



MPIMG Data Access Agreement

This agreement governs the terms on which access will be granted to the controlled access datasets generated by the Max Planck Institute for Molecular Genetics (MPIMG Data as defined below).

By signing this agreement, you are agreeing to be bound by the terms and conditions of access set out in this agreement.

For the sake of clarity, the terms of access set out in this agreement apply both to the User and to the User's Institution (as defined below).

Definitions:

MPIMG: means the Max Planck Institute for Molecular Genetics

MPIMG Data: means Controlled Access Data produced by the Max Planck Institute for Molecular Genetics

User: An applicant (principal investigator), having signed this Data Access Agreement, whose User Institution has co-signed this Data Access Agreement, both of them having received acknowledgment of its acceptance.

User Institution(s): Institution(s) or organization at which the User is employed, affiliated or enrolled. A representative of it has co-signed this Data Access Agreement with the User and received acknowledgment of its acceptance.

External Collaborator: A collaborator of the User, working for an institution other than the User Institution(s).

Data Subject: means a person, who has been provided informed consent for the use of biologic material for research.

Project Data: Refers to the data generated in the project to which the User has requested access to.

Publications: Means, without limitation, articles published in print journals, electronic journals, reviews, books, posters and other written and verbal presentations of research, including all digital work.

Terms and Conditions:

In signing this agreement:

1. The User and the User Institution(s) agree to only use the MPIMG Data for the objectives and analyses requested in the Appendix - Data Access Application Form. Use of the MPIMG Data for a new purpose or project will require a new application and approval.



2. The User and the User Institution(s) agree that the MPIMG Data are made available for one (1) year. The User and the User Institution(s) agree to destroy any MPIMG Data held on all devices and storage locations once it is no longer used for the project described in the Appendix - Data Access Application Form or after the end of the granted time-period of one year unless obligated to retain the MPIMG Data for archival purposes in conformity with national audits or legal requirements. To extend the use of MPIMG Data after the one-year period, Users and User Institution(s) must re-apply to access the data.
3. The User and the User Institution(s) agree to preserve, at all times, the confidentiality of the information and MPIMG Data. In particular, they undertake not to use, or attempt to use the MPIMG Data to compromise or otherwise infringe the confidentiality of information on research participants. The User and the User Institution(s) will not, and will ensure that its employees will not, identify or contact or attempt to identify or contact, or aid any person or entity in identifying or contacting, any donor, donor family or source of any clinical information. The User and the User Institution(s) agree to protect the confidentiality of research participants in any research papers or publications that they prepare by taking all reasonable care to limit the possibility of identification.
4. The User and the User Institution(s) agree not to link or combine the MPIMG Data provided under this agreement to other information or archived data available in a way that could re-identify the research participants, even if access to the data has been formally granted to the User and the User Institution(s).
5. User and User Institution (s) agree not to transfer, share or disclose the MPIMG Data, in whole or in part, to or with anybody else, whether or not he or she is affiliated with the User Institution.
6. The User and the User Institution(s) agree not to transfer, share or disclose the MPIMG Data, in whole or part, or any material derived from the MPIMG Data, to anyone not listed in section A "Name of applicant (principal investigator), including affiliations and contact details" of the Appendix - Data Access Application Form, except as necessary for data safety monitoring, national audits or program management. Should the User or the User Institution(s) wish to share the MPIMG Data with an external collaborator, the external collaborator must complete a separate application for access to the MPIMG Data.
7. The User and the User Institution(s) accept that the original data producers, or copyright holders, or the funders of the MPIMG Data or any part of the MPIMG Data supplied:
 - a) bear no legal responsibility for accuracy or comprehensiveness of the MPIMG Data
 - b) accept no liability for indirect, consequential, or incidental, damages or losses arising from use of the MPIMG Data, or from the unavailability of, interruption in MPIMG Data access for whatever reason
 - c) bear no responsibility for the further analysis or interpretation of these MPIMG Data
8. The User and the User Institution(s) agree to recognize the contribution of the MPIMG and to include a proper acknowledgement in any work based in whole or part on the MPIMG Data by citing/referencing the respective original publication.
9. The User and the User Institution(s) accept that MPIMG Data may be reissued from time to time, with suitable versioning. If the reissue is at the request of a research



participant and/or other ethical scrutiny, the User and the User Institution(s) will destroy earlier versions of the data.

