

# CHILD MIND INSTITUTE BIOBANK

## HOW TO REQUEST ACCESS

1. Overview. The successful submission of a complete Access Request, including the execution of the attached Data Use Agreement (“**DUA**”), is necessary to receive access to the data in the Child Mind Institute Biobank, an initiative coordinated by Child Mind Institute, Inc. (“**CMI**”) with the goal of building a rich resource of imaging, genetic, and phenotypic data. Data is collected from multiple research protocols, each of which is described in Appendix 2. Users can request to access data from one or more of the research protocols described. While CMI’s goal is to provide the least restrictive requirements for access to and usage of shared datasets, protection of participant privacy must be the highest priority. The need for a DUA arises from the increased risk of identification engendered by the robust phenotypic and psychometric data included in the Child Mind Institute Biobank (the “**Biobank Data**”).
2. Required Documents. Users seeking access to the Biobank Data must submit:
  - a. the DUA, certified and co-signed by the Principal Investigator and an authorized institutional official;
  - b. a Recipient Scope of Work, if applicable; and
  - c. an up-to-date CV or biosketch for the Principal Investigator.
3. Procedure. To request access, follow these steps:
  - a. Read the DUA, sign the Recipient Information and Certifications page, and obtain your authorized institutional official’s signature. Collaborators at different organizations must complete separate Access Requests.
  - b. Send a scanned copy of the required documents by email to [CMIDataUsage@childmind.org](mailto:CMIDataUsage@childmind.org).
  - c. Following CMI’s review and approval of your Access Request, an account will be created and you will receive a unique user name, password, and instructions by email.
4. Review Criteria. CMI will review each Access Request, including the DUA, and determine whether to provide access based on the expectations outlined in the following pages, which include privacy, confidentiality and security. In the event that an Access Request raises particular concerns related to privacy and confidentiality, risks to populations or groups or other concerns, CMI will consult other experts as appropriate to reach a determination. CMI reserves the right to suspend or revoke approved Access Requests at any time if concerns arise regarding the appropriateness of data usage by a recipient or a recipient’s compliance with the DUA.

# CHILD MIND INSTITUTE BIOBANK

## DATA USE AGREEMENT

I (“**Recipient Principal Investigator**”) request approval to access the Biobank Data (as defined above) for the purpose of scientific investigation or the planning of clinical research studies as described in this Access Request. I, and the institution or organization with which I am affiliated, which is identified on the signature page hereto (“**Recipient Institution**” and, together with Recipient Principal Investigator, “**Recipient**”), agree to the terms and conditions of this DUA, which shall be effective as of the date last signed on the Recipient Information and Certifications page below.

1. Defined Terms. For purposes of this DUA, the following terms shall have the meanings set forth below:

- a. “**Access Request**” shall mean the complete application, comprised of this DUA, including an executed Recipient Information and Certifications page, a Recipient Scope of Work, if applicable, and a CV or biosketch, submitted to CMI for the purpose of requesting access to the Biobank Data.
- b. “**Approved Scope of Work**” shall mean the Standard Scope of Work or Recipient Scope of Work, as applicable, in an approved Access Request.
- c. “**Recipient Parties**” shall mean Recipient Institution, Recipient Principal Investigator, Recipient Principal Investigator’s research team members and Recipient Institution’s employees, officers, directors, students and agents.
- d. “**Standard Scope of Work**” shall mean the scope of research that is provided on the Recipient Information and Certifications page of this DUA.

2. Scope of Work.

- a. If Recipient anticipates using the Biobank Data outside of the Standard Scope of Work, Recipient may apply to broaden access rights to the Biobank Data by including a rider to the Access Request that provides detailed information describing the anticipated project scope (the “**Recipient Scope of Work**”).
- b. All Biobank Data must be used by Recipient solely in connection with the Approved Scope of Work and for no other purpose.
- c. The Biobank Data must not be used in any research that is not within the Approved Scope of Work. Should Recipient’s intended use of the Biobank Data exceed the limits of the Approved Scope of Work or should Recipient desire to make a material change or changes to the Approved Scope of Work, Recipient must submit a revised DUA and Recipient Scope of Work, and Recipient shall not use any Biobank Data for any such additional purpose unless and until it is approved by CMI.

