.

1.6. SITE COORDINATOR

Definition:
Site personnel responsible for the administrative tasks involved in the consent process and not authorized to countersign the consent document.

Note - There might be some jurisdictions and in line with local regulations where site coordinators can act as a delegate of the site investigator and countersign.

Examples:
Site nurse.

1.7. STUDY OVERSIGHT STAKEHOLDER

Definition:
Any additional role not linked to the participant or site and with no active role in the consent process between participant and site. Depending on the role, they might have different access.

Examples:
Monitor, auditor, inspector, sponsor staff, CRO/vendor staff, Ethics Committee, Health Authority

2. PARTICIPANT/SITE LOCATION

2.1. IN THE SAME LOCATION

Definition:
Refers to a participant and site investigator/delegate being physically in the same location to conduct all steps of the consent process.

Examples:
Investigator site (most common), participant's home or primary address (e.g., university home for a student), pharmacy, community health center.

2.2. NOT IN THE SAME LOCATION

Definition:
Refers to a participant and site investigator/delegate not being in the same location to conduct all steps of the consent process (interest confirmed, inform, discuss, sign and provision of signed copy).

Examples:
Interaction is usually supported by a "Communication Channels" digital feature (see section 1.10, examples are email, chatbot, video call), but it might also be done using traditional paper processes and couriers (no digital feature involved).

2.3. MIXED LOCATION

Definition:
Refers to a participant and site investigator/delegate where some consent process steps are done in the same location, while others are not conducted in the same location.

Examples:
Sharing of the consent information with participant is done via email (Not in the Same Location) while the discussion with the site investigator/delegate is done at the investigator site (In the Same Location).

3. TIMING OF SIGNATURES

3.1. DISCUSS / SIGN AT THE SAME TIME

Definition:
Participant and site investigator/delegate are signing at the same time of the discussion.

This can apply to any type of location of the participant and investigator/delegate.

Examples:

Signing on paper and/or electronically is done immediately following the discussion.

3.2. DISCUSS / SIGN NOT AT THE SAME TIME

Definition:
Participant and site investigator/delegate are NOT signing at the same time of the discussion.

As there is an interruption after the discussion step, identity authentication of participant might need to be done/repeated when re-starting the signing process.

Examples:

Signing on paper and/or electronically occurs at a later moment (e.g., participant wanted to first discuss with their family).

4. DEVICE DEPLOYMENT

4.1. OWN ELECTRONIC DEVICE

Definition:
The site or participant (and/or stakeholders) will use their own electronic device for the consent process.

Other terminologies used are Bring Your Own Device (BYOD)

Examples:
Site, Participant's and/or other stakeholders' own mobile phone, tablet, PC, etc.

4.2. PROVISIONED ELECTRONIC DEVICE

Definition:
The site or participant (and/or stakeholders) receives an electronic device provided by the sponsor/CRO that can be used for the consent process. The device access might be restricted to the consent information only or have access to other websites.

Examples:
Sponsor-provisioned mobile phone, tablet, etc.

5. CONSENT CATEGORIZATION

5.1. MAIN CONSENT DOCUMENT

Definition
Mandatory consent document(s) where participant confirms their participation in the clinical study.

Not confirming participation to the main consent document(s) excludes the participant from participating in the clinical study.

There can be more than one main consent document in a clinical study . For example, a screening main consent document, a first stage/phase main consent document.

Examples:
Main clinical study consent document, Main screening consent document, main cohort consent document.

5.2. OPTIONAL CONSENT DOCUMENT

Definition:
Additional consent document(s) to non-mandatory aspects of a clinical study or beyond the clinical study. Not confirming participation to an optional consent document does not exclude the participant from participating in the clinical study.

Examples:
Optional consent document for DNA sampling, bio sampling, video calls, meta-consent (e.g., broad consent for exploratory analysis), novel data models (e.g., use of Artificial Intelligence).

5.3. ASSENT DOCUMENT

Definition:
Consent document used for a minor or participant with severely impaired decision-making capacity[4,11].

Depending on the age and/or capacity of the minor or participant with severely impaired decision-making capacity, the assent document can be a "Main" (mandatory) or "Optional Consent Document" (see section 5.1 and 5.2). Additional confirmation to participate needs to be obtained from the parent or legally authorized/acceptable representative representative, as appropriate.

Examples:
Paediatric participants, adults with cognitive impairment (e.g., Alzheimer's disease)

6. CONSENT WORKFLOW

6.1. INITIAL CONSENT

Definition:
Process of obtaining the first confirmation to participate from a participant for a specific form (main consent document, optional consent document).

The initial consent document might differ between participants (e.g., version and date) in case updates to the consent document occurred during the recruitment process.

New versions that are signed by the participant or the same version where responses were changed will be named a reconsent (see 6.2).

Examples:
Initial consent on main consent document, initial consent on optional consent document.

6.2. DECLINED

Definition:
Process whereby a participant does not confirm or declines their participation in a clinical study and/or for a certain part of the clinical study.

Examples:

Participant declines to participate in the clinical study or to a part of the clinical study (e.g., bio sampling).

6.3. RECONSENT

Definition:
Process of obtaining renewed confirmation to participate from a participant for a specific document (main consent document, optional consent document).

Reconsent typically occurs when are there are significant changes to the study protocol, safety information, study design or participant's rights that may impact the contents of the latest version of the main consent that the participant signed. However, reconsent for a main consent form might also be planned or predefined in a study.

Reconsent on an optional consent might be linked to a change in the optional consent.

Examples:
Yearly reconsent, age-driven reconsents, or study stage consents are examples of planned reconsents.

Amendments linked to a protocol, safety update, etc are examples of non-planned reconsents.

6.4. WITHDRAWAL

Definition:
Process whereby a participant revokes their decision to participate in a clinical study and/or for a certain part of the clinical study.

