

Laboratory Use of Banked Samples and Data Obstetrics and Gynecology Research Network

Background

The Department of Obstetrics and Gynecology conducts research through an administrative group called the Obstetrics and Gynecology Research Network (OGRN). The OGRN team manages research operations for faculty, fellows, and other research staff within the Department.

Laboratory space is available for all researchers within the department. This laboratory contains equipment and personnel to assist with processing and storage of samples used for research. This is located on the 3rd floor of MREB on the School of Medicine Campus.

Samples that are stored for unspecified future research will be maintained and shared using the process outlined below. This process is set up to provide appropriate controls that will ensure the protection of our research participants and protection of the intellectual property of the samples being stored.

The Laboratory Manager is available to assist investigators with storage, documentation, and acquisition of samples. The Associate Director of Research for OGRN will also be available in the event the Laboratory Manager is not available.

Definitions:

Administrative Director – Individual member of the OB/GYN department who is responsible for the overall operations of the Department of Obstetrics and Gynecology.

Associate Director of Research – Individual member of OGRN that oversees the overall operations.

Contributing Investigator – Faculty member, fellow, resident or staff member of OB/GYN that contributes samples through IRB-approved protocols for use of samples in future research.

Investigator – Faculty member, fellow, resident, or staff member of OB/GYN that initiates research and proposes the use of samples and/or data from the bank.

Laboratory Manager – Individual member of OGRN that oversees the operations of the research laboratory. This individual is the primary contact for use and storage of specimens and data.

Obstetrics and Gynecology Research Network (OGRN) – Department of Obstetrics and Gynecology unit that provides (but is not limited to) research infrastructure in pre-award operations, post-award and accounting management, human resource expertise, and compliance.

Vice-Chair for Research – Individual faculty member who is responsible for the administrative function of the OGRN.

Submitting Samples

Before samples are stored, the Contributing Investigator must provide documentation that the study is approved for storage of future research. This documentation will be confirmed with an IRB approval letter and a copy of the approved informed consent document.

If the consent document has the option for participation for future research, storage of the sample must first be confirmed using the signed consent document. This will ensure that samples or data is not stored without permission from the participant.

Some studies require that the sample be completely de-identified or give the participant the option to allow future research with coded samples. The participant's option will be confirmed prior to storing a sample.

No samples or data will be stored for future research without confirmation of IRB approval and consent for their use.

Laboratory Processing and Systems

The Laboratory Manager will work directly with the Contributing Investigator and/or staff to identify what elements can/should be entered into the database, confirm how samples are to be stored, and provide barcode labels.

All of the Biobank freezers are wired into a Sensaphone alarm system which notifies the Lab Manager 24/7/365 if there is a change in freezer temperature within 10 degrees of normal. In addition to the alarm system, all of the freezers are plugged into outlets with generator backup power.

Confidentiality of Samples and Data

Only those that have been authorized by the Department will have access to the laboratory space, database and samples.

Samples will be identified using a bar code system, without any direct identifiers on the label. The code can be matched to a master list that is accessible to the Laboratory Manager, Principal Investigator, and delegated research staff.

For studies where complete de-identification is done, the samples will be stripped of any identifiable information and no link will be kept to identify it to a particular participant.

Laboratory databases are protected by University firewall and Information Technology (IT) policies. Only those that are authorized to access the data will be given unique passwords. Back-up systems are in place through the University IT policies.

Data released to Investigators or research staff will be released per the IRB approved protocol that will be utilizing the samples. The protocol will be reviewed to verify datapoints that are requested from the Laboratory database.

Requesting Samples

Once an Investigator has identified a study and needs to utilize the samples for analyses, the Laboratory Manager must be contacted for access and distribution. The Investigator will be asked to complete a request form. This form will be routed through

the Laboratory Manager, to the Contributing Investigator, and OGRN Administration to verify that data and/or samples can be released.

No samples will be released to an investigator without IRB approval of the project. The protocol will be reviewed to ensure that samples are released according to the process approved by the IRB.

Samples will be released per the Investigator's approved protocol (e.g., de-identified, coded, etc.).

The handling of the samples is the responsibility of the Investigator once they are released from the Laboratory Manager.

Any unused portions of the samples used for a particular project need to be returned to the Laboratory Manager. These will be stored for other projects in the future.

Sharing Samples for Research

If an Investigator identifies a collaborator at an external institution for research purposes, samples must be requested from the Laboratory Manager using the request form.

Before these samples are released/shipped to that institution, the following must be documented.

- IRB approval with receiving institution clearly noted in the protocol
- Material Transfer Agreement (MTA) with the correct institution

If an Investigator requests to send samples to a laboratory that is completing the analysis as a fee-for-service/commercial purpose, a Service Agreement must be on file prior to releasing the samples.

Since samples are collected for the OGRN sample and data bank from multiple studies and/or Investigators, the Laboratory Manager will contact the Contributing Investigator(s) for approval prior to release of any samples or information.

For samples that are shared between departments at the University of Utah, an Interdepartmental Agreement should be on file.

Tracking of Samples

Biospecimen information is tracked using either REDCap (a secure, web-based application for database management) or the itBioPath database designed and supported by the Huntsman Cancer Institute Informatics group. This includes sample location, type of specimen, volume, barcode identifier, and any other information required for a particular sample.

Ownership of Samples

As a condition of employment and/or volunteer faculty appointment (if applicable) and as a condition of the use of University of Utah ("University") resources, the University owns all title and rights to any and all work product or other property created or developed by anyone employed by the University, including without limitation, all (1) research samples, tissue, fluid, cells, or other biological material; (2) cell lines; (3) research data and records; and (4) intellectual property relating to or derived from any research, or any research samples, cell lines, data, or other sources. This does not apply to copyrights or

other work product which may be retained by an Investigator under applicable University policies.

In the event that an Investigator leaves the University of Utah, any samples or data stored will only be transferred to an external facility/investigator after approval and appropriate agreement(s) are obtained from the following:

- University of Utah Institutional Review Board
- Department Chair
- Vice Chair of Research
- University of Utah Technology and Venture Commercialization Office (TVC)

If a new University of Utah Investigator is not identified by the Investigator to assume the oversight of samples stored in the Laboratory, the Department Chair and/or Vice Chair of Research will determine who will be responsible for further oversight. Investigator will be determined by the Department Chair and/or Vice Chair of Research.

Results to Participants and Sharing of Benefits

Since this bank is meant for research purposes, there will most likely be no results shared with participants. However, the protocol that the Investigator submits for IRB approval will outline any process for sharing results and/or benefits, if it is deemed appropriate for that particular study. Those processes will be handled through the Investigator and his/her research staff. The Laboratory Manager will only be involved if contact information is required. The IRB application will be reviewed to ensure that the protocol submitted by the Investigator outlines the release of any information directly to participants.

Governance and Oversight

The data and tissue bank will be primarily overseen through the OGRN. The Associate Director will report to the Administrative Director of OB/GYN and/or the Vice-Chair for Research. Any issues that need to be addressed regarding laboratory processes or policies will be discussed with OGRN Administration and appropriate actions taken.

The IRB will approve all research prior to the conduct of research, either by Contributing Investigators or Investigators.

Any adverse events and/or unanticipated problems will be reviewed and reported to the IRB per University policy.

Forms

1. Request for Use of Samples