

[To be printed and signed on Investigator's letterhead]

Audio Visual (A-V) Recording Declaration

I Dr. Arijit Nag being an Investigator for “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” clinical trial, being conducted at Tata Medical Center, 14 Major Arterial Road (EW) New Town, Rajarhat, Kolkata- 700160, West Bengal, India (the “Site”) do hereby declare that:

1. I have been made aware that vide New Drugs and Clinical Trials Rules (“New Rules”), 2019 (Gazette Notification G.S.R. 227(E), dated 19th March 2019) it is required that Audio-Video (AV) recording of the informed consent process is mandatory for all vulnerable subjects who will take part in clinical trials in India.
2. Each of the new subjects, being my patients and having participated in “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” clinical trial at the Site have provided, both their consent to the A-V recording of the informed consent process and have provided their informed consent in accordance with the New Rules.
3. The A-V recordings taken of the said new subjects in accordance with the New Rules are of the quality (both audio and visual) required by the Site's Standard Operating Procedures (SOP's) and serves the intended process and is at least of a minimum standard required for the purpose.
4. The A-V recordings taken of the said new subjects in accordance with the New Rules shall be preserved safely after the completion/termination of the study for a period of at least five (5) years.
5. The A-V recordings taken of the said new subjects in accordance with the New Rules are of a quality (both audio and visual), where the subject's responses to the questions, being a part of the informed consent process can be easily discerned.

Verified on this [] day of [] of the year [], that the contents of this declaration are true and correct to the best of my knowledge and belief and nothing has been concealed[#]

Dr. Arijit Nag

Protocol Number : TAK-226-3001

Sponsor Name: Takeda Development Center Americas, Inc.

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[#] Where the SOP requires that this declaration be notarized (recommended), then the notaries stamp to be affixed. In the absence of the said instruction in the SOP, the official seal/stamp of the site to be affixed.