Biorepository Facility **Translational Health Science and Technology Institute** **Faridabad, Haryana, India** **Standard Operating Procedure** **Title: Biospecimen and associated data access and sharing procedure for the study "Inter-Institutional Program for Maternal, Neonatal and Infant sciences: A translational approach-interdisciplinary Group for Advanced Research on BirtH outcome-DBT India Initiative (GARBH-Ini)".**	**SOP No: BRF/MCH/SOP/002** **Version No: 1.0** **Issue date:** 15 Jul 2019 **Effective date:** 22 Jul 2019/ Jul 2021 **Next review date:** 15 Jul 2021/ Jul 2024 **Page 1 of 16**

Amendment sheet

Sl. No.	Page No.	Section/ Clause No.	Date	Nature of amendment	Authorization

	Prepared by	Reviewed by	Approved by
Signature	SD	SD	SD
Name	Dr. Savita Singh	Dr. Pallavi Kshetrapal	Dr. Shinjini Bhatnagar
Designation	Junior Research Scientist	Faculty In-charge	Program Coordinator
Date	10 Jul 2019	12 Jul 2019	15 Jul 2019

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1. Introduction

As a part of the study "Inter-Institutional Program for Maternal, Neonatal and Infant sciences: A translational approach- interdisciplinary Group for Advanced Research on BirtH outcome-DBT India Initiative (GARBH-Ini)", the interdisciplinary group for GARBH-Ini pregnancy cohort was established in May 2015 at the Civil hospital in Gurugram (GCH), Haryana, India to understand the multifactorial causes for preterm birth. A highly standardized infrastructure was established at the clinical sites (GCH as the primary clinical site and Safdarjung Hospital as the referral hospital) including a research laboratory at the district hospital.

Primary objective of the program is to predict & diagnose preterm birth (PTB) by increasing the understanding of the underlying pathophysiological mechanisms, which would facilitate use of existing or novel therapeutic agents & appropriate timing of clinical intervention. It is envisaged that the clinically relevant research outputs from the study will be appropriate characterization of biological, clinical and epidemiological risk factors to achieve appropriate risk stratification of mothers who may deliver before term.

2. Purpose

The overall aim of this SOP is to define the bioresource access and sharing policy under the study "Inter-Institutional Program for Maternal, Neonatal and Infant sciences: A translational

approach- interdisciplinary Group for Advanced Research on BirtH outcome- DBT India Initiative".

3. Scope

3.1. This document aims to:

3.2.1. Outline the procedures for biospecimen/ data access request and sharing

3.2.2. Define the governance of the biospecimen/ data access

3.2.3. Define the roles and responsibilities involved in this process

4. Definitions

4.1. **Sample/Data Sharing:** This encompasses samples/data release and transfer to institutional or external applicants.

4.2. **Access Committee:** A designated Access Committee, to evaluate the application for request of the samples/data on the basis of its scientific merit, feasibility and usefulness in terms of public health importance.

4.3. **Institutional Biosafety Committee:** This Committee shall be constituted by all institutions handling hazardous samples and/or GE organisms.

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4.4. **Institutional Ethics Committee** shall mean the Ethics Committee of the hospitals from where the biospecimen are being collected from enrolled consented participants and that of institutes where the biorepository is hosted.

4.5. **ISBER:** ISBER is a global biobanking organization.

5. Abbreviations

5.1. GARBH-Ini: **G**roup for **A**dvanced **R**esearch on **B**irt**H** outcome- DBT **In**dia **I**nitiative

5.2. BMaD: Biological Material and Associated Data

5.3. IBSC: Institutional Biosafety Committee

5.4. IEC: Institutional Ethics Committee

5.5. IP: Intellectual Property

5.6. PMC: Program Management Committee

5.7. PI: Principal Investigator

5.8. LOI: Letter of Intent

5.9. GE: Genetically Engineered

5.10. CAPA: Corrective and Preventive Actions

5.11. GLP: Good Laboratory Practices

5.12. GCLP: Good Clinical Laboratory Practices

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6. Responsibility

6.1. **Executive Director**

6.1.1. Executes to oversee the functioning of the facility through the biorepository team.

6.1.2. Ensures management and sustainability planning, access and governance of biorepository.

6.2. **Project Coordinator- GARBH-Ini**

6.2.1. Approval on the access form in case the sample/ data access is approved by PMC and steering committee for that respective application.

6.3. **Program Management Committee and Steering Committee**

6.3.1. Reviews the request received to access the sample and associated data for sub-studies utilizing samples from the pregnancy cohort.

