**DEEP Data Access Agreement**

**This agreement governs the terms on which access will be granted to the controlled access datasets generated by the Deutsches Epigenom Programm DEEP (DEEP 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:**

**Consortium:** The Deutsches Epigenom Programm (DEEP) consortium. A list of members can be found on the consortium website [www.deutsches-epigenom-programm.de](http://www.deutsches-epigenom-programm.de).

**Data Producer:** A member of the DEEP consortium producing data.

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

**DEEP Data:** The controlled access data of the DEEP consortium as defined in section E1.3 “Data access and patient protection” of the International Human Epigenome Consortium (IHEC) goals, structure, policies and guidelines (Version Jan 2013), included in Annex I.

**Publications:** Includes, without limitation, articles published in print journals, electronic journals, reviews, books, posters and other written and verbal presentations of research.

**Research Participant:** An individual having contributed their personal data/biomaterial to DEEP.

**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) 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.

**Terms and Conditions:**

In signing this Agreement:

1. The User and the User Institution(s) agree to use the DEEP Data in compliance with the IHEC Informed Consent guidelines as outlined in section E.1 of the IHEC goals, structure, policies and guidelines (Version Jan 2013), included in Annex I of this agreement.
2. The User and the User Institution(s) agree to only use the DEEP Data for the objectives and analyses outlined in section E “Scientific abstract” and as approved by their ethics committee(s) in the letter requested in section I “Research ethics” of the Data Access

Application form (if so required). Use of the DEEP Data for a new purpose or project will require a new application and approval.

1. The User and the User Institution(s) agree that the DEEP Data are made available for one (1) year. The User and the User Institution(s) agree to destroy/discard any DEEP Data held once it is no longer used for the project described in section E “Scientific abstract” of the Data Access Application Form or after the end of the granted time-period of one year unless obligated to retain the DEEP Data for archival purposes in conformity with national audits or legal requirements. To extend the use of DEEP Data after the one-year period, Users and User Institution(s) must re-apply to access the data.
2. The User and the User Institution(s) agree to preserve, at all times, the confidentiality of the information and DEEP Data. In particular, they undertake not to use, or attempt to use the DEEP Data to compromise or otherwise infringe the confidentiality of information on Research Participants.
3. 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 DEEP 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), or is freely available without restriction.
5. The User and the User Institution(s) agree not to transfer or disclose the DEEP Data, in whole or part, or any material derived from the DEEP Data, to anyone not listed in sections A “Name of applicant (principal investigator), including affiliations and contact details“ and B “Name of authorized personnel within your institution, including affiliations and contact details.“ of the 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 DEEP Data with an External Collaborator, the External Collaborator must complete a separate application for Access to the DEEP Data.
6. The User and the User Institution(s) accept that the Consortium, the original Data Producers, or copyright holders, or the funders of the DEEP Data or any part of the DEEP Data supplied:
7. bear no legal responsibility for accuracy or comprehensiveness of the DEEP Data
8. accept no liability for indirect, consequential, or incidental, damages or losses arising from use of the DEEP Data, or from the unavailability of, interruption in DEEP Data access for whatever reason
9. bear no responsibility for the further analysis or interpretation of these DEEP Data, over and above that published by the Consortium
10. The User and the User Institution(s) agree that they have the secure computation infrastructure and expertise to analyse the DEEP Data.
11. The User and the User Institution(s) agree to follow the IHEC publication policy as outlined in section E.5 of IHEC goals, structure, policies and guidelines (Version Jan 2013), included in Annex I of this agreement. This includes respecting the moratorium period of nine months from the time of data release, thus agreeing that you will not use the DEEP Data in a Publication before the end of this nine-month period, or until the DEEP Data is published be the Consortium, whichever occurs first.
12. The User and the User Institution(s) agree to recognize the contribution of the Consortium and to include a proper acknowledgement in any work based in whole or part on the DEEP Data.
13. The User and the User Institution(s) accept that DEEP 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.
14. The User and the User Institution(s) agree not to make intellectual property claims on the DEEP Data and not to use intellectual property protection in ways that would prevent or block access to, or use of, any element of the DEEP data, or conclusions drawn directly from the DEEP Data.
15. The User and the User Institution(s) can elect to perform further research that would add intellectual and resource capital to the DEEP 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 and to follow a national guideline that is in conformity with the OECD, “Guidelines for the Licensing of the Genetic Inventions”.
16. The User and the User Institution(s) will update the list of authorized personnel (section B in the Data Access Application form) to reflect any changes in researchers, collaborators and personnel within 30 days of the changes made. This update can be sent by email to datarequest@deutsches-epigenom-programm.de.
17. The User and the User Institution(s) must notify the DDEP DAC prior to any significant change to the research protocol of the User. This update can be sent by email to datarequest@deutsches-epigenom-programm.de
18. The User and the User Institution(s) will notify the DEEP DAC as soon as they become aware of a breach of the terms or conditions of this agreement.
19. 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) or any authorized personnel mentioned in section B “Name of authorized personnel within your institution, including affiliations and contact details.“ of the Data Access Application form. In this case, the User and the User Institution(s) will be required to destroy/discard any DEEP Data held, including copies and backup copies. This clause does not prevent the User or the User Institution(s) from retaining the DEEP Data for archival purposes in conformity with national audits or legal requirements.
20. The User and the User Institution(s) accept that it may be necessary for the Consortium or its appointed agent to alter the terms of this agreement from time to time. In this event, the Consortium or its appointed agent will contact the User and the User Institution(s) to inform them of any changes.
21. If requested, the User and the User Institution(s) will allow data security and management documentation to be inspected to verify that they are complying with the terms of this Data Access Agreement.
22. The User and the User Institution(s) agree to distribute a copy of this agreement and explain its content to any person mentioned in section B “Name of authorized personnel within your institution, including affiliations and contact details“ of the Data Access Application form.

I have read the Appendix listed at the end of this document.

**Applicant:**

Name:

Signed:

Date:

**Authorized institutional representative:**

Name:

Signed:

Date:

The completed agreement must be sent by email to [datarequest@deutsches-epigenom-programm.de](mailto:datarequest@deutsches-epigenom-programm.de)

**Annex I:** IHEC goals, structure, policies and guidelines