

## **Iranome project: a genomic database for Iranian populations**

### **Data Access Agreement**

Our study, Iranian Population Genomics (Iranome), supported by the Deputy of Research, University of Social Welfare and Rehabilitation Sciences, Deputy of Research of Ministry of Health and Medical Education, Iran Vice-President Office for Science and Technology, has sequenced exome of 800 Iranian Individuals from 8 ethnic groups using the Illumina sequencing platform.

The Iranome project aims to present variations in the exome of healthy Iranian populations settled across the country. Iranome project can be applied to link genetic variants and phenotypes and determine their roles in disease and well-being. We are willing to consider applications from the scientific community to access pseudonymized exome sequence data of the Iranome Project in genotype data (VCF files) and general allele frequency data (txt file) format.

Researchers are required to describe their planned project and the intended use of the Iranome data and sign the Data Access Agreement. The request will be evaluated by the Data Access Committee (DAC) and, if approved, the data will be provided to the researcher.

A qualified researcher refers to a principal investigator employed or legitimately affiliated with an academic, non-profit or government institution. Access is conditional on a signed agreement by the researcher(s) and the responsible employing institution to abide by the term and conditions related to publication, data ownership, data disposal, confidentiality and commercialization referred herein.

### **Available data**

Whole exome sequence data from genomic DNA of 800 Iranian healthy people from 8 Iranian ethnic groups (Iranian Arabs, Azeris, Baluchis, Kurds, Lurs, Persians, Persian Gulf Islanders, and Turkmen) are available. Please refer to our paper for more details (Hum Mutat. 2019 Nov;40(11):1968-1984. doi: 10.1002/humu.23880. Epub 2019 Aug 17). Available data will be accessible by arrangement with the DAC, that will be eventually subject to all relevant ethical considerations.

### **Data Access Committee**

The application from (**Annex 3**) an applicant must send to the Iranome Data Access Committee (DAC).

## **Procedures on Data Access**

Applications must be submitted to Iranome DAC, using the standard Application Form according to **Annex 3**. Received applications will be treated as confidential and will only be passed on to those responsible for evaluating the application. This data will be exclusively used for the evaluation unless mentioned by the applicant. The research topic of the applications will be brought out on the Project's website following it has been granted.

Applicants are allowed to only use the Project Data for the approved project and purpose described in the application. If the applicants want to use the data for another purpose or project, he/she should send a new application and obtain relevant approval.

Applicants should include all collaborators' names, and each institution must give its sign on a separate Data Access Agreement. If an applicant wants to share the data with additional collaborators who have not been previously approved, these additional collaborators must send a separate application form (**Annex 3**) to access the Project Data. Applications must be specific and clearly defined (Specific, Measurable, Attainable, Resourced and Timely (SMART)).

## **Request data process**

Variant calls data can be requested as follows:

1. Fill in the form below and email it to the project email to [info@iranome.com](mailto:info@iranome.com). The DAC will evaluate your data request.
2. If positive, you will receive a data access agreement to be signed.
3. You will be granted access to the data using a suitable method.

It is expected to add suitable acknowledgement and citation of the Iranome Project in the related publications.

## **Criteria for the evaluation**

The Iranome DAC will assess each application if:

1. It has been submitted by a qualified researcher(s), who is employed by or affiliated with a recognized research institution through providing institutional responsibility for the research guidance;
2. The research proposal has been peer-reviewed, and obtained the relevant ethical approvals and commitments for the proposed use of the Project Data (should be in attachment);
3. The purpose of the use of the Project Data is in line with the aims of the Iranome Project;
4. It meets the ethical considerations in the consent form of Iranome (**Annex3**);
5. The use of the Project Data will not be able to identify the personal information of sample donors;
6. Any potential adverse impact of the proposed research has explicitly been declared;
7. It declares the nature of the funding of the application and the applicant.

