National Institute on Aging

AgingResearch Biobank

User's Guide

July 2026

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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.

Recently, the AgingResearchBiobank has introduced a collection of animal-derived materials originating 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

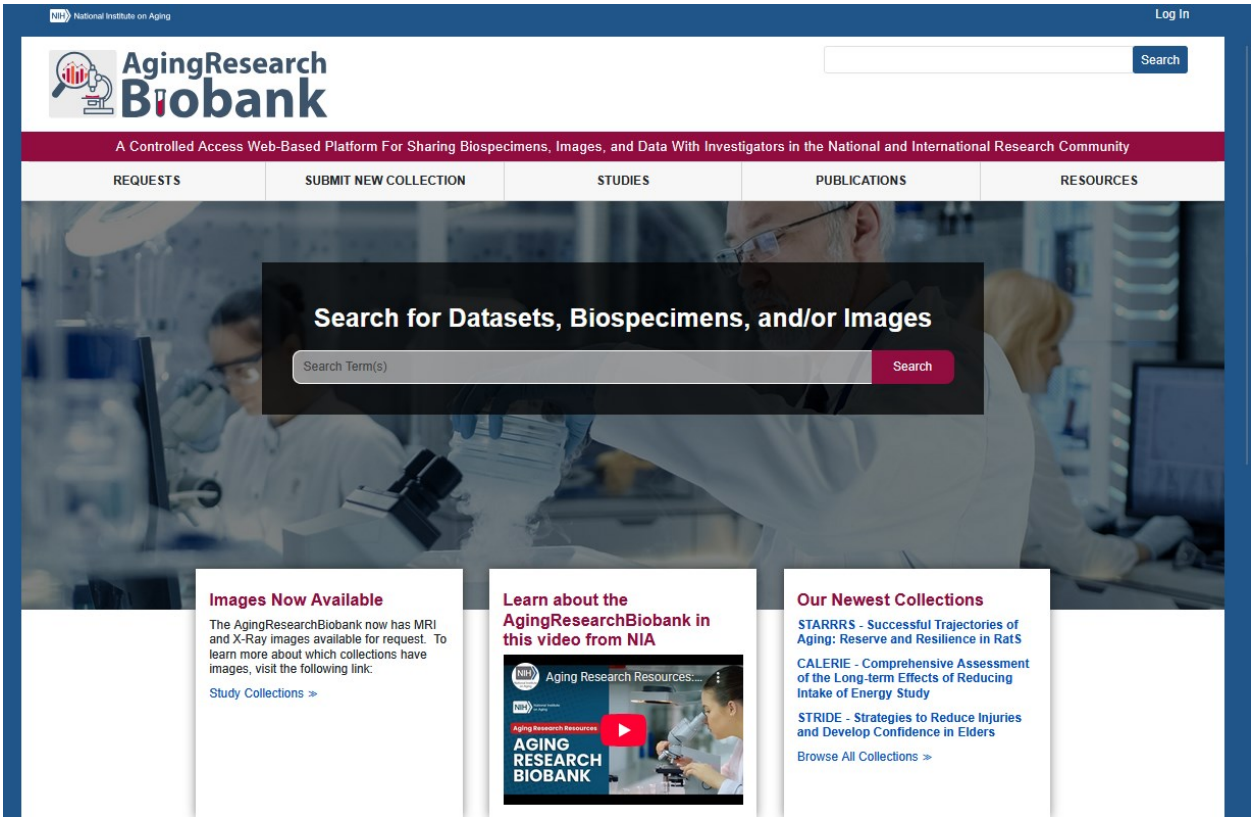
1.1 OVERVIEW

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 Section 2.6 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 Section 2.4 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 retrieval 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

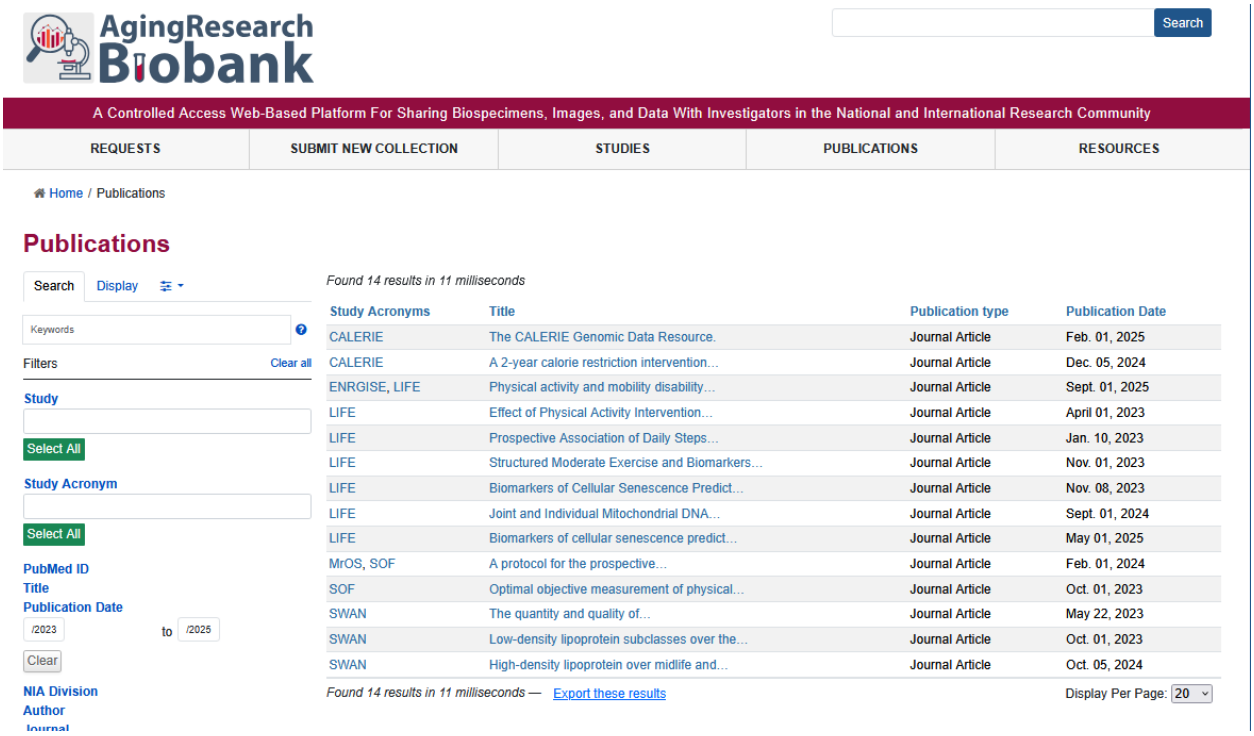
Currently Available Study Collections (biospecimens, phenotypic, clinical and/or imaging data) – Contains a list of study collections with resources and materials available for request

