

# FaceBase Data Use Certification Agreement

*Agreement pertaining to FaceBase datasets containing data from human subjects*

## Introduction and Statement of Policy

FaceBase is a central repository for data generated by the FaceBase Consortium as well as data offered for inclusion by other investigators working on similar projects. Both the FaceBase database and the consortium are funded by the National Institute of Dental and Craniofacial Research (NIDCR) of the National Institutes of Health (NIH). Implicit in the establishment of the FaceBase data repository is the idea that scientific progress in understanding craniofacial development and disorders of that process will be greatly enhanced if the data produced by the Consortium's studies are readily available to investigators in the wider research community.

Dataset access will be provided to research investigators who, along with their institutions, have certified their agreement with the expectations and terms of access detailed below. It is the intent of the NIH, the NIDCR, and the FaceBase Consortium that Approved Users of FaceBase-provided datasets recognize any restrictions on data use delineated within the original informed consent agreements of contributing studies, as identified by the submitting institutions and stated on database websites and under "Research Use" below.

Definitions of terminology used in this document are found in the Appendix.

The parties to this agreement include: the Principal Investigator (PI) requesting access to the FaceBase dataset ("the Approved User"), his/her home institution as represented by its Authorized Representative ("the Requester"), the FaceBase Consortium as represented by its Data Access Committee (the FaceBase DAC), and the NIDCR/NIH. The effective date of this agreement shall be the Project Approval Date, as specified on the Data Access Committee approval notification.

## Terms of Access

### 1. Research Use

The Requester agrees that, if access is approved, the following personnel shall become Approved Users of the requested dataset(s):

- the Principal Investigator named in the Data Access Request (DAR) submitted to the FaceBase DAC;
- those named in the Collaborators section of the DAR; and
- any trainee or employee working on the proposed research project under the direct supervision of these individuals.

Research access to the requested dataset(s) is granted for a period of one (1) year as defined below. Access to the data set beyond the end of this one year period can be obtained through resubmission of the DAR.

Research use will occur solely in connection with the research project described in the DAR, which includes a description of the research objectives and design. Any modification of the project will require submission of an amendment to this application (e.g., the addition of new aims related to the approved project, adding or deleting collaborators from the same institution). The applicant will be required to demonstrate institutional approval for the modified project. New uses of these data outside those described in the DAR will require submission of a new DAR.

Each FaceBase project has specific limitations on use. The research project described in the DAR must be consistent with these limitations.

Specific limitations:

3D Facial Norms Database (PIs: Weinberg/Marazita)

*Limited to research studies of facial shape or craniofacial birth defects*

Genetic Determinants of Orofacial Shape and Relationship to Cleft Lip/Palate (PI: Spritz)

*Limited to research studies of facial shape or craniofacial birth defects*

Oral Clefts: Moving from Genome Wide Studies toward Functional Genomics (PI: Beaty)

*Limited to genetic research on cleft lip/palate or other craniofacial anomalies*

## **2. Institutional and Approved User Responsibilities**

The Requester agrees through the submission of the Data Access Request (DAR) that the PI named in the DAR has reviewed and understands the principles for responsible research use and data handling of the datasets as detailed in this Data Use Certification agreement. The Requester and Approved Users further acknowledge that they are responsible for ensuring that all uses of the data are consistent with federal, state, and local laws and regulations and any relevant institutional policies. Through submission of the DAR, the Principal Investigator also agrees to submit data use reports to the FaceBase Data Access Committee (DAC) describing the research use of the Approved Users in either the form of an annual request for renewal of access to the dataset(s) (section 10, below) or as a final report (section 11, below).

Some FaceBase datasets contain information that could potentially be linked to the research participants (e.g., mesh images derived from facial photographs). Access to any FaceBase dataset requires prior review of the project by the Requestor's IRB, with either a written determination that the research is not considered human subjects research or approval for human subjects research. The Authorized Representative, by approving and submitting the attached Data Access Request, provides assurance that relevant institutional policies and applicable federal, state, or local laws and regulations (if any) have been followed. The Authorized Representative also assures through the approval of the Data Access Request that other organizations within the institution with relevant authorities (e.g., the Office of Human Subjects Research, the Office of Information Technology, the Office of Technology Transfer, etc.) have reviewed the relevant sections of this Data Use Certification and the associated procedures and are in agreement with the principles defined.

It is anticipated that, at least in some cases, these datasets will be updated with additional information. Unless otherwise indicated, all statements herein are presumed to be true and applicable to the access and use of all versions of these datasets.

## **3. Public Posting of Approved User's Research Use Statement**

The Principal Investigator agrees that, if he or she becomes an Approved User, information about the PI and the approved research use may be posted on the FaceBase website as well as a public, US government web site that describes approved research projects. The information may include the Approved User's name and institution, project name, and Specific Aims as described in the DAR. In addition, citations resulting from the use of FaceBase datasets may be posted on the FaceBase and relevant NIDCR websites.

