





# User's Guide

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## Table of Contents

Introduction to the AgingResearchBiobank	3
Chapter 1: Navigating the AgingResearchBiobank Website	4
1.1 OVERVIEW	4
1.2 HOME PAGE	4
1.3 MAIN MENU	5
1.3.1 REQUESTS	5
1.3.2 SUBMIT NEW COLLECTION	5
1.3.3 STUDIES	5
1.3.4 PUBLICATIONS	6
1.3.4 RESOURCES	6
Chapter 2: How to Create a Request for Materials (Data, Images, and/or Biospecimens)	8
2.1 OVERVIEW	8
2.2 DEFINITIONS	9
2.3 FINDING AVAILABLE ELEMENTS WITHIN A STUDY'S DATA PACKAGE	10
2.4 THE STUDY SEARCH PAGE	10
2.5 THE STUDY PAGE	11
2.5.1 STUDY DOCUMENTS	12
2.6 REGISTRATION	13
2.7 SUBMITTING A REQUEST	14
2.8 THE REQUEST FORM	14
2.8.1 REQUEST FOR MATERIALS FORM FIELDS AND FUNCTIONS	14
2.9 THE MY REQUESTS PAGE	18
2.10 REQUEST TABS	18
2.12 DATA and/or IMAGES REQUEST PROCESS	22
2.13 BIOSPECIMENS REQUEST PROCESS	23
2.13 AGREEMENT EXPIRATIONS AND RENEWALS	25

## Introduction to the AgingResearchBiobank

The National Institute on Aging (NIA) at the National Institutes of Health (NIH), U.S. Department of Health and Human Services (HHS), conducts and funds various longitudinal and clinical studies on aging that generate or have generated a collection of biospecimens and related phenotypic, clinical and imaging data. In 2018, the NIA's Division of Geriatrics and Clinical Gerontology established the AgingResearchBiobank to provide a state-of-the-art inventory system for the storage and distribution of these collections to the broader scientific community. Over the years, study collections have made significant contributions to public health and will continue to do so. The use of such collections will expand aging research to address new promising scientific questions targeting the development of prognostics, markers, and therapeutics for conditions aging-related and to provide a better understanding of the aging process. Collections included in the AgingResearchBiobank were built over many years from studies that carefully selected subjects and are available in a finite quantity. Each biospecimen is unique and cannot be replaced. Together with the opportunity to potentially pool data across study collections, significant increases in the value and power of future research findings can be attained from the resources offered by the AgingResearchBiobank.

More recently, the AgingResearchBiobank has introduced a collection of animal-derived materials originated from a study conducted in rats.

This User's Guide is intended to facilitate navigation through the AgingResearchBiobank Website by providing information on its different components.

### Chapter 1: Navigating the AgingResearchBiobank Website

#### **1.1 OVERVIEW**

This Chapter provides information on navigating the AgingResearchBiobank Website. Requesting materials through the website is covered in separate chapters for each request type. This section is focused on the layout and functionality of public areas of the site.

#### 1.2 HOME PAGE

The AgingResearchBiobank homepage, as seen in Figure 1.1 below, is a hub for information and accessing other sections of the AgingResearchBiobank Website.

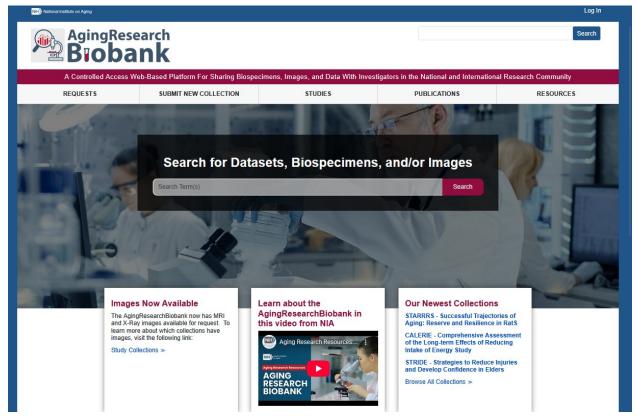


Figure 1.1 – The AgingResearchBiobank Homepage

The page has the following sections:

**Login** – A link to the registration system described in <u>Section 2.6</u> below. Registration is required to submit a request of any type. This is also accessible from any page via the button at the top right.

**AgingResearchBiobank Logo** – This logo can be used as a link back to the Home Page from anywhere in the site.

Main Menu – The main menu is described in Section 1.3 below.

**Search for Datasets, Biospecimens and/or Images**– A search box that will bring the user to the study search page discussed in <u>Section 2.4</u> below.

**Information Tiles** – These areas highlight recently added features, a video about the AgingResearchBiobank, Recently Added Collections, and Featured News.

Footer – Links to informational pages are located in the footer and available from anywhere in the site.

#### 1.3 MAIN MENU

The main menu is visible at the top of every page within the AgingResearchBiobank Website. It provides quick access to many of the website's pages from anywhere on the site. Each section is discussed below.

#### 1.3.1 REQUESTS

The Requests menu provides links to information about requests and direct links to request forms:

My Requests – A list of all requests submitted by the user

How to Make a Request – Contains information step-by-step on how to make a request

Request For Materials – Create a request for biospecimens, data, and/or images

Request Letter of Biospecimen Availability – Create a request for a letter of biospecimen availability

Approved Requests – A list of all requests for data, images, and/or biospecimens fulfilled by the Biobank

Costs – A list of the current fees charged for retrievel and shipment of requested specimens and data

Sample Material Transfer Agreement – An uneditable copy of a transfer agreement for information only

**Standard Acknowledgement** –Acknowledgement language to be included in all publications resulting from an approved request for materials from the AgingResearchBiobank

#### 1.3.2 SUBMIT NEW COLLECTION

**Submit Datasets** – Information on how to submit datasets from a study collection (NO biospecimens) for inclusion in the AgingResearchBiobank

**Submit Biospecimens and Datasets** – Information on how to submit a biospecimen and data collection for inclusion in the AgingResearchBiobank

#### **1.3.3 STUDIES**

**Currently Available Study Collections** (biospecomiens, phenotypic, clinical and/or imaging data) – Contains a list of study collections with resources and materials available for request

**Other NIA-Supported Studies** – Contains a list of other NIA-supported studies that may have their resources available from different repositories

#### 1.3.4 PUBLICATIONS

This menu contains links to the publication module, a page listing publications for each posted study collection. Selecting an individual study will subset the publications to those for that one study, and choosing All Publications lists all known publications. Each publication is also linked to PubMed. The publication module is shown in Figure 1.2 below.

