South African Childhood Diabetes Mellitus Registry

PATIENT INFORMATION AND INFORMED CONSENT DOCUMENT

Dear Parent/Guardian,

Your child/ward has been diagnosed with diabetes and requires treatment. The Paediatric and Adolescent Endocrinology and Diabetes Society of South Africa (PAEDS-SA) has established a register of children (18 years old and less) who have diabetes. The reason for the register is to learn about how many children have diabetes and where in the country they live. This information is also important in helping to plan for care of these children.

We need you permission to enter your child/ward into this register. Should you agree, then all your child/ward's information shall be entered but your child/ward shall be identified in the future by a numerical code (i.e. a set of numbers). This is in order to ensure that you, your doctor and the person entering and checking information are the only people that would know the identity of your child. Your childs' full information is needed to make sure that he/she is not entered into the register on more than one occasion. Your child's identity would not be disclosed to anyone without your permission. In the future, you may get requests to have your child's name disclosed to other researchers. If this happens then you would need to give further consent for your child/wards identity to be disclosed. You are not compelled to provide this consent now or in the future.

If you do not give us permission, your child's information without name, address or contact details shall be entered into the register, which means that the data will be anonymous. There shall be no penalty on your child because you did not give permission for the entry into the register.

Ethics Committee
This Data Collection System has been approved by the Research Ethics Committee of the South African Medical Association.

Consent:
I understand that this information is to be used as part of the registry of children and adolescents with type 1 diabetes in South Africa. This information will not be divulged to anyone except for the purpose of determining the trends in incidence and epidemiology of type 1 diabetes in South Africa. When information is shared, there shall be no information that identifies your child. Any further research that emanates from this information would require my further consent.

_____	_____	_____
Name	*Signature*	*Relationship*

Assent (for children old enough to understand):
I understand that my name will be entered into a register of children who have diabetes. I know that my identity shall not be given to anyone else without my permission or the permission of my parents/guardian.

_____	_____
Name	*Signature*

Witness:

_____	_____
Name	*Signature*

Witness' signature confirms that he/she has witnessed the consent procedure and relevant signature and witnessed the fact that the patient was informed. Witness name, signature and date must be completed by the witness at the same time that this document is signed and dated by the patient and the Study Doctor. A competent witness is a person 16 years or older and of sound mind and who is not involved with the trial.