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:

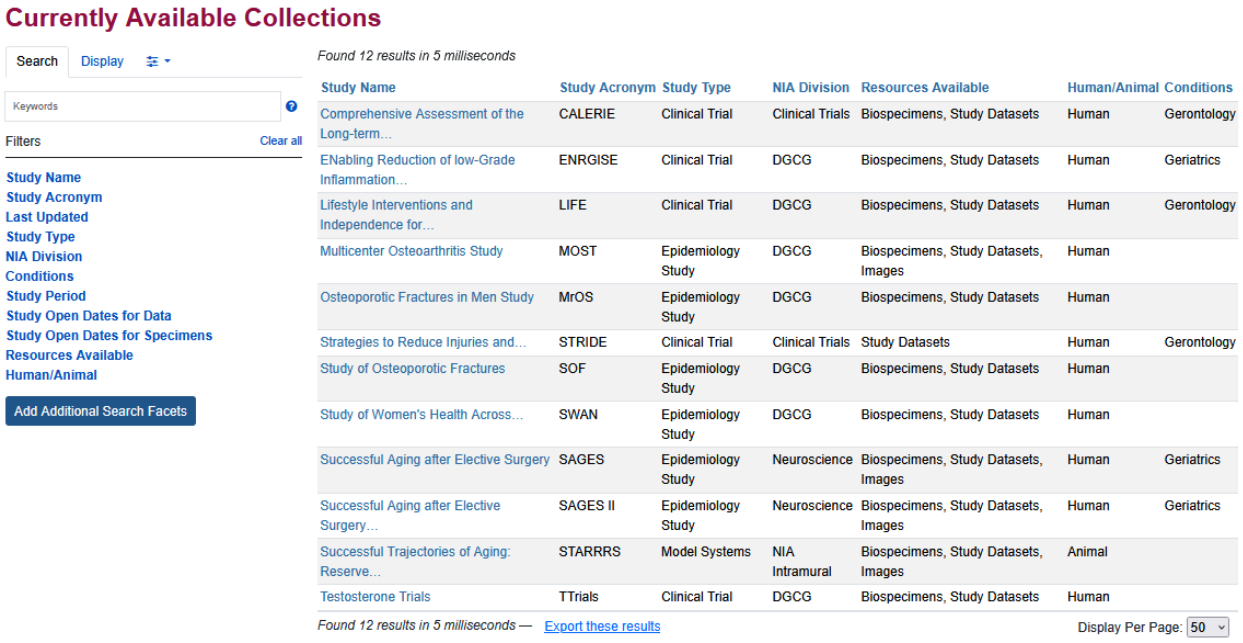
- **Relevant Information to Help Investigators Develop Resources Management and Sharing Plans** A list of links to reliable web resources and/or documents (policies, guidance, and others) to help investigators with information relevant for planning a study or preparing a study collection for deposit 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

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.

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

- 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 Letter of Biospecimen Availability 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:

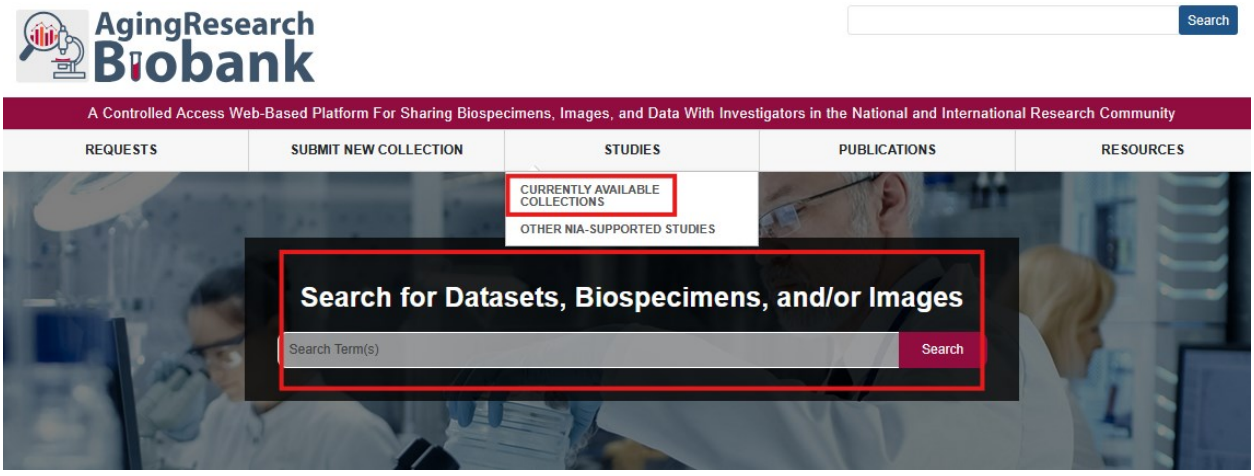
- Submitting grant applications on behalf of the company, organization, institution, or Government.
- Signing grant applications and the required certifications and/or assurances necessary to fulfill the requirements of the application process.