## **4. Non-Identification**

Approved Users agree not to use the requested datasets, either alone or in concert with any other information, to identify or contact individual participants from whom phenotype data (including facial images) and DNA samples were collected.

## **5. Non-Transferability**

The Requester and Approved Users agree to retain control over the data and further agree not to distribute data obtained through this Data Access Request to any entity or individual not covered in the submitted DAR.

If Approved Users are provided access to FaceBase datasets for inter-institutional collaborative research described in the Specific Aims and Analysis Plan sections of the Data Access Request, and all members of the collaboration are also Approved Users through their home institution(s), data obtained through this Data Access Request may be securely transmitted within the collaborative group. All data security practices and other terms of use defined in this agreement and the [dbGaP Security Best Practices](#) for the raw data are expected to be followed for the derived data, including any transmission of the data.

The Requester and Approved Users acknowledge responsibility for ensuring the review and agreement to the terms within this Data Use Certification and the appropriate research use of FaceBase data by research staff associated with any approved project, subject to applicable laws and regulations. FaceBase datasets obtained through this Data Access Request, in whole or in part, may not be sold to any individual at any point in time for any purpose.

Approved Users agree that if they change institutions during the access period, they will submit a new Data Access Request and Data Use Certification in which the new institution agrees to the conditions stipulated in this Data Use Certification before data access resumes. Any versions of data stored at the prior institution for the approved use will be destroyed and the destruction documented through a Final Report as described below. However, if advance written notice and approval by the FaceBase Data Access Committee is obtained to transfer responsibility for the approved research project to another Approved User within the original institution, the data may not need to be destroyed.

## **6. Data Security and Data Release Reporting**

FaceBase has adopted the data security and data release reporting procedures developed by the NIH for dbGaP. The Requester and Approved Users acknowledge that they have reviewed and agree to handle the requested dataset(s) according to the current [dbGaP Security Best Practices](#), including its detailed description of requirements for security and encryption. These include, but are not limited to:

- all Approved Users have completed all required computer security training required by their institution, for example, the <http://irtsectraining.nih.gov/>, or the equivalent;
- the data will always be physically secured (for example, through camera surveillance, locks on doors/computers, security guard);
- servers must not be accessible directly from the internet (for example, they must be behind a firewall or not connected to a larger network), and unnecessary services should be disabled;
- use of portable media, e.g., on a CD, flash drive or laptop, is discouraged, but if necessary then they should be encrypted consistent with applicable law;
- use of up to date anti-virus/anti-spyware software;
- security auditing/intrusion detection software, detection and regular scans of potential data intrusions;
- use of strong password policies for file access; and
- all copies of the dataset should be destroyed, as permitted by law, whenever any of the following occurs:
  - the DUC expires and renewal is not sought;
  - access renewal is not granted;
  - the FaceBase Consortium, the NIDCR or the NIH requests destruction of the dataset; or
  - the continued use of the data would no longer be consistent with the DUC.

In addition, the Requester and Approved Users agree to keep the data secure and confidential at all times and to adhere to information technology practices in all aspects of data management to assure that only authorized individuals can gain access to FaceBase datasets. This agreement includes the maintenance of appropriate controls over any copies or derivatives of the data obtained through this Data Access Request.

Requesters and Approved Users agree to notify the FaceBase Data Access Committee and the NIDCR of any unauthorized data sharing, breaches of data security, or inadvertent data releases

that may compromise data confidentiality within 24 hours of when the incident is identified. As permitted by law, notifications should include the known information regarding the incident and a general description of the activities or process in place to fully define and remediate the situation. Within 3 business days of the FaceBase Data Access Committee notification, the Requester, through the Approved User and the Authorized Representative, agree to submit to the FaceBase Data Access Committee and NIDCR a more detailed written report including the date and nature of the event, actions taken or to be taken to remediate the issue(s), and plans or processes developed to prevent further problems, including specific information on timelines anticipated for action.

**All notifications and written reports of data release incidents should be sent to:**

FaceBase Data Access Committee  
URGENT Email: [nidcrufacedac@mail.nih.gov](mailto:nidcrufacedac@mail.nih.gov)

The NIDCR, the NIH, or another entity designated by the NIH may, as permitted by law, also investigate any data security incident. Approved Users and their associates agree to support such investigations and provide information, within the limits of applicable local, state and federal laws and regulations. In addition, Requesters and Approved Users agree to work with the NIDCR and the NIH to assure that plans and procedures developed to address identified problems are mutually acceptable consistent with applicable law.

