SingHealth Group

Title : **SingHealth Cluster Research Data Management Policy – PRISM Data Deposition Policy**	Initial Released: **26/04/2018**	Document Number: **SHS-RSH-OOR-CWP-204**	
Type: **Policy & Procedure**	Revision date: **-**	Revision No: **0**	Page: **1 of 7**

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HISTORY LOG

Revision Number	Details of Amendment	Date
0	Initial release	26/04/2018

1. PURPOSE

1.1 This policy should be read in conjunction with the SingHealth Cluster Research Data Management Policy – General Policy (SHS-RSH-OOR-CWP-202).

1.2 The purpose of this policy is to safeguard genomic data arising from the analysis of patients managed under the SingHealth Duke-NUS Academic Medical Centre (AMC) such that:

1.2.1 The genomic data is consolidated within SingHealth Duke-NUS where it can be safely archived on a long-term basis;
1.2.2 The genomic data is available within SingHealth Duke-NUS even after the principal investigator (PI) has left the institution;
1.2.3 The genomic data is subsequently made available for use by other investigators;
1.2.4 The genomic data is available should the need arise to check reproducibility of results.

1.3 SingHealth Duke-NUS Institute of Precision Medicine (PRISM) will act as the central data management resource for such SingHealth Duke-NUS related genomic data.

2. SCOPE

2.1 The scope encompasses the deposition of genomic data into PRISM, and access of these data by other investigators within or outside the AMC.

3. DEFINITION(S)

3.1 “Originating PIs” under PRISM’s policy refers to PIs whom through their research project had generated genomic data from patients managed by the AMC. These are also the same PIs whose names were submitted in the relevant projects’ applications to the Institutional Review Board for ethics review and approval.

3.2 “Originating Teams” refers to the research teams who are officially listed in the approved Institutional Review Board (IRB) application and had also generated genomic data from patients managed by the AMC.

3.3 "Applying Teams" refers to PIs and their team members who had not generate the genomic data and that they are applying to DACO for data access. They are applying to use the genomic data stored by the Originating PIs or Originating Teams with PRISM.

3.4 List of Acronyms

AMC	Academic Medical Centre
DACO	Data Access Committee
IRB	Institutional Review Board
PI	Principle Investigator
PRISM	Institute of Precision Medicine

4. REFERENCE(S)

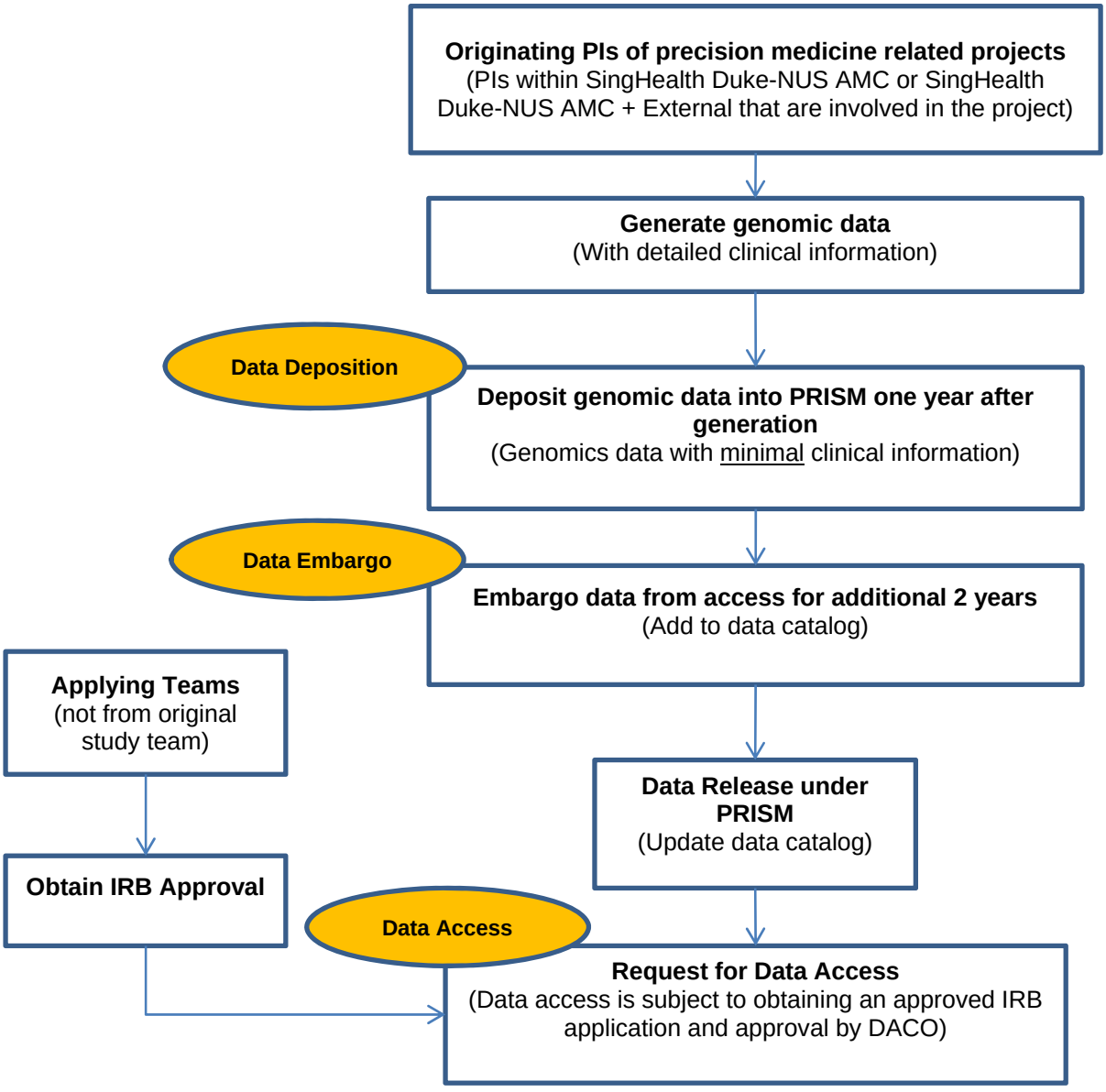
Document Number	Title of Document
SHS-RSH-OOR-CWP-202	SingHealth Cluster Research Data Management Policy – General Policy