## **Decision on access**

After receiving all pertinent information within a reasonable time, the DAC will decide on an application. If the DAC approves an application, additional agreements may be required regarding authorships and the Publication Policy (**Annex 2**). Rejections of applications will provide applicants with a reason.

## **How to access Data**

The pseudonymized Project Data will be available through secure download from sftp server at the University of Social Welfare and Rehabilitation Sciences (USWR). Each user will be given a separate login for downloading, which expires after 15 days.

For access to Project Data, DAC Iranome should receive the signed and dated Data Access Agreement (**Annex1**) by the applicant(s) and the responsible employing Institution(s)/ university (ies).

## Data Access Agreement (Annex1)

This agreement provides the terms and conditions on which access will be granted to the Project Data. By signing this agreement, you will agree to comply with the terms and conditions of access defined in this agreement.

### Definitions:

1. "Committee" refers to the Data Access Committee (DAC).
2. Within the agreement "User Institution: organization at which the User is employed or affiliated" and "User: a researcher who has successfully applied for access to Project Data" are referred to as "You" and "Your".
3. "Project" refers to the Exome of the Iranome project.
4. "Project Data" refers to the Iranian exome data generated by the Project ("Iranome data").
5. "Data Subject" refers to the individuals whose blood have been used to generate Project Data.
6. "Publications" refers to articles published in print journals, electronic journals, reviews, books, posters and other written/verbal presentations, without any limitation.

### Terms and conditions

#### In signing this agreement:

1. You agree to use Iranome data exclusively for scientific purposes and not to use Iranome data for any commercial purpose.
2. You acknowledge that Iranome data you receive is pseudonymized and identification of individuals is prohibited and you are not allowed to contact individual Data Subjects.
3. You agree to store Iranome data on a computer with adequate security controls that prevent unauthorized access to Iranome data and then you agree to keep Project data confidentially.
4. You agree to retain control over Iranome data and NOT TO DISTRIBUTE (individual-level or aggregated) Iranome data provided under this agreement, in any form, to any entity or individual and not to transfer, share or disclose Iranome data, in whole or in part, to or with anybody else. In the case you need to share Project Data only to those of Your employees who strictly need access to it in line with the purpose of your approved study, they should comply with the data confidentiality. Thus, upon request by the DAC, you agree to provide the DAC with the names of all Authorized Recipients who have obtained access to Project Data.
5. You agree to provide all required ethical approvals and commitments, as well as approval from the relevant medical ethical review board, for the use of the Project Data in combination with Your data.
6. You agree not to try to link Project Data to other archive data available for the data sets provided to You under this agreement, without the required consents and approvals.
7. You agree to use Iranome data for the purpose and project you described in the box below. Use of the data for a new purpose or project or by another researcher will require a new

application and approval. Substantive modification of the original application requires the submission of an amendment to the original application.

8. You agree that Project Data will be reissued with appropriate modifications time to time. If the reissue is subject to ethical investigation, You will demolish earlier versions of the Project Data.

9. You agree to destroy the Iranome data after the resulting paper has been published. You accept to comply with the terms outlined in the DAC 'Publication Policy' as indicated in **Annex 2**.

10. You agree to acknowledge and cite our published paper from which the Iranome data derives, in any work based in whole or in part on Iranome data.

11. You understand and acknowledge that Iranome data are protected by copyright, database right and other intellectual property and proprietary rights, and that duplication, sale, licensing or any other form of disposing or distribution or making available, of all or part of the Iranome data on any media is not permitted.

12. You agree that the original Project Data generators and the funders of the Project Data carry no legal responsibility for the accuracy, and comprehensiveness of the Project Data.

13. You agree that it may be obligatory for the DAC to modify or change the terms of this agreement in a way to address new concerns. In this case, the DAC will contact You to inform You of any changes and You accept to enter into a new version of agreement to be able to use Project Data.

14. You agree that You will submit a report to the DAC, upon its request and the DAC accepts to treat the report as confidential information.