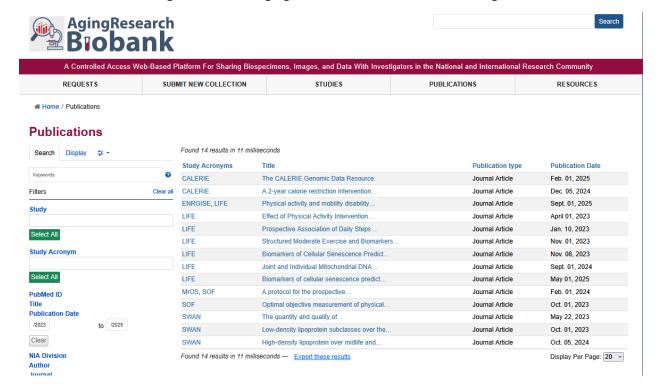


Figure 1.2 - The AgingResearchBiobank Publications Page

#### 1.3.4 RESOURCES

This menu item contains links to relevant information or documents that can assist users of the AgingResearchBiobank:

- Relevant Information to Help Investigators Develop Resources Management and Sharing Plans
   A list of links to reliable web resources and/or documents (policies, guidance, and others) to
   help investigators with information relevant for planning a study or preparing a study collection
   for deposit in a repository.
- **NIH Policies** A list of links to the NIH policies including Data Sharing and Security, which govern the AgingResearchBiobank
- **FAQ** A list of frequently asked questions and their answers about the AgingResearchBiobank and biobanking-related topics.

- **Glossary** A list of biobanking/biorepository-related terms
- New Study Collection Guide A guide to best practices when creating a biospecimen collection
- **Forms** A page containing helpful documents for submitting requests to the AgingResearchBiobank
- Common Data Elements (CDEs) A list of links to information about Common Data Elements that can be used by investigators who are building a data collection to make their data more sharable
- Other Resources A page containing links to other NIH repositories and informational sources related to the AgingResearchBiobank
- **Biobanking Information** A list of links to sites providing information on issues surrounding human research subjects and biobanking
- Contact Us Displays a form for submitting questions to the AgingResearchBiobank

# Chapter 2: How to Create a Request for Materials (Data, Images, and/or Biospecimens)

#### 2.1 OVERVIEW

**Currently Available Collections** Found 12 results in 5 milliseconds Study Acronym Study Type NIA Division Resources Available Human/Animal Conditions Keywords Comprehensive Assessment of the CALERIE Clinical Trial Clinical Trials Biospecimens, Study Datasets Gerontology Human Long-term.. Filters ENabling Reduction of low-Grade Clinical Trial Biospecimens, Study Datasets Human Geriatrics Study Name Study Acronym Clinical Trial Lifestyle Interventions and LIFE DGCG Biospecimens, Study Datasets Human Gerontology Last Updated Independence for. Study Type Epidemiology Multicenter Osteoarthritis Study Biospecimens, Study Datasets, NIA Division Conditions Study Period Osteoporotic Fractures in Men Study MrOS Epidemiology DGCG Biospecimens, Study Datasets Human Study Open Dates for Data Study Study Open Dates for Specimens Resources Available Study of Osteoporotic Fractures SOF Epidemiology DGCG Biospecimens, Study Datasets Human/Animal Study Add Additional Search Facets Study of Women's Health Across. Epidemiology Biospecimens, Study Datasets Human Study Successful Aging after Elective Surgery SAGES Fnidemiology Neuroscience Biospecimens, Study Datasets, Geriatrics Study Images Successful Aging after Elective Epidemiology Neuroscience Biospecimens, Study Datasets, Geriatrics Study Images

Figure 2.1 – Studies Available for Request

This Chapter provides information on the submission, review, and fulfillment of requests to access data, images and/or biospecimens via the AgingResearchBiobank Website. It describes the process by which investigators may identify the available data elements (including images) and biospecimens, and apply for access to these materials from NIA-funded clinical trials and longitudinal/observational studies, as well from animal study collections.

STARRRS

Model Systems

Clinical Trial

NIA

DGCG

Intramural

Images

Biospecimens, Study Datasets,

Biospecimens, Study Datasets

Display Per Page: 50 v

The process of applying for data, images, and/or biospecimens takes place over a period of time:

Successful Trajectories of Aging:

Found 12 results in 5 milliseconds — Export these results

Reserve.

- First, the requestor seeks out materials appropriate for his/her research and receives a statement on their availability from the AgingResearchBiobank.
- If the requestor has already obtained funding for the research proposal, AgingResearchBiobank Staff will verify the information and submit the request for review by the Biobank's scientific review committee(s) and/or specific data access committee, followed by recommendations by the committee(s) and subject to final approval by the NIA.
- If the requestor does not have yet the funding needed to complete an analysis of biospecimens, a <a href="Letter of Biospecimen Availability">Letter of Biospecimen Availability</a> may be requested from the Biobank to be included in any application for funding to use the Biobank's materials. Once the grant application is approved, the requestor should upload a copy of the approval to the Comments tab of his/her request to continue the request process. In this case, AgingResearchBiobank

Staff will then obtain additional information from the requestor and submit the request for review by the scientific and/or data access committee(s) and approval by the NIA's official with oversight of the Biobank's scientific and business operations.

