

Data Access Policy for “South Asia Biobank - UK Arm” dataset and samples

Project title: South Asia Biobank – UK arm (comprising LOLIPOP 2003, 2020 cohorts).

IRB approval: NRES Committee London – Fulham 07/H0712/150: 20/PR/0553

Version: 3.0

Contact email: lolipop@sabiobank.org

This document describes the data access policies for use of the population data and samples that is being jointly collected by researchers in the South Asia Biobank – UK arm (comprising LOLIPOP 2003, 2020 cohorts), sponsored by Imperial College London. These data and samples form the basis in UK for the **South Asia Biobank – UK arm**. The aim of these policies is to ensure that the data and samples are available and used for appropriate research.

All correspondence regarding data access, publications policy and IP should be channelled via the contact email provided above.

General principles for data access

1. All access to the data must be approved by **South Asia Biobank – UK arm**, based on an application made using the accompanying **Data Access Form**.
2. Since samples are a depletable resources, applications for samples will be expected to have a very strong justification.
3. The South Asia Biobank – UK arm will maintain an active registry of data access requests and monitor progress. A list of approved applications will be made available through the study website.
4. IRB approvals are in place to enable the data to be used for a wide range of biomedical research. In some circumstances, a new IRB approval may be needed to enable specific research to occur.
5. In the initial phase, there are no data access fees. In the future, the South Asia Biobank – UK arm may consider introducing reasonable data access fees to applicants (cost-recovery), to help ensure the sustainability of maintaining the data for use.
6. The South Asia Biobank – UK arm reserves the right to adapt these guidelines on a case-by-case basis, based on the specifics of the proposed data access request. The policies will also be updated periodically.
7. The South Asia Biobank – UK arm also reserves the right to block submission of manuscripts, and contact relevant journals to raise concerns, if non-compliance to these policies is discovered.

Responsibilities of Applicants

Applicants must submit a completed Data Access Form to the South Asia Biobank – UK arm via the contact email provided above. In doing so, the applicants named agree to the following terms and conditions:

1. The data provided must only be used by the applicants named on the proposal and their direct research teams at the named institutions, and only for the research described in the application. **Broader use, or onward sharing of data is not permitted.**

2. The data provided must be held securely and the data must be destroyed at the end of the study (or earlier if asked to do so by the South Asia Biobank – UK arm).
3. Applicants agree to make no attempt to re-identify individuals in the study.
4. Applicants will provide progress reports regularly to the South Asia Biobank – UK arm, or on request.
5. Applicants agree to return the complete results for any assays carried out on South Asia Biobank – UK arm samples, in such a way that advances can be built on by others. Results should be returned to the study database in a timely manner (on publication, or as directed by the South Asia Biobank – UK arm).
6. The data freeze used in manuscripts should be indicated.
7. Investigators must inform the South Asia Biobank – UK arm promptly of any Intellectual Property (IP) identified during the course of the research and respect the IP requirements of the South Asia Biobank – UK arm contract or any other research collaboration agreements in place with the applicants.
8. Applicants must submit all manuscripts that use the South Asia Biobank – UK arm data provided, to the South Asia Biobank – UK arm for approval of author arrangements and review of IP, at least 2 weeks prior to journal submission. This includes deposition of manuscripts in pre-publication archives (eg BioRxiv).
9. Applicants must also agree to any other conditions of use specified by the South Asia Biobank – UK arm.

¹ <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>

South Asia Biobank Data Access Form

Address for correspondence and submission of application forms:

lolipop@sabiobank.org

Data Access Committee, National Heart Lung Institute, Imperial College London, Norfolk Place, London W2.

For official use

Request received date:

Click or tap to enter a date.

Request number:

Section A: Main applicant details

A1. Full name:

A2. Designation:

A3. Department / organisation:

A4. Email address:

A5. Phone number:

A6. ORCID:

A7. Date of request: Click or tap to enter a date.

Section B: Details of request

B1. Title of research study:

B2. Proposed start date: Click or tap to enter a date.

B3. Proposed end date: Click or tap to enter a date.

