

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 invited to participate in a clinical trial conducted by Johnson & Johnson Pvt. Ltd. Participation in the clinical trial is voluntary. According to Indian regulations for clinical trials, audio-visual recording of the informed consent process is mandatory to participate in the trial.

By signing the consent form,

- I have no objection to audio-visual recording of the informed consent process for the clinical trial referred above.
- I have been informed that the recording will be protected following principles of confidentiality.
- I understand that my consent is voluntary, I do not need to sign the consent and I may refuse to sign this, that will restrict audio-visual recording. I also understand that I will be unable to participate in the clinical trial above in compliance with regulations.

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

You will receive one copy of the signed form.

Signature (or thumb impression) of the subject /
legally acceptable representative

Date (dd-MON-yyyy)

Signatory's name

Signature of the investigator

Date (dd-MON-yyyy)

Name of the study investigator

Statement of impartial witness

I confirm that information provided in the consent form was explained to the subject and/or legally acceptable representative of the subject accurately and was understood by them clearly, and that consent was given by the subject and/or legally acceptable representative of the subject freely.

Signature of impartial witness

Date (dd-MON-yyyy)

Full name of impartial witness

(A copy of duly filled and signed informed consent form for audio-visual recording will be given to the subject or his/ his/her attendant)