BIS Governance Policy

Last updated July 2024

Background

The Barwon Infant Study (BIS) is a collaborative project involving the Murdoch Children's Research Institute (MCRI), Barwon Health (Barwon), and Deakin University (Deakin).

MCRI, Deakin and Barwon have entered into a Collaborative Framework Agreement that sets out the terms and conditions of their collaboration on the BIS, as well as the terms and conditions upon which access to BIS data and/or BIS biospecimens will be granted. MCRI, Deakin and Barwon have agreed that MCRI will act as the lead party in the establishment and maintenance of collaborations with third parties wishing to access and use the BIS data and/or BIS biospecimens. Decisions regarding access to BIS data and BIS biological specimens will be determined by the BIS Steering Committee, as set out in this Policy. If access to BIS data and/or BIS biological specimens is granted by the BIS Steering Committee, the party requesting access to BIS data and/or BIS biological specimens will enter into an agreement with MCRI (on behalf of the BIS Partnership and in accordance with the terms of the Collaborative Framework Agreement.

The purpose of the BIS Governance Policy is to facilitate effective and harmonious collaboration so that Murdoch Children's Research Institute (MCRI), Deakin University (Deakin) and Barwon Health (Barwon) (together, we) and other parties can maximise the value of the BIS and any related project.

The BIS Steering Committee

The role of the BIS Steering Committee will be to provide leadership for and supervision of the BIS program and its investigators. In the future the BIS Steering Committee may create (a) Publications and (b) Biospecimens Access subcommittees. For the time being, however, these functions will be performed by the Steering Committee Itself.

Responsibilities

The responsibilities of the BIS Steering Committee include:

- Reviewing the strategic direction of the BIS;
- Monitoring the performance of BIS;
- Monitoring BIS collaborations and ensuring they are properly managed;
- Supervising the structure of the BIS and review of nominations of collaborators and investigators;
- Monitoring the financial status of the BIS;
- Evaluating and approving applications to access BIS data;
- Approving and monitoring applications to access BIS biospecimens;
- Keeping a record of any project using BIS data and/or BIS biospecimens as notified by MCRI, Deakin or Barwon or one of their investigators, including a copy of the BIS Material Transfer Agreement that has been entered into between MCRI and a third-party collaborator;
- Overseeing and approving scientific reports; Approving and monitoring non-scientific reports.
- Overseeing the regular reporting of study progress and related matters,including ethical issues
- Obtaining funding and other support for BIS projects and core operations.
- Representing the BIS Steering Committee in research collaborations with third parties. This includes a responsibility for guiding collaborators through the BIS governance process; ensuring BIS data and samples are appropriately managed; that the BIS Steering Committee has an opportunity to contribute to manuscripts arisng from the collaboration; and reporting on the progress of the Collaboration to the BIS Steering Committee.
- Mentoring and training early career researchers working within the BIS program.
- Exercising leadership within their area of expertise.
- Contributing annually to the content of the BIS Investigator Meeting in their area of expertise.
- Providing the study participants and general community with updates on BIS within their area of expertise.

Composition and appointments

The composition of the Steering Committee will be reviewed annually to ensure an adequate mix of skills, expertise and experience. All parties must be represented by at least 2 members of the Steering Committee. All new members must be nominated by a Steering Committee member and shall be elected by majority vote of the Steering Committee. Circumstances permitting, members of the BIS Steering Committee are required to attend at least 4 of the 6 Steering Committee meetings per year; and 4 of the 6 Investigator Meetings per year.

The current BIS Steering Committee members, and their areas of particular responsibilty are:

- Peter Vuillermin: Co-Principal Investigator; microbiome, allergy and asthma; clinical phenotyping; the Barwon context
- Anne-Louise Ponsonby: Co-Principal Investigator; data management and epidemiology; environmental chemicals; neurodevelopment
- Mimi Tang: immunology and allergic disease.
- Richard Saffery: molecular biology, genetics, epigenetics and future 'omics
- Fiona Collier: immunology; biobanking and basic science
- Sarath Ranganathan: lung function and respiratory health
- David Burgner: cardiometabolic outcomes, infections and inflammation
- Peter Sly: lung function and respiratorty health; environmental chemicals
- Len Harrison: microbiome and immunology
- Toby Mansell: molecular biology and data science
- Martin O'Hely: data management; bioinformatics and biostatistics; student and early career researcher training

