

Informed Consent Form Amendment

The Informed Consent Form is typically 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.

Any new information that might affect a participant's decision to stay in a clinical trial should be reviewed to see if re-consent is needed. Depending on the trial stage, consideration should be given whether the update applies only to new participants or also to those already enrolled.

If re-consent is required, such as for new safety concerns, the updated details must be clearly identified in the revised consent form. These revised materials must be approved by the Ethics Committee before use.

During the trial, participants or their legal representatives must receive copies (paper or electronic) of any updated consent forms and related materials.