B4. Co-investigators (data may only be used by investigators named and their direct research teams at the named institutions, add more lines if required)

	Investigator (name and email address)	Institution (name and address)
1		
2		
3		
4		
5		
6		
7		
8		

B5. Data access requested:

- De-identified individual level data, i.e. coded with surrogate identifiers in place of personally identifiable information
- Anonymised individual level data, i.e. data will not be linkable to the original dataset
- Aggregate data
- Other, please specify:

B6. Does this request relate to any previous request from the South Asia Biobank – UK arm?

- No, this is a first request/this has no connection with previous request(s).
- Yes. *Please state request form reference number and specify how they are related:*

B7. Data sources requested

Centres from which data is requested	Tick one only
<ul style="list-style-type: none"> • ALL UK CENTRES 	
<ul style="list-style-type: none"> • CENTRE SPECIFIC DATA 	
If centre specific data is requested, specify centres	

Brief justification for basis of selection.

B8. Data types requested

South Asia Biobank data variables requested	Tick one only
<ul style="list-style-type: none"> • ALL VARIABLES 	
<ul style="list-style-type: none"> • DOMAIN SPECIFIC VARIABLES 	

If specific variables are requested, specify domains	Tick all that apply
<ul style="list-style-type: none"> Demographic 	
<ul style="list-style-type: none"> Questionnaire 	
<ul style="list-style-type: none"> Anthropometry and blood pressure 	
<ul style="list-style-type: none"> 12 lead ECG 	
<ul style="list-style-type: none"> Retinal images 	
<ul style="list-style-type: none"> Biochemistry 	
<ul style="list-style-type: none"> Others (specify) 	
<p>Brief justification for basis of selection.</p>	
<p>B9. Samples requested</p>	
South Asia Biobank samples requested	Tick one only
<ul style="list-style-type: none"> No 	
<ul style="list-style-type: none"> Yes 	

Brief justification for basis

B10. Abstract (Lay Summary- this will be published on the South Asia Biobank – UK arm website) (~200 words)

B11. Hypothesis and Specific Aims (~200 words)

B12. Background (~500 words)**B13. Overview of study design (~500 words)**

B14. Data analysis plan (~500 words)**B15. Key references (up to 10)**

Section C: Acknowledgment by applicant

I confirm that the information provided above is true and accurate, and confirm that the investigators on this application agree to comply with and be bound by the following terms and conditions for use of the South Asia Biobank – UK arm data and / or samples:

- *We confirm that the data will only be used by the investigators listed in the application, and their direct research team at the named institutions, and only for the purpose described in this application.*
- *We agree: i. to ensure data are held securely, ii. to make no attempt to re-identify individuals in the study, iii. to return the full results of assays performed on South Asia Biobank – UK arm samples, iv. provide an annual report on study progress, and v. to destroy the data at the end of the study, or when asked to do so by the South Asia Biobank – UK arm.*
- *We agree to include South Asia Biobank – UK arm investigators as co-authors, and/or a “South Asia Biobank – UK arm Consortium” author block in all publications and presentation, as appropriate to scientific contributions.*
- *We agree to recognize the roles of the funders, South Asia Biobank – UK arm investigators and partner organisations in the acknowledgements section of manuscripts using wording provided by the South Asia Biobank – UK arm, and to indicate the South Asia Biobank data freeze used in the manuscript.*
- *We agree to inform the South Asia Biobank – UK arm on any intellectual property generated as a result of the use of South Asia Biobank – UK arm data and samples, and to work with the South Asia Biobank – UK arm to protect the intellectual property in keeping with the framework described in the relevant RCA.*
- *We agree to provide a copy of all manuscripts to the South Asia Biobank – UK arm for review, **prior to submission**. This will include evaluation for authorship arrangements and intellectual property.*
- *If we substantially change the proposed use of the data (eg change in analysis theme, change in lead or senior authors), we agree to submit a new data access form.*
- *We agree to have our data request listed on a public web-site.*
- *We agree to respect any specific requests made by the South Asia Biobank – UK arm in relation to this application.*

Signature of Lead applicant, on behalf of all the named investigators & Date

Signature of Requestor’s line manager & Date

Signature of Institution Representative & Date

In situations where non-compliance to these policies are discovered, the South Asia Biobank – UK arm reserves the right to block submission of manuscripts, and may consider contacting relevant journals to raise concerns.