3. Non-Identification of Subjects. The Biobank Data must not be used, either alone or in conjunction with any other information, in any effort whatsoever to establish the individual identities of any of the subjects from whom the datasets in the Biobank Data were obtained. Recipient shall promptly notify CMI if, upon use of the Biobank Data, Recipient discovers any information that, alone or in conjunction with other information, can be used to identify a specific individual, other than research site. Failure to adhere to the requirements of this DUA may result in denial of access to the Biobank Data.

4. Data Disclaimers. All Biobank Data is provided “AS IS” and without any representations or warranties of any kind, whether express or implied, including accuracy or completeness and implied warranties of merchantability or fitness for a particular purpose. Recipient agrees that CMI does not warrant and cannot warrant the results that may be obtained by using any Biobank Data.

5. Assumption of Risk. Recipient Institution shall be fully responsible for the acts and omissions of Recipient Parties with respect to their failure to adhere to the terms of the Approved Scope of Work, applicable regulations and this DUA. It is the intention of Recipient that CMI will not be liable to any parties for any liabilities, demands, damages, expenses, or losses arising from Recipient Parties’ use for any purpose of the Biobank Data.

6. Indemnification; Remedies.

a. Recipient shall defend, indemnify and hold harmless Child Mind Institute, Inc., Child Mind Medical Practice, PLLC and Child Mind Medical Practice, PC, and each of their subsidiaries, affiliates, and respective officers, directors, members, shareholders, employees, agents, successors and permitted assigns (collectively, the “**Indemnitees**”) from and against all losses, damages, liabilities, deficiencies, actions, judgments, interest, awards, penalties, fines, costs or expenses of whatever kind, including reasonable attorneys' fees, the cost of enforcing any right to indemnification hereunder and the cost of pursuing any insurance providers, to the extent arising out of, relating to or resulting from Recipient Parties’ failure to comply with any of Recipient’s obligations under this DUA.

b. Recipient (i) acknowledges that any breach of its covenants or obligations set forth in this DUA may cause the Indemnitees irreparable harm for which monetary damages would not be adequate compensation and (ii) agrees that, in the event of such breach or threatened breach, the Indemnitees are entitled to seek equitable relief, including a restraining order, injunctive relief, specific performance and any other relief that may be available from any court, in addition to any other remedy to which the Indemnitees may be entitled at law or in equity. Such remedies shall not be deemed to be exclusive but shall be in addition to all other remedies available at law or in equity, subject to any express exclusions or limitations in this DUA to the contrary.

7. Notification of Publication. Prompt publication or other public disclosure of the results of an Approved Scope of Work is encouraged. Recipient shall notify CMI via email at [CMIDataUsage@childmind.org](mailto:CMIDataUsage@childmind.org) as to when and where a publication (or other public disclosure) of a report that falls within the Approved Scope of Work will appear.

8. Ownership. The parties agree that, as between the parties, CMI exclusively retains all right, title and interest in and to the Biobank Data and that Recipient does not obtain any right, title, or interest in or to any of the Biobank Data.

9. Confidentiality.

a. By signing this DUA, Recipient certifies that all Recipient Parties are aware of the confidential nature of the Biobank Data and of the necessity of maintaining its confidentiality.

b. Recipient shall retain control over the Biobank Data, and further agrees not to transfer or allow access to the Biobank Data, with or without charge, to any other entity or any individual outside of the scope of this DUA. Recipient agrees not to sell the Biobank Data in any form or version to any entity or individual or to distribute the Biobank Data to anyone other than his/her research staff members who also agree to the terms of this DUA.

c. Recipient shall establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the Biobank Data and to prevent unauthorized use of or access to the Biobank Data. Recipient acknowledges that the use of unsecured telecommunications, including the Internet, to transmit individually identifiable or deducible information derived from the Biobank Data is prohibited.

d. Recipient shall not transfer or disclose any data or any information about individual subjects, except as permitted by this DUA or as required by law. Recipient must provide adequate security for the Biobank Data, including safeguards intended to prevent unauthorized use or disclosure of such information. In addition, each Recipient shall report in writing to CMI any use or disclosure of any portion of the Biobank Data of which it becomes aware that is not permitted by this DUA, including disclosures that are required by law.

e. Recipient shall ensure that Recipient Parties not disclose or transfer any Biobank Data to anyone who is not authorized to receive such data except as permitted by this DUA or as required by law.

