

PREGNANCY IN CLINICAL STUDY INFORMED CONSENT FORM

A Phase 3 Randomized Study Comparing JNJ-79635322 versus Teclistamab in Participants with Relapsed or Refractory Multiple Myeloma after 1 to 3 Prior Lines of Therapy, Including an Anti-CD38 Antibody and Lenalidomide (TRIlogy-5)

Study ID: Protocol 79635322MMY3002

Dr. Jeevan Kumar is conducting this study, which is sponsored by a pharmaceutical company, Janssen Research & Development, LLC.

You are requested to share medical information about your pregnancy and its outcome with the clinical staff and the sponsor. If you agree, the clinical staff will request this information from you after the birth of your child. This form explains what is involved if you agree to share this information.

Here are a few things to know:

- Sharing this medical information is entirely voluntary, and it is not part of the routine medical care for the pregnancy or the child.
- Take your time to carefully read this Informed Consent Form (ICF) so that you can understand why it is being requested and what it involves.
- Discuss this with your doctors, medical professionals, family, and friends about this.
- Ask questions and request any additional information from the clinical staff at the study site.
- Your participation does not enroll you in the research study.
- By participating in this, you will not receive any medical advice or treatment for the pregnancy nor the baby (either before or after birth). You should continue to visit your own doctor(s).
- You are free to decide whether or not to share your/ your child's medical information; and if you agree to do so now, you may change your mind at any time. Whether or not you share this is up to you. Whatever choice you make, you will not lose access to the medical care you already receive, gain any penalty or give up any of your existing rights or benefits.

Thank you for taking the time to consider providing this information.

The sponsor may share sensitive company information with you to assist you in making a decision about /sharing your/ your baby's medical information. We kindly ask you to consider this when discussing details about the study with people other than your healthcare provider(s), family and friends or when using social media.

YOUR CONTACTS

Study Sponsor Janssen Research & Development, LLC	Represented by: JOHNSON & JOHNSON PRIVATE LIMITED HIGI house, LBS Marg, Mulund (West), Mumbai – 400080
Name of Principal Investigator: Dr. Jeevan Kumar Name and Address of the Site: Tata Medical Center, 14-MAR (E-W), New-town, Rajarhat, Kolkata - 700160, India. Contact number of the Principal Investigator: +91-9007016755 24-hour telephone (if applicable): NA	

OVERVIEW AND GENERAL INFORMATION

Why am I being asked to share information about my pregnancy and its outcome?

We are requesting this information because your partner, who is the biological parent of your unborn baby, is (or was) participating in a clinical research study. Your partner is receiving (or has received) an experimental drug named “JNJ-79635322 or teclistamab,” which is being developed as a possible treatment for multiple myeloma.

Since JNJ-79635322 is an experimental drug, no information is available about the risks of pregnancy and its effects on an unborn child during treatment with JNJ-79635322 or teclistamab. The effect of the study drug on eggs, sperm, and reproductive organs is unknown. It is unknown whether the study drug can reduce the effectiveness of hormonal contraceptives. Therefore, the sponsor wishes to collect information from you to learn more about JNJ-79635322 or teclistamab, and any possible effects it may have in this circumstance.

We will collect information on the pregnancy outcomes and the health of the baby.

WHAT ARE THE BENEFITS OF AGREEING TO SHARE THIS INFORMATION?

This will not provide any direct benefit to you or your child; however, by sharing this information, you can help future patients who may need to take this medicine.

You can change your mind about sharing this information at any time by informing the clinical staff. Please note that any information collected before you change your mind, will continue to be used by the sponsor. If you do not agree to share this information, it will have no impact on your partner's participation in the study. Please note that you will not receive any payment for sharing this information. This will incur no cost to you; however, all expenses related to your pregnancy will be covered by you, your insurance company, or your government health scheme as standard practice.

HOW WILL PRIVACY BE PROTECTED?

The clinical staff and the Sponsor will safeguard your and your child's personal data (information collected from you and your child). The Study Staff and the Sponsor will manage your personal data (information about your child) in compliance with applicable data protection and privacy laws in India and in the manner described in this consent form. The “Privacy Appendix” provided in this document describes your rights about the use and protection of your personal data.

PRIVACY APPENDIX TO PREGNANCY INFORMED CONSENT

The sponsors and their representatives will use the information collected about your child for study purposes and for scientific research, such as the study of your child's disease and genetic research [if applicable]. The sponsor and their representatives may also use this information to apply for permission to sell the drug in certain countries. The information will be stored on both paper and computer. To protect your privacy, the information will be labeled in such a way that your child cannot be identified. If the results of the study are published, your identity will be kept confidential. By signing this form, you are authorizing this use of your child's information.

Your study doctor will retain your child's personal medical records and a list linking each patient's name to their code number for at least 15 years.

Regulatory authorities, members of the Ethics Committee/Institutional Review Board, employees at the study site, and representatives of the sponsor will have access to this list and will be able to compare and verify the study information collected about your child with information in your child's medical records. As far as the law allows, your child's medical records will not be made public. By signing this form, you are granting direct access to your child's medical records to individuals who have a valid reason to view them.

The collected information may be shared with other members of the Johnson & Johnson group of companies, contractors working on their behalf, and regulatory authorities.

You can make arrangements with your child's study doctor to view the information collected about your child, and you can ask for any errors to be corrected. If it would interfere with the study, the sponsor and its representatives may postpone your access to your child's information. If you decide to leave the study at any time, the sponsor and its representatives may still use your child's information collected up to that point, if the law allows.

Medical Record - information and data, including personal details, recorded by the clinical staff; stays on-site.

Study Record – Medical record data from the study participant, their pregnant partner, and the child (without personal identifiers), documented by the clinical staff and shared with the sponsor.

1. What personal data will clinical staff collect?

If you agree, the clinical staff will collect and share your and your child's personal data for research purposes. **Personal data** may include:

- Information about your and your child's health. This may include medical images and written descriptions (including records of phone calls, visits, and examinations).
- Direct personal identifiers such as your and your child's name, initials, date of birth, address,
- Other sensitive data such as racial or ethnic origin, sex assigned at birth, gender identity, lifestyle, religious or philosophical beliefs, sexual behavior, or sexual orientation are collected only when necessary to evaluate the results of the study.

2. Who will have access to my and/or my child's medical records?

Your and your child's medical records will be stored in paper files and electronic databases, including those that can be accessed remotely (if approved in your country). The clinical staff will have access to your and your child's medical record. Additionally, the people listed below may have direct access to your and your child's personal data (to ensure that the research study is being conducted properly).

- Monitors and auditors from the sponsor or the sponsor's representatives.
- The Institutional Review Board (IRB) or Independent Ethics Committee (IEC) (a group of people who review research studies to protect the rights and welfare of individuals participating in the research).
- Regulatory authorities: local and outside your country.
- Other persons or groups, as required by law, who may be located outside your country. The level of protection for your information may vary under the laws of other countries.

3. How will my and my child's personal data be protected?

The clinical staff will also enter information from your and your child's medical records into the **Study Record**. These data are provided to the sponsor for study purposes. This will be identified only through the study number and participant number. Direct personal identifiers such as your or your child's name, initials, date of birth will not be included in Study Record. The clinical staff may match the study records to your name, but this information will be kept confidential and not shared with the sponsor or anyone, except where required by law.

4. How will my and my child's Study Record be used and shared?

The sponsor and other authorized parties identified in this consent form will use and share your and your child's Study Records for scientific research and compatible research purposes, such as:

- Evaluating and understanding study drugs, diseases and related health problems;
- advancing clinical science and medical knowledge.

Authorized parties may include organisations providing services for the sponsor (such as laboratories), researchers, collaborators, and companies that may have a common interest in the study drug or disease.

The sponsor, other authorized parties and Regulatory Authorities may be located outside of your country, where laws may provide a different level of protection.

5. Data transfer

As required by applicable laws, safeguards are in place to protect your and your child's personal data when it is transferred outside of your country. This also applies to people who have remote access to your and your child's data, as well as when this data is shared as described above.

6. How long will my and my child's personal data be kept?

Clinical staff will maintain your and your child's Medical Records at the site, in accordance with local laws and requirements. The sponsor may retain your and your child's **Study Records** for as long as required OR 15 years in accordance with applicable laws.

7. What rights do I have regarding my and my child's personal data?

If you would like to review, correct, delete personal data or make other requests in accordance with the laws of your country, you should contact clinical staff at +91-9007016755. You may not be able to review your data until the study ends. Your request to delete your personal data may be denied based on the regulations and laws under which the retention of clinical research and personal data is mandatory.

YOUR CONSENT TO PARTICIPATE

If you consent (agree) to all the statements below, please sign below. You will receive a copy of this signed Informed Consent Form.

I have read (or it has been read out to me) the entire consent document, with Appendix, which contains information on privacy. I understand the provided information and consent to share relevant information as a pregnant partner of the study participant.

- All my questions about sharing of information related to pregnancy and the baby's health have been answered to my satisfaction.
- I understand that sharing this information is voluntary, and I can change my mind at any time.
- By signing this form, I have not waived any of my legal rights.
- I agree that my doctor(s), who is responsible for the pregnancy or the health of my child, may share health information with clinical staff for use by the sponsor, as described in this form.
- I consent to the processing and transfer of my data as described in this consent form.
- I understand my rights, and that I can withdraw my consent at any time.
- I consent to share my and my child's health information with the study doctor for use by the sponsor for the research described in this form.

Signature (or Thumb impression) of
Pregnant Partner of Male
Subject/Legally Acceptable _____
Representative:

Date: ____/____/____
dd-MON-YYYY

Signature of the Investigator: _____

Date: ____/____/____
dd-MON-YYYY

Name of Study Investigator: _____

Legally Acceptable Representative:

The signature of a legally acceptable representative is required below only if the male study participant's pregnant partner is a minor or an incapacitated adult. Relationship with the pregnant partner must be included.

Printed Name of Legally Designated Representative, in Full (if applicable)

Legally Acceptable Representative: _____

Date: ____/____/____
dd-MON-YYYY

Relationship of Legally Designated Representative to Pregnant Partner of Male Study Participant:

Statement of Impartial Witness: I confirm that the information in the consent form was accurately explained to the Male Subject's Pregnant Partner and that she clearly understood it, and that consent was freely given by the Pregnant Partner of Male Subject.

Signature of the Witness: _____

Date: ____/____/____
dd-MON-YYYY

Name of the Witness: _____

A copy of the duly completed Informed Consent Form shall be handed over to the Pregnant partner of the male subject.