

RESEARCH CONSENT FORM

Title of the Project: Genomics and other Omics tools for Enabling Medical Decision (GOMED)

Institute address: CSIR-Institute of Genomics and Integrative Biology, Council of Scientific and Industrial Research, New Delhi, India.

Reference Code:

I,

Son/daughter/wife of.....aged.....

Residing at.....

.....

hereby consent to freely participate in the genetic study aimed at understanding the human genome. I have been informed about the implications of my personal genome data being made publicly available through public databases as well as scientific communications. I have been advised to discuss my participation in this study with my family members. I have been provided written information that may be circulated to them, if necessary. I have been further informed that personal and medical data collected during this study will be associated with my publicly available genome and may be used for scientific analysis. My participation in this study is entirely voluntary and I am free to withdraw from this study as and when I feel so inclined.

1. **I choose to disclose / not to disclose my identity** (select one option).
2. **I choose to be / not to be informed of the results of the analysis that may impact my health** (Applicable only to those who have chosen to disclose their identity - select one option).
3. **I choose to exclude the information attached on the “Exclusion Form” from analysis / public disclosure** (Applicable only to those who have chosen to disclose their identity).

(Signature/ Thumb impression of volunteer)

Date:

Certified that the above consent has been signed in my presence. The purpose for which the sample will be used has been explained to the above volunteer. The individual is free to withdraw from the study as and when he/she feels so inclined.

(Signature of the investigator)

Date:

Exclusion Form

I choose to exclude the following information from the questionnaire with respect to analysis or public disclosure (please indicate the relevant question numbers from the attached questionnaire)

1. Analysis:

2. Public disclosure:

Filling Instructions

Hand print individual characters in Capital letter in the center of the space provided. Take care that the characters do not touch the boundary.

Correctly Filled

R	A	V	I
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0	0	6	7	1	2
---	---	---	---	---	---

Wrongly Filled

R	A	V	I
---	---	---	---

6	7	1	2		
---	---	---	---	--	--

Fill complete oval with pencil or pen.

Correctly Filled

	1	2	3	4
1	○	○	●	○
2	○	●	○	○
3	●	○	○	○
4	○	○	○	●

Wrongly Filled

	1	2	3	4
1	○	○	○	○
2	○	○	●	○
3	○	○	○	○
4	○	○	○	○

- **Please Ensure that there are no stray marks on form.**
- **Please don't write anything near the Registration Marks, i.e. , the dotted lines at the two sides of the form.**
- **Fill in the form as neatly as possible.**
- **Do not fold or bend the pages of the form.**
- **All alphabets must be written in UPPER CASE.**

8. Gender Male <input type="radio"/> Female <input type="radio"/>	9. Weight (Kg) <input type="text"/> <input type="text"/> <input type="text"/>	10. Height (cm) <input type="text"/> <input type="text"/> <input type="text"/>	11. Age <input type="text"/> <input type="text"/> <input type="text"/>	12. Ear Lobes Attached <input type="radio"/> Free <input type="radio"/>
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13. Type of Diet Vegetarian <input type="radio"/> Non-veg <input type="radio"/>	14. Colour of Hair Black <input type="radio"/> Brown <input type="radio"/> Gray <input type="radio"/>	If gray, at what age hair started graying? <input type="text"/> <input type="text"/>	15. Eye Colour Black <input type="radio"/> Brown <input type="radio"/> Gray <input type="radio"/>
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16. Setting, where you live Rural <input type="radio"/> Urban <input type="radio"/> Slums <input type="radio"/> Not Sure <input type="radio"/>	17. Setting where you grew up Rural <input type="radio"/> Urban <input type="radio"/> Slums <input type="radio"/> Not Sure <input type="radio"/>	18. Do you drink alcohol? Occasionally <input type="radio"/> Regular <input type="radio"/> Donot Drink <input type="radio"/>
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19. Do you or did you in the past smoke/chew tobacco? Yes <input type="radio"/> No <input type="radio"/>	If yes, Age of starting <input type="text"/> <input type="text"/>	Age of quitting <input type="text"/> <input type="text"/>	Average no. Of cigarettes per day <input type="text"/> <input type="text"/>
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20. State in which you live		
<input type="radio"/> Assam <input type="radio"/> Andaman & Nicobar <input type="radio"/> Andhra Pradesh <input type="radio"/> Arunachal Pradesh <input type="radio"/> Bihar <input type="radio"/> Chhattisgarh <input type="radio"/> Delhi <input type="radio"/> Gujarat <input type="radio"/> Goa <input type="radio"/> Haryana	<input type="radio"/> Himachal Pradesh <input type="radio"/> Jammu & Kashmir <input type="radio"/> Jharkhand <input type="radio"/> Kerala <input type="radio"/> Karnataka <input type="radio"/> Maharashtra <input type="radio"/> Madhya Pradesh <input type="radio"/> Meghalaya <input type="radio"/> Manipur <input type="radio"/> Mizoram	<input type="radio"/> Nagaland <input type="radio"/> Orissa <input type="radio"/> Punjab <input type="radio"/> Rajasthan <input type="radio"/> Sikkim <input type="radio"/> Tripura <input type="radio"/> Tamil Nadu <input type="radio"/> Uttar Pradesh <input type="radio"/> Uttaranchal <input type="radio"/> West Bengal

