



eConsent Digital Features Glossary

General Information

Creating harmonized terms to describe the different digital features that can be used during the consent process is the first fundamental step that needs to be taken to ensure that everyone speaks and understands the “same” and to eliminate the numerous conflicting messages of acceptance and non-acceptance at a local level.

As an example, a common misunderstanding of eConsent is that it is about remote consent or electronic signatures, but these are just certain digital features that could be used for eConsent. It is important to understand that there is “no one size fits all” eConsent model. Each study, site, participant might have different needs and different eConsent digital features may or may not be used.

Harmonized terms are also the foundation to create harmonized consent processes and getting insight into the different value models of all stakeholders (sponsors, vendors, participants, sites, ethics committees, and health authorities) involved.

This eConsent Digital Features glossary was developed by European Forum Good Clinical Practice (EFGCP) eConsent team and provides an overview of different terminologies of digital features that can be considered to use for eConsent, including a definition and some examples. The focus was on clustering and combining digital features in line with their specific characteristics rather than describing a huge number of individual examples.

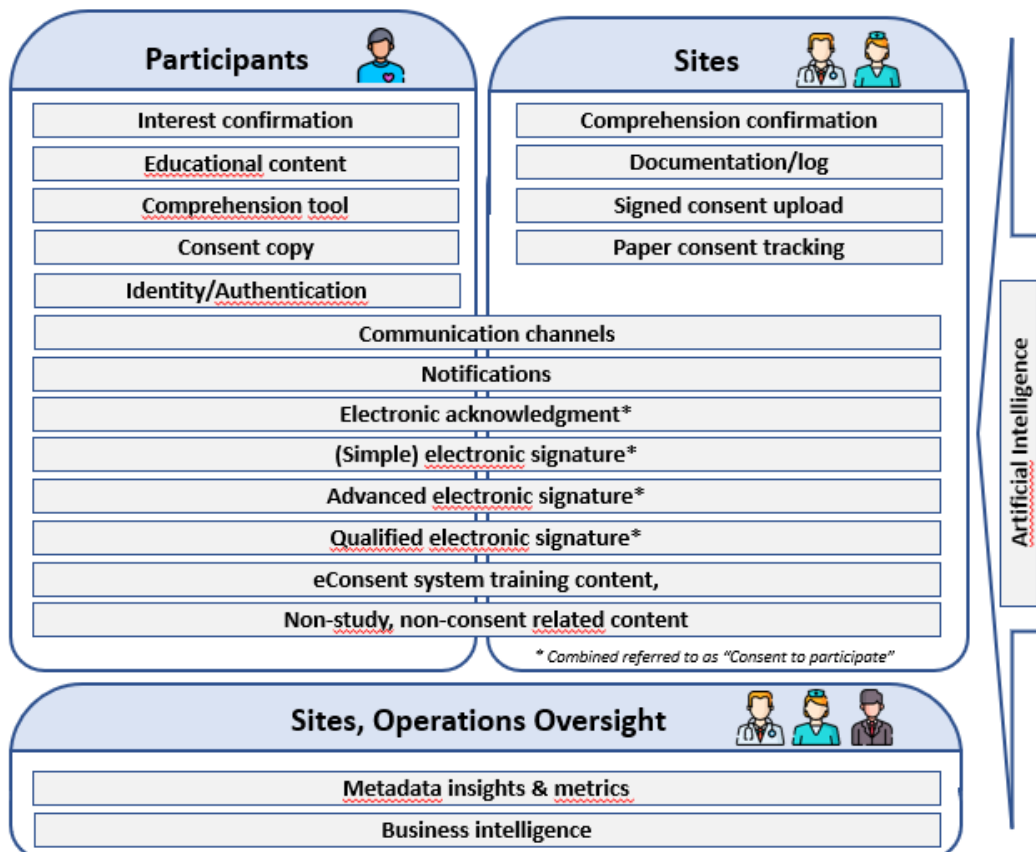
The term “eConsent Digital Features” was selected as the umbrella term to combine specific functionalities that can be found in digital products or services related to the consent process. Digital features might also be referred to in the industry as e.g. digital components, digital technologies, digital media, digital elements, digital solutions

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Overview of different terminologies for “eConsent Digital Features” and “Stakeholders”



If terminologies are used as standalones, you might need to add “Consent” and “Digital” to avoid misinterpretations or confusion.

