

CONSENT FOR A-V RECORDING OF THE INFORMED CONSENT PROCESS

Study Protocol:	TAK-226-3001
Study Title:	A Phase 3, Multicenter, Open Label, Randomized Trial to Compare the Efficacy and Safety of Elritercept versus Epoetin Alfa for the Treatment of Anemia Due to IPSS-R Very Low, Low, or Intermediate Risk Myelodysplastic Syndromes in ESA-naïve Adult Participants Who Require Red Blood Cell Transfusions (“Study”)
Study Drug:	Elritercept (TAK-226), mentioned throughout the document as the “study drug”
Sponsor of the study:	Takeda Development Center Americas, Inc. 500 Kendall Street Cambridge, MA 02142 USA
Phase of the study:	III

Investigator:	Dr. Arijit Nag
Site Number (in case applicable):	24003
Site Name & Address:	Tata Medical Center, 14 Major Arterial Road (EW) New Town, Rajarhat, Kolkata- 700160, West Bengal, India.
Country:	India

According to New Drugs and Clinical Trials Rules (“New Rules”), 2019 (Gazette Notification G.S.R. 227(E), dated 19th March 2019 issued by the Ministry of Health and Family Welfare), Audio-Video (A-V) recording of the informed consent process for the participation in the Study is for all vulnerable subjects who will participate in the Study in India.

In case you consent to this A-V recording of the informed consent process for the participation in this Study, the trial specific informed consent form (ICF) will be provided to you, which explains in detail the trial and the potential risks and benefits of participation. The informed consent method with the Investigator for your participation in the Study will be recorded and stored securely at the trial site together with documentation of other study for a period of not less than 15 years post this clinical trial’s completion/termination and then for as long as required to meet legal, regulatory, scientific or other needs of the countries or regions where the study drug will be launched (“Retention Period”). Following the Retention Period above, the recording will be discarded. Normally, the A-V recording will only be reviewed by the Investigator, Ethics Committee and Regulatory Authority representative on-site, and your confidentiality will be maintained by these parties.

Participating in the study is completely voluntary. Though, in case you do not consent to this needed A-V recording of the informed consent process, you will be unable to take part in the Study.

At any time, you might deny to take part or leave the trial, without penalty or loss of benefits to which you are else entitled. It is up to you whether or not you want to participate. Details regarding the risks and benefits of participation in the Study how the personal information will be gathered, utilized, processed, stored and revealed in the Study, the withdrawal process from the Study, and your rights in the Study, etc., will be given in the Study specific ICF. Kindly carefully read the Study ICF for these details and kindly discuss with your study doctor for the Study ICF details.

In addition, in the event the Sponsor sells or licenses out Elritercept to another company, as part of this study your coded data collected might be shared with that company as part of that transaction.

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Study Participant Name:		Study Participant Initials:	
Date of Birth / Age:		Study Participant ID:	
Study Participant Address:			

STATEMENT OF VOLUNTARY CONSENT TO THE AUDIO-VISUAL RECORDING OF INFORMED CONSENT PROCESS

By putting a signature on this form, I hereby provide permission to carry out the audio-video recording of my image, voice, etc. for recording the informed consent process of my participation in the Study, and the process of the A-V recording and all information contained in and/or related to it pursuant to this Consent for A-V Recording of the Informed Consent Process.

I have read and completely informed myself of the content of this Consent for A-V Recording of the Informed Consent Process prior to putting a signature on it.

Sr.	Statement	Initial (Study Participant)
(i)	I affirm that I have read this consent form for A-V recording of the informed consent process, and have had the chance to ask queries, which were answered to my satisfaction.	
(ii)	I consent that even though I leave the trial later, the Investigator, Ethics Committee, Regulatory Authorities, sponsor and/or its representative and/or its business partner will not require my permission to look at the A-V recording. I consent to this access. Though, I am aware that my confidentiality will be maintained and my identity will not be disclosed in any information released to third parties apart from those mentioned above or published, unless otherwise needed by any applicable laws and regulations or might be used in courts.	
(iii)	I consent that the said A-V recording and other related documents (which includes however not limited to this document) shall be safely preserved for a period of not less than 25 years post this clinical trial's completion/termination and then for as long as required to meet legal, regulatory, scientific or other needs of the countries or regions where the study drug will be launched.	
(iv)	I consent that nothing contained in this shall preclude any judicial officer from viewing the said A-V recording without my consent.	

CONSENT FOR A-V RECORDING OF THE INFORMED CONSENT PROCESS

I consent to the audio-visual recording of consenting process.

Study Participant Name (print):	
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Signature (or Thumb impression) of the Study Participant

Date

Name of the Investigator	
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Signature of the Investigator

Date

(* In case a study participant has reading and writing limited ability, a witness must be present at the time of the complete informed consent discussion).

In these instances, the study participant places his/ her left thumb impression in the place of the signature.

Study Participant's Legally Acceptable Representative's Statement

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Not Applicable

I, as the study participant's legally acceptable representative, was present at the time of the consenting method for the audio-video recording of informed consent and understand the preceding information.

Name of the Legally Acceptable Representative (print):	
Relationship to the Study Participant :	
Address of the legally acceptable representative:	
Phone No:	

Signature of the Legally Acceptable Representative

Date

CONSENT FOR A-V RECORDING OF THE INFORMED CONSENT PROCESS

Witness Declaration of Study Participant's Informed
Consent

☐	Not Applicable
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By putting a signature on this consent form, I certify that the information was described to and apparently understood by the subject and the legally acceptable representative (in case applicable) and that informed consent was liberally provided by the subject.

Name of the Witness: (print):			
Address of the Witness:			
Phone No:			
Signature of the Witness		Date	

(A copy of the Consent for Audio-Visual (A-V) Recording of the Informed Consent Process shall be given to the study participant or his/her attendant)