21. State where your family comes from		
<input type="radio"/> Assam <input type="radio"/> Andaman & Nicobar <input type="radio"/> Andhra Pradesh <input type="radio"/> Arunachal Pradesh <input type="radio"/> Bihar <input type="radio"/> Chhattisgarh <input type="radio"/> Delhi <input type="radio"/> Gujarat <input type="radio"/> Goa <input type="radio"/> Haryana	<input type="radio"/> Himachal Pradesh <input type="radio"/> Jammu & Kashmir <input type="radio"/> Jharkhand <input type="radio"/> Kerala <input type="radio"/> Karnataka <input type="radio"/> Maharashtra <input type="radio"/> Madhya Pradesh <input type="radio"/> Meghalaya <input type="radio"/> Manipur <input type="radio"/> Mizoram	<input type="radio"/> Nagaland <input type="radio"/> Orissa <input type="radio"/> Punjab <input type="radio"/> Rajasthan <input type="radio"/> Sikkim <input type="radio"/> Tripura <input type="radio"/> Tamil Nadu <input type="radio"/> Uttar Pradesh <input type="radio"/> Uttaranchal <input type="radio"/> West Bengal

22. Language you speak at home. <input type="radio"/> Assamese <input type="radio"/> Bengali <input type="radio"/> Gujarati <input type="radio"/> Hindi <input type="radio"/> Kashmiri <input type="radio"/> Konkani <input type="radio"/> Marathi <input type="radio"/> Malayalam <input type="radio"/> Oriya <input type="radio"/> Punjabi <input type="radio"/> Sindhi <input type="radio"/> Telugu <input type="radio"/> Tamil <input type="radio"/> Urdu <input type="radio"/> Others	23. Your Mother Tongue <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
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24. Educational status Illiterate <input type="radio"/> High School <input type="radio"/> Literate <input type="radio"/> Graduation <input type="radio"/> Professional course <input type="radio"/>

34. Do you have a family history of any of the following?

(A) (Darken at the appropriate place)

	Hypertension	Heart Disease	Neurological Disorder	Respiratory Disorder	Epilepsy	DMT1	DMT2	Psychiatric Problems	Tuberculosis	Liver Disease	Kidney Disease	Infectious Disease	Bones related	Bronchial Asthma	Eye Disease	Others*
You	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Father	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Mother	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sister	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Brother	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wife	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Son	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Daughter	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Maternal Grandparents	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Paternal Grandparents	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Maternal Uncles / Aunts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Paternal Uncles / Aunts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Maternal First Cousins	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Paternal First Cousins	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

* IF the column OTHERS(Malaria, Kala-Azar, Cholera, Filariasis, Tremor, Dementia & Cancer) is marked then Please specify :

Name of Disease	Age when Affected
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>

Note : The information given in this form will be CONFIDENTIAL. *Please do NOT mark below this line.

Date of Collection.

D	D	M	M	Y	E	A	R
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Code No.

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Sample collection by :

<input type="text"/>

Blood collected for

DNA Serum

RNA Plasma

Any other observations : Yes No

If yes specify -

<input type="text"/>

INFORMATION FOR THE VOLUNTEERS

1. Purpose of study

The principle scientific goal of this study is to explore avenues to study genetic variability between individuals and to correlate the variability to the phenotypes. The data generated (i.e., human DNA sequence, medical information and physical traits) may be used for scientific and clinical research such as development of computational tools and interfaces for scientist, clinicians and individuals in addition to developing general public awareness on potential benefits and risks of having whole genome level information available to the public.

2. Enrolment procedures

A. Collection of baseline trait data:

You are required to provide baseline trait data about yourself, including: data of birth, medications, allergies, vaccines, personal and family medical history, race/ethnicity/ancestry and vital signs (e.g. height, weight, blood pressure etc) in the attached questionnaire.

B. Monozygotic twin:

If you have any identical twin(s), such sibling(s) will need to provide consent for your participation in this research.

