Newborn Screening Informed Consent

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FirstScreen

New born Screening (NBS) is an early screening program of selected genetic and metabolic diseases. The rapid detection allows for the implementation of early treatment.

The collection procedure: collection is done 48-72 hours after birth. Blood is collected by a heel prick to the baby. This causes minimal discomfort to the baby. 5 drops of blood are needed to be blotted on the card provided.

Test results will be made known to you within 7 days of testing.

Please note: Repeat tests may be requested in about 10% of cases. It does not mean that there is anything wrong with the baby – it may be that the sample was not collected properly and not enough blood was available for testing.

If something is found to be abnormal with the results, a repeat test and sometimes additional urine and blood tests will be required.

If these repeat test come back positive for a disorder, your paediatrician will contact you immediately. Each disorder is treatable in its own way even though they are not curable.

Research and long term sample storage

After the NBS testing is done, the residual samples are an invaluable source of research material that could be of great benefit to the society as a whole.

This unique time frame of blood collection soon after birth ensures that the new born is relatively free from environmental and medicinal effects. Due to the "pureness" of the sample, long term storage for future use should be considered. The following are possible uses of stored samples:

1. Residual samples are essential in the testing of new analytical methods and assuring the quality of the new born screening program. This is worldwide common practise in NBS programmes and any sample could potentially be used for this purpose.
2. The patient or legal guardian may request the sample at a later stage for additional testing if the sample is deemed the only and most appropriate sample for testings.
3. Should I consent, the sample may be used for research purposes which may or may not include genetic testing if such research has been approved by a recognised ethics committee. There are two possible research scenarios:
   - 3.1 Population surveillance including public health research projects: An approved independent third party separates all information that makes the sample traceable to the patient before handing it over to the investigator. This assures the privacy of the patient. This process is known as anonymisation and is standard practise.
   - 3.2 The investigator will require additional information and/or tests from the patient. In addition to ethics consent, the investigator has to contact the patient or legal guardian or both, to obtain informed consent.

The sample will be stored at the North-West University NBS laboratory. There will be no charge for long term storage. All research on NBS samples adheres to strict protocol which are available on request.

I understand that I have three options with regards to consent which I will express on the request form. Below are the three options available to me:

01
This sample may only be used for **newborn screening purposes** which include testing, program and quality assurance and test improvement practises. The sample must be **discarded within 3 years from collection**. This is the default selection if no selection is made.

02
This sample may be used for newborn screening purposes which include testing, program and quality assurance and test improvement practises. Long term storage of the sample is requested. . Please note that there are no fees related to long term storage of the sample. However, any future testing of the samples will be for the patients account.

03
This sample may be used for newborn screening purposes which include testing, program and quality assurance and test improvement practises. It may also be **used for research projects** that meet the requirements specified in this consent form and long term storage of the sample is requested. Please note that there are no fees related to long term storage of the sample.

Signature .....

Date .....

Block B, Gateway Creek, Ariane Ave.
International Business Gateway
Corner New Road and 6th Road
Midrand, 1685, Johannesburg, South Africa
PO Box 1664, Parklands 2121