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 Section 2.4 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.

Figure 2.2 – Searching for Studies from the AgingResearchBiobank Homepage

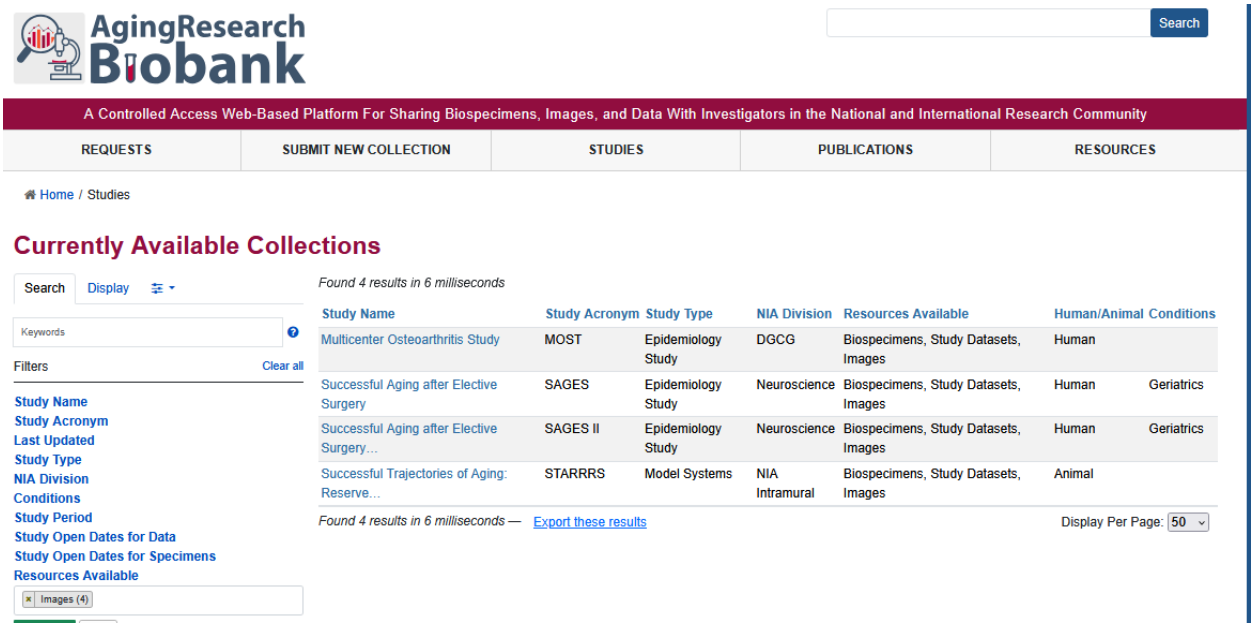


2.4 THE STUDY SEARCH PAGE

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 Section 2.5 below.

Figure 2.3 – The Study Search Page



2.5 THE STUDY PAGE

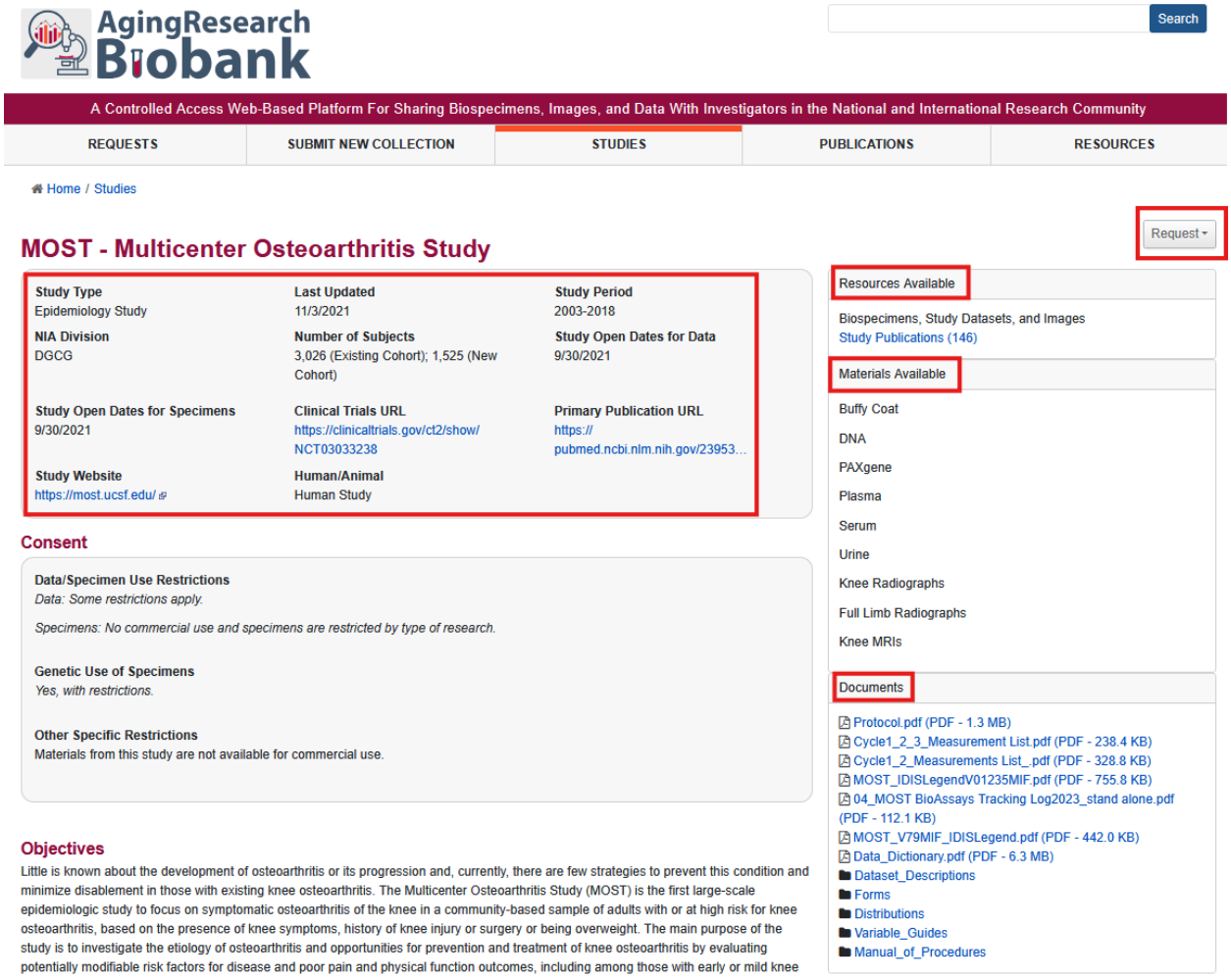
As seen in the example in Figure 2.4 below, each requestable study within the AgingResearchBiobank has its own study page.