Details on stakeholders involved, including a definition and some examples, are layout in the table below. The term “Participant” is used as umbrella term throughout the glossary text but also includes participant related stakeholders, non-participant related stakeholders and miscellaneous study stakeholders. Which stakeholder will be involved in a digital feature might vary from study to study.

Stakeholders	Definition	Examples
Participant	An individual (e.g. patient, healthy volunteer) who participates in a research investigation (e.g. clinical trials, real world, non-interventional studies) and who will sign off on the consent form, except if he/she is not capable to sign off.	Participant, other terms used are subject, patient, etc.
Participant Related Stakeholders	Individuals that are involved in the consent process and can sign off on behalf of and/or sign off in addition to the participant.	Legal Authorized Representative, caregiver, study partner, consultee, parental guardian, next of kin, etc.
Non-participant related stakeholders	Individuals that are not related to the participant but having a supporting and/or witnessing role in the consenting process. They may sign off on the consent form and/or their participation in the consent process is separately documented.	Translator, witness.
Miscellaneous Study Stakeholder	Individuals that are directly or indirectly linked with the participant and may sign off on a separate form and/or their involvement is separately documented next to the consent process. They might not be part of the overall consent process.	Pregnant female partner of a male participant, nursing care staff in retirement house not acting as caregiver.
Site Investigator or delegate	Site personnel responsible for the discussion and sign off on the consent form together with the participant and involved stakeholders.	Principle Investigator or delegate (e.g. sub-Investigator).
Site Coordinator	Site personnel responsible for the administrative tasks involved in the consent process. They are not authorized to sign off.	Site nurse, site coordinator.
Operations Oversight Stakeholders	Any additional role not linked to the participant or site and with no active role in the consenting process between participant and site.	Monitor, auditor, inspector, sponsor staff, CRO/vendor staff.

Terms and Definitions

1. INTEREST CONFIRMATION

Definition:

First consent/agreement of the participant's interest and that consent information can be shared using digital features. This might include or not that participant's personal identifiers (e.g. email, phone number) can be used for sharing the study consent information.

Examples:

Acknowledgement/consent obtained via e.g. recruitment portals/websites.

Primary stakeholders involved:

Participants.

2. EDUCATIONAL CONTENT

Definition:

Digital educational material(s) that participant can read, watch, listen, etc. to inform/introduce what the study is about.

Examples:

Chapter/section or continuous consent views, multimedia tiered consent, videos, audio, dictionary/glossary, Frequently Asked Questions, etc.

Primary stakeholders involved:

Participants.

3. COMPREHENSION TOOL

Definition:

Digital interactive comprehension material where an interaction of the participant might or is required.

Examples:

Knowledge assessment, content flags, comment boxes, free text field, section/chapter-based confirmation/attestation of understanding.

Primary stakeholders involved:

Participants.

4. CONSENT COPY

Definition:

A copy of the consent document(s) that participants should have access to, e.g. unsigned version, fully signed version, different versions.

Examples:

Emailed copy, ability to download a copy, ability to print a copy.

Primary stakeholder involved:

Participants.

5. IDENTITY/ AUTHENTICATION

Definition:

Use of digital technologies to identify/authenticate participants.

Examples:

Locally approved/certified identity devices/systems, sharing of identity card via digital media, two factor authentications, etc. Different methods might be required depending on the study, country, etc.

Primary stakeholders involved:

Participants, Sites.

6. COMPREHENSION CONFIRMATION

Definition:

The ability for the site investigator or delegate to address any participant questions, and/or confirm participant comprehension of the consent materials.

Example:

Confirmation box where site confirms and/or explains certain highlights/measurements (e.g. results of knowledge assessments, questions raised by participant), and documents that the participant has understood what the study is about and all questions have been answered.

Primary stakeholders involved:

Sites.

7. DOCUMENTATION/LOG

Definition:

Ability for the site investigator or delegate to electronically capture specific information about the participant's consent process.

Examples:

Note logs, comment boxes.

Primary stakeholders involved:

Sites.

8. SIGNED CONSENT UPLOAD

Definition:

Capability for the site to upload a signed paper consent in the eConsent tool (wet signature management) and confirm that it is an exact copy of the original document.

Examples:

Upload signed paper consent feature in eConsent tool.

Primary stakeholders involved:

Sites.

9. PAPER CONSENT TRACKING

Definition:

Capability of the site to document the process of paper consenting.