10. Security Practices. Recipient shall, at a minimum and in addition to all other measures employed by Recipient in connection with highly-sensitive and confidential data, comply with the “**Information Technology Security Best Practices**” at Appendix 1 in connection with its access, receipt and use of the Biobank Data.

11. Unauthorized Disclosures; Security Breaches.

a. Recipient agrees that in the event that CMI determines or has a reasonable belief that Recipient has made or may have made a use, reuse or disclosure of the Biobank Data that is not authorized by this DUA, CMI, at its sole discretion, may require Recipient to: (i) promptly investigate and report the Recipient’s determinations regarding any alleged or actual unauthorized use, reuse or disclosure; (ii) promptly resolve any problems identified by the investigation; (iii) submit a formal response to an allegation of unauthorized use, reuse or disclosure; (iv) submit a corrective action plan with steps designed to prevent any future unauthorized uses, reuses or disclosures; and (v) return data files to CMI or destroy such data files. Recipient understands that as a result of CMI’s determination or reasonable belief that unauthorized uses, reuses or disclosures have taken place, CMI may terminate access to the Biobank Data for a period of time to be determined by CMI.

b. Recipient shall report to the U.S. Department of Health and Human Services any (i) breach of personally identifiable information (“**PII**”) from the Biobank Data, (ii) loss of such data or (iii) disclosure of such data to any unauthorized persons within twenty-four (24) hours and cooperate fully in the federal security incident process or any notification process required by law. Recipient shall bear the cost and liability for any breaches of PII while such data are entrusted to Recipient. Furthermore, if CMI determines that the risk of harm requires notification of affected individual persons of the security breach and/or other remedies, Recipient agrees to carry out such remedies without cost to CMI.

12. Non-Endorsement. Recipient agrees not to claim or imply endorsement by CMI of (a) the project or projects being conducted under the Approved Scope of Work, (b) Recipient Parties or any other entities or personnel related to or involved in the project(s) or (c) any resulting commercial product(s).

13. Recipient's Compliance with Institutional Requirements. Recipient agrees to comply with all Recipient Institution’s applicable rules for the protection of human subjects, which may include the regulations at 45 C.F.R. Part 46, and other federal and state laws governing the use of the Biobank Data. The terms of this DUA are in addition to, and do not supersede any of, Recipient Institution's

institutional policies or any local, state, and/or federal laws and regulations that provide additional protections for human subjects.

14. Recipient's Compliance with Approved Scope of Work, Law and the DUA. Recipient agrees that any access, receipt and use of the Biobank Data shall be in accordance with the Approved Scope of Work, all applicable state and federal law and regulations (including the Health Information Technology for Economic and Clinical Health Act) and this DUA. Recipient shall report promptly to CMI any material change in the Approved Scope of Work and any unanticipated problems involving risks to the subjects. In addition, Recipient shall promptly report any violations of the terms of this DUA to CMI.

For avoidance of doubt, Recipient agrees that Biobank Data may not be used in any data-science competitions sponsored by CMI, and Recipient shall not under any circumstances use the Biobank Data for such purposes. Violation of this provision shall result in termination of Recipient's access to Biobank Data.

15. Publicity. Recipient hereby acknowledges and agrees that CMI may summarize on its website the Approved Scope of Work along with Recipient's name.

16. Credit. Recipient shall acknowledge the contribution of CMI in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of the Biobank Data. Acknowledgement of the contribution of specific CMI investigators is expected in all oral and written presentations. Recipient will acknowledge the source of the Biobank Data by including language similar to the following either in the acknowledgment or in the text of the manuscript:

"This manuscript was prepared using a limited access dataset obtained from the Child Mind Institute Biobank, [SPECIFY DATASET]. This manuscript reflects the views of the authors and does not necessarily reflect the opinions or views of the Child Mind Institute."

