BIS concept template

Title

Date:

Investigators:

Lead investigator name:	
Lead investigator position:	
Lead investigator email:	
Lead investigator telephone (required):	
Lead applicant institution:	
Co-applicants: *Provide contact details for all external co-applicants. At least one BIS Steering Committee member must be included as an applicant or sponsor.*	

Background

Aims

Hypotheses

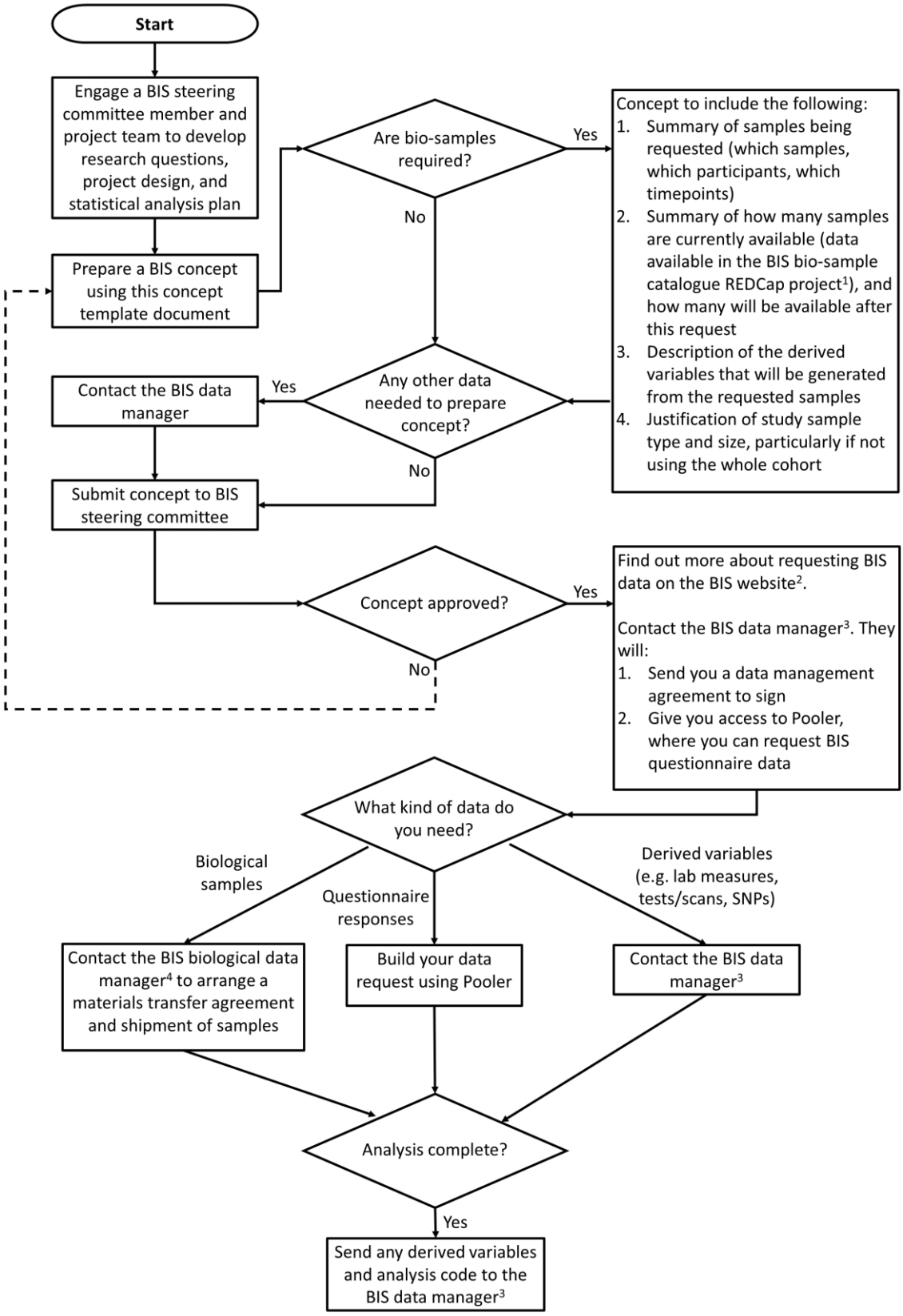
1.