#### 2.2 DEFINITIONS

- **AgingResearchBiobank Staff** Personnel at the contractor level responsible for the maintenance of the data repository and AgingResearchBiobank Website
- NIA Official with Oversight of the Biobank's Scientific and Business Operations NIA personnel responsible for the administrative and scientific oversight of the AgingResearchBiobank as a whole. The NIA official has expertise on biobanking and data issues, as well as on specific NIA-funded studies hosted by the AgingResearchBiobank.
- **Study Collection** A particular clinical trial, longitudinal/observational study, or animal study that has been funded by NIA and which has submitted materials to the AgingResearchBiobank.
- Requestor The user who submits a request to the AgingResearchBiobank Website. All requests to access materials (biospecimens, data, and/or images) or letters of availability MUST be submitted by a P.I./Senior Researcher who:
  - Is a permanent employee of their institution(s) at a level equivalent to, at a minimum, a tenure-track professor or senior researcher. This does not include lab technicians or trainees, e.g. post-docs or graduate students.
  - Has oversight responsibility for others named on the request who will be granted access to the data.
  - Is accountable for ensuring that all aspects of biospecimen, image, and/or data usage align with the terms of our outgoing human resources or data transfer agreements (OHRTA/OHDTA) and institutional policy.
- Principal Investigator (P.I.) The person responsible for oversight of a project involving materials requested from the AgingResearchBiobank. In legal documentation this person is also referred to as the "requestor" and must also be the requestor noted above. This person must sign a transfer agreement to obtain access to AgingResearchBiobank's biospecimens and/or data (including images). The requestor is generally the P.I. and leads the analysis.
- Institutional Review Board (IRB) A body that reviews proposed research to ensure ethical guidelines are followed. When referred to in the context of the AgingResearchBiobank, this is the body overseeing the research proposed by the requestor. It may be affiliated with the requestor's institution or may be an independent body. IRBs may grant approval of the research or determine that it does not involve human subjects, i.e. is not regulated. Equivalent international bodies (e.g. Research Ethics Boards) are also recognized by the NIA.
- Institutional Signing Official (SO) Also known as the authorized signatory. The individual, named by the applicant's organization, who is authorized to act for the requestor's institution and to assume the obligations imposed by Federal and state laws, regulations, requirements, and conditions that apply to grant applications or grant awards. This official is usually the Signing Official (SO) registered in the eRA Commons, i.e., holds the SO Role. This person must sign on behalf of the recipient institution for a transfer agreement to be valid.

Responsibilities of an SO may include:

- Submitting grant applications on behalf of the company, organization, institution, or Government.
- Signing grant applications and the required certifications and/or assurances necessary to fulfill the requirements of the application process.

#### 2.3 FINDING AVAILABLE ELEMENTS WITHIN A STUDY'S DATA PACKAGE

Prior to the submission of a request to the AgingResearchBiobank, investigators are encouraged to examine the study documentation and other information provided on the website. Each collection hosted by the AgingResearchBiobank has its own Study Page that includes information on the available biospecimen material types, documentation of the available data elements, information on imaging data, and an overview of the study's design, including the population and interventions involved in the parent study. Data documentation contains a listing of the available elements within the study's data package and guidance as to the organization of the data. Investigators should note that data are redacted to protect the privacy of research participants. Therefore, certain elements, e.g. geographic location, are not listed within the data documentation. Data not listed publicly is not available via the AgingResearchBiobank.

Figure 2.2 below shows the home page of the AgingResearchBiobank Website. The circles indicate the ways in which a user can access the list of available studies. The first is through the main menu, which provides a direct link to the study search page described in <a href="Section 2.4">Section 2.4</a> below. The second is the search input in the center of the page. This will bring a user to the same page while also applying the search term across all studies listed on the AgingResearchBiobank Website.

A Controlled Access Web-Based Platform For Sharing Biospecimens, Images, and Data With Investigators in the National and International Research Community

REQUESTS SUBMIT NEW COLLECTION STUDIES PUBLICATIONS RESOURCES

CURRENTLY AVAILABLE COLLECTIONS

OTHER NIA-SUPPORTED STUDIES

Search for Datasets, Biospecimens, and/or Images

Search Term(s)

Search

Figure 2.2 – Searching for Studies from the AgingResearchBiobank Homepage

#### 2.4 THE STUDY SEARCH PAGE

The study search page, as seen in Figure 2.3 below, is the interface through which a user can search for applicable studies with available materials. The search bar to the left of the page is used to search the study descriptions for the terms entered. The left side of the page contains a variety of filters that can be used to narrow down studies. When a filter is applied, the matching studies will be displayed within

the table on the center of the page. Clicking on the name of the study brings the user to the study page, described in <u>Section 2.5</u> below.

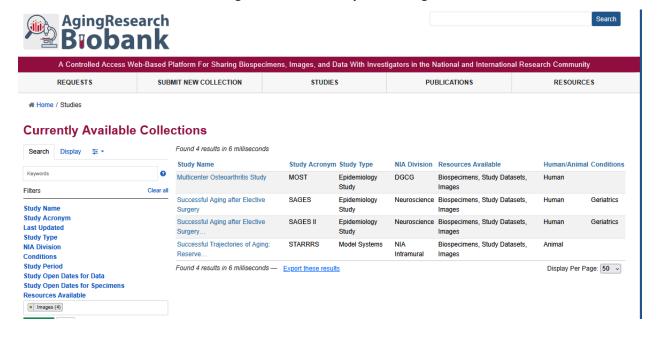


Figure 2.3 - The Study Search Page

#### 2.5 THE STUDY PAGE

As seen in the example in Figure 2.4 below, each requestable study within the AgingResearchBiobank has its own study page.

The study page contains several sections: What about the Study or Data Catalog info? Do requestors see it? If yes, we need to mention it.

- A summary of key facts about the study are found in the box at the top center of the page.
   These include the number of subjects included in the data, type of study, area of research, etc.
   Links to additional study-related websites, not maintained by the AgingResearchBiobank, are also posted here.
- A second box contains summarized information about the Informed Consents signed by the study participants, specifically any restrictions on secondary use of their data (including images) and biospecimens.
- A long form description of the study is found in the center of the page below the basic facts of the study. This describes the study's purpose, population, and design in greater depth. This section is divided into relevant subsections.
- To the right of the page is a button to submit a request for materials from this study. There are two options for most studies: Request for Materials (biospecimens, data, and/or images) and Request Letter of Biospecimen Availability. Requests for biospecimens or images are always accompanied by the related clinical data.
- Below the Request button, in a box labeled "Resources Available", is a description of the types of materials that can be requested.

- Below the "Resources Available" box is a box labeled "Materials Available". This box describes
  any biospecimens that may be available from the study.
- Below "Resources Available" is a box containing links to Study Documents. The available
  documents vary by study and several common types are described in <u>Section 2.5.1</u> below.