17. Privacy Notification. Recipient hereby acknowledges and agrees that information collected from Recipient, as part of this DUA, may be made public in part or in whole for tracking and reporting purposes. The primary uses of this information are to document, track, and monitor and evaluate the use of the Biobank Data, as well as to notify interested recipients of updates, corrections or other changes to the database.

18. Amendments. Amendments to this DUA must be made in writing and signed by authorized representatives of the Recipient Institution, Recipient Principal Investigator and CMI.

19. Termination/Survival of Obligations.

a. Termination by Recipient. Recipient may terminate this DUA at any time by notifying CMI of its intent to terminate and returning or destroying any data obtained under this DUA.

b. Termination by CMI. CMI may terminate this DUA at any time by providing thirty (30) days' prior written notice to Recipient.

c. Termination for Breach. CMI may terminate this DUA by providing two (2) days' prior written notice if CMI determines, in its sole discretion, that Recipient has committed a material breach of this DUA. CMI may, in its sole discretion, provide Recipient with an opportunity to remedy a breach before termination but is not obligated to do so. CMI may consider reactivating terminated accounts upon submission of a new Access Request.

d. Automatic Termination. This DUA shall automatically terminate (i) as provided in Section 20, (ii) if Recipient completes the work provided for in the Approved Scope of Work or

terminates the work prior to its completion or (iii) if Recipient Principal Investigator disaffiliates or is disaffiliated from the Approved Scope of Work or the Recipient Institution.

e. Survival. All obligations of this DUA with respect to the Biobank Data accessed by Recipient prior to termination shall survive and remain in effect following termination.

f. Destruction of Data. Recipient agrees that upon termination of this DUA, or completion of the use of the data under this DUA, all copies of the Biobank Data will be returned to CMI or destroyed or otherwise disposed of properly as permitted by law, and Recipient shall notify CMI of such destruction or disposal.

20. Term and Access Period. Recipients who are granted permission to access the Biobank Data shall receive an account that is valid for a period of seven (7) years. This DUA and the associated account will automatically terminate at the end of seven (7) years. An account may be renewed upon approval of a new Access Request.

21. Non-transferability of Agreement. This DUA is not transferable. If the Recipient Institution appoints another principal investigator to complete the research project, Recipient Institution must submit a new DUA together with the new principal investigator. If the Recipient Principal Investigator changes institutions and wishes to retain access to the Biobank Data, the Recipient Principal Investigator must submit a new DUA together with the new institution. In either case, Recipient shall not use the Biobank Data pending approval of a new DUA.

22. Rules of Interpretation. The words “include” and “including,” and other words of similar import when used in this DUA shall not be deemed to be terms of limitation but rather shall be deemed to be followed in each case by the words “without limitation.” Any reference to a section of any particular law will be interpreted to include any revision of or successor to that section regardless of how it is numbered or classified.

23. Governing Law. This DUA shall be governed by the laws of New York, except where the Federal Supremacy Clause requires otherwise.

*[Signature (Recipient Information and Certifications) page to follow]*

## APPENDIX 1

### INFORMATION TECHNOLOGY SECURITY BEST PRACTICES

The purpose of these Information Technology Security Best Practices, which are subject to applicable law, is to provide minimum security standards and best practices for individuals who use Biobank Data. Keeping Biobank Data secure through these best practices is important. Subject to applicable law, Recipient agrees to promptly report to CMI breaches of data confidentiality that are known or that should reasonably have been known by Recipient. For the avoidance of doubt, each defined term used within these Information Technology Security Best Practices has the same meaning attributed to it in the Data Use Agreement.

We require that you:

- Do not attempt to override technical or management controls to access data for which you have not been expressly authorized.
- Do not use your trusted position and access rights to exploit system controls or access Biobank Data for any reason other than in the performance of the proposed research within the Approved Scope of Work.
- Ensure that anyone directed to use the system has access to, and is aware of, these Information Technology Security Best Practices and all existing policies and procedures relevant to the use of the Biobank Data.
- Follow a secure password policy, which includes:
  - Choosing a password of at least seven (7) characters including at least three of the following types of characters: capital letters, lower case letters, numeric characters and other special characters.
  - Changing your password every two (2) months.
  - Protecting your password from access by other individuals—for example, by storing it electronically in a secure location.
  - Notifying CMI, as permitted by law, at [CMIDataUsage@childmind.org](mailto:CMIDataUsage@childmind.org) of security incidents, or any incidents of suspected misuse of Biobank Data or when access to Biobank Data is no longer required.