Examples:

Confirmation box or data entry fields where site can document the paper consent process and confirm that participant has signed on paper. Especially useful for countries where no paper consent can be uploaded in the eConsent tool.

Primary stakeholders involved:

Sites.

10. COMMUNICATION CHANNELS

Definition:

Communication channel to perform consent activities (e.g. sharing of information, discussion) between the participant and site using electronic devices.

Examples:

Email, web portal, video call, etc. Electronic devices can include PC, smartphones, etc.

Primary stakeholders involved:

Participants, Sites.

11. NOTIFICATIONS

Definition:

Notifications that are being sent to the participant and/or site about the consent process.

Examples:

Notifications on progress of remote consenting, re-consent availability notification, etc.

Primary stakeholders involved:

Participants, Sites.

12. ELECTRONIC ACKNOWLEDGEMENT

Definition:

No signature but other digital methods used by the participant and site investigator or delegate to confirm consent.

Examples:

Registration of names and tick boxes to confirm participation (no real signature).

Primary stakeholders involved:

Participants, Sites.

13. (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. (~ eIDAS definition)

No biometric data are used. Additional identity verification/authentication might be required in line with local regulations (e.g. in person, electronically) and study type.

Depending on the regulations (e.g. FDA), certain examples such as “a handwritten signature drawn by finger or stylus on an electronic device” are not considered an electronic signature.

Examples:

Uploaded picture of a signature, username and password, a handwritten signature drawn by finger or stylus on an electronic device. These examples of electronic signatures might also be considered an advanced electronic signature when additional capabilities are added, see below.

Primary stakeholders involved:

Participants, Sites.

14. ADVANCED ELECTRONIC SIGNATURE

Definition:

Signature that is uniquely linked to the signatory, capable of identifying the signatory, created using means that signatories can maintain under their sole control, linked to the electronic document to be authenticated. This ensured that any subsequent change in that document is detectable. (~ eIDAS definition)

Examples:

Simple electronic signature (e.g. username/password, handwritten signature drawn by finger or stylus on an electronic device) combined with for example 1) multi-factor authentication (e.g. registration code, security questions) or 2) biometric data collection (e.g. fingerprints, facial recognition, retina scan, voice recognition).

Primary stakeholders involved:

Participants, Sites.

15. QUALIFIED ELECTRONIC SIGNATURE

Definition:

An advanced electronic signature that is created by a qualified electronic creation device, and which is based on a qualified certificate for electronic signatures. (~ eIDAS definition)

Examples:

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

Primary stakeholders involved:

Participants, Sites.

16. ECONSENT SYSTEM TRAINING CONTENT

Definition:

Supporting digital content or guidance that can be given to the participant for interacting with the eConsent tool, and/or to the site for helping in using the eConsent tool.

Examples:

For participants, how to use the app material; for sites, mock eConsent app where they can consent a mock participant or digital consent training material.

Primary stakeholders involved:

Participants, Sites.

17. NON-STUDY, NON-CONSENT RELATED CONTENT

Definition:

Non-study, non-consent related content that is part of the eConsent tool and applicable for participants and/or sites.

Examples:

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

Primary stakeholders involved:

Participants, Sites.



18. METADATA INSIGHTS AND METRICS

Definition:

Generated insights of usage of the eConsent tool from the start to end for either a single participant or group of participants that can be used by the site and/or operations oversight stakeholders. Generation of information may be passive or active.

Examples:

Time registrations (e.g. per section, time to completion, time to submission, participant overall review time), use of functionalities (e.g. video, FAQ), timing of dropouts/withdrawal, reconsents, repeating questions that appear across various participants, etc.

Primary stakeholders involved:

Sites, Operation oversights stakeholders.

19. BUSINESS INTELLIGENCE

Definition:

Consent related overviews of the individual participant and across participants at a site, country, regional and global level (access level depends on role).

Examples:

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

Primary stakeholders involved:

Sites, Operations oversight stakeholders.

20. ARTIFICIAL INTELLIGENCE

Definition:

Use of Artificial Intelligence (AI) to enhance the consent process for various stakeholders. AI covers a very broad set of algorithms, which enable computers to mimic human intelligence. It ranges from simple if-then rules and decision trees to machine learning and deep learning.

Examples:

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

Primary stakeholders involved:

Participants, Sites, Operations oversight stakeholders.