AgingResearch Search Web-Based Platform For Sharing Biospecimens, Images, and Data With Investigators in the National and International Research Community REQUESTS SUBMIT NEW COLLECTION STUDIES PUBLICATIONS RESOURCES # Home / Studies Request + MOST - Multicenter Osteoarthritis Study Resources Available Last Updated Study Period Epidemiology Study 11/3/2021 2003-2018 Biospecimens, Study Datasets, and Images NIA Division Number of Subjects Study Open Dates for Data Study Publications (146) DGCG 3,026 (Existing Cohort); 1,525 (New 9/30/2021 Materials Available Cohort) Buffy Coat Study Open Dates for Specimens Clinical Trials URL Primary Publication URL 9/30/2021 https://clinicaltrials.gov/ct2/show/ https:// DNA NCT03033238 pubmed.ncbi.nlm.nih.gov/23953 PAXgene Study Website Human/Animal https://most.ucsf.edu/ @ Human Study Consent Data/Specimen Use Restrictions Knee Radiographs Data: Some restrictions apply. Full Limb Radiographs Specimens: No commercial use and specimens are restricted by type of research Knee MRIs Genetic Use of Specimens Documents Yes, with restrictions Protocol pdf (PDF - 1.3 MB) Other Specific Restrictions Cycle1\_2\_3\_Measurement List.pdf (PDF - 238.4 KB) Materials from this study are not available for commercial use Cycle1 2 Measurements List .pdf (PDF - 328.8 KB) MOST\_IDISLegendV01235MIF.pdf (PDF - 755.8 KB) O4\_MOST BioAssays Tracking Log2023\_stand alone.pdf (PDF - 112.1 KB) MOST\_V79MIF\_IDISLegend.pdf (PDF - 442.0 KB) Objectives Data\_Dictionary.pdf (PDF - 6.3 MB) Little is known about the development of osteoarthritis or its progression and, currently, there are few strategies to prevent this condition and **■** Dataset Descriptions minimize disablement in those with existing knee osteoarthritis. The Multicenter Osteoarthritis Study (MOST) is the first large-scale ■ Forms epidemiologic study to focus on symptomatic osteoarthritis of the knee in a community-based sample of adults with or at high risk for knee Distributions osteoarthritis, based on the presence of knee symptoms, history of knee injury or surgery or being overweight. The main purpose of the study is to investigate the etiology of osteoarthritis and opportunities for prevention and treatment of knee osteoarthritis by evaluating ■ Manual\_of\_Procedures

Figure 2.4 – An Example Study Page

#### **2.5.1 STUDY DOCUMENTS**

Contained within the Study Documents box described above are links to download the documentation provided by the study to the AgingResearchBiobank. Documents provided by each study vary in name and content, but generally fall into the following categories:

**Data Dictionary** – A document listing the variable labels and descriptions. These are organized according to the datasets provided by the study.

potentially modifiable risk factors for disease and poor pain and physical function outcomes, including among those with early or mild knee

**Forms** – The forms used to generate portions of the data. Can be used in conjunction with the data dictionary to see the details of a particular variable's origin.

**Protocol** – A description of the study by the original investigators

**Manual of Procedures (MOP)** – Also called Manual of Operations (MOO) in some studies. This describes the study procedures in detail.

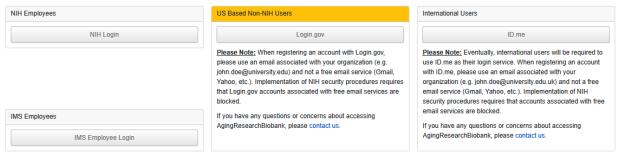
#### 2.6 REGISTRATION

Prior to submitting a request via either of the methods discussed below, a user must register an account on the AgingResearchBiobank Website. This can be done via the "Login" button at the top right of any page on the website. The Login page is shown in Figure 2.5 below.

Figure 2.5 – The Login and Registration Page

#### Log In

The services listed below allow logging into the AgingResearchBiobank. If you have credentials at one of the services, simply click the appropriate link and follow the instructions. If you do not have credentials at any of the services listed above, you can register for a new account using Login.gov (US) or ID.me (international) a. If you experience any issues logging in to your account, please email agingresearchbiobank@imsweb.com with your username and the email you used to register.



Please log out of the system if you expect to be inactive for 60 or more minutes.

#### Warning Notice for U.S. Government Systems

- This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes (1) this computer network, (2) all computers connected to this network, and (3) all devices and storage media attached to this network or to a computer on this network.
- This system is provided for Government-authorized use only.
- . Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties.
- Personal use of social media and networking sites on this system is limited as to not interfere with official work duties and is subject to monitoring.
- By using this system, you understand and consent to the following:
- The Government may monitor, record, and audit your system usage, including usage of personal devices and email systems for official duties or to conduct HHS business. Therefore, you have no
  reasonable expectation of privacy regarding any communication or data transiting or stored on this system. At any time, and for any lawful Government purpose, the government may monitor, intercept, and
  search and seize any communication or data transiting or stored on this system.
- Any communication or data transiting or stored on this system may be disclosed or used for any lawful Government purpose

There are two options for creating an account:

- NIH Staff can login using their existing credentials using their PIV card by clicking the upper leftmost button. When logging in for the first time via this method, users will be asked for some additional details.
- Users who are not NIH Staff should register via the Login.gov or ID.me options (Login.gov requires a U.S. state-issued ID; ID.me can be used by international users) by clicking the center or rightmost button. On-screen prompts will guide the user through registration.
   Documentation verifying your identity and e-mail confirmation is required to create an account. When registering an account, please use an email associated with your organization (e.g. john.doe@university.edu) DO NOT use free email services (Gmail, Yahoo, etc.). Implementation of NIH security procedures requires that accounts associated with free email services be blocked.

Note that only AgingResearchBiobank Website Staff use the button on the bottom left.

#### 2.7 SUBMITTING A REQUEST

A Request For Materials may be submitted in two ways. The first is via the Request button on the study page seen in Figure 2.4 above, and selecting the type of request, if multiple types are available. This brings up the request form and pre-selects the study from which the request was initiated.

The second way to submit a request is via the Request For Materials option from the Requests Menu. (See Figure 2.6) This brings up the request form with no study pre-selected. Note that you must be logged in to begin the process of submitting a request.