## **7. Intellectual Property**

The FaceBase Consortium follows the intellectual property principles developed by the NIH. By requesting access to FaceBase dataset(s), the Requester and Approved Users acknowledge that anyone authorized for research access through the attached Data Access Request follow the intellectual property principles summarized below:

Achieving maximum public benefit is the ultimate goal of data distribution through the FaceBase data repository. Following the NIH principles, the FaceBase Consortium considers these data as pre-competitive, and urges Approved Users to avoid making IP claims derived directly from the FaceBase dataset(s). However, the FaceBase Consortium also recognizes the importance of the subsequent development of IP on downstream discoveries, especially in therapeutics, which will be necessary to support full investment in products to benefit the public.

It is expected that the data provided through an approved DAR, and conclusions derived therefrom, will remain freely available, without requirement for licensing. The NIH encourages broad use of genomic datasets coupled with a responsible approach to management of intellectual property derived from downstream discoveries in a manner consistent with the [NIH's Best Practices for the Licensing of Genomic Inventions](#) and the [NIH Research Tools Policy](#).

## **8. Research Dissemination and Acknowledgement of FaceBase Datasets**

It is the intent of the FaceBase Consortium and NIDCR to promote the dissemination of research findings from FaceBase dataset(s) as widely as possible through scientific publication or other appropriate public dissemination mechanisms. Approved Users are strongly encouraged to publish their results in peer-reviewed journals and to present research findings at scientific meetings, etc.

Images of individuals derived from 3D facial photography (*e.g.*, 3D or 2.5D mesh images) are comparable to a full facial photograph and are therefore considered an individual identifier under the HIPAA rules (45 CFR 164.514). Therefore, derived images from any individual included in a dataset obtained from FaceBase must not be used in publications or presentations. The publication of composite (*e.g.*, averaged) facial images is permitted.

Publications and presentations describing the results of research conducted using FaceBase datasets must acknowledge the individual project(s) that generated the data, the FaceBase Data Management Hub, and the FaceBase Consortium. They should also acknowledge any relevant FaceBase consortium publications describing the creation of the dataset, which will be posted on the FaceBase website ([www.facebase.org](http://www.facebase.org)) when they are available. Public acknowledgements

should also credit the NIDCR as the source of FaceBase funding.

Sample statements for the acknowledgment of FaceBase datasets follow:

*Morphometric data from normal faces were obtained from FaceBase (www.facebase.org), and were generated by projects U01DE020078 and U01DE020054. The FaceBase Data Management Hub (U01DE020057) and the FaceBase Consortium are funded by the National Institute of Dental and Craniofacial Research.*

*Genomic data for individuals with cleft lip and/or cleft palate were obtained from FaceBase (www.facebase.org), and were generated by project U01DE020073. The FaceBase Data Management Hub (U01DE020057) and the FaceBase Consortium are funded by the National Institute of Dental and Craniofacial Research.*

## **9. Departures from the Previously Approved Research Plan**

To assure that FaceBase and NIH policies and procedures for human subjects data use are adhered to, any departure from the project described in the original DAR must be reported to the FaceBase DAC prior to implementation. Such reports must demonstrate that appropriate institutional approvals for the revisions have been obtained by the Approved Users, and that the project's aims remain consistent with any data use limitations for the approved datasets. This includes changes in the project's Collaborators.

## **10. Renewal of Dataset Access**

Approval of access to FaceBase datasets will be for one year at a time. Principal Investigators, through their Authorized Representatives, can request continued access to FaceBase datasets by submitting a renewal request to the FaceBase DAC prior to the anniversary of the Project Approval Date specified on the Data Access Committee approval notification (<https://www.facebase.org/odocs/human-data-access-request>). The renewal application will describe how these data have been used during the previous year, any results that have been generated as a result of access to the data including patents and publications, and any proposed departures from the originally proposed research plan. Renewal requests should also provide evidence of review of the renewal request by the IRB at the Approved User's institution.

This information will be used by the FaceBase Data Access Committee and NIDCR staff for program evaluation activities, and may be considered by the NIDCR as part of the NIH effort to provide ongoing oversight and management of all NIH data sharing activities.

**Renewal Requests should be submitted by e-mail to:**

[nidcrfacebasedac@mail.nih.gov](mailto:nidcrfacebasedac@mail.nih.gov)

## **11. Final Reporting at Termination of Dataset Access**

Principal Investigators not seeking renewal agree to provide the FaceBase DAC, through their Authorized Representative, a Final Report no later than one month after the end of the anniversary of the Project Approval Date (<https://www.facebase.org/odocs/human-data-access-final-report>). This report will provide information regarding potentially significant findings and publications or presentations that resulted from the use of the requested dataset(s), any violations of the terms of access described within this Data Use Certification and the implemented remediation, and information on any downstream intellectual property generated as a result of the data. This Final report should either confirm that the Approved Users' copies of the FaceBase dataset(s) have been destroyed in accordance with this document or explain why the conditions for retention of the dataset(s) described in Section 12 (below) pertain. If the conditions for retention described in Section 12 do pertain, the Final Report should address when the dataset(s) will be destroyed and arrangements for secure storage of the dataset(s) during the interim period.

