

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 Medication:	Elritercept (TAK-226), referred to throughout the document as the "study medication"
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 (if 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 agree 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 given to you, which explains in detail the trial and the possible risks and benefits of participation. The informed consent procedure with the Investigator for your participation in the Study will be recorded and securely stored at the trial site together with other study documentation for a period of not less than 15 years after the completion/termination of this clinical trial and then for as long as needed to meet legal, regulatory, scientific or other requirements of the countries or regions where the study drug will be launched ("Retention Period"). After the Retention Period mentioned above, the recording will be destroyed. The A-V recording will normally be reviewed only on-site by the Investigator, Ethics Committee and Regulatory Authority representative, and your confidentiality will be maintained by these parties.

Participating in the study is totally voluntary. However, if you do not consent to this needed A-V recording of the informed consent process, you cannot take part in the study.

You may say no to take part or leave the trial, at any time, without being penalized or loss of benefits to which you are otherwise entitled. It is up to you if you do or do not wish to participate. The Study specific ICF will give details about the risks and benefits of participation in the Study, how the personal information will be taken, used, processed, stored and revealed in the Study, the withdrawal process from the Study, and your rights in the Study, etc. Kindly read the Study ICF cautiously for these details and kindly discuss with your study doctor for the details of the Study ICF.

Also, in case the Sponsor sells or licenses out Elritercept to another company, your coded data taken as part of this study 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 give permission to conduct 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 before putting a signature on it.

Sr.	Statement	Initial (Study Participant)
(i)	I confirm that I have read this consent form for A-V recording of the informed consent process, and I have had the chance to ask queries, which were satisfactorily answered to me.	
(ii)	I agree that the Investigator, Ethics Committee, Regulatory Authorities, sponsor and/or its representative and/or its business partner will not require my permission to see the A-V recording, even if I later withdraw from the trial. I agree to this access. However, I know that my confidentiality will be maintained and my identity will not be disclosed in any information released to third parties other than those stated above or published, unless otherwise needed by any applicable laws and regulations or can be used in courts.	
(iii)	I agree that the said A-V recording and other related documents (which include but not limited to this document) shall be safely preserved for a period of not less than 25 years after the completion/termination of this clinical trial and then for as long as needed to meet legal, regulatory, scientific or other requirements of the countries or regions where the study medication will be launched.	
(iv)	I agree that nothing contained herein shall preclude any judicial officer from looking at the said A-V recording without my consent.	

CONSENT FOR A-V RECORDING OF THE INFORMED CONSENT PROCESS

I agree 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

(* If a study participant has limited ability to read and write, a witness must be present during the entire informed consent discussion).

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

Study Participant's Legally Acceptable Representative's Statement

☐ Not Applicable

As the study participant's legally acceptable representative, I was present during the consenting procedure 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 Number:	

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

By putting a signature on this consent form, I attest that the information was described to the subject and the legally acceptable representative (if applicable) and this information was apparently understood by them, and that informed consent was given by the subject independently.

Name of the Witness (print):		
Address of the Witness:		
Phone Number:		

Signature of the Witness

Date

(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)