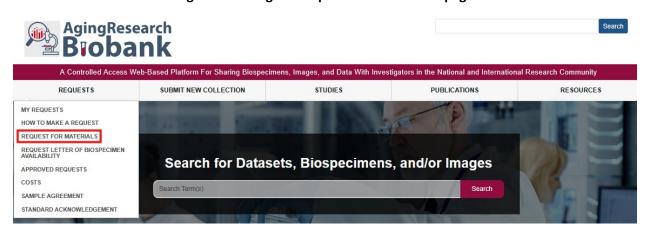


Figure 2.6 - Begin a Request from the Homepage

#### 2.8 THE REQUEST FORM

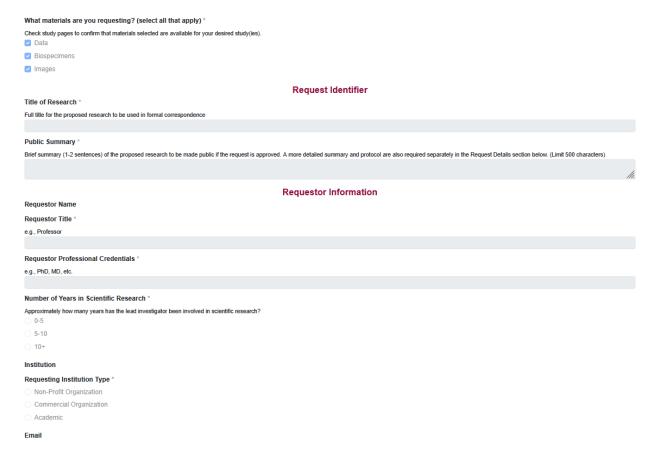
Upon initiating a request via one of the methods described above, the user is brought to the request form. The form is seen in Figure 2.7 below. <u>Section 2.8.1</u> below describes the sections of the request form, the required information, and the functionality of the buttons on the form.

#### 2.8.1 REQUEST FOR MATERIALS FORM FIELDS AND FUNCTIONS

What materials are you requesting? – The form begins with a selection for the type of materials you are requesting: Data, Biospecimens, and/or Images. You may select all that apply. You should check study pages to confirm that the materials selected are available for your desired study(ies).

**Request Identifier Section** – Next you will find a section and two fields for the Title of Research and a Public Summary. The title is used both in the transfer agreement and as an identifier for users submitting multiple requests. The title will show up in your list of requests (discussed in <u>Section 2.9</u> below).





Requestor/Principal Investigator/Authorized Users/Signing Official Information Sections – These sections contain fields describing the requestor, the Principal Investigator (P.I.), and any other Authorized Users who will have access to the requested materials, as well as the Institution's Signing Official (SO) who will sign and oversee the conditions of the Transfer Agreement. (Requestor information is partially auto filled from the user's profile but may be edited.) The P.I., Authorized Users, and SO sections are shown in Figure 2.8 below.

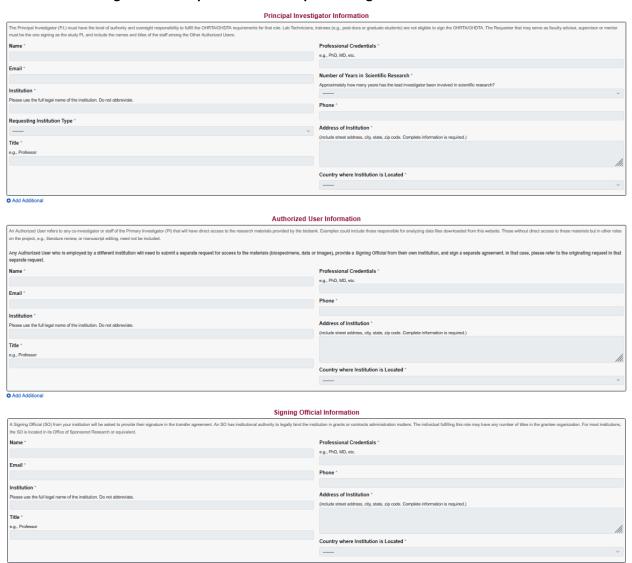
Everyone listed must be employed at the same institution, must use their institutional email address for all correspondence, and will be party to the transfer agreement overseen by the P.I. and the institution's SO. Additional collaborators who are employed by other institutions MUST submit a separate request referring to the originating request, and sign a separate transfer agreement validated by their own institution's SO.

#### The P.I. must be:

• A permanent employee of their institution(s) at a level equivalent to, at a minimum, a tenure-track professor or senior researcher. This does not include lab technicians or trainees, e.g. post-docs or graduate students.

- Has oversight responsibility for others named on the request who will be granted access to the data.
- Accountable for ensuring that all aspects of biospecimen, image, and/or data usage align with the terms of our transfer agreements (OHRTA/OHDTA) and institutional policy.
- ▶ Note: Data access requestors' responsibilities cannot be delegated.

Figure 2.8 – Request Form: Principal Investigator and Authorized Users



**Support Information Section** – This section contains questions describing the funding source. A federal grant may also be added if applicable. If this is a request for biospecimens, and funding is not yet available, a Letter of Biospecimen Availabilty to be included in a grant application can be requested.

**Request Details** – This section allows the user to specify the study or studies they wish to request. Multiple studies may be selected from the drop-down list. Selected studies will all appear in the field. A

user may begin typing the name or acronym of a study to filter the selectable studies. This section also contains fields where the user provides a summary and a full description of the proposed analysis; descriptions of the desired biospecimens, image types, and subject characteristics (if applicable), and fields describing the security measures that will safeguard the data if they are provided. Finally, there is a field for miscellaneous comments regarding the request.

#### This section has several fields:

- The study selection field allows the requestor to specify the study or studies they wish to request. Multiple studies may be selected from the drop-down list. Selected studies will all appear in the field. A user may begin typing the name or acronym of a study to filter the selectable studies.
- The proposed research should be summarized briefly in the description field.
- The specimen requirements field provides a place for the requestor to describe the
  characteristics of the specimens desired. For example, the timepoint within a longitudinal study
  is required for a successful search. Requirements for unthawed biospecimens or those with a
  certain preservative should be noted here as well.
- The subject characteristics field provides a place for the requestor to list the clinical characteristics of the subjects that should be included in the request for biospecimens. If the entire study population is eligible, the requestor may simply note that without posting the eligibility criteria.
- The requested study visits field can be used to request biospecimens from specific visits. Requestors should also indicate whether biospecimens from all requested visits or a specific subset of visits must be present for the subject to be used in the proposed research.
- The desired number of subjects and biospecimens fields provide a space for the requestor to list an estimate of the total number of biospecimens they are requesting
- The material type field provides a space for the requestor to specify the material type(s) desired. This should match the available materials for the study and correspond to the minimum volume or mass field below.
- The minimum and optimum volume or mass fields provide a place to specify the minimum and optimum volume or mass (if DNA) for the materials being requested. If multiple material types are being requested, the minimum/optimum volumes for each should be specified. Requestors are encouraged to provide the absolute minimum volume they can accept, as the AgingResearchBiobank report details impact based on this volume. The impact of a given amount of material on the collection is a factor in approval of a request.
- The proposed analytes and assays as well as the rationale for the number of biospecimens requested will be considered as part of the request's review for approval.
- The Specimen Shipping Information Section contains a field for the shipping address and email address of the user that will be receiving the biospecimens. It also contains a field for the shipping company and account number the requestor would like to use. For example, the requesting institution's FedEx or UPS account number. The AgingResearchBiobank asks for this because institutional rates are often less than the public rate charged to the AgingResearchBiobank.
- The information security section contains fields describing the security measures that will safeguard the data if it is provided.