3. Tissue (Blood/Saliva) collection

- A. Blood sample will be collected from the upper arm by venipuncture. Twenty-five ml of blood sample will drawn by an authorized medical doctor or an authorized technician under the supervision of an authorized medical doctor, in the presence of the principal investigator. Fresh blood sample will be collected in designated containers (which will be provided by CSIR/IGIB). Serum would be isolated from the collected blood sample for biochemical analysis.

- B. Saliva sample will be collected by voluntary spitting. Two to four ml of saliva will be collected in designated containers (which will be provided by CSIR/IGIB).

4. Genomics analysis

Analysis of DNA, RNA including but not limited to whole genome sequencing and other biochemical analysis will be performed on tissue samples collected from the individual. The nature and extent of analysis will be determined by CSIR/IGIB at its sole discretion.

5. Public release of research data

Upon completion of genomics analysis, your DNA sequence data will be made available through the CSIR/IGIB website and other scientific communications (including but not limited to publication in scientific journals). This information is for research purpose only and may not be used by you for any medical or clinical purpose unless the relevant research data (DNA sequence) is first confirmed and discussed in consultation with a health care professional. By signing this consent form, you hereby agree and authorize CSIR/IGIB to proceed with the full public release of your DNA/RNA sequence data and other information (data of birth, medications, allergies, vaccines, personal and family medical history, race/ ethnicity /ancestry and vital signs) voluntarily made available by you, without any legal restriction and without your further consent through CSIR/IGIB website and database or other formats of standard scientific communications (including but limited to publication in scientific journals), and you hereby acknowledge the risk associated with the public release of such data and information.

Your identity will be held confidential if you choose, even though the identity-stripped information would be publicly available.

6. Risks and discomforts

- A. Venipuncture: This procedure is associated with minimal discomfort and is free of significant adverse effects.

B. Data analysis: You are strongly advised to discuss this study and the potential risks, as outlined below with your Parents, Siblings and Descendants, hereinafter 'family members', as well as your health care provider(s). You are also advised to directly discuss any additional concerns with the Principal Investigator.

The following non-comprehensive list of hypothetical scenarios that could pose risk for you and your family members:

(i) The data provided by you (such as traits and vital signs or DNA sequence data) may be used to identify you, resulting in higher than normal levels of contacts from the press and other members of the public. This could result in a loss of privacy and personal time.

(ii) Anyone with sufficient knowledge and resources could take your DNA sequence data and or your personal trait information and utilize the data, with or without modification, to (1) infer paternity or other features of your genealogy, (2) reveal the possibility of a disease or risk for a disease. Such information could lead to social and financial consequences including but not limited to employment and insurance.

(iii) Your family members could also be subject to discrimination for employment, insurance or financial service on the basis of the public disclosure of your genetic and trait information.

(iv) If you have previously made or plan to make available genetic information in a confidential setting, the data provided by you as part of this study may reveal your identity.

(v) Any conclusions derived from the publicly available information may be speculative with respect to you and even less predictive with respect to your family members. The complete set of risks posed to you and your family members due to the public release of the DNA sequence and trait data is not known at this time. We encourage you to discuss this aspect with your family members.

7. Benefits

- (i). At present there are no proven benefits to you for your participation in this study.
- (ii). This study may benefit the medical and research community in particular, and humanity in general and may help in establishing genetic causes and predisposition for common diseases.
- (iii). You may experience satisfaction from participating in research that may benefit medical science.

8. Intellectual property rights and benefit sharing

You will not be financially compensated for your participation in this study. Neither you nor your heirs shall claim from CSIR/IGIB any financial benefits or rights, for any information, data, discoveries, whether or not of a commercial nature, made using the information generated in this study. However, as per International (HUGO, UNESCO) and National Guidelines (National Bioethical Committee, Ethical Guidelines for Biomedical Research on Human Participants) it is necessary for national/international entities deriving economic benefit out of the knowledge resulting by the use of the human genetic material, to dedicate a percentage (e.g. 1%-3%) of their annual profit for the benefit of the community/ public health.

9. Confidentiality

The results of this study may be published in a medical book, journal, website or webpage or used for teaching purpose. Your name and other identifiers will be disclosed only if you have consented to disclosure of your identity. You may not be notified by CSIR/IGIB prior to such use.

10. Withdrawal of participation

Participation in this study is voluntary. You may withdraw your participation and/or your data from this study at any time, as described in the consent form. However once the DNA sequence and associated information is in public domain, it is likely to get disseminated widely and rapidly. Therefore, it may not be possible to retract the data in response to a withdrawal request.