

INFORMED CONSENT

Genomics and other omics technologies for enabling Medical Decisions

CSIR Institute of Genomics and Integrative Biology (CSIR-IGIB)

Sample ID		Date	
Referred by	Dr.	Place	

Patient's Name	
Name Parent/Guardian/LAR	
Age	
Sex	
Phone/Mobile Number	
Email (optional)	

I have been explained the details of the genetic test for _____
(fill in the requested test here) and my question(s) regarding the study have been answered to my satisfaction in a language understood by me.

1. I understand that DNA testing, which is done on a small sample of blood or other tissue, looks at one or more parts of the particular gene associated with above disease. Genes contain the information that guides proper functioning of the body. A change in genetic information can result in an abnormal gene that doesn't work properly.
2. I understand that the genetic test is investigational and not a diagnostic. I understand the limitations of the genetic test and have discussed with by referring clinician regarding the same.
3. I have the right to withdraw from the test at any time and to decline to answer any particular question at any point in time.
4. I understood that my participation in this study is confidential and that no material that could identify me will be used in the analysis and in any reports based on this study.
5. I consent to my blood (a maximum of 10 ml) being drawn for the purpose of genetic testing . I understand that on withdrawal from the analysis, my blood sample(s) will be destroyed. I also understand that if there is any problem with any of the blood tests or measurement taken, I will be informed and the report will be kept confidential.
6. I understand that most often DNA testing directly detects the most common disease-causing changes in a gene, the test result is highly accurate (~98%). In other cases, an indirect method called linkage analysis is used which may produce an (3-5%) uncertainty in predicting carrier status or diagnosis due to naturally occurring rearrangements in the DNA (recombination). Rare variations in individuals can also cause uncertainty in the results. In other words, the test is not 100% accurate. The linked markers may not be informative in some families and hence, this DNA test can not provide results for the family, or for some members of that family.
7. I understand that based on the results from initial tests, subsequent analysis may be performed on the sample for better understanding of the disease
8. If the DNA testing does not show a known genetic change, the probability that the person is a carrier or is affected is reduced. However, there is still a small chance to be a carrier or to be affected because the current testing cannot find all the possible changes within a gene.
9. I understand that the accuracy of DNA analysis is entirely dependent on clinical diagnosis made elsewhere, the samples collected and forwarded and CSIR-IGIB cannot be responsible for erroneous clinical diagnosis or sample related problems made at other centres.

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- 10. I understand that unknown genetic changes are different in different populations. Providing the laboratory with accurate information about family history and ethnic background will make the interpretation of the test results more accurate.
- 11. I understand that the results of this testing will be disclosed **ONLY** to the patient/relative specified by the patient/doctor named and to associated medical personnel.

Tick/cross in circle(s) below

- I hereby provide my consent for future research use of the genetic data.**
A part of this sample not used for diagnostic testing may be stored and used for medical research or education as long as any names and other identifying information have been removed.
- I hereby provide my consent for the genetic test.**

I authorise Dr. _____ to obtain the results of the genetic analysis on my behalf

	Date Place
Signature/Thumb Impression (Self/Parent/Guardian)	
	Date Place
Signature of witness	
Name Address of Witness Relationship	
	Date Place Reg No
Signature of referring clinician <i>(Please affix stamp below signature)</i>	