15. You agree that You are responsible for ensuring compliance with applicable laws in case the Project Data is being protected by and subject to national and international laws.

16. This agreement shall be interpreted and governed by the laws of the Islamic Republic of Iran and shall be subject to the exclusive jurisdiction of the Ethical committee at Ministry of Health and Medical Education.

Briefly describe your planned project and the planned use of the Iranome data and also attach your complete proposal.

Signed by:

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Name of Applicant:  
(Principal investigator)

Legal representative of Applicant's Institution:

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Affiliation of Applicant with Institution:

Name of Applicant's Institution:

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Place: .....

Place: .....

Date: .....

Date: .....

Seal of applicant institution:

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## Publication Policy (Annex 2)

Authors who use Iranome Data must:

1. Acknowledge the Project using the following wording:  
"This study used the data generated by the Iranome data project (<http://www.iranome.com/>)."
2. Cite the relevant primary Iranome publication:  
Zohreh Fattahi, Maryam Beheshtian, Marzieh Mohseni, Hossein Poustchi, Erin Sellars, Sayyed Hossein Nezhadi, Amir Amini, Sanaz Arzhang, Khadijeh Jalalvand, Peyman Jamali, Zahra Mohammadi, Behzad Davarnia, Pooneh Nikuei, Morteza Oladnabi, Akbar Mohammadzadeh, Elham Zohrehvand, Azim Nejatizadeh, Mohammad Shekari, Maryam Bagherzadeh, Ehsan Shamsi-Gooshki, Stefan Börno, Bernd Timmermann, Aliakbar Haghdoost, Reza Najafipour, Hamid Reza Khorram Khorshid, Kimia Kahrizi, Reza Malekzadeh, Mohammad R. Akbari, Hossein Najmabadi. Iranome: A catalog of genomic variations in the Iranian population. Hum Mutat. 2019 Nov;40(11):1968-1984. doi: 10.1002/humu.23880. Epub 2019 Aug 17. PMID: 31343797.

This agreement provides the terms and conditions on which access will be granted to the Project Data. By signing this agreement, you will agree to comply with the terms and conditions of access defined in this agreement.

### **Application Form for Access to Iranome Data (Annex 3)**

1. Name and position of the Applicant, including employment or affiliation with any organization \*

Please ensure that a full postal and email address is included for each applicant.

2. Title of the study (less than 30 words) \*

3. Research Question

Please describe the study in no more than 750 words.

Include:

a. Outline of the study design;

b. An indication of the methodologies to be used;

c. Proposed use of the Project Data;

d. Preceding peer-reviews of the study (if any present);

e. Specific details of what you plan to do with the Project Data;

f. It is assumed that for most of the studies access to the general allele frequency data in txt file format will be enough, however, if you need access to individual level genotype data in VCF file format, please justify it here to be reviewed by the DAC.

g. Timeline;

h. Key references.

#### 4. Consent and Approvals

If your proposed use of Project Data involves use of your own data, please confirm that you have obtained all approvals required by the rules and regulations of your jurisdiction, including your institution's institutional rules, and the consent of your data subjects, for your use of your own data in the study, by ticking the following box:

- Yes, I have approval to carry out the proposed research, obtained from (please specify IRB [Institutional Review Board] below):
- No

Please specify official IRB.

#### 5. The Project Data applied for

#### 6. Resources, Feasibility & Expertise

Please confirm that you have secured funding for your proposed use of the Project Data and that you will carry out your research within a reasonable period of time after the granting of this application: by ticking the following box:

- Yes, I have funding to carry out the proposed research
- No

Please describe your experience and expertise, and that of your collaborators, and how this will be applied to the proposed study (in 250 words).

Please provide a list of recent publications (max. 10).

#### 7. Access Conditions

Please declare that you have read and agree to abide by the terms and conditions outlined in the Iranome data access agreement (which you will need to sign on approval of this project), by ticking the following box:

- Yes, I have read and agree to Iranome data access agreement
- No