5. RECORD(S)

Name of Record	Storage Location	Retention Period	Disposal
SingHealth Duke-NUS Genomic data	Password secured computer systems (PRISM premises)	Indefinitely	NA

6. PROCEDURE

6.1 Process on deposition, embargo and access of genomic data



7. GUIDELINES

7.1 Data Deposition

7.1.1 Only human nucleic sequences need to be deposited at PRISM.

7.1.2 A copy of the genomic data with minimal clinical information should be deposited into PRISM one-year after data generation.

7.1.3 Genomic data deposited in PRISM will be treated as de-identified data, stored under password secured computer systems that is controlled by PRISM administrator.

7.1.4 All new genomic data from patients managed under the AMC generated by ongoing or new projects must be deposited into PRISM. PRISM will reserve the right to require selected sets of genomic data generated from past projects to be deposited with PRISM based on its relevance, significance or strategic nature.

7.1.5 PRISM will only request minimal clinical information (i.e. age, race, sex and broad diagnosis) from the Originating PIs. PRISM may also request technical details of the genomic data such as type of DNA sequencer, configuration of sequencing (e.g. single end vs paired end), sequence read length etc.

7.1.6 Genomic data should be archived in either “fastq” or “bam” format, which are international standards for storing raw nucleic acid data. Researchers are encouraged to submit “vcf” format data (where available) which refers to sequence data that has been processed.

7.1.7 Each data set deposited into PRISM will be associated with names, departments and institutions of the Originating PIs from the original study to recognise them as the original data generators.

7.2 Data Embargo

7.2.1 After deposition, access to the genomic data will be embargoed for another two (2) years. This means Investigators (not involved in the original study) will not be able to access these data for a total of three (3) years. This is to grant Originating PIs a total lead time of three (3) years to have sole access to the data for publishing their findings.

7.2.2 During the embargo period, Originating PIs are free to maintain their own copy of the genomic data for further research or to share with their collaborators.

7.2.3 DACO will inform the original PIS and will keep a webpage with information on projects/PIs that have been granted access.

7.3 Data Embargo Exemptions

7.3.1 Originating PIs may apply to the DACO for a shorter or longer embargo period.

7.3.2 Originating PIs are not allowed to request for new embargo period to be put in place after the first embargo period has lapsed.

7.3.3 DACO will review these requests on a case-by-case basis.

7.4 Data Access

7.4.1 DACO[1] will only consider requests for data access that have obtained IRB approval.

7.4.2 Originating Teams can have access to the original data.

7.4.3 External parties outside the AMC, who are not private companies, are required to obtain IRB approval and sign a non-disclosure agreement before seeking approval from DACO to access the genomic data. External parties having access to genomic data are required to abide by any existing SingHealth data sharing policy.

