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## **2.0. ORGANIZATIONAL STRUCTURE AND FUNCTIONS**

### **2.1. REPOSITORY ADMINISTRATION AT THE UNIVERSITY OF MICHIGAN**

#### **2.1.1. Purpose and Activities**

Primary responsibility for Repository administration and management is located at the University of Michigan (UM), although no specimens are stored there (see 2.6 Repository Physical Facilities). At UM, current Repository PI Siobán Harlow, Co-I Daniel McConnell, Repository manager Steffenie Merillat, administrator Charlotte Carlson, and web developer Robin Wylie work together, along with an analyst as needed for sample design strategies, to provide ethical and productive stewardship for Repository resources. The UM team is specifically responsible for:

- Securing and administering fiscal resources for the Repository;
- Overseeing the physical storage (subcontracted to Precision Bioservices) and inventory database system (subcontracted to IMS, Inc.);
- Managing all activities related to the selection, distribution, and recovery of resources, including Material Transfer and Data Transfer Agreements (MTA, DTA) including data recovery;
- Managing the Repository and its resources in an ethical manner consistent with Institutional Review Board and NIH data-sharing and resource distribution requirements;

- Assuring activities are consistent with repository best practices (codified by the International Society of Biological and Experimental Repositories (ISBER));
- Administering the online inquiry and application submission and review process;
- Optimizing accessibility to resources for the applicant including making data resources available in user-friendly formats and preparing documentation;
- Promoting awareness about Repository resources in the scientific community; and
- Interfacing with the SWAN Coordinating Center (CC), the SWAN Steering Committee (SC) and the NIA.

The SWAN Repository has an effective collaborative structure that actively interfaces with the SWAN CC and Steering Committee (SC) and the CLASS Lab. The inter-linked administrative infrastructure ensures smooth Repository functioning while providing the platform for formation of a SWAN Legacy Organization. SWAN CC staff and SWAN investigators serve on the key operational and advisory bodies of the Repository.

#### 2.1.2. Key Personnel & Contact Information, UM Repository Team

**Siobán D. Harlow, PhD**

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*Director, Center for Midlife Science (CMS)*  
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**Daniel S. McConnell, PhD**

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*Director, CLASS LAB*  
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## **2.2. THE SWAN REPOSITORY ORGANIZATION (SRO)**

### **2.2.1. SRO Purpose and Activities**

The SWAN Repository Organization (SRO) is a committee which provides oversight and guidance on Repository ethical and operational issues and reviews all applications for Repository resources. The SRO is responsible for three major activities:

- Performing the initial review and approval of Repository applications, specifically reviewing proposals for: sample size and adequate power; negotiating reasonable sample requests with respect to number and volume of samples to ensure lowest necessary impact on inventory, especially to scarce samples; ensuring acceptable lab procedures; and performing New Studies functions (checking for overlap).
- Monitoring Repository operations, reviewing quarterly reports from the Repository's physical facility (Precision Bioservices), and participating in the oversight and direction of activities such as inventory investigations, molecular work, aliquoting, and culling.
- Providing expertise and input to help shape Repository policies and procedures, including policies such as the cost-recovery program, data-sharing, value of specimens and

guidelines for approving release of high-value specimens, and promotional programs to increase utilization of Repository resources.

### 2.2.2. SRO Membership

The SRO is comprised of Repository investigators, SWAN investigators including the New Studies Chair and CC representatives and statisticians, outside experts in genetics and biobanking, and an NIA representative. The SRO meets at least quarterly by conference call.

Current SRO Members include:

Siobán Harlow, Repository PI, UM  
Daniel McConnell, Repository Co-I, CLASS laboratory, University of Michigan  
Steffenie Merillat, Repository Manager, UM, ex-officio  
Sybil Crawford, SWAN CC statistician, University of Massachusetts, Worcester  
Sherri-Ann Burnett-Bowie, SWAN New Studies Chair, Massachusetts General Hospital  
Deborah Martin, SWAN CC data coordinator  
Sharon Kardia, statistical geneticist, UM  
Janet Sinsheimer, statistical geneticist, University of California Los Angeles  
Elaine Gunter, biorepository consultant, Specimen Solutions, LLC  
Chhanda Dutta, SWAN Project Officer, NIA  
Maria Mori Brooks, SWAN CC PI and statistician, University of Pittsburgh, *ad hoc*