The study page contains several sections:

- 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 Section 2.5.1 below.

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.

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.

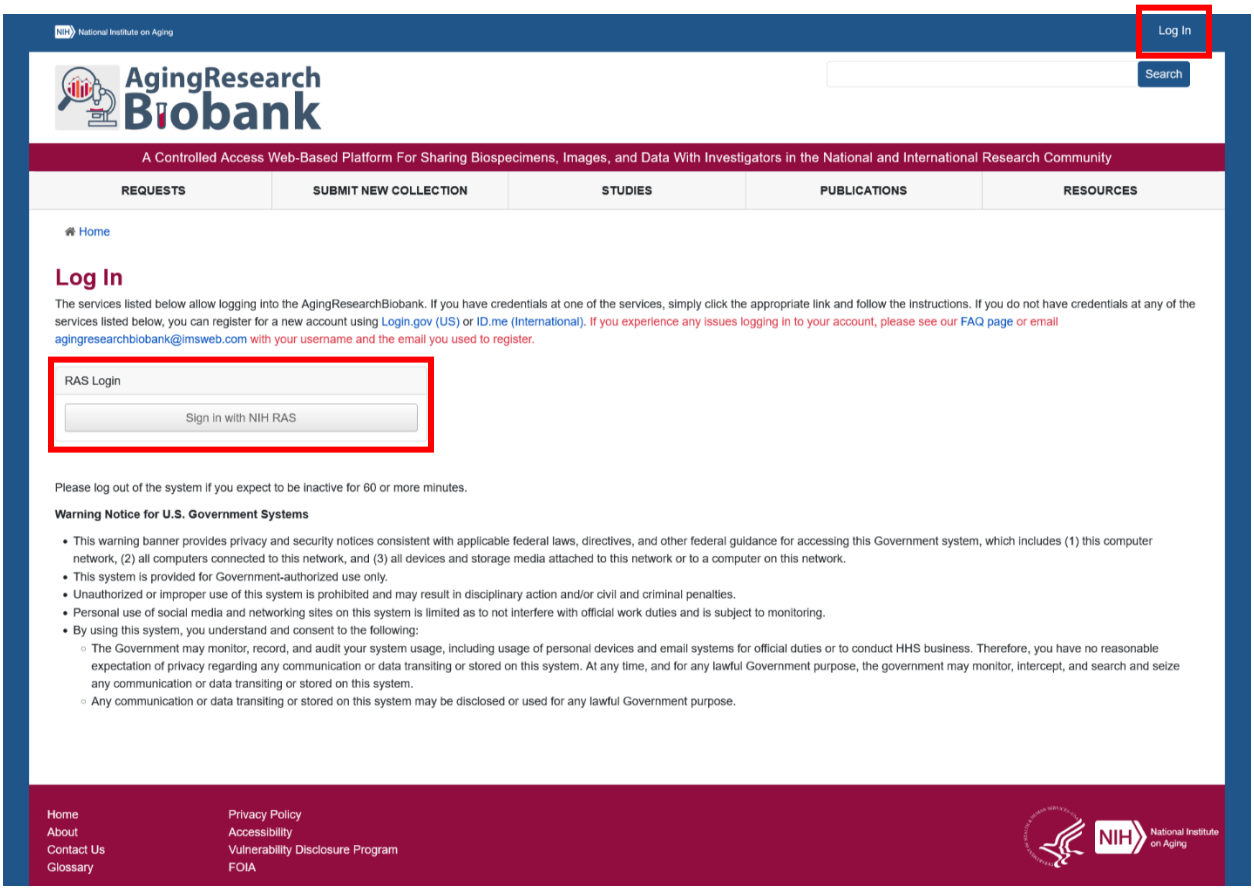
Protocol – A description of the study by the original investigators