Study population

BIS data to be used

- **<u>Statement of principles regarding sample/data access</u>**
  - Requests for BIS biospecimens for assay, platform, or method development or beta testing will generally not be appropriate.
  - Following approval of a project via a BIS Sample/Data Concept Form, the applicant will gain exclusive access to the requested sample type(s) for analyses in their field of research for 12 months. The purpose of this exclusivity period is to provide the applicant with sufficient time to produce and analyse the data in preparation for publication. After 12 months, the application should report on their progress to the BIS Steering Committee. The Steering Committee may choose to extend the period of exclusivity in order to achieve a publication.
- **<u>Statement of principles regarding sample/data access</u>**
  1. Applicants are recommended to develop research questions, a formal project design, and a statistical analysis plan before submitting the BIS Concept Biospecimen Form.
  2. Before completing the BIS Concept Biospecimen Form, applicants should contact the BIS Data Manager via email for a feasibility assessment according to sample/data availability. If further clarification is required, a member of the BIS Project Management Team or Steering Committee will contact the applicant.

Summary of the BIS data request/approval procedure



[1] **BIS website:** https://www.barwoninfantstudy.org.au/page.cfm?pageId=466
[2] **BIS bio-sample catalogue:** https://redcap.mcri.edu.au/redcap_v12.2.11/index.php?pid=11289
[3] **BIS data manager:** James Hedley (james.hedley@mcri.edu.au)
[4] **BIS biological data manager:** Luba Sominsky (luba.sominsky@deakin.edu.au)

Biological samples

Timelines:

Date samples/data required:	1/08/2021
Anticipated completion date of analysis:	1/12/2022

Funding status:

☐ **Funding secured** *Provide details of funding body, application ID, and amount available to proposed project including sample transport costs*	
☐ **Requesting access for funding application** *Provide details of funding body, application ID and budget requested for proposed project*	

Details of biological samples required

Which samples? (e.g., plasma, urine, breast milk)
How much of each sample? (e.g., microlitres, nanograms, number of aliquots)
Samples from mothers or children?
Which participants/how many participants? (e.g., random sub-cohort, N=? diagnosed with asthma)
Which timepoints? (e.g., antenatal, birth, 4 years)

Biological sample depletion

For each sample and each timepoint, please complete a table showing the distribution of sample availability currently, and after the requested samples have been provided. Data on current biological samples available can be accessed in the BIS bio-sample catalogue: https://redcap.mcri.edu.au/redcap_v12.2.11/index.php?pid=11289

Example table:

Genomic DNA - birth (cord blood)

	Available		After request	
Quantity (ng)	N	%	N	%
0				
0.1 - 49.9				
50 - 99.9				
100 - 149.9				
150 - 199.9				
200+				
Total	1074	100%	1074	100%

Who will undertake biospecimen measures? How will this be paid for or supported?

What data will be generated from the biospecimen use?

Statistical analysis plan
Please include power calculations for the actual number of participants for whom biological samples are available

Cost implications

References

Assurances:
In submitting this Sample/Data Access Concept Form, I/we agree to the following conditions:

- The samples/data requested will only be used for the purposes outlined herein. Any deviation from this proposal, including the stated timelines, must be agreed upon by the BIS Study Steering Committee.
- Samples should be stored under optimal conditions that will preserve viability. Care should also be taken during handling processes (for example, thawing and re-freezing) to minimise damaging the future integrity of the sample.
- Sample/data will not be passed on or shared with a third party unless agreed upon by the BIS Study Steering Committee.
- Electronic BIS data, or data generated from BIS materials, should be stored on restricted access, password-protected computer and should only be accessible by the approved individuals.
- Requested biospecimens will only be committed to established assays, platforms and/or methods and will not be used for developing novel or beta testing novel assays, platforms and/or methods unless agreed upon by the BIS Study Steering Committee.
- Newly derived variables generated on BIS data will be sent to BIS Steering Committee at 3-monthly intervals as they arise.
- Acquiring the relevant HREC/IRB approvals will be the responsibility of the applicant(s) and sample/data access will not be provided until this has been demonstrated to the BIS Study Steering Committee.
- By receiving samples/data, I/we acknowledge that we are bound by the BIS Study Publications Policy including providing appropriate acknowledgements of the BIS Study Team and its sources of funding. I/We will submit publications generated using BIS Study materials to the BIS Publications Committee for approval prior to journal submission.
- At the completion of the project any remaining biospecimens will be returned to the BIS Study biorepository.

Signature of lead investigator:	
Date:	