

Consent for Audio Visual Recording of Informed Consent Process

NOTE: THIS INFORMED CONSENT FORM ON AUDIO VISUAL RECORDING OF CONSENT NEEDS TO BE SIGNED ONLY ONCE DURING INITIAL SCREENING CONSENT PRIOR TO STUDY PARTICIPATION AND NEED NOT BE ADMINISTERED AGAIN FOR RECONSENTING ON FUTURE ICF AMENDMENTS, UNLESS THE SITE PRACTICE REQUIRES THE SAME.

Sponsor: Janssen Research & Development, LLC

Represented by: JOHNSON & JOHNSON PRIVATE LIMITED, HIGI house, LBS Marg, Mulund (West), Mumbai – 400080

Protocol Number: 79635322MMY3002

Dr. Jeevan Kumar

Tata Medical Center, Kolkata, India.

You are being invited to take part in a clinical trial conducted by Johnson & Johnson Private Limited. Participating in this clinical trial is voluntary. As per the Indian Regulations for Clinical Trials, it is mandatory to make an audio-visual recording of the informed consent process for participation in this trial.

By signing this consent form,

- I have no objection to the audio-visual recording of the informed consent process of the clinical trial mentioned above.
- I have been informed that the recording will be stored, adhering to the principles of confidentiality.
- I understand that my consent is voluntary, that I am not required to sign this consent and that I may refuse to sign it, thereby prohibiting the audio visual recording. I also understand that in compliance with regulations I would thereby be unable to participate in the clinical trial referenced above.

If you consent to the audio-visual recording of the informed consent process, please sign below.

You will receive a copy of this signed Form.

Signature (or Thumb impression) of the
Participant/Legally Acceptable Representative

Date (dd-MON-yyyy)

Signatory's Name

Signature of the Investigator

Date (dd-MON-yyyy)

Name of the Study Investigator

Impartial Witness Statement

I confirm that the information in the consent form was accurately explained to, and apparently understood by, the participant and/or the participant's legally acceptable representative, and that consent was freely given by the participant and/or the participant's legally acceptable representative.

Signature of Impartial Witness

Date (dd-MON-yyyy)

Name of Impartial Witness, in full

(Copy of the duly completed and signed Informed Consent form for Audio Visual Recording shall be handed over to the subject or his/her attendant)