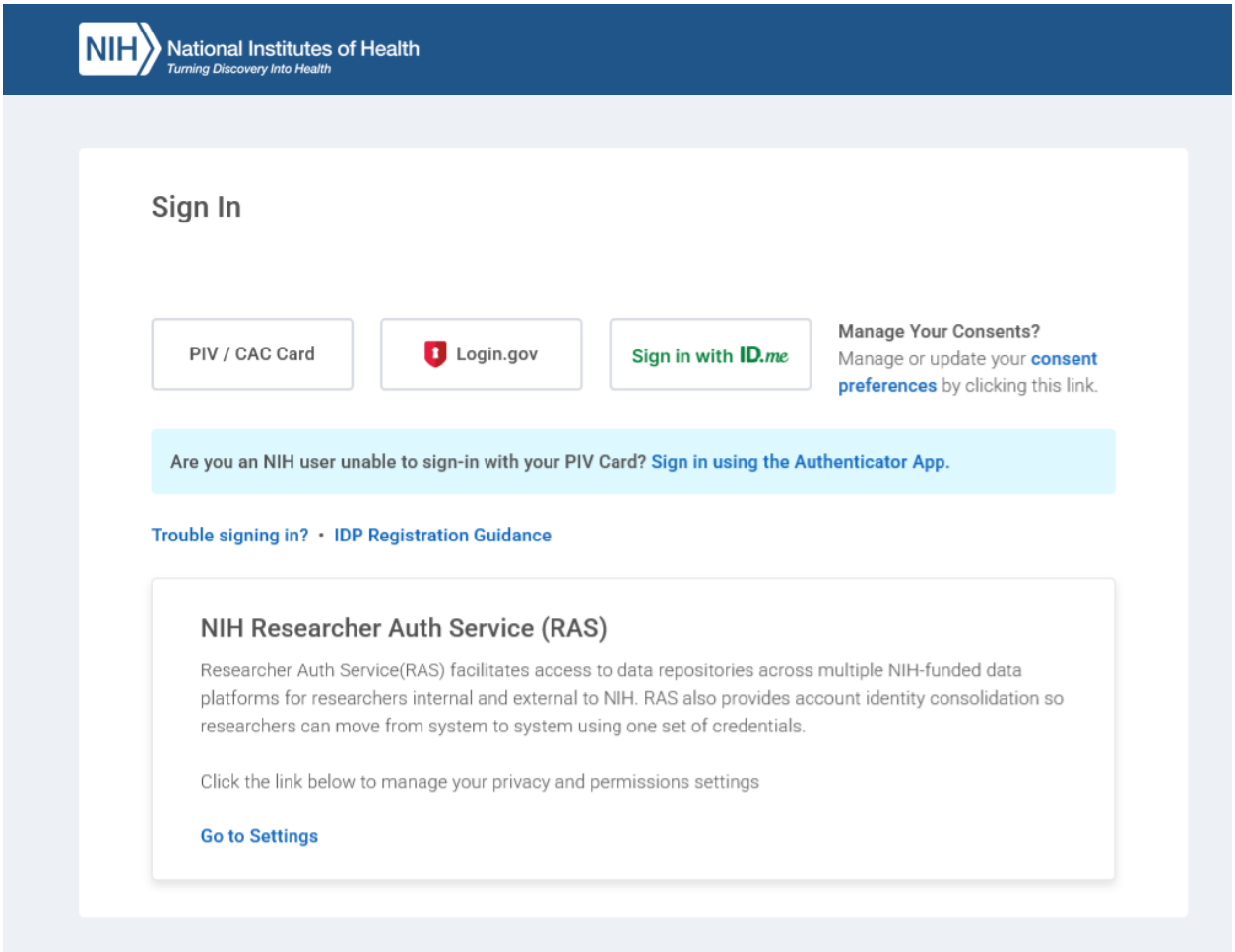
Manual of Procedures (MOP) – Also called Manual of Operations (MOO) in some studies. This describes the study procedures in detail.

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. Login is handled by NIH's Researcher Auth Service (RAS), which can be reached via the "Login" button at the top right of any page on the website. After clicking on "Sign in with NIH RAS" on the Login page, you will be redirected to the NIH RAS page. These two Login pages are shown in Figure 2.5 below. Note that the first time you use a login method (e.g., Login.gov or ID.me), you will be redirected to the identity provider's webpages that may require you to provide personal documents and a phone number in order to verify your identity.

Figure 2.5 – Login Pages





There are three 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 or U.S. 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 with each of these identity providers. 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. You will be able to add your organizational email to an existing Login.gov account created for personal use.

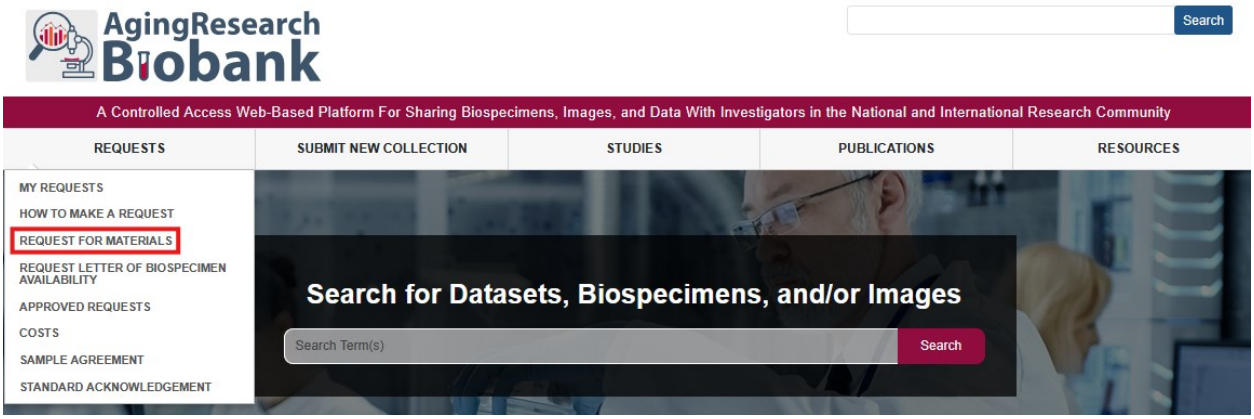
Once your identity has been verified, you will be redirected to your Profile page on the website. You must fill in your Institution before proceeding.

