

## **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:** 2.0

**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 channeled 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. At this stage of our programme, we will prioritise applications from **working groups** within the **South Asia Biobank – UK arm**, to enable them to complete research expected by the study funders.
3. Applications for data / samples are expected to include **South Asia Biobank – UK arm** investigators to ensure equity, inclusivity, and appropriate interpretation / reporting of the dataset.
4. Publications and presentations arising from the work should include **South Asia Biobank – UK arm** investigators as co-authors in a manner that reflects the scale and complexity of the data and must also recognize the contributions of the funders and partner organisations. Presentations should include approved study, funder and institutional logos (available from the South Asia Biobank – UK arm).
5. Since samples are a depletable resources, applications for samples will be expected to have a very strong justification.
6. 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.
7. 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.
8. 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.
9. 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.

10. 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. South Asia Biobank – UK arm investigators with significant contributions to the generation or analysis of the dataset should be included as co-authors on publications and presentations, in line with international guidance.<sup>1</sup> An additional South Asia Biobank – UK arm consortium author block may also be appropriate.
7. Presentations should include approved study, funder and institutional logos. Applicants must also appropriately acknowledge the contributions of the funders (including NIHR, WT), South Asia Biobank – UK arm investigators and the partner organisations involved in all grants, publications and presentations. Contact the South Asia Biobank – UK arm for the approved presentation templates and ‘acknowledgments’ text.
8. The data freeze used in manuscripts should be indicated.
9. 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.
10. 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).
11. Applicants must also agree to any other conditions of use specified by the South Asia Biobank – UK arm.

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<sup>1</sup> <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](mailto: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
• All UK CENTRES	
• CENTRE SPECIFIC DATA	
<b>If centre specific data is requested, specify centres</b>	

Brief justification for basis of selection.

**B8. Data types requested**

South Asia Biobank data variables requested	Tick one only
• ALL VARIABLES	
• DOMAIN SPECIFIC VARIABLES	

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

• Serum	
• Citrate plasma	
• EDTA plasma	
• Packed red cells	
• Urine	

Brief justification for basis of selection.

**B10. South Asia Biobank – UK arm Working group alignment.**

**Which of the South Asia Biobank – UK arm working groups does this application align to?**

<i>Working Group</i>		<i>Tick all that apply</i>	<i>Discussed with WG leads?</i>
1	Epidemiology		Yes / No / NA
2	Risk stratification and biomarkers		Yes / No / NA
3	Molecular pathways		Yes / No / NA
4	Other (specify) _____		
5			
6			

**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)**

**B15. Research Collaboration Agreement (RCA)**

Investigators outside the South Asia Biobank – UK arm may need a separate RCA for use of the data / samples, and are advised to contact the DAC to discuss the need for an RCA as part of the process of preparing an application.

South Asia Biobank – UK arm master RCA	
Other RCA: Specify _____	
No RCA needed Justify _____	



## 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.***

## **SECTION D. South Asia Biobank: Data Access Form review**

### **D1. Application received**

Received date: Click or tap to enter a date.	Request number:
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### **D2. Administrative check complete**

Checked date: Click or tap to enter a date.	Completed by:
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### **D3. Applicant identities, institutions and email address verified**

Verified date: Click or tap to enter a date.	Verified by:
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### **D4. Reviewed by DAC**

Presented date: Click or tap to enter a date.	Presented by:
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### **D5. DAC committee members present**

Name:	Centre	Present at DAC
Jaspal S Kooner	Imperial College London	
Paul Elliott	Imperial College London	
Abbas Dehghan	Imperial College London	
Marc Chadaeu-Hyam	Imperial College London	
Shivani Misra	Imperial College London	
Angad S Kooner	Imperial College London	

### **D6. Summary of discussion**

D7. DAC committee members recommendations			
Name:	Approve	Reject	Comment
Jaspal S Kooner (Director)			
Paul Elliott			
Abbas Dehghan			
Marc Chadaeu-Hyam			
Shivani Misra			
Angad S Kooner			
D8. Decision and any limitations imposed on approval			
Application outcome:	Approve / Revise and resubmit / Reject		
<p>If approved, specify any restrictions on data or sample sharing (eg centre specific data not to be included in data release) and summarise justification for the restriction.</p>			
D9. Comments for co-author requirements			
D10. Additional comments or requirements for applicants from DAC			
D11. Draft of outcome circulated within DAC			

Circulation date: Click or tap to enter a date.	Circulated by:
<b>D12. Outcome above finalized by DAC</b>	
Final decision date: Click or tap to enter a date.	Recorded by:
<b>D13. Outcome communicated to applicant</b>	
Communication date: Click or tap to enter a date.	Communicated by:
<b>D14. Outcome passed to Data Management Team</b>	
DMT date: Click or tap to enter a date.	Communicated by:
<b>D15. Data shared by Data Management Team</b>	
DMT date: Click or tap to enter a date.	Released by:
<b>D16. Outcome passed to Sample Management Team</b>	
SMT date: Click or tap to enter a date.	Communicated by:
<b>D17. Samples shared by Data Management Team</b>	
SMT date: Click or tap to enter a date.	Released by:
<b>D18. Administrative comments</b>	