The Comments field provides a space for miscellaneous comments regarding the request.

**Attachments** – This section allows the user to attach documents such as a full analysis protocol or IRB approval or exemption at the start of the request. IRB documentation is not required at submission but will be required before the request is reviewed. An <u>Collaborator Attestation</u> must be submitted which lists everyone who will have access to the study materials, and is signed by the P.I. and Institutional Signing Official (SO).

**Submit and Save for Later** – These buttons will save or submit the form. A saved form is available to the user via My Requests, discussed in <u>Section 2.9</u> below but not visible to the AgingResearchBiobank. This should be used if the user intends to return and complete the form at a later time. Note that the request form will timeout after one hour of inactivity. To ensure no input is lost, please save it within one hour of beginning the form. Submitting the request both saves the form and alerts AgingResearchBiobank Staff to review the input.

#### 2.9 THE MY REQUESTS PAGE

The My Requests screen is the hub for accessing your saved and submitted requests. It is available to users who have logged in to the AgingResearchBiobank Website and can be reached from the Requests section of the main menu at the top of all pages. As seen in Figure 2.9 below, the page will contain a table of your requests with pertinent information. Requests are accessed by clicking on the row within the table. There are sections for saved and submitted requests. The search field and filter on the left can be used to search for a specific request or to view all requests, only those that have been completed, or those that are in progress.

 Home / Requests My Requests Search □ Saved Request □ In Progress ✓ Completed Search My Requests Date Date Show Request Name Request Type Requestor Created Modified **Status** O All Submitted Requests Completed In Progress My Request Request for Requestor ✓ Request Nov. 17, Nov. 18, Materials Requestor Fulfilled 2025, 2:03 2025, 10:16 Search Reset p.m. EST a.m. EST

Figure 2.9 - My Requests Page

#### 2.10 REQUEST TABS

When a request is accessed via the My Requests page, there are several tabs accessible to the user. These are located below the header, which contains the most important information regarding the request. The tabs are:

**View Request**— This tab allows the user to view the information from the request form. The view page is a locked version of the request for reference. To make edits to your request, see Request Actions in Section 2.11 below.

Comments – The Comments tab, seen in Figure 2.10 below, provides a space for AgingResearchBiobank Staff and requestors to interact and share files. All communication should take place through this tab and emails should not be sent directly to the AgingResearchBiobank. Each time the requestor adds a comment and/or attachment to the Comments tab, AgingResearchBiobank staff will be notified, review the additional input, and respond as appropriate via the Comments tab. Likewise, each time AgingResearchBiobank staff respond via the Comments tab, the requestor will receive an email indicating that the request has been updated and a direct link to the Comments tab will be included.

Post Update Request for Biospecimens and Data RA-2025-008 - My Request Principal Investigator Date Requested Last Modified Study Request Fulfilled Testing LIFE Nov. 17, 2025, 2:03 p.m. Nov. 18, 2025, 10:16 a.m. EST View Request Comments Data Progress Reports Cost Tracking Email notifications from the AgingResearchBioBank are sent from No-Reply-AgingResearchBioBank@imsweb.com. To help prevent emails from going to your spam folder, please add this email to your contacts list. Do not send any email to No-Reply-AgingResearchBioBank@imsweb.com. If you try to reply, no one will read the email, and you will receive a bounce back email. To communicate, please post a comment in the request here Nov. 18, 2025, 10:16 a.m. — Bradly Rutten has updated the status of this request to: Request Fulfilled Comment 5 0 Attachments Browse... No files selected. You may upload the following file types: txt, pdf, doc, docx, xls, xlsx, csv Post Update

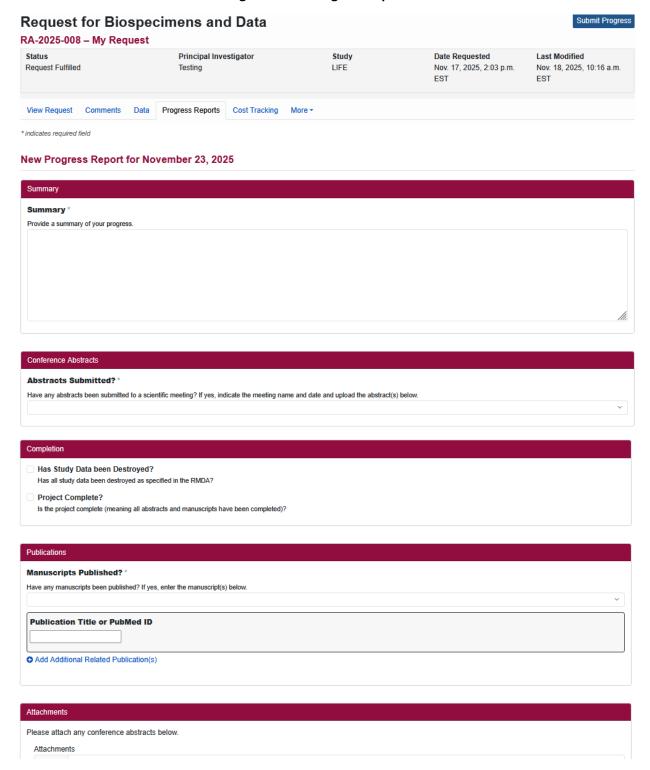
Figure 2.10 - The Comments Tab

**Data** – The *Data tab* will appear after a request has been approved. It contains links for the P.I. to download the approved data packages and/or images.