6.3.2. Approve/ reject the requests.

6.4. **Biorepository faculty In-charge**

6.4.1. Ensures the implementation of biospecimen/ data sharing, governance and SOPs of the biorepository.

6.4.2. Coordinates with the PMC & Steering Committee for the review process of samples requested for sub-studies utilizing samples from the pregnancy cohort.

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6.4.3. Responsible for management, troubleshooting and smooth running of the biorepository processes.

6.5. **Junior Research Scientist**

6.5.1. Is the lead contact for biorepository access requests and shipping.

6.5.2. Facilitates the Biorepository Faculty In-charge in discussions with PIs requesting samples prior to sample/ data access and the PMC review process for sample requested for conducting sub-studies utilizing samples from the pregnancy cohort.

6.5.3. Reviews the SOP/s

6.5.4. Trains the personnel in the laboratory for this document with the Quality Control Manager.

6.5.5. Ensures that all the personnel (existing or newly recruited) in the laboratory have received the document training for implementation of the SOP and reassesses that all job descriptions defined per personnel are being followed.

6.5.6. Ensures compliance of all the points mentioned in the SOP including the quality control.

6.5.7. Assists in recording the minutes of the PMC and Steering Committee and circulation.

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6.6. **Quality Control Manager**

6.6.1. Ensures training of the laboratory staff and compliance with the current version of the SOP.

6.6.2. Facilitates the implementation of SOP.

6.6.3. Ensures filling of protocol deviations if any and associated CAPA.

6.6.4. Reviews and suggests amendments in the SOP as and when required.

6.7. **Data Management team**

6.7.1. Extraction and documentation of clinical and all meta data and responsible for secure transfer of data, as required.

6.7.2. Responsible for the dashboard of the pregnancy study.

6.8.**Technical Officer**

6.8.1. Checking the availability of the requested samples.

6.8.2. Retrieval of the biospecimen from the respective location/ deep freezer upon availability

6.9.**Technical Assistant/ Technicians**

6.9.1. Retrieval of biospecimen collected from study participants, as per the study SOPs.

6.9.2. Day to day management and inventory of maintenance activities at the biorepository.

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7. Safety

7.1. Wear proper personal protection equipment like gloves, mask etc. as required while receiving/transporting the samples.

7.2. All healthcare providers, research personnel, and technicians should be trained in GLP and GCLP. They need to follow universal safety precautions when handling biological or hazardous materials and when performing any of the procedures described in this SOP.

7.3. All healthcare providers, research personnel, and technicians should be trained in SOP titled "Procedure for Receiving, Accessioning, Barcoding and Archival of varied biospecimen at their optimal temperature for their long-term storage" (BRF/TEC/SOP/011).

7.4. All documents (forms, approvals, minutes etc.) to be filed, scanned and uploaded on hard drive/ institutional server.

7.5. All data should be stored in a manner so that they are safe, away from destructive natural forces of air, water, fire and rodents. They should also be easily retrievable.

7.6. All hard copies of forms and formats are properly placed in closed cabinets with limited access to authorized biorepository personnel only.

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8. Material and equipment

S.No	Description of consumables and reagents	Make (same or equivalent)	Catalogue No.
1	Personal Protective Equipment including shoe covers, gloves (nitrile or equivalent), appropriate PPE (head gear; protective goggles; masks)	---------	---------
2.	Squeeze and spray bottles with 70% ethanol		
3.	Computer system/ Laptop	Dell/Lenovo /Acer	--------
4.	Scanner	Datalogic QuickScan Lite	---------
5.	Cryo gloves	Cryo-Protection	DW-LWS-008

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9. Procedure

9.1. **Process to access the biospecimen stored in the BRF for meeting the requirements of GARBH-Ini study objectives.**

9.1.1. Submission of duly filled biorepository access form should also be submitted to the Biorepository in charge at (biorepository@thsti.res.in).

9.1.2. Biospecimen availability detail is prepared by the technical team and the proposal is presented to the Program Management Committee (PMC) and Steering Committee of the GARBH-Ini study group.

9.1.3. For approved objectives of the study that are funded under the study, are discussed at the Program Management Committee (PMC) and Steering Committee of the GARBH-Ini study group meetings, no further approvals are required.

9.1.4. Following the approval of the request, an approval email is sent to the project PI requesting the samples and the sample details received from the data management team are directed to the technical team for retrieval.

