NOTE: ALL FIELDS ARE MANDATORY

INVESTIGATOR INFORMATION

Principal Investigator's Name:
Title/Position:
Affiliation:
Email Address:
Phone Number:
Fax Number:
Mailing Address:
If the principal investigator is not a faculty member (e.g., post-doc or student):
Name of Mentor or Supervisor:
Title/Position:
Affiliation:
Email Address:
Phone Number:
Fax Number:
Mailing Address:

I

PROJECT INFORMATION

Title of Previously Approved Project:
DAR Approval Number (previously assigned by FaceBase)
Last date of DAR Approval:
Do you have IRB approval for <u>renewal</u> of this project?
[If Yes] IRB Protocol #:
Date of Approval:
[<i>If N</i> o] Has the IRB provided written documentation that this research is considered: Exempt human subjects research □ Yes □ No

Projects must have IRB approval or a letter of determination from the IRB of the investigator's institution in order for the project to be reviewed by the DAC.

Please submit a copy of the IRB approval or other appropriate documentation from the IRB in conjunction with the DAR. Proposals will not be reviewed by the DAC without this documentation.

Federalwide Assurance Number (FWA#) for Institution (if available):

The FWA # can be found at <u>http://ohrp.cit.nih.gov/search/</u>. If you have questions about finding your institution's FWA # or about applying for an FWA #, please contact you institution's Office of Research.

I am requesting <u>renewal</u> of access to data from the following project(s): (check all that apply)(Please note that access to FaceBase datasets not previously approved requires submission of a new DAR)

- 3D Facial Norms Database (PIs: Weinberg/Marazita)
 Use of these data is limited to research studies of facial shape or craniofacial birth defects
- Genetic Determinants of Orofacial Shape and Relationship to Cleft Lip/Palate (PI: Spritz) Use of these data is limited to research studies of facial shape or craniofacial birth defects
- □ Oral Clefts: Moving from Genome Wide Studies toward Functional Genomics (PI: Beaty) Use of these data is limited to genetic research on cleft lip/palate or other craniofacial anomalies

Are you requesting renewed access to 3D facial image data? Yes No

Note: Due to the potentially sensitive nature of facial images, access to this data will be limited to investigators with IRB approval as <u>non-exempt</u> human subjects research.

Brief description of your use of FaceBase data in the past year:

• Findings from studies already conducted (< 500 words)

• Manuscripts resulting from studies using FaceBase data (*please include manuscripts in press*)

• Description of data security measures implemented by the investigator (please see the FaceBase Data Use Certification document for more info: [https://www.facebase.org/odocs/data-use-certification]

• Describe any data security breaches or unintentional releases of FaceBase data during the past year and how those incidents were dealt with.

Brief description of project proposed for the next year:

• Specific Aims of Project (< 500 words)

• Analysis plan (< 500 words)

If there are changes to the previously approved project, have these changes been presented to and approved by your local IRB?
 Yes INO Not Applicable If yes, date of approval: _______

• Explanation of how the proposed research <u>continues</u> to be consistent with the data use *restrictions* for the requested data (please see the FaceBase Data Use Certification document for more info: [https://www.facebase.org/odocs/data-use-certification]).

- List of all collaborators at your organization who will have access to the data. Please indicate any collaborators that are being added to the project with this renewal request.

• List all collaborators from other organizations involved in the project, indicating any new collaborators to be added this year. Describe any planned data sharing among these collaborators. Note that collaborators from other institutions who wish to have access to data are required to submit their own DARs to the FaceBase DAC.

Date:	
Name (print):	
Name (signature):	
Email Address:	
Mentor/Supervisor Signature (required if applicant is not a faculty member)	
Date:	
Name (print):	
Name (signature):	
Email Address:	
A legally authorized institutional representative (e.g., a signing official) must also sig	n the DAR.
Date:	
Name (print):	
Name (authorized signature):	
Email Address:	
Name of Institution:	

PLEASE SUBMIT SIGNED AND COMPLETED DAR RENEWAL DOCUMENT AS A <u>PDF FILE</u>, ALONG WITH:

- EVIDENCE OF CURRENT IRB APPROVAL (IF APPROPRIATE) AND,
- THE SIGNED FACEBASE DATA USE CERTIFICATION DOCUMENT,

TO THE FOLLOWING EMAIL ADDRESS: [dac@facebase.org]

Principal Investigator Signature