**Progress Reports** – The *Progress Reports tab*, seen in Figure 2.11 below, will appear after a request has been approved and materials have been received. You can return to your request at any time to update the *Progress Report tab* with an update on your analysis, a citation for a new publication or conference abstract, or to notify the AgingResearchBiobank of analysis completion and data destruction. Your data must be destroyed upon expiration of your transfer agreement. Once destroyed, check the *Data* 

*Destroyed box* and upload a <u>Certificate of Destruction</u>, signed by your institutional signing officer, to this tab. Annual reminders to update the *Progress Report tab* will be sent until you have checked the Project Complete box and confirmed destruction of the data provided.

Figure 2.11 - Progress Report tab



Cost Tracking – Once a request for biospecimens is approved by NIA, the *Cost Tracking tab* provides a location where AgingResearchBiobank Staff will post a cost estimate for processing the biospecimens and requestors will approve that estimate as well as input the information to be used by the AgingResearchBiobank when it comes time to invoice for the cost of processing the biospecimens. An example of the *Cost Tracking tab* with a cost estimate is shown in Figure 2.12 below. In this example the requestor would approve the cost by using the "Cost Accepted" drop-down list. At that time the requestor would also need to complete the billing contact information and should attach a purchase order if their institution has provided one.

View Request Comments Data Progress Reports Cost Tracking More ▼ under \$5000, the requested samples will be processed after cost approval. For cost estimates greater than \$5000 and international orders, requested samples will not be processed until payment is received. For costs and payment policy please see our costs page. Cost Estimate and Approval Item Description Quantity Unit Price Total 10.00 0 7.91 0 79.10 0 Pulling vials for shipment Pulling and aliquoting vials for shipment 10.00 0 9.80 0 98.00 0 10.00 0 29.09 0 290.90 0 Option 1 - Custom Nucleic Acid Distribution Option 2 - Fixed Volume at Stock Concentration 10.00 0 10.00 0 Data Subject Matter Expert Support 10.00 0 124.00 0 1240.00 0 Cost Estimate: 1808.00 **Cost Accepted?** Yes **Purchase Order Number** Attach Purchase Order files below PO12345 Attachments Browse... No files selected You may upload the following file types: txt, pdf, doc, docx, xls, xlsx, csv **Billing Information Billing Contact Billing Address** Address **Billing Email** john.doe@example.com **Billing Phone** 123456789

Figure 2.12 - The Cost Tracking Tab

#### 2.11 REQUEST ACTIONS

Within the header of the request, seen in Figures 2.10, 2.11, and 2.12 above, there is a tab called *More*, listing certain actions the requestor can take. The following actions are available:

**Edit Request** – Opens an *Edit tab* where you can edit your request. The *Edit tab* has the same functionality as the *View Request tab* described in <u>Section 2.8</u> above.

**Add Approved Users** – Opens a page where additional registered users can be provided access to view and edit the request. These users have the same privileges as the requestor. To add a user, the

requestor must search for them via the email address they used to register. Current approved users are displayed below the interface to add new users.

**Generate PDF** – Generates a PDF of the request form as it is currently filled-in.

#### 2.12 DATA and/or IMAGES REQUEST PROCESS

After submitting the request form described in Section 2.8, the following will occur:

- 1. AgingResearchBiobank Staff will review the requestor's input for completeness.
- 2. If the request form is incomplete, AgingResearchBiobank Staff will set the request to a status of "Pending Requestor Documentation" and post a comment asking the user to edit the request form to provide complete information. If there are other issues that require input from the requestor, the request will be set to a status of "Pending Requestor Input". In both cases, the requestor will receive an email indicating that the request has been updated and a direct link to the *Comments tab* will be included. Note that the request can also be accessed from the My Requests Page (see Section 2.9), without using the link from the email. When the requestor responds, AgingResearchBiobank Staff will review the input again and respond as appropriate.
- 3. Once the request form is complete and all documentation, including IRB approval and Collaborator Attestation have been attached, NIA Staff will review the request for appropriateness and feasibility. The status of the request will be set to "Under Biobank Scientific Review." The Review could take several weeks to complete. The requestor will be notified of approval/disapproval via the *Comments Tab*.
  - Occasionally, the Review Committee may request clarification before final approval. Those inquiries will be communicated via the *Comments tab* as well, and an email will be sent notifying the Requestor that the *Comments tab* has been updated. The Review Committee will reconsider approval once those questions are answered. The Requestor should post their responses to the Review Committee's inquiries in the *Comments tab* as soon as possible.
- 4. If the request is Approved, a Letter of Approval will be uploaded to the Comments tab, the Requestor will be notified of the update, and the NIA will be notified to begin working on a Transfer Agreement. The status of the request will be set to "Pending Requestor Agreement Signature". The NIA will provide the P.I. with an agreement for the P.I. and an institutional signing official (SO) to sign. The P.I. will return a signed copy of the agreement to the NIA via email. Authorized NIA Staff will countersign the agreement and a copy will be posted to the Comments tab. AgingResearchBiobank Staff will inform the requestor of the agreement's availability.
- 5. If NIA staff do not approve, AgingResearchBiobank Staff will relay their concerns to the requestor via the *Comments Tab*. A requestor may address the Review Committee's concerns via the *Comments Tab* or choose to abandon the request.
- 6. After the transfer agreement is fully signed, AgingResearchBiobank Staff will inform the requestor via the *Comments tab*, the Requestor will be notified of the update, and the *Data tab* will become visible. The data package and/or images for each study will be made available for download by the P.I. via a link on the *Data tab*.
- 7. The request will be set to a status of "Fulfilled" once the data package(s) and/or images have been made available for download.

8. If the requestor has questions regarding the data and/or images after downloading, they may post them in the *Comments tab*. AgingResearchBiobank Staff will be notified and the request will be set to a status of "Questions/Comments Post Completion". AgingResearchBiobank Staff will respond via the *Comments tab* and set the status as appropriate.

#### 2.13 BIOSPECIMENS REQUEST PROCESS

In addition to the steps outlined in <u>Section 2.12</u>, the processing of a Biospecimens Request requires several additional steps.