7.4.4 Requests from private companies for access to genomic data will be considered on a case-by-case basis but will have to comply with applicable legislations and SingHealth intellectual property policies.

7.4.5 DACO will aim to provide a timely response to all applicants on the outcome of the latters' applications.

7.4.6 All projects that have been granted data access will be listed on the PRISM website for transparency purposes.

7.5 Usage of Genomics Data

7.5.1 Data users must acknowledge the Originating PIs in any related publication by listing each individual's name, department and institution.

7.6 Ownership of Genomics Data

7.6.1 If any SingHealth institution (be it SGH, NCCS, etc) undertakes a research collaboration with a local academic partner (e.g. an A*STAR RI), the foreground data associated with the collaboration will be owned as outlined in the Singapore Master Research Collaboration Agreement. When the collaboration reaches the point of publication, the joint publication could be reviewed by both parties, and one party can request to remove any confidential or proprietary information. However, neither party acting solely can prevent publication. If there are discussions regarding commercialization of the data, both collaborating parties must be informed and joint profit sharing agreed upon.

7.6.2 Transmission of research data back to patients is not warranted.

[1] In the event that there is appeal to the decision made by the Data Management Committee, the appeal will be raised to Group Chief Executive Officer and Deputy Group Chief Executive Officer (Research & Education) for resolution.

7.6.3 If the original PI leaves the Institution, first rights or any rights to publish should pass on to the institution as the original PI contributed to the research work on behalf of the institution.

8. ANNEXES

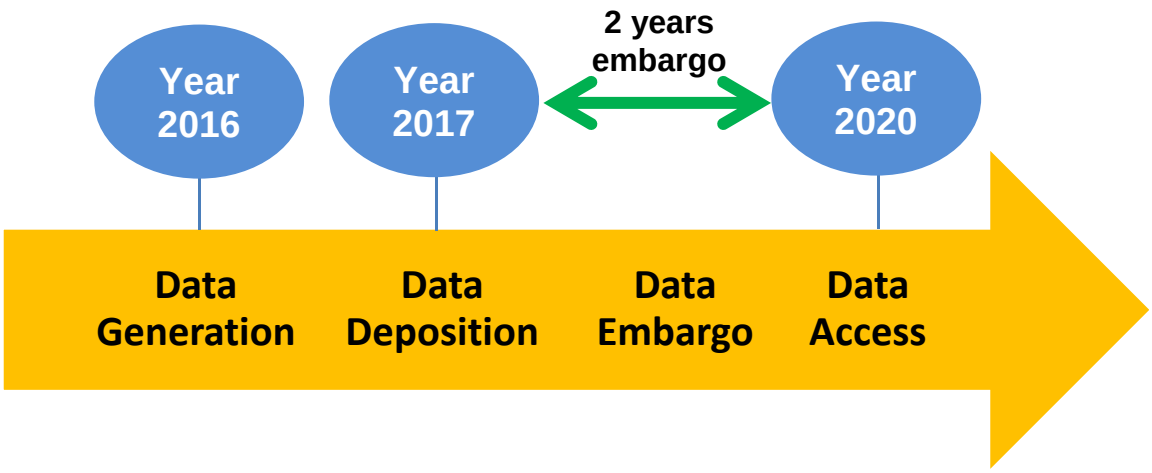
Annex A: Timeline on deposition, embargo and access of genomics research data
Annex B: Roles and responsibilities of DACO

9. SPECIAL INSTRUCTIONS

Nil

Annex A

Timeline on deposition, embargo and access of genomic data
(For illustration purposes only)



Annex B

DATA ACCESS COMMITTEE (DACO)
Composition, Roles and Responsibilities

1. Composition of DACO

1.1. DACO will comprise of members from SingHealth Duke-NUS AMC. The composition of DACO is as follows:
- 1.1.1. A Chairman
- 1.1.2. Three members. Of which, one member should represent the community and/or patient
- 1.1.3. A Clinician Scientist

2. Roles and Responsibilities of DACO

2.1. Reporting to PRISM Director, DACO has the following roles and responsibilities:
- 2.1.1. Review all applications within 15 working days
- 2.1.2. Facilitate high quality research
- 2.1.3. Ensure protection of personal data from participant subjects

3. Frequency of DACO Meetings

3.1. DACO will hold monthly meetings

3.2. In order to expedite the reviewing process DACO may decide to discuss requests for data access through teleconference, or via email.

4. Review of DACO's Roles and Responsibilities

4.1. PRISM shall review DACO's roles and responsibilities annually or where situations necessitate a review.