Decision-making mechanism

In general, decisions can be made if:

i. at least four members of the Steering Committee are present at an advertised meeting, and
ii. consensus has been achieved, and
iii. there have been no objections lodged by those members who were unable to attend within 10 working days of minutes being circulated

However, input from all members of the Steering Committee will be required if:

i. there are dissenting views, or
ii. any member states that they believe the decision in question requires specific input from the full committee.

If the Steering Committee deems it necessary they may seek independent professional advice to resolve a disagreement.

Where the Steering Committee accepts a request for accessing BIS data and/or BIS biological specimens, it must inform MCRI legal (legal@mcri.edu.au) so that MCRI can prepare the appropriate agreement (if applicable) as per the terms of the Collaborative Framework Agreement.

Meetings

The Steering Committee shall meet every 2 months. Meetings may be conducted face-to-face, via teleconference, or video conference or other appropriate means.

Documentation relevant to upcoming meetings will be posted by Barwon on the BIS Website (www.barwoninfantstudy.org.au) a minimum of seven days prior to the upcoming Steering Committee meeting. Steering Committee members will receive an email reminding them of the upcoming meeting and they will then be responsible for reviewing the relevant information on the Website. Steering Committee members will receive a copy of the minutes within 5 working days of the preceding meeting. They will then have 10 working days to acknowledge that they have received and reviewed the minutes and to lodge any objections. In general these objections will be discussed at the next meeting rather than via email.

Steering Committee Performance
The Steering Committee members will complete a self-assessment annually to review the performance of the current members of the Steering Committee and the effectiveness of the governance structure.

Conflicts of Interest
Steering Committee members are expected to avoid any action, position or interest that may conflict with an interest of the BIS and its collaborators. Any conflicts of interest must be declared and documented.

The BIS Investigator Group
The BIS Investigator Group is composed of researchers who have made a substantial and ongoing contribution to the development and implementation of the BIS. The membership of the Investigator Team will be determined by the Steering Committee and will be reviewed at least annually. In addition to the Steering Committee members, the current members of the BIS Investigator Group differ by content area. The full membership of BIS Investigator Team is available at www.barwoninfantstudy.org.au

The BIS Investigator Group meets monthly. This is a BIS Steering Committee meeting or a BIS Investigator meeting on alternate months.

Data and biological specimens access policy
All hard copy data from the BIS are stored in a locked facility in the Child Health Research Unit, at Barwon. A digital copy of all data from the BIS will be maintained at MCRI under the stewardship of the BIS Steering Committee.

All biospecimens from the BIS will be stored in the Barwon Biomedical Research (BBR) laboratory at Barwon. Aliquots of the specimens will be forwarded to collaborating laboratories subject to approval by the BIS Steering Committee.

Requests to access BIS data and/or BIS biospecimens must be lodged on the BIS Website as a 'New Concept'. The New Concept will then be considered at the subsequent BIS Steering Committee Meeting. Each new BIS Concept will have an identified lead steering committee member who will coordinate with the third party with regard to BIS Concept formulation and submission. Once approved, this Steering Committee member will also oversee the executon and completion of the BIS concept.

Data or Materials Transfer Agreements
Where MCRI, Deakin or Barwon wishes to use the BIS data and/or BIS biospecimens, they must lodge a request to the BIS Steering Committee for approval. After the request is approved, MCRI, Deakin or Barwon can use the BIS data and/or BIS biospecimens in accordance with the terms of the Collaborative Framework Agreement entered between them.

Where an external party requests access to the BIS data and/or BIS biospecimens, they must lodge a request to the BIS Steering Committee for approval. Such request must be lodged through the identified lead BIS Investigator Team member. After the request is approved, the external party will be sent a BIS Reasearch Collborative Agreement in the form of a Material Transfer Agreement and/or or Data Sharing Agreement as required, substantially in a form agreed by Deakin, MCRI and Barwon in the Collaborative Framework Agreement between them. It is expected the external party will interact with the nominated liaison BIS Steering Committee member at least every six months and provide updates on project progress.

