Where Science, Quality & Ethics Meet

# EFGCP eConsent Initiative

## *eConsent Survey for Institutional Review Boards and Ethics Committees*

**This document gives an overview of the questions and related information of the on-line eConsent Survey for Institutional Review Boards and Ethics Committees.**
**Completion of survey needs to be done on-line using the following link**
https://form.jotform.com/231161629241045

**Click on the below section to navigate**

# Survey Introduction

**Introduction**

We are gathering information regarding industry experience, perceptions, and expectations around the use of electronic informed consent (eConsent) in clinical trials. Your responses will help inform strategies for improving the use of this technology for the benefit of participant, sites, and sponsors.

The survey should take approximately 15-20 minutes to complete. Your responses are anonymous unless you chose, at the end, to provide your email for further involvement in this research or related initiatives from the European Forum for Good Clinical Practice.

EFGCP eConsent initiative is a non-profit multistakeholder initiative focusing on harmonizing terminologies and processes associated with eConsent, to increase insight in different stakeholder value models and to provide a consistent country-level overview of acceptance/non-acceptance of certain eConsent aspects. A common misunderstanding on eConsent is that it is about remote consenting or electronic signatures, however these are just some of the features that could be used for eConsent. A glossary of various eConsent digital features has been created by the EFGCP eConsent team and can be accessed here.

# Organization Information

1. Which of the following best describes your organization?
   - Central or Independent Institutional Review Board
   - Local Institutional Review Board (academic or medical facility - based IRB)
   - Ethics Review Committee at an academic institution or medical facility outside the US
   - Ethics Review Committee outside the US, not affiliated with a specific academic institution or medical facility.
   - Other

2. Please indicate the Country in which your Institutional Review Board or Ethics Committee has jurisdiction.
   - Select a country

3. Please indicate any relevant locality/state/site in which your Institutional Review Board or Ethics Committee has jurisdiction.

# Survey Questions

4. Please indicate which of these statements best describes your experience with electronic informed consent (eConsent)
   - We have never been asked to approve use of eConsent
   - We have reviewed and rejected use of eConsent in at least one instance
   - We generally approve all requests to use eConsent
   - We have reviewed and approved at least one instance of eConsent
   - We have reviewed multiple applications for eConsent and have approved some but rejected others
   - We have no opinion on the use of eConsent or eConsent use is irrelevant to our approvals

If the selected answers are "*We have reviewed and rejected use of eConsent in at least one instance*" or "*We have reviewed multiple applications for eConsent and have approved some but rejected others*"

4.1 Please explain why the use of eConsent was rejected

5. We are interested in understanding how to advance the acceptability of electronic signatures together with electronic informed consent for clinical trials. How important is each of the following features, in your decision to approve the use of eConsent with eSignature.

| | Not at all | Somewhat important | Very important | Essential |
|---|---|---|---|---|
| Ease of using eSignature for participants | | | | |
| Evidence of adequate data security and privacy for eSigned documents | | | | |
| Availability of guidelines from our national health authority regarding eSignature | | | | |
| Compliance with regulations such as CFR-Part 11, GDPR, and EMA guidelines on computerized systems | | | | |
| Use of a specific signature type (advanced/biometric or qualified electronic signature) | | | | |

6. What is the most important factor driving a decision to approve an eConsent technology in your country/jurisdiction?
   - patient-centricity, i.e., patients first.
   - knowing it is accounted for in site document guidance, i.e., Standard Operating Procedures (SOPs)
   - knowing the process allows for a true informed consent procedure without removing the interaction between physician and participant.
   - the regulatory body within my country accepts eConsent technology.
   - that it enables decentralized trials.
   - that there is easy access to the technology and documentation/training.
   - other

7. Does your Ethics Committee have a guidance document related to informed consent?
   - Yes
   - No

If the answer is "*No*"

7.1. Is there anything that would need to be adapted in order to accommodate use of eConsent?
   - No, nothing in the document prohibits use of eConsent
   - Yes, there is language that should be modified to address eConsent

If the answer is "Yes, there is language that should be modified to address eConsent"

7.2. Please explain or describe the language that needs to be adapted

8. For each of the consent scenarios below, please consider what the minimum requirement is for signature types is in a Phase 1-3 interventional trial.

In Europe, there are three types of electronic signature under eIDAS regulation:

1. **Simple electronic:** 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.
2. **Advanced electronic:** Meets the following requirements: 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.
3. **Qualified electronic:** An advanced electronic signature that is created by a qualified electronic creation device, which is based on a qualified certificate for electronic signatures.

In the US, a biometric electronic signature is the equivalent of an advanced electronic signature in Europe.

Other countries may use different designations and definitions.

The following question will ask you to consider the minimum signature requirement in each instance where the participants and the method of identity verification differs.

For the purpose of this question, "on-site consent visit" is a visit where the study investigator and the potential participant are in the same location and the investigator personally validates the identity of the potential participant.