10. The User and the User Institution(s) agree not to make intellectual property claims on the MPIMG Data and not to use intellectual property protection in ways that would prevent or block access to, or use of, any element of the MPIMG Data, or conclusions drawn directly from the MPIMG Data.
11. The User and the User Institution(s) can elect to perform further research that would add intellectual and resource capital to the MPIMG Data and decide to obtain intellectual property rights on these downstream discoveries. In this case, the User and the User Institution(s) agree to implement licensing policies that will not obstruct further research.
12. User and User Institution(s) agree to ensure that any authorized personnel within your institution, who have access to MPIMG Data, comply with all obligations of the present agreement. User and User Institution(s) agree to disclose MPIMG Data only to the authorized users, who are bound by a duty of confidentiality which is at least as strict as provided for in this agreement. User and User Institution agree to be responsible for all breaches of confidentiality and of the terms of this agreement by the authorized users.
13. The User and the User Institution(s) must notify the MPIMG DAC prior to any significant change to the research protocol of the User. This update can be sent by email to datarequest@molgen.mpg.de. The User and the User Institution(s) agree that they have the secure computation infrastructure and expertise to analyze the MPIMG Data.
14. User and User Institution(s) agree to store project data on a computer system with adequate security controls that prevent unauthorized access to or loss of project data and to maintain appropriate control over the project data. User and User Institution(s) represent and warrant to have in place, and agree that will keep having in place, state of the art technical and organizational security measures preventing unauthorized access and loss of project data or other forms of unlawful processing of project data, including without limitation, physical security measures, access controls, security and privacy technologies, security checks in relation to personnel, security incident response management and audit arrangements.
15. The User and the User Institution(s) will notify the MPIMG DAC as soon as they become aware of a breach of the terms or conditions of this agreement.
16. The User and the User Institution(s) accept that this agreement may terminate upon any breach of this agreement from the User, the User Institution(s). In this case, the User and the User Institution(s) will be required to destroy/discard any MPIMG Data held, including copies and backup copies. This clause does not prevent the User or the User Institution(s) from retaining the MPIMG Data for archival purposes in conformity with national audits or legal requirements.
17. The User and the User Institution(s) accept that it may be necessary to alter the terms of this agreement from time to time. In this event, the MPIMG DAC will contact the User and the User Institution(s) to inform them of any changes.
18. User and User Institution(s) accept that project data may be protected by and subject to national and international laws. User and User Institution(s) are responsible for ensuring compliance with any such applicable law with respect to the use and processing of the project data. The Data Access Committee reserves the right to



request and inspect User Institution's data security and management documentation to verify that they are complying with the terms of this Data Access Agreement.

For and behalf of the User

Signature of Applicant:

Name:

Signed:

Date:

Signature of Information Technology or Data Protection Officer:

Name:

Signed:

Date:

Authorized institutional representative:

Name:

Signed:

Date:

Appendix - Data Access Application Form for MPIMG Controlled Access Data

This application form is for requests for access to controlled data of the MPIMG. To receive access the entire following application form must be completed. Applications for access to data can be submitted at any time. The MPIMG Data Access Committee (MPIMG DAC) will review applications on a rolling basis and aim to provide a decision within 30 days of receipt. The application will be checked for conformity by the MPIMG DAC. If your application is refused it remains possible to re-apply in the future.



A. Name of applicant (principal investigator), including affiliations and contact details*

Enter the primary e-mail correspondence address you would like to use

E-mail address:

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

Name:

Title:

Position:

Affiliation:

Institutional e-mail address:

Website of the institution:

Mailing address:

*Collaborators at the same or other institutions will have to submit a full separate agreement for access to MPIMG Data.