Publications

Abstracts & Posters
Authors are required to circulate abstracts to the BIS Steering Committee 7 days prior to submission to provide an opportunity to contribute and/or raise concerns. The authorship list should be determined by the lead authors on the basis of contribution. The circulating email should state that the author list on the abstract will not restrict the authorship list on the resulting paper. The abstract authorship list must include 'the BIS Investigator Group'.

A number of students (at the level of PhD and 4th year Honours) make a substantial contribution to the BIS and where possible and appropriate they will be considered for inclusion as authors on publications.

Manuscripts

A Proposed Manuscript Application must be submitted to the BIS Steering Committee Website seven days prior to the upcoming Steering Committee Meeting. The application will be required to indicate:

i. Working title
ii. Whether this is a re-submission
iii. Initial working group
iv. Research questions that are being addressed
v. The specific BIS data to be included
vi. The specific BIS biospecimens used
vii. Outcome and explanatory variables to be used in the analysis
viii. Overview of analysis and statistical methods to be used

The Proposed Manuscript Application will be listed and accessible on the BIS website, available only to the BIS Steering Committee, for a period of seven days before the upcoming Steering Committee Meeting. The website will generate an email notifying the BIS Investigator Team that a manuscript proposal has been logged. Members of the BIS Investigator Team may comment or contribute to discussions regarding the manuscript via the website.

At the BIS Investigator Team Meeting, the Steering Committee will determine whether the Proposed Manuscript Application is:

i. Approved – the authors may proceed as planned
ii. Approved subject to amendment – the amended abstract must be reviewed by a nominated member (or members) of the Steering Committee prior to submission.
iii. Requiring significant amendment – requires re-submission to the BIS Website and review at the next Investigator Meeting.

The outcome of this process, and where appropriate the final version of the Proposed Manuscript Application, will be posted on the Website.

Following approval of a Proposed Manuscript Application the authors will have a period of 12 months to post a draft of the manuscript on the BIS Website for review by the Steering Committee. Authors may apply for an extension of this period.

The authors leading the manuscript development are encouraged to circulate the manuscript at an early stage and facilitate contributions from the broader team. For example, a meeting/teleconference should be arranged once the Results section is largely completed. A draft of the manuscript must be circulated to the BIS Steering Committee prior to insertion of an authorship list, to allow an opportunity to contribution. The authors leading the manuscript will take responsibility for determining the final authorship list and whether a manuscript is ready for journal submission. Individually named authorship will be determined in accordance with the Vancouver guidelines on authorship[1]. Members of the BIS Steering Committee who do not meet criteria for individually named authorship will be listed following the statemnt ‘the other BIS Investigator Group are:’, unless they opt-out. If disputes arise regarding the content of the paper or the composition of the authorship team the manuscript must be approved for submission at a BIS Steering Committee Meeting prior to submission.

Prior to submission of the paper to a journal or any other external use of the research results (e.g. patent applications, conference presentation, discussion with third parties), the authors leading the manuscript or generating the newly derived measures or notes on the newly derived measures are responsible to provide to the current BIS Data Manager with all related cleaning do-files or other coding and derived variables or other created data or communications on the newly derived data , expedited as needed by the nominated lead contact on the BIS Steering Committee for the project.

References

1. Uniform requirements for manuscripts submitted to biomedical journals. International Committee of Medical Journal Editors. *Ann Intern Med* 1997;126(1):36-47.

Abstract and journal article authorship template

Name*, name*, name*, on behalf of the Barwon Infant Study1,2,3,4,5,6

The Murdoch Children's Research Institute, Melbourne, Australia
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Department of Respiratory Medicine, Royal Children's Hospital, Melbourne, Australia
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The full authorship of this manuscript includes the following members of the Barwon Infant Study Investigator Team. The full membership of BIS Investigator team is available at www.barwoninfantstudy.org.au

Use of name or logo

Authors may not use the name or other indicia (including without limitation, logos) of an institution without the prior written consent of that institution.

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