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

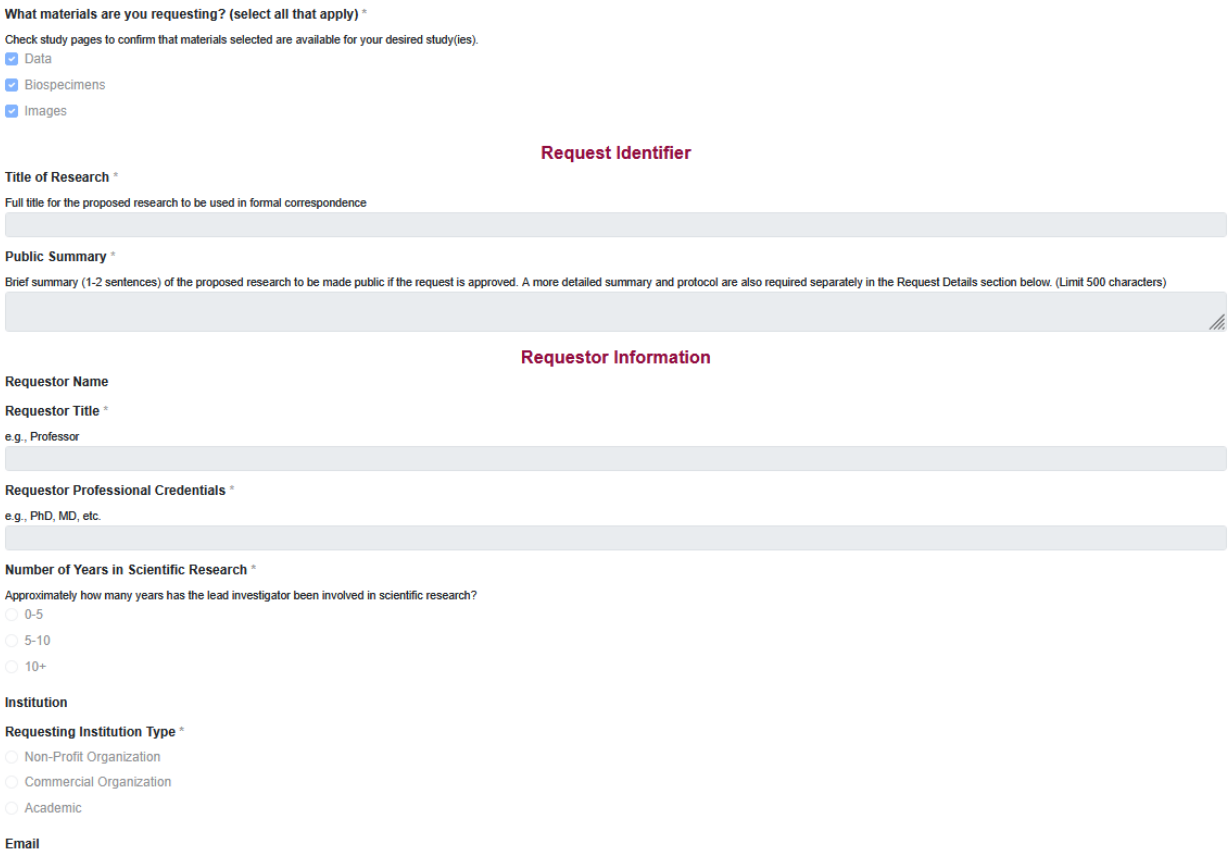
Upon initiating a request via one of the methods described above, the user is brought to the request form. The form is seen in Figure 2.7 below. Section 2.8.1 below describes the sections of the request form, the required information, and the functionality of the buttons on the form.

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 Section 2.9 below).

Figure 2.7 – The Request For Materials Form



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.

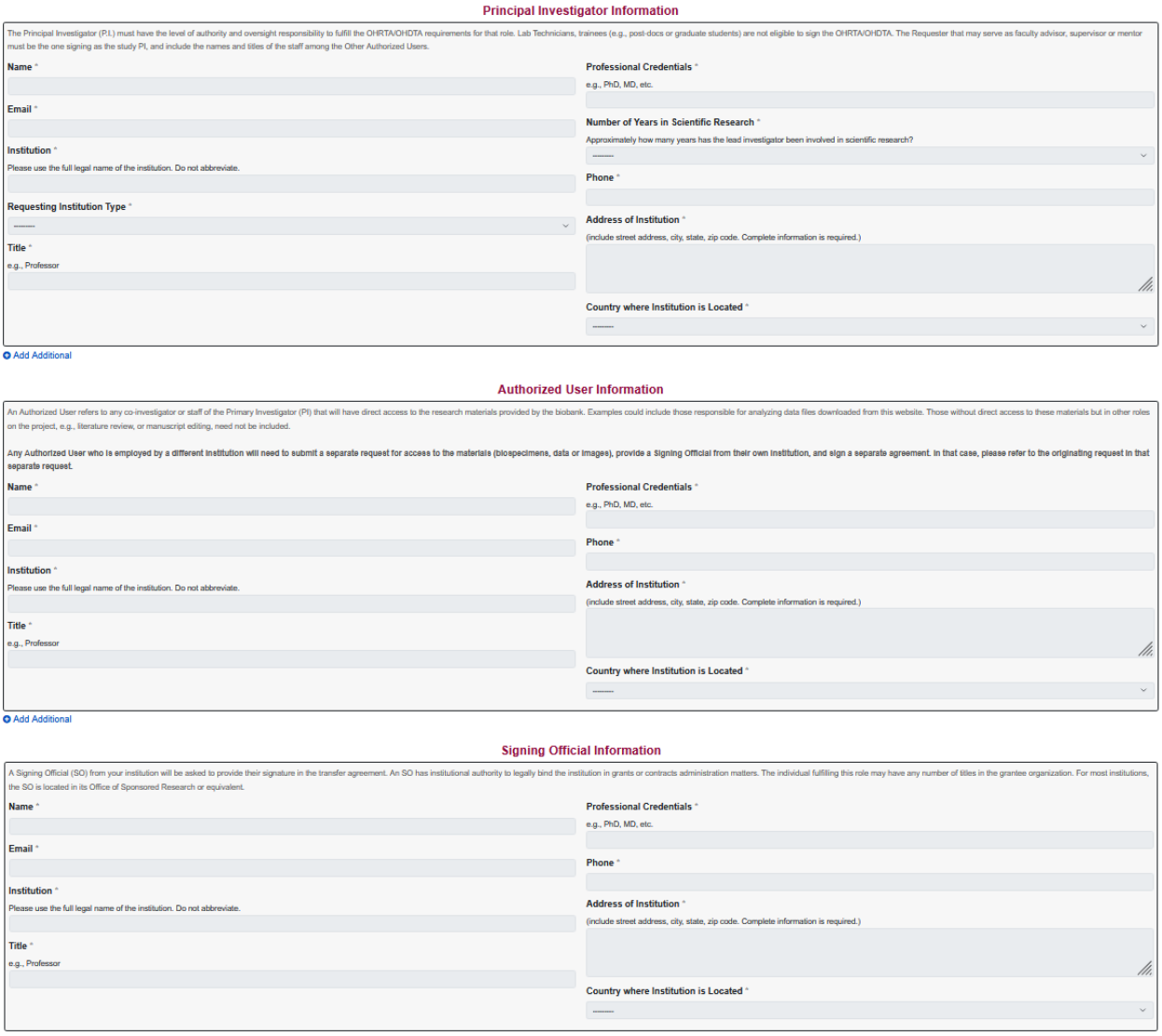
The P.I. must be:

- 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 Availability 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.

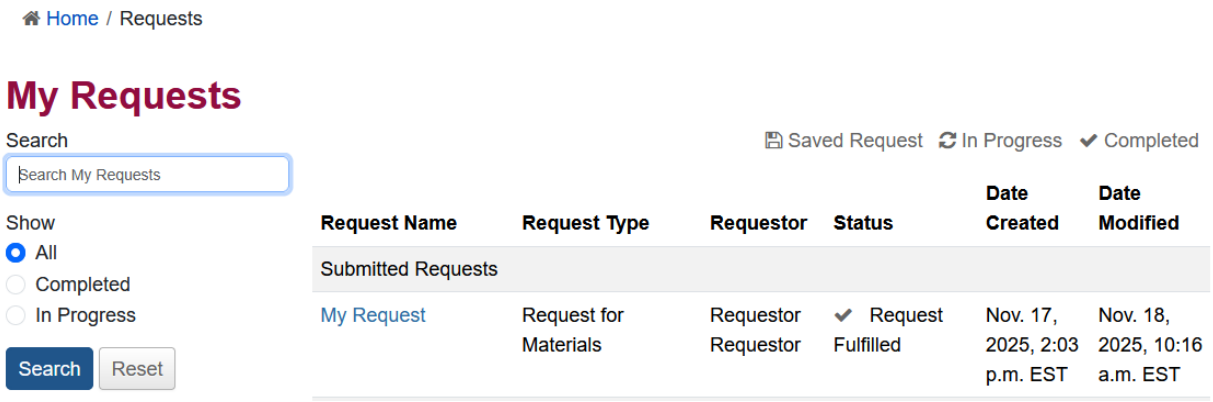
Attachments – This section allows the user to attach documents such as a full analysis protocol or IRB approval or exemption at the start of the request. IRB documentation is not required at submission but will be required before the request is reviewed. An Collaborator Attestation must be submitted 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 Section 2.9 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.