#### ***Security Standards***

We require that you:

- Protect the Biobank Data, providing access solely to authorized researchers permitted access to such data by your institution or to others as required by law.
- When you download Biobank Data, download the data to a secured computer or server with strong password protection.
- For the computers hosting Biobank Data, ensure that they have the latest security patches and are running virus protection software.
- Ensure that the Biobank Data are not exposed to the Internet or posted to a website that may be discovered by Internet search engines.
- If you leave your office, close out of data files or lock your computer. Consider the installation of a timed screen saver with password protection.
- Avoid storing Biobank Data on a laptop or other portable medium. If it is necessary to store Biobank Data on such a device, encrypt the data.
- When finished using the Biobank Data, destroy the data or otherwise dispose of it properly, as permitted by law.

## APPENDIX 2

### AVAILABLE DATA SETS

Below are descriptions of each available data set in the Child Mind Institute Biobank. On the Recipient Information and Certifications page, indicate which data set(s) you would like to access.

#### **The Healthy Brain Network (HBN)**

An initiative coordinated by CMI with the goal of building a rich resource of multimodal brain imaging, electroencephalogram, phenotypic and genetics data collected from 10,000 children and adolescents (ages 5-21) over five years from communities across New York City. Particular focus is placed on the study of mental health and learning disorders.

#### **Multimodal Resource for Studying Information Processing in the Developing Brain (MIPDB)**

An initiative coordinated by CMI with the goal of providing a prospective open science resource focused on dimensional, multi-domain neuro-phenotyping of psychiatric and healthy populations (ages 6-44). MIPDB includes a novel battery of EEG-based paradigms that focuses on multiple key domains of cognitive function that may be useful for advancing the study of clinical cognitive neuroscience.



**CHILD MIND INSTITUTE BIOBANK  
RECIPIENT INFORMATION AND CERTIFICATIONS**

First Name: \_\_\_\_\_ Last Name: \_\_\_\_\_

Degree: \_\_\_\_\_ Academic Position (or Title): \_\_\_\_\_

Institution: \_\_\_\_\_ Department: \_\_\_\_\_

Street Address: \_\_\_\_\_

City: \_\_\_\_\_ State/Province: \_\_\_\_\_

Zip/Postal Code: \_\_\_\_\_ Country: \_\_\_\_\_

Telephone: \_\_\_\_\_ FAX: \_\_\_\_\_

E-mail Address: \_\_\_\_\_

Research Project (title): \_\_\_\_\_

Data Requested (check all that apply):  HBN  MIPDB

**Standard Scope of Work:**

“Exploration of brain structure and function, including its phenotype relationships, using a combination of morphometric MRI, functional MRI, diffusion MRI data and EEG data, as available, as well as any accompanying medical, physical, laboratory, psychiatric, cognitive and behavioral phenotyping measures.”

*\* To request any additions to the Standard Scope of Work, please attach a page(s) to this application with detailed information regarding your request.*

By signing this DUA, Recipient Institution’s duly authorized institutional official and I hereby certify that:

- Recipient will abide by the DUA and the principles, policies and procedures for the use of the Biobank Data.
- Recipient is not seeking access to the Biobank Data in relation to present or any potential future involvement in Kaggle (or similar) data-science competitions sponsored by CMI, and that no data that the Recipient has access to under this DUA will be used by Recipient or otherwise in connection with Recipient’s participation in such competitions.
- Recipient Principal Investigator further certifies that he/she has shared this document and the relevant Biobank Data policies and procedures with any research staff who will access the Biobank Data.
- Recipient Institution’s authorized institutional official further certifies that he/she has shared this document and the relevant Biobank Data policies and procedures with appropriate institutional entities and individuals.

<b>Recipient Principal Investigator</b>	<b>Recipient Institution (authorized official)</b>
Signature:	Signature:
Name:	Name:
Title:	Title:
Institution:	Institution:
Date:	Date: