

Information Provided

- These potential participants should be informed about the trial in a manner that facilitates their understanding
- Neither the investigator nor the investigator site staff should coerce or unduly influence a participant to participate or to continue their participation in the trial
- The consent information must not include any language that makes the participant give up legal rights or release site team or sponsor from liability for negligence
- The investigator or authorized staff must obtain consent as per regulations. If the participant cannot consent, a legally acceptable representative should do so on their behalf
- Before giving consent, participants or their legal representatives must be given enough time and opportunity to ask questions and decide about joining the trial. All questions should be answered to their satisfaction, unless limited by urgent circumstances (e.g. in an emergency situation)

Information Understood and Decision Made

- Before joining the trial, the consent form must be signed and dated by the participant or their legal representative and if needed, an impartial witness and the investigator or delegated staff. Signing confirms that consent was freely given, clearly explained and understood. Signatures may be physical or electronic
- If the participant or their legal representative can't read, an impartial witness must be present (remotely or in person) throughout the consent discussion. After the information is explained and oral consent is given, the witness signs the form to confirm that the consent was clearly explained, understood and freely given

- Before participation, the participant or their legal representative must receive a copy (paper or electronic) of the signed consent form and related materials, as per regulatory requirements