This information will be used by the FaceBase Data Access Committee and NIDCR staff for program evaluation activities, and may be considered by the NIDCR as part of the NIH effort to

provide ongoing oversight and management of all NIH data sharing activities.

**Final Reports should be submitted by e-mail to:**

[nidcrfacebasedac@mail.nih.gov](mailto:nidcrfacebasedac@mail.nih.gov)

**12. Final Disposition of Dataset(s)**

At the end of the approved access period, Approved Users agree to destroy all copies of the requested dataset(s), except as required by publication practices or law to retain them. The FaceBase DAC will inform the Approved Users' IRB and Authorized Representative of the expiration/termination of the Approved Users' access to the FaceBase dataset(s) and of the need to destroy all copies of the dataset(s) provided to the previously Approved Users.

Copies of FaceBase dataset(s) may not need to be destroyed if, with advance notice and approval by the FaceBase Data Access Committee, the project has been transferred to another Approved User at the same institution. In this case, documentation must be provided that other Approved Users are using the dataset(s) under an active FaceBase DAC approved research project.

**13. Non-Endorsement, Indemnification**

The Requester and Approved Users acknowledge that although all reasonable efforts have been taken to ensure the accuracy and reliability of FaceBase data. The FaceBase Consortium, the NIDCR, the NIH, the FaceBase Data Access Committee, and Contributing Investigators do not and cannot warrant the results that may be obtained by using any data included therein. The NIDCR, the NIH, the FaceBase Data Access Committee, and all contributors to these datasets disclaim all warranties as to performance or fitness of the data for any particular purpose.

No indemnification for any loss, claim, damage or liability is intended or provided by any party under this agreement. Each party shall be liable for any loss, claim, damage, or liability that said party incurs as a result of its activities under this agreement, except that the NIH, as an agency of the United States, may be liable only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. 2671 et seq.

**14. Termination and Violations**

The Requester and Approved User acknowledge that the FaceBase Consortium, the NIH or the NIDCR may terminate this agreement and immediately revoke access to all FaceBase datasets at any time if the Requester is found to be no longer in agreement with the policies, principles and procedures of the FaceBase Consortium, the NIDCR, and the NIH.

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By submission of the attached Data Access Request, the Requester through the Authorized Representative attests to the Approved Users' qualifications for access to and use of FaceBase dataset(s) and certifies their agreement to the FaceBase and NIH principles, policies, and procedures for the use of the requested datasets as articulated in this document, including the potential termination of access should a violation of any of these agreement terms be identified.

Requesters and the Principal Investigator further acknowledge that they have shared this document and the FaceBase data sharing policies and procedures for access and use of FaceBase datasets with any Approved Users, appropriate research staff, and all other Collaborators identified in the DAR.

Authorized Representatives acknowledge that they have considered the relevant FaceBase policies and procedures, that they have shared this document and the relevant policies and procedures with appropriate institutional organizations, and have assured compliance with local institutional policies related to technology transfer, information technology, privacy, and human subjects research.

**Information Technology (IT) Director** (signature not required):

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Printed Name

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Position at Institution

**Principal Investigator:**

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Printed Name

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Position at Institution

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Signature

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Date

**Authorized Representative:**

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Printed Name

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Position at Institution

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Signature

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Date

## Appendix

### Definitions of Terminology

**Approved User:** Post-DAC approval will include the PI, collaborators at the home institution who are named in the Collaborators section of the DAR, and trainees or staff to these investigators.

**Authorized Representative:** A person who has organizational authority to sign for an NIH grant application, also known as the Authorized Organizational Representative or the Signing Official.

**Contributing Investigator:** The researcher who submitted the dataset to FaceBase.

**Data Derivative:** Any data including individual-level data or aggregate genomic data that stems from the original dataset obtained through FaceBase. Excepted from this term is summary information that is expected to be shared through community publication practices.

**Final Report:** A final report submitted to the FaceBase DAC at the conclusion of the approved access period when no additional access is sought, or when leaving an institution. This report should summarize the analysis of FaceBase datasets obtained through the Data Access Request and any significant findings derived from the work.

**Information Technology Director:** Someone with the authority to vouch for the IT capacities at an institution, or higher-level division of an institution (e.g., the School of Medicine).

**Requester:** The home institution/organization for the Primary Investigator (PI) that will use the requested data.

**Collaborators:** Senior/Key Persons participating in the project at the home institution.