## 2.3. THE SWAN REPOSITORY ADVISORY GROUP (SRAG)

### 2.3.1. SRAG Purpose and Activities

The SWAN Repository Advisory Group (SRAG) is a committee which meets quarterly by conference call to provide recommendations on major policy issues and Repository direction, to review Repository applications requesting genetics specimens or any samples deemed rare or “reserved” (see section 7.1.3). SRAG members are also responsible for reviewing the quality of the science in any Repository application not receiving external peer review (i.e., through NIH). In the past, SRAG provided guidance in the development of the Repository DNA resources.

SRAG review is conducted when any of the following conditions are true of applications:

- Applications are requesting Genetic specimens;
- Applications are requesting Reserved specimens; or
- No scientific peer review will be done on the proposal.

### 2.3.2. SRAG Membership

The SRAG committee includes representative SWAN investigators; scientists outside of SWAN with expertise in epidemiology, genetics, geriatrics, and ethics; and Ad Hoc scientists for review of applications with subject areas outside the expertise of current SRAG members.

Current SRAG Members include:

Siobán Harlow, Repository PI, UM – ex-officio  
Gail Greendale, SWAN investigator and geriatrician, University of California Los Angeles  
Howard Kravitz, SWAN investigator, Rush University  
Ann Boyd, Ethicist, Hood College  
Jeffrey Williamson, geriatrician, Wake Forest Baptist Medical Center  
Sharon Kardia, statistical geneticist, UM  
Janet Sinsheimer, statistical geneticist, University of California Los Angeles

## **2.4. THE ROLE OF THE SWAN STEERING COMMITTEE (SC)**

The SWAN Steering Committee (SC) provides final approval on all applications for specimen release recommended through the Repository review process. The SC includes SWAN PIs from each clinical site. Approval is obtained after discussion on regular SC calls, as needed, and voting through email or a confidential online poll. Email communication with the SC goes through the SWAN Coordinating Center, typically Vicky Palombizio ([palombiziov@edc.pitt.edu](mailto:palombiziov@edc.pitt.edu)) and/or Joyce Monroe ([MonroeJ@edc.pitt.edu](mailto:MonroeJ@edc.pitt.edu)).

## **2.5. THE ROLE OF THE NATIONAL INSTITUTE OF AGING (NIA)**

NIA approval is required on all requests for Reserved and/or Restricted Repository samples. NIA approval comes from Chhanda Dutta ([DuttaC@nia.nih.gov](mailto:DuttaC@nia.nih.gov)), Program officer for the SWAN Repository, via email from Dr. Harlow, Repository PI.

## **2.6. REPOSITORY'S PHYSICAL FACILITY – PRECISION BIOSERVICES**

### **2.6.1. Purpose and Activities**

Physical specimen storage and maintenance of SWAN Repository specimens are contracted to Precision Bioservices (formerly SeraCare), located in Frederick, MD (<http://www.precisionbioservices.com/>).

Precision is responsible for the receipt of frozen specimens from clinical sites, completing thorough inventory processes, maintaining and documenting appropriate storage conditions (both mechanical and liquid nitrogen freezers), retrieving specimens for distribution based on specifications provided by the Repository, and shipping designated specimens as requested. Precision Bioservices Cell Biology division also performs specimen services such as aliquotting, immortalization of B-lymphocytes, and DNA extraction.

Precision Bioservices is accredited by the College of American Pathologists (CAP) Biorepository Accreditation Program (BAP) and is ISO9001 and ISO 13485 certified. Precision performs tasks under Standard Operating Procedures, and follows ISBER and NCI Best Practices for Biorepositories and applicable IATA shipping procedures.

The Precision Bioservices Standard Operating Procedures (SOPs) relevant to SWAN are listed in section 7.5.1.