9.1.5. Ethics Committee approval documents from individual institutes (from where the study proposal is applied) and from THSTI are sought, i.e. a blanket approval for the GARBH-Ini study and filed appropriately.

9.1.6. Institutional Bio Safety Committee (IBSC) certificate should also be obtained from the institute where the research work will be carried out and are filed appropriately before the release of the biospecimen.

9.1.7. The biospecimen release from the bio-repository is performed, subject to all the above-mentioned approvals including the IEC and IBSC documents and a scanned copy of the same are submitted to the Biorepository In-charge at the (biorepository@thsti.res.in).

9.2. **Process to access the Biospecimen stored in the Biorepository Facility for sub-studies**

9.2.1. **To access the biospecimen stored at the Biorepository Facility for Sub-studies in the pregnancy cohort the below mentioned steps need to be followed:**

9.2.1.1. Submission of the duly filled forms to the biorepository at (biorepository@thsti.res.in).

9.2.1.1.1. THSTI Biorepository Sample Access Form

9.2.1.1.2. Letter of Intent (Two Pages)

9.2.1.2. Biospecimen availability details is prepared by the technical team and the proposal is presented to the Program Management Committee (PMC).

9.2.1.3. Study Program Management Committee (PMC) of the GARBH-Ini study group peer reviews the proposal and may send it out to domain experts if required. There after these proposals will also be sent via e-mail correspondence to the Steering

Committee members of the GARBH-Ini study group or presented to them at the Steering Committee meeting if there is one being organized soon.

9.2.1.4. Both the Committees hold the discretion of approving or disapproving the study proposals judging them on the criteria of novelty of the question asked for further development on the area of the maternal and child health and the expected outcomes.

9.2.1.5. After the approvals from the PMC and Steering Committee of the GARBH -Ini study group, Ethics Committee approval from individual institutes (from where the study proposal is applied)

9.2.1.6. Institutional Bio Safety Committee (IBSC) should be obtained from the institute where the research work will be carried out.

9.2.1.7. The biospecimen will be released from the bio-repository subject to all the above-mentioned approvals, a scanned copy of the same needs to be submitted to Biorepository in charge at (biorepository@thsti.res.in).

9.2.1.8. The biospecimen when received by the individual principal investigators (PI/s) will be scanned into the retrieval screen of the LMS software at the time of retrieval and a Biorepository sample retrieval form (hard copy) needs to be signed and filed along

with the list of enrolment IDs in the study specific Sample Retrieval and Access File maintained at the Biorepository Facility.

9.3. **Distribution/ release of biospecimen and associated data**

9.3.1. **General requirement**

9.3.1.1. Release of biospecimen and associated data will be subject to the approval as stated above.

9.3.1.2. Once the approvals are obtained, scanned copies of all the supporting documents need to be submitted by the requesting investigators to biorepository at (biorepository@thsti.res.in).

9.3.1.3. The biospecimen will be released from the biorepository subjected to all mentioned approvals.

9.3.1.4. The transport/ shipping of the biospecimen (Blood, Serum, Plasma, DNA etc.) should be transported as UN3373, "Biological Substance Category B".

9.3.1.5. The shipment of Bioresource will be done as per IATA guidelines. (https://www.iata.org/contentassets/b08040a138dc4442a4f066e6fb99fe2a/dgr-62-en-pi650.pdf).

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9.4. **Biospecimen/ data receipt and progress reporting**

9.4.1. Applicants should acknowledge receipt of biospecimen/data and report immediately if there are any problems with the data/ biospecimen (appropriate forms will be provided for feedback).

9.4.2. Onward sharing of data/ residual samples is not permitted, interested investigators will have to submit fresh applications to the biorepository.

10. Validity Statement

10.1. This document is valid for two years from the effective date.

11. References

11.1. National Data Sharing and Accessibility Policy 2012

11.2. ICMR Guidelines 2017

11.3. Institutional Repository of the Garbh-ini cohort (IRGC), Rakshita/DBT/PBC/PTB Version 1.0, July 2, 2018, DATA/SAMPLE SHARING POLICY GUIDELINES

11.4. ISBER Best Practices

11.5. Authorship Policy, Authorship Policy for the Garbh-ini – Interdisciplinary Group for Advanced Research on BirtH outcomes-DBT INdia Initiative

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12. Appendices

12.1. Bio-Repository Access Form for GARBH-Ini Cohort

12.2. Format for LOI submission

12.3. Bio-Repository Sample Retrieval Form

12.4. Bio-repository Sample Reposition/Return Form

12.5. Shipment/receiving form for GARBH-Ini Cohort

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