

Insert study title

Consent Form for parents/legal representative of the child participating in the clinical study

[Insert version number and date]

Please **initial** the boxes if you agree:

1. I confirm that I have received, read and understood the written information sheet dated version for the above study. I was also informed verbally about the study and all my questions regarding the trial were answered. I have been given enough time to decide whether or not to allow my child to participate.

2. I hereby voluntarily declare will that I am willing to allow my child to take part in this study. I understand that I can revoke mine and my child's consent to take part at any time and without giving reason, and without suffering any consequences regarding my child's medical care as a result.

3. I understand that others working on the study sponsor's behalf, regulatory agencies, and authorized representatives from will need to have access to my child's records in respect of the current study and further research, and I agree to this access.

4. I consent to the collection, processing, reporting and transfer of my child's health information within and outside my country of residence for healthcare and/or medical research purposes as described in the information sheet.

5. I consent to the collection, transfer, processing and storage of my child's blood and urine samples within and outside of my country of residence for healthcare and / or medical research purposes as described in the patient information sheet.

6. I agree that on completion of this study, any leftover blood samples can be stored and used by scientists worldwide for future research purposes, provided my child's identity is not disclosed. If consent is not granted, the samples will be destroyed upon completion of the clinical trial. – *[This is optional if you are planning to use / keep samples after the study had ended]*

7. I agree that my child's General Practitioner will be informed about my child's participation in the study. *[If you are informing the GP, you will need to draft and submit a template Letter to the GP for regulatory approval]*

8. I agree to my child taking part in the above study

Subject's (Child's) name (Print)

_____ Name of child's Parent/Guardian (in print)	_____ Signature of child's Parent/Guardian	_____ Date
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_____ Name of child's Parent/Guardian (in print)	_____ Signature of child's Parent/Guardian	_____ Date
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CERTIFICATION OF INFORMED CONSENT:

I certify that I have explained the nature and purpose of this screening to the above mentioned child's Parent(s) /Guardian(s) , and I have discussed the potential benefits and possible risks of study participation. Any questions the child's Parent(s)/Guardian(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ Printed Name of Person Obtaining Consent	_____ Role in Research Study
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_____ Signature of Person Obtaining Consent	_____ Date
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