For the purpose of this question, "remote consent visit" is a visit where the study investigator and the potential participant are not in the same location.

| | Simple Digital Signature is acceptable | Advanced Electronic / Biometric Signature is minimum standard | Qualified Electronic Signature is only acceptable eSign | No electronic signature is allowed / Wet-ink only |
|---|---|---|---|---|
| An **on-site consent** visit where the study investigator personally verifies the potential participant | | | | |
| An **on-site consent** visit where the study investigator personally verifies the potential participants who require assistance by caregivers or parents - with both consent and assent documents | | | | |
| An **on-site consent** visit where the study investigator personally verifies a Legally Acceptable Representative (LAR) for participation by a patient who is incapacitated | | | | |
| A **remote consent via televisit**, where the study investigator verifies the potential participant(s) identity over a video connection | | | | |
| A **remote consent via televisit** where the study investigator verifies a potential participant who requires assistance by caregivers or parents - with both consent and assent documents reviewed over a video connection | | | | |
| A **remote consent via televisit** where the study investigator verifies a Legally Acceptable Representative (LAR) over a video connection, for participation by a patient who is incapacitated | | | | |
| A **remote consent via phone call**, where the study investigator verifies the potential participant(s) via verbal exchange only (no video) | | | | |
| A **remote consent via phone** where the study investigator verifies a potential participant who requires assistance by caregivers or parents - with both consent and assent documents (no video) | | | | |
| A **remote consent via phone call** where the study investigator verifies a Legally Acceptable Representative (LAR) via a verbal exchange only for participation by a patient who is incapacitated (no video) | | | | |
| For Phase 4 studies, consumer health and/or registries there is often a different standard for signature. Please indicate what type of signature is acceptable in these studies | | | | |

9. Do local laws or regulations require that directly identifiable personal data (e.g., names and signatures on consent forms) be hosted locally in your country or region?
   - Must be on site of Investigator
   - Should at least be in region (N. America / EU, APAC)
   - I am not sure what my local laws around storage of Personal Data are
   - Must be in-country
   - No restrictions as long as appropriate encryption and security is in place
   - Other

10. Please describe criteria for storing directly identifiable data outside the country and/or indicate which laws govern the storage of this data

11. Which of these materials is required for submission and approval of eConsent? (check all that apply)

    - System privacy and security documentation
    - Attestation that eICF content is identical to paper ICF
    - Screenshots of digitized consent
    - Storyboards of multi-media content used to supplement the consent documents
    - System-printed PDF of document
    - Access to the electronic platform for IRB/EC preview
    - Other

12. Do you have any timeline requirements for archives of eConsent data that exceed the GCP requirements?
    - Yes
    - No

If the answer is "*yes*"

12.1. Please specify

13. Are there any differences in expectation for monitoring of eConsent versus paper consent?
    - Yes
    - No

If the answer is "*yes*"

13.1. Please explain why

14. Would your IRB/EC be supportive of a stipulation in the protocol that consent can only be given electronically?

    In many clinical trials there is no paper alternative to the use of electronic patient reported outcomes (ePRO) - the use of this technology is required for study participation.

    The Netherlands has already approved that protocols may stipulate use of electronic consent without a paper alternative.

    - Yes
    - No
    - Other

15. Would you be interested in participating in future research (interviews or focus groups) or initiatives regarding eConsent?
    - Yes
    - No

    If the answer is "*yes*"

    Thank you for your interest in supporting eConsent. Please provide an email address where you can be contacted.

    - First name
    - Last name
    - Organization
    - E-mail

# Terms of Use and Data Protection Policies

Please find below the Data Protection Policies.

Thank you for confirming your agreement by ticking the box at the bottom of this page before clicking on the « submit » button.
Once your results are submitted, you will not be able to make changes anymore.

If you want to receive your survey submission results by email, please tick the box below and enter your email in the field that will appear. This email address will be used to send the results automatically by Jotform and stored in JotForm, it will however not be used by EFGCP to contact you.

**Survey Data**

Survey Submission Results

- I want to receive my survey submission results by email

If "*I want to receive my survey submission results by email*" is ticked, please enter your email

By participating in this survey, you are consenting to have your responses used in the analysis and a publication of the results, if applicable. However, your responses will not be identified by name or any other identifying information.

Your data will be provided to the EFGCP eConsent Database workstream carrying out the analysis of the results. The information will be handled by EFGCP within the framework of the eConsent Initiative according to the EFGCP Privacy Policy. If you have additional questions on data privacy policy or you might want to have your personal data deleted or amended, you can contact the EFGCP Data Protection Officer of the EFGCP in writing at secretariat@efgcp.eu.

In the scope of this survey, EFGCP will process your data as data controller for the purposes that were presented to you. The legal basis for processing your personal data is consent (Article 6(1)(a) of Regulation (EU) 2016/679). Your data will be processed according to the EFGCP Privacy Policy.

All data will be used exclusively within the framework of the EFGCP eConsent initiative.

In case you have accepted to be contacted, within this survey, you agree for your personal data to be stored and accessible only to EFGCP Staff Members in the JotForm system, and made accessible to the EFGCP eConsent Database WS Lead(s) and EFGCP eConsent initiative lead. You have the right to ask your personal data to be amended or deleted by contacting secretariat@efgcp.eu.

EFGCP will provide its services in a professional and compliant manner using best efforts to protect personal data. When sharing your personal data for the purpose of the eConsent Initiative to the participating stakeholders, EFGCP will implement appropriate safeguards. Each participating stakeholder is an independent controller and has agreed to carry out the tasks assigned to it in this Initiative with care and diligence applying their own safeguards for the received personal data. The parties hereto acknowledge and agree that nothing in this statement contained, and nothing done pursuant hereto by participating stakeholders shall be deemed to constitute a direct or indirect guarantee by EFGCP of any liability. EFGCP cannot be held responsible for any data leaks, IT issues, hacks, misuses, or any harms to you, your organizations or your activities, due to your involvement in the eConsent Initiative Activities.

Personal Data Gathered (if agreed):
- Name, Surname, Organization

- eMail Address

Agreement tick box

- I agree to Terms of Use and Data Protection Policies