

## **Theirworld Edinburgh Birth Cohort (TEBC)**

### **Data Access and Collaboration Policy**

**Version 1.7 (10<sup>th</sup> March 2020)**

#### **Purpose of the policy**

This Data Access and Collaboration Policy sets out the terms and conditions on which TEBC (deidentified) data, stimuli and tasks will be accessible. It clarifies the process for requests for data, stimuli or tasks as well as requests to collaborate on nested studies. It also provides guidance on intellectual property rights and matters relating to authorship and publication.

#### **Sharing with established repositories**

Imaging, genetic and epigenetic data will be made available through repositories: BRAINS and NCBI Gene Expression Omnibus GEO<sup>1,2</sup>. Requests for access should be made directly to the appropriate repository. Terms and conditions of access on which the data are accessible as set out by these repositories will apply.

#### **Process for data, stimuli or tasks request**

TEBC has a data dictionary (available at [www.tebc.ed.ac.uk](http://www.tebc.ed.ac.uk)) to assist applicants to discern whether the data types, stimuli or tasks they wish to use are present. Availability of data types for sharing will be dependent on planned TEBC analyses having taken place. All requests for access to data, stimuli or tasks should be made using the 'Data Access Request Form' (also available on the study website) and submitted to the Study Co-ordinator. Acceptance of the terms and conditions set out in the aforementioned should be signed by the principal applicant. Applicants should include the proposed study title, contact details for the principal applicant as well as other named researchers, funding status, provisional author list, a brief rationale for the study, data types, stimuli or tasks requested and the journal(s) being considered for publication. All proposals will be reviewed by the TEBC Study Management Group (SMG). Applications will be authorised (or not) within two months of receipt of application, although data retrieval may take longer depending on the nature of the request. All applications will be reviewed using standardised criteria: scientific

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<sup>1</sup> Job DE, Dickie DA, Rodriguez D, et al. A brain imaging repository of normal structural MRI across the life course: Brain Images of Normal Subjects (BRAINS). *NeuroImage*. 2016 Jan 18.

<sup>2</sup> Gene Expression Omnibus (<https://www.ncbi.nlm.nih.gov/geo/> accessed 30/05/2017)

justification of the research plan; readiness of TEBC data for sharing; and evidence of resource and capacity to analyse the data. If access is refused, feedback will be provided. The decision of the TEBC SMG is final and no appeal will be entered into. If access is granted, the data should be used only for the purposes detailed in the application however, requests for permission to make a minor amendment to the purposes set out in the application may be made directly to the SMG. All other requests should be submitted in a fresh application. Approved requests will be conducted in collaboration with appropriate members of the TEBC study team. For data requests from outside the University of Edinburgh, data will be released upon receipt of the Data Access Agreement.

### **Process for collaboration request**

Requests to develop a research proposal working with the TEBC to run a 'nested study' should be made using the 'Data Access Request Form' and submitted to the Study Co-ordinator. Applicants should include the proposed study title, contact details for the principal applicant as well as other named researchers, a scientific outline of the proposed study, and evidence of funding and capacity to deliver the proposed work. TEBC is a longitudinal study and as such, any requests to run a nested study will be considered in the context of the need to maintain the integrity of TEBC data. Governance of a nested study will be the responsibility of the applicant Principal Investigator where appropriate. Governance approvals must be in place prior to final approval by the TEBC Study Management Group. The TEBC Chief Investigator will be responsible for the design, conduct and governance of the TEBC platform study. The Data Access Agreement must be signed and returned before release of data.

### **Derived data and new data**

Applicants must notify the Chief Investigator of any potential errors discovered while using TEBC data. If derived data or new data are generated (e.g. new variables), these should be lodged with the main TEBC database at the end of the project time or at any time requested by TEBC Chief Investigator. Derived and new data will remain the property of the TEBC (University of Edinburgh) unless otherwise agreed and will be subject to this data access policy. The applicant must provide sufficient data about the new variables to allow future analyses. No investigator will have access to new data produced by an applicant without their prior knowledge and opportunity to comment on appropriateness. Applicants will be offered opportunity to be involved in future work that uses their variables. The TEBC Chief Investigator will adjudicate any irreconcilable differences between investigators with reference to the TEBC Scientific Advisory Board if necessary. The Data Access agreement must be signed and returned before release of data.

## Intellectual Property (IP)

IP derived from the TEBC study is owned by the University of Edinburgh. Division of IP will be considered where collaborators have made a particular contribution, however this must be considered and agreed before collaboration begins.

## Publications

TEBC should be acknowledged in any presentations or publications using the data. It should be easily identified (including in electronic searches).

For abstracts, posters and slides, TEBC must be cited as the source of the data [insert protocol paper reference] and include the project webpage ([www.tebc.ed.ac.uk](http://www.tebc.ed.ac.uk)).

A study protocol has been published and should be referred to in all methods sections (or equivalent).<sup>3</sup> Authorship of papers should follow standard practice according to the recommendations of the International Committee of Medical Journal Editors<sup>4</sup>. All manuscripts should include TEBC individual authors the identity of whom will be decided on a case by case basis: draft manuscripts that include data from TEBC should be sent to TEBC Study Management Group to decide authorship. TEBC investigators who meet authorship criteria will be included in the manuscript author list. Manuscripts should also contain an acknowledgement of the contribution of TEBC participants ('Results were obtained using data made available from the Theirworld Edinburgh Birth Cohort Study [insert protocol paper reference]. We are grateful to the families who participate in the Theirworld Edinburgh Birth Cohort study.'). Two weeks before anticipated submission of a manuscript or abstract, applicants should send a copy to TEBC SMG to ensure the TEBC is correctly described, authorship is agreed, and for correction of any factual errors. Applicants must notify the TEBC co-author when a manuscript is accepted by forwarding the acceptance email and a copy of the accepted manuscript. All press releases on research arising from the study must be approved by the TEBC Chief Investigator or University of Edinburgh press office.

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<sup>3</sup> Boardman JP, Hall J, Thrippleton MJ, et al. Impact of preterm birth on brain development and long-term outcome: protocol for a cohort study in Scotland. *BMJ Open* 2020;10:e035854. doi:10.1136/bmjopen-2019-035854

<sup>4</sup> Defining the Role of Authors and Contributors, International Committee of Medical Journal Editors (<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>) accessed 11/09/2017).