

.GOVERNMENT OF NCT OF DELHI MAULANA AZAD MEDICAL COLLEGE

And Associated Lok Nayak, G. B. Pant Hospital & Guru Nanak Eye Centre, 2-B.S.Z. Marg, New Delhi-02

ASSENT FORM (CHILDREN 7-13 yrs)

We want to tell you about a research study we are doing. A research study is a way to learn more about something. We would like to find out more about [insert topic and describe goals in simple language]. You are being asked to join the study because [insert name of condition or other reason(s) for inclusion].

If you agree to join this study, you will be asked to [describe procedures, (e.g., questionnaires, activities) in words a child would know and understand. Also include number of visits and time frame in words easily understood by a child].

Describe possible risks (e.g., discomforts) in simple language.

Use any of the following statements that are appropriate:

We do not know if being in this study will help you.

We expect that the study will help you by [describe how].

We may learn something that will help other children with [insert name of condition or topic under investigation] some day.

This study will help us learn more about [topic under investigation].

You do not have to join this study. It is up to you. You can say okay now and change your mind later. All you have to do is tell us you want to stop. No one will be mad at you if you don't want to be in the study or if you join the study and change your mind later and stop.

Before you say **yes or no** to being in this study, we will answer any questions you have. If you join the study, you can ask questions at any time. Just tell the researcher that you have a question.

If you have any questions about this study please feel free to contact [Insert Study Contact name and contact number]

(Please read note. Not to be incorporated in the final assent form: Assent forms are typically used with children who are 7 to 13 years of age. Therefore, the target language level is a 4th grade reading level. This means that some very young children will need to have the information in assent form read to them).



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ASSENT FOR PARTICIPATION IN THE STUDY

I/my parent or legal guardian has read the previous page(s) of the consent form and the investigator has explained the details of the study. I/my parent or legal guardian understands that I am free to ask additional questions.

I/my parent or guardian understands that participation in this study entitled [insert name of study] is voluntary and I/my parent or legal guardian may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I/my parent or legal guardian, acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I agree to participate in the study and have been given a copy of this form.

Signature of Participant Printed name of Participant	Date
Printed Name of Person who explained form	

• If the child is not able to read the Assent form, and verbal assent is obtained using the content in the patient information sheet of the assent form, the person obtaining assent should place at the bottom of the Patient information sheet for assent a statement with the following content.

I have discussed this clinical research study with <u>(insert name of child)</u> using language which is understandable and appropriate for the participant. I believe that I have fully informed him/her of the nature of the study and its possible risks and benefits. I believe the participant understood this explanation and assent to participate in this study