## 2.6.2. Key Personnel & Contact Information

### **Precision Bioservices**

8425 Progress Drive  
Frederick, MD 21701  
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### **Deborah Phippard, PhD**

Sr. Vice President, Research  
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### **Misti Dowell**

Project Manager for SWAN  
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### **Teresa Pokladowski**

Marketing Manager  
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## 2.6.3. History and Changes of Physical Facilities since SWAN Study Inception

Transition from CLASS to McKesson: When the SWAN Study began collecting its baseline visit samples from participants in 1996, no physical facility was designated as a repository. Instead, clinic sites collected extra specimens with long term storage in mind and shipped them to SWAN's central laboratory, CLASS. The CLASS lab stored these samples until 2000, when the SWAN Repository was initialized and funded as a separate entity. This funding provided for the storage and maintenance of the SWAN Repository samples in a specialized biobank facility. Chosen for this role was McKesson Bioservices located in Rockville, MD. All samples designated as Repository samples were then shipped from the CLASS Lab at UM to McKesson in 2000.

Transition from McKesson to SeraCare: In 2005, at the time of the Repository's grant renewal, the subcontract for Repository storage services was re-bid and SeraCare Bioservices took over the task of housing SWAN Repository specimens. Samples were shipped by truck from McKesson to SeraCare in November, 2005. At the same time, new database structures were built to fit the specific needs of the SWAN Repository. Inventory Management Services, Inc. (IMS) provided this work (see section below).

NOTE: BBI=SeraCare=Precision. SeraCare Bioservices was named BBI Biotech at the time of the initial subcontract. Soon after, they were acquired and renamed SeraCare Life Sciences. Later in April, 2012, SeraCare Life Sciences was acquired by Linden, LLC and officially changed its name to Precision Bioservices in January 2013. (McKesson is now Fisher BioServices.)

## 2.7. INVENTORY MANAGEMENT SERVICES

### 2.7.1. IMS Purpose and Activities

The SWAN Repository subcontracts inventory management services to Information Management Services (IMS), who work closely with Precision Bioservices. IMS is responsible for building and maintaining databases and electronic resources necessary for tracking and managing the SWAN Repository specimen inventories. IMS is the developer of Biological Systems Inventory (BSI-II), one of the major repository inventory management and control systems which fully meet Federal IT requirements. IMS provides updated inventory files monthly, with an automated data transfer to UM occurring at the first of each month.

2.7.2. Key Personnel & Contact Information

**Information Management Services, Inc.**

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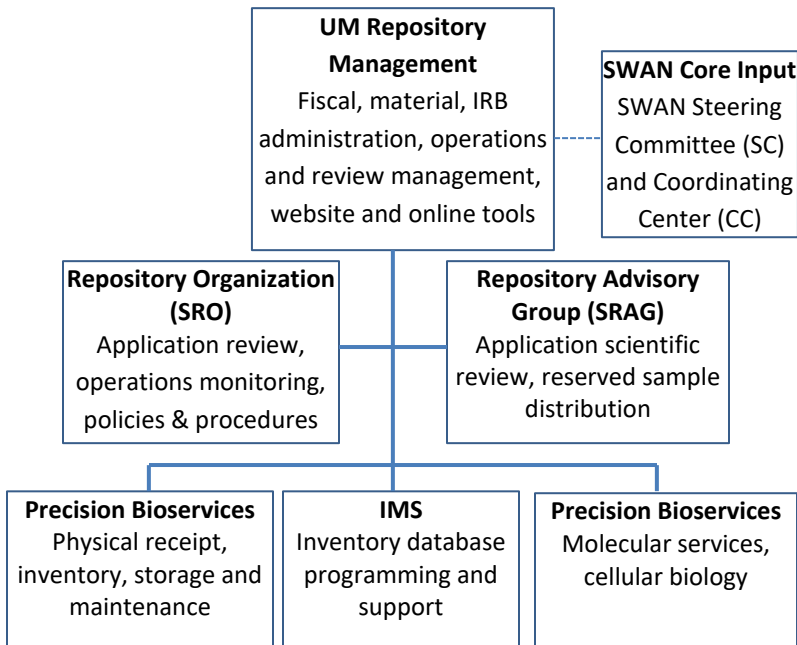
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2.8. DIAGRAM OF SWAN REPOSITORY ORGANIZATIONS AND FUNCTIONS



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