This might also include study termination or participant lost to follow up.

Examples:
Patient withdraws from the study or from a certain part (e.g., optional bio sampling).

6.5. DYNAMIC CONSENT

Definition:
No change in the content of the consent document (main or optional consent document), but participant´s confirmation to participate is evaluated and re-confirmed throughout the course of the study.

This is often also seen as a more engaged (dynamic) way to keep participants updated about what is ongoing (e.g., with their bio-samples) while also re-checking their former confirmation to participate.

Examples:
An example of a dynamic consent study is CHRIS (Corporate Health Research in South Tyrol)[12], where participants are regularly updated about what is happening with their bio-samples, can reconsent for other research studies, and can also reconsider their initial consent.

7. DATA ACCESS

7.1. PERSONAL DATA ACCESS

Definition:
Ability of an individual to access personal data of a participant.

Examples:
Site personnel and monitors have access to personal data of a participant.

7.2. NON-PERSONAL DATA ACCESS

Definition:
Ability of an individual to access non-personal data of a participant.

Examples:
Sponsor personnel (other than monitor) have only access to non-personal data of a participant.

7.3. EDIT ACCESS

Definition:
Ability of an individual to access consent data and create, update, and/or perform other activities within the eConsent platform. Activities that can be done will depend on a user's assigned role and/or permission within the eConsent platform.

Examples:
Site investigator/delegate can create the participant's account, update information in line with their role and/or permission, and countersign. Site coordinator can create account, update information in line with their role and/or permission. Participant can update and complete their consent data and sign.

7.4. READ ACCESS

Definition:
Ability of an individual to access consent data but they cannot make updates to the consent data. Depending on a user's role, they might be able to query data.

Examples:
Study oversight stakeholders such as monitors.

8. HEALTH AUTHORITY AND ETHICS COMMITTEE SUBMISSION

Definition:
Process that supports regulatory and/or Ethics Committee (e.g., Independent Ethics Committee (IEC), Institutional Review Board (IRB)) review and approval.

Which documents to submit for eConsent platform and operational aspects might vary depending on the study and local requirements. EFGCP eConsent Workstream is currently drafting a recommendation and study overview template and the reference to these details will be incorporated in this glossary once finalized.

Examples:
Electronic submission of eConsent participant-facing content, summary and/or description of eConsent platform aspects and digital features, summary and/or description of eConsent operational aspects, access to actual eConsent platform.

9. MONITORING

Definition:
The review of consent data for the purpose of ensuring the clinical study is conducted, recorded, and reported in accordance with the protocol, GCP and the applicable regulatory requirement(s).

Monitoring using eConsent platforms may provide additional tools and insights not traditionally available in paper.

Monitoring may be conducted either on-site, remotely, or both, and is done by a sponsor/CRO representative from the study oversight stakeholders. Consent monitoring process should be detailed in study-specific monitoring plans.

Examples:
Monitoring individual participant consent data or aggregated consent data via the eConsent platform.

10.AUDITING / INSPECTING

Definition:
The review of consent data for the purpose of ensuring compliance by an auditor/inspector, either on-site, remote or both.

Audits/inspections using eConsent platforms may derive insights not traditionally available in paper.

Examples:
Audit/inspection of individual participant consent data or aggregated consent data via the eConsent platform.

11.TRAINING

Definition:
Process of providing information to sites and/or participants and/or sponsor regarding the use of the eConsent platform. This training information on how to use the platform can be platform-agnostic or platform-specific.

Examples:
Site eConsent platform-agnostic training with training certificates including (but not limited to): site training certificates, participant trainings and/or instructions, sponsor training certificates.

12.SUPPORT

Definition:
Process of providing support that may be available to sites, sponsors, participants, or other stakeholders, to support the use of the eConsent platform.

Examples:
Helpdesk, live chat, email, facilitation (coordination of video call).

13.ARCHIVING / PERMANENT RECORD

13.1. SITE CONSENT ARCHIVING

Definition:
All blank study consent content (e.g., blank informed consent documents) are archived by the site. Additional eConsent content (e.g., Frequently Asked Questions or glossary document) may be archived by the site. Archiving at the site can be either electronically or on paper.

Individual participant eConsent data with personal data and/or aggregate participant eConsent data is archived by the site.

The archived data and forms must be retrievable in case of regulatory inspection throughout the required retention period.

Examples:
eConsent data files including all data, reports, signed consent forms, etc and personal data for that site.

13.2. SPONSOR CONSENT ARCHIVING

Definition:
All blank study consent content and additional electronic consent content (e.g., blank informed consent, video script, quiz as applicable, platform validation documentation, certificates) are archived by the sponsor.

Individual participant eConsent data without personal data and/or aggregate non-personal data participant eConsent data may be archived by the sponsor, if compliant with all relevant data protection regulations and guidelines, and sponsor SOPs and needs (e.g., operational perspective to analyze for performance metrics or quality gaps).

The archived data and forms must be stored securely with access restricted to authorized individuals only and retrievable in case of inspection by a regulatory authority throughout the required retention period.

Examples:
Blank study eConsent content, potentially also individual or aggregated eConsent data files without personal data, and compliant with applicable data protection regulations and guidelines.

13.3. PARTICIPANT CONSENT PERMANENT RECORDS

Definition:
A paper or electronic copy of the signed and dated electronic consent form downloaded by the participant and/or provided by the site to the participant at the time of execution.

Capabilities to ensure participant has downloaded the fully signed consent document prior to study eConsent platform closure, in case the fully signed printed copy was not provided, is highly recommended.

If consent is done completely on paper, a paper signed copy is provided to the participant.

Examples:
Participants download fully signed consent copy, site provides a fully signed consent copy.

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