B. Name of the authorized institutional representative, including affiliations and contact details

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

Name:

Title:

Position:

Affiliation:

Institutional e-mail address:

Mailing address:

C. Title of the Project

If available, please provide also the address of the project website.



D. Scientific abstract

Please provide a clear description of the project and its specific aims in no more than 300 words. This should include specific details of what you plan to do with the data and key references (not counted in word limit).

E. Feasibility

Please describe fully your experience and expertise, and how this will be applied to the proposed study. Include a list of relevant publications of which you were an author or co-author. The committee needs assurance of competence in handling datasets of this size and nature.

F. Datasets Requested



G. Research ethics

Do you foresee any ethical issues arising as a result of your research? If so, how do you plan to address such issues?

My country/region does not require my project to undergo ethics review.

My country requires my project to undergo ethics review. The project has been approved by the responsible institutional review board or research ethics committee, and the approval letter is attached.

The MPIMG DAC is not responsible for the ethics approval and monitoring of the applicant's research projects and bears no responsibility for the applicant's failure to comply with local/national ethical requirements.

I will use the data commercially

Yes

No

H. IT Security Assessment

In order to avoid inadvertent disclosure of the private data of patients to unauthorized individuals, the MPIMG DAC asks you to observe basic information security practices. If you make local copies of MPIMG Data, you must minimize the risk that this information might be disclosed to individuals who have not agreed to the MPIMG's patient privacy protection conditions.

Acceptable practices include:

- Physical security: MPIMG Data will be maintained on physically secure computer systems, such as in a locked office. If the data is stored on a laptop computer, it must be encrypted to avoid its disclosure in case of loss or theft.
- Access security: Only individuals who are listed on the data access request should have access to MPIMG Data. If copies of the data are stored locally on a shared computer or a file server, then it should be password or encryption protected so that only the individuals named in the request have access to it. If the computer that holds MPIMG Data is backed up, the backup media should either be encrypted or stored in a physical secure location.
- Network security: If MPIMG Data is stored on a network-accessible computer, there should be controls in place to prevent access by computer "hackers", or contamination by viruses and spyware. Network security is usually implemented by your institution's IT department and will consist of some combination of network firewalls, network intrusion monitoring, and virus scanning software.



- End of project: After finishing the project for which you are requesting access, you must destroy all local copies, including backups. However, only if necessary, you may keep the MPIMG Data solely for archival purpose in conformity with national audits or legal requirements.
- Training: Everyone who will use controlled MPIMG Data should be trained in the responsible use of patient confidentiality information, familiarized with the terms and conditions of the Data Access Agreement and briefed on the security plans you describe here.

Access to MPIMG Data is a procedure that entails legal and ethical obligations. We require that you and your institutions have a modern, up to date, data protection and information technology (IT) policy in place that must include the following items:

- Logging and auditing of access to data and to computer network
- Password protection to computer network
- Virus and malware protection to computers on computer networks
- Auditable data destruction procedure, when necessary
- Secure data backup procedure, when necessary
- Strong encryption on any portable device which may store or provide access to MPIMG Data

You must agree to the following procedures in order to have access to the MPIMG Data:

1. I will keep all computers on which MPIMG Data reside, or which provide access to such data, up to date with respect to software patches and antivirus file definitions (if applicable).
☐ Yes
2. I will protect MPIMG Data against disclosure to unauthorized individuals.
☐ Yes
3. I will monitor and control which individuals have access to MPIMG Data.
☐ Yes
4. I will destroy all copies of MPIMG Data in accordance with the terms and conditions of the MPIMG Data Access Agreement.
☐ Yes
5. I will familiarize all individuals who have access to MPIMG Datasets with the restrictions on its use.
☐ Yes
6. I agree to swiftly provide a copy of both my institutional and project related IT policy documents upon request from a MPIMG DAC representative.
☐ Yes

I have read, completed and returned the MPIMG Data Access Agreement and its Appendix- Data Access Application Form.

The completed agreement and application must be sent to datarequest@molgen.mpg.de