



Informed Consent Form

Informed consent is the process where a participant or their legally acceptable representative voluntarily agrees to join a trial after being fully informed about all relevant aspects of the clinical trial and given a chance to ask questions.

Information can be shared in various ways, such as text, images, videos, phone calls or

video conferencing with investigator site staff. Consent can also be obtained remotely when appropriate.

The informed consent form is signed and dated by the participant or their legally acceptable representative at the conclusion of the consent process along with Investigator/designee, which can be either a physical signature or electronic signature and date

Essential elements of Informed Consent Form:

The content of an Informed Consent Form is important to ensure that people who join a research study fully understand what the study involves and what their rights are. Written in simple and clear language, the Informed Consent Form helps protect participants, making sure they can make informed choices about joining a study without any pressure

The key elements of the Informed Consent Form include the following:

- Purpose of the trial, treatments and trial procedures
- Possible risks, burdens and benefits
- Alternative procedures or courses of treatment
- Extent of confidentiality of personal records and direct access by authorities
- Voluntary participation and the right to withdraw or stop taking the Investigational Product

- Consequences and follow-up procedures for withdrawal or stopping Investigational Product
- Compensation and treatment in the event of trial-related injury
- Statement allowing direct access to source records for monitoring, auditing, Ethics Committee review and regulatory inspection, complying with regulatory requirements
- Statement that mentions that the Participant or legally acceptable representative will be promptly informed of new information that might affect their decision to continue in the trial
- Whom to contact for trial information, participant rights and suspected trial related injury
- Access to trial results and treatment information upon request

Key users of Informed Consent Form:

In clinical trials, informed consent forms are used to ensure participants fully understand the study before agreeing to take part. These forms help protect the rights and safety of volunteers by clearly explaining the purpose, procedures, risks and benefits of the trial. They are a vital tool for maintaining transparency and ethical standards throughout the research process. Listed below are the key stakeholders who are associated with the informed consent form:

- **Participants:** To understand the trial purpose, procedures, risks and benefits, enabling them to make an informed decision about participation and to ensure their rights are respected throughout the trial
- **Principal Investigator & Site Staff:** To document voluntary consent, ensure participant understanding, maintain ethical standards and communicate ongoing updates or changes in the trial
- **Sponsor:** To provide oversight and assurance that the trial is conducted ethically and legally, maintaining data integrity and participant safety
- **Monitors/Auditors:** To verify proper consent was obtained and documented as part of compliance and quality assurance during trial monitoring or auditing

Informed Consent Form Amendment

The Informed Consent Form can be amended for the following reasons:

- If there is a significant change in the protocol such as:
- Modifications to study design, such as dosage, duration or procedures
- Any change in eligibility criteria, who can or cannot participate in the trial
- Changes in study endpoints or objectives
- Discovery of additional risks, side effects or adverse events that is availability of new safety data

This ensures that participants receive the most current information about the study and any new risks involved