After submitting the request form described in Section 2.8, the following will occur:

- 1. AgingResearchBiobank Staff will review the requestor's input in light of the available biospecimens within the AgingResearchBiobank, and for completeness.
- 2. If the request form does not contain sufficient information for a search of the AgingResearchBiobank's biospecimen inventory or if there are issues that require additional input from the requestor, AgingResearchBiobank Staff will contact the requestor via the Comments tab and ask them to provide additional details on their requirements. AgingResearchBiobank Staff will also contact the requestor via this tab if the materials are not available. In either case, the requestor will receive an email indicating that the request has been updated and a direct link to the Comments tab will be included. Note that the request can also be accessed from the My Requests Page (see Section 2.9), without using the link from the email. When the requestor responds in sufficient detail, the request will proceed to the next step.
- 3. If the request criteria are complete and AgingResearchBiobank Staff have sufficient information to perform a search for appropriate biospecimens, they will acknowledge to the requestor that a search has begun.
- 4. Upon successful completion of a search, AgingResearchBiobank Staff will inform the requestor of the available biospecimens via the *Comments tab*. The requestor will review this information and may ask for modifications at this time.
- 5. If the search results are acceptable, please acknowledge this in the *Comments tab* of the request.
- 6. If needed, a Letter of Biospecimen Availability will be posted to the *Comments tab* and can be submitted with any grant for funding. The status of the request will be set to "Pending Grant Funding Information" until the grant is awarded. When funding is obtained, the requestor should return to the request via the My Requests page and add a comment and upload a copy of the approval to the *Comments tab* to continue the process of obtaining biospecimens.
- 7. If funding has already been obtained, NIA Staff will review the request for appropriateness and feasibility. The status of the request will be set to "Under Biobank Scientific Review." The Review could take several weeks to complete. The requestor will be notified of approval/disapproval via the *Comments tab* and the Requestor will be notified of the update by email. Occasionally, the Review Committee may request clarification before final approval. Those inquiries will be communicated via the *Comments tab* as well. The Review Committee will reconsider approval once those questions are answered. The Requestor should post their responses to the Review Committee's inquiries in the *Comments tab* as soon as possible.

- 8. If the request is Approved, a Letter of Approval will be uploaded to the *Comments tab*, the Requestor will be notified of the update, and the NIA will be notified to begin working on a Transfer Agreement. The status of the request will be set to "MTA in process". The NIA will provide the P.I. with an agreement for the P.I. and an institutional signing official (SO) to sign. The P.I. will return a signed copy of the agreement to the NIA via email. Authorized NIA Staff will countersign the agreement and a copy will be posted to the *Comments tab*. AgingResearchBiobank Staff will inform the requestor of the agreement's availability.
- 9. If NIA staff do not approve, AgingResearchBiobank Staff will relay their concerns to the requestor via the *Comments tab*. A requestor may address the Review Committee's concerns via the *Comments tab* or choose to abandon the request.
- 10. Concurrently with the Transfer Agreement process, AgingResearchBiobank Staff will provide a cost estimate for processing the biospecimens via the Cost Tracking tab. The requestor will receive an email asking them to approve the cost estimate posted to the Cost Tracking tab and input their billing contact. The requestor should review the cost and approve via the dropdown menu for cost approval. If there are questions regarding the cost, they should be posted in the Comments tab.
- 11. AgingResearchBiobank Staff will send an invoice to the contacts provided in the *Cost Tracking tab*. Invoices are sent as a PDF via e-mail from <a href="mailto:AgingResearchBiobank@imsweb.com">AgingResearchBiobank@imsweb.com</a>. They are sent to the billing contact, P.I., and requestor (if not the P.I.). A purchase order will be referenced and included as an attachment if it was provided to the AgingResearchBiobank.
  - a. The requesting institution should follow the instructions within the invoice to remit payment to the AgingResearchBiobank. Payment can only be made via check; credit cards are not accepted. Failure to abide by the terms on the invoice will result in referral to NIA officials. Questions regarding payment should be sent directly to <u>AgingResearchBiobank@imsweb.com</u>.
  - b. AgingResearchBiobank Staff will await payment before proceeding to the next step.
- 12. Upon payment, AgingResearchBiobank Staff will submit the biospecimens to the Biorepository for processing and set the request to "Biorepository Processing Biospecimens".
- 13. When the biospecimens are ready for shipment, the shipping contact will be emailed to arrange a receipt date. Biospecimens will be shipped to the specified address.
- 14. After shipment and receipt is confirmed by the biorepository, the *Data tab* will become visible. The data package for each approved study will be made available for download by the P.I. via a link on the *Data tab*. A file linking the biospecimens to the data will also be added to the *Comments tab*.
- 15. The request will be set to a status of "Fulfilled" once the data package has been made available for download and the biospecimens have been shipped.
- 16. If the requestor has questions regarding the data after downloading the data package, they may post them in the *Comments tab*. AgingResearchBiobank Staff will be notified and the request will be set to a status of "Questions/Comments Post Completion". AgingResearchBiobank Staff will respond via the *Comments tab* and set the status as appropriate.

#### 2.13 AGREEMENT EXPIRATIONS AND RENEWALS

Agreements are valid for 12 months from the date of execution. As expiration approaches, AgingResearchBiobank Staff will send an email to the P.I. informing them that expiration is approaching. If the data and/or images are no longer needed, they should be removed from local systems. Any remaining/residual biospecimens should also be destroyed. A <u>Certificate of Destruction</u> signed by the P.I. and their institutional signing official (SO) should be submitted via the <u>Progress Report tab</u> and the Data Destroyed box should be checked. This will be noted by AgingResearchBiobank Staff and the date of destruction noted in the request. If you wish to use any remaining/residual biospecimens for another project, a new request must be submitted to the AgingResearchBiobank and subsequently approved in order to retain the biospecimens.

If the data, images, and/or biospecimens are still in use, the P.I. should notify AgingResearchBiobank staff to begin the process of obtaining an extension letter. This process will be handled through NIA, via email. The extension must be signed by the P.I. and an authorized institutional signing official (SO) in the same manner as the original agreement. In addition, an updated <u>Collaborator Attestation</u>, listing anyone who currently has access to the study materials and signed by the P.I. and SO, should be posted to the *Comments tab*. Approved extension letters will be archived on the *Comments tab* and the date of expiration updated to reflect the extension of the agreement for another year.

If at any time during the tenure of the agreement or extension the requestor or the P.I. leave the institution whose SO signed the original agreement, the requestor must notify the AgingResearchBiobank through a comment in the *Comments tab*. A new agreement will be generated and will require a signature from the new institution's SO.