Figure 2.9 – My Requests Page



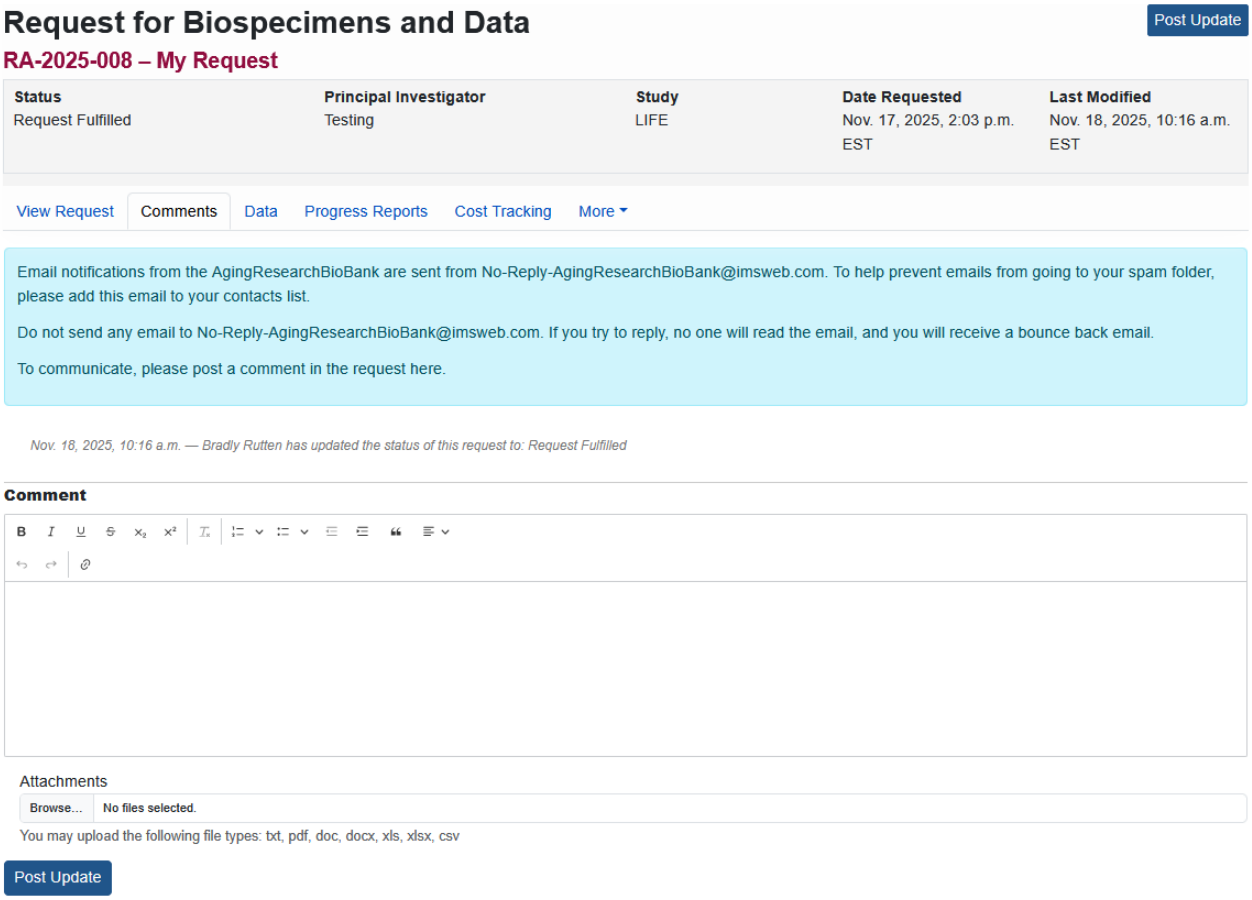
2.10 REQUEST TABS

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.

Figure 2.10 – The Comments Tab

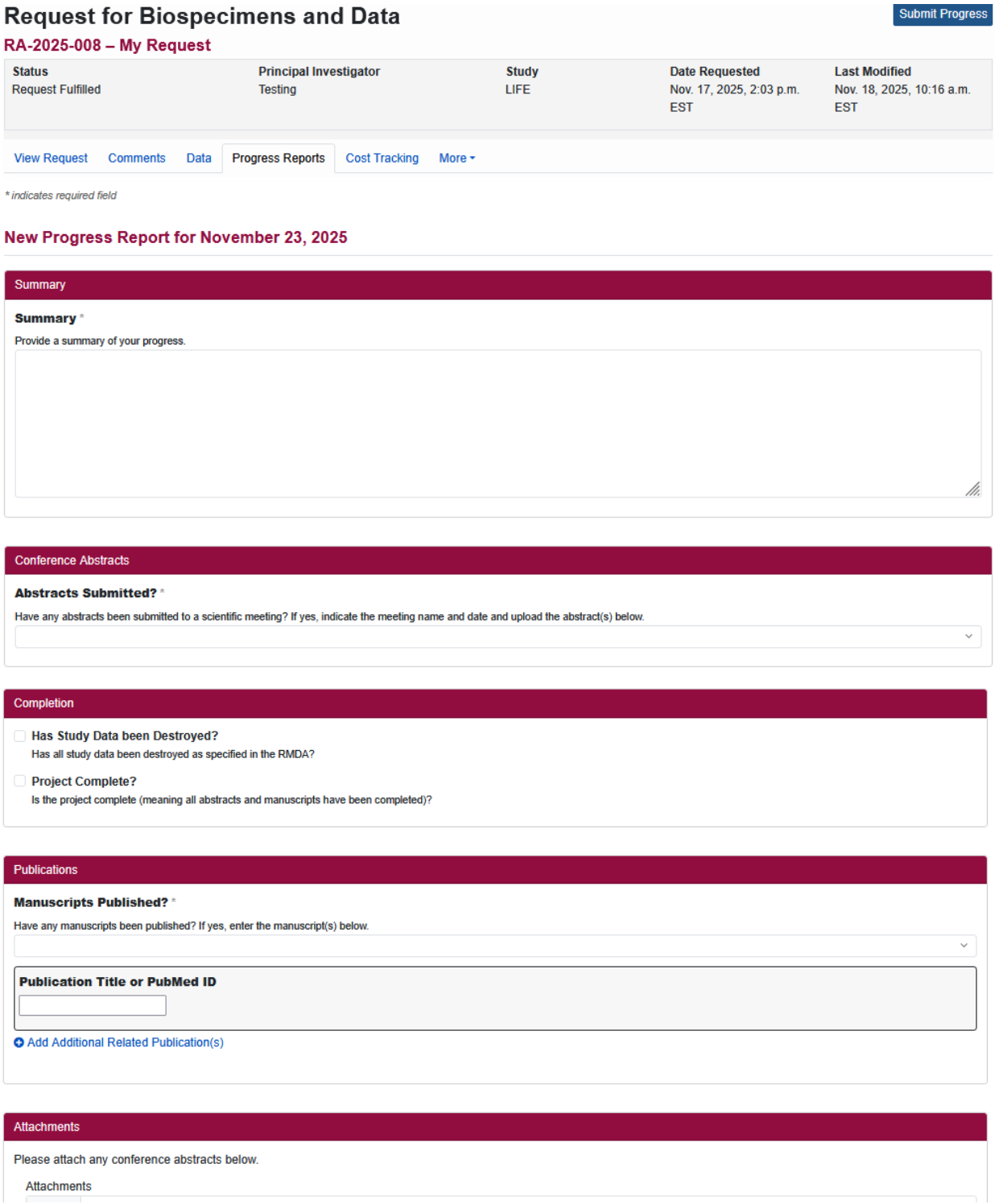


Data – The *Data tab* will appear after a request has been approved. It contains links for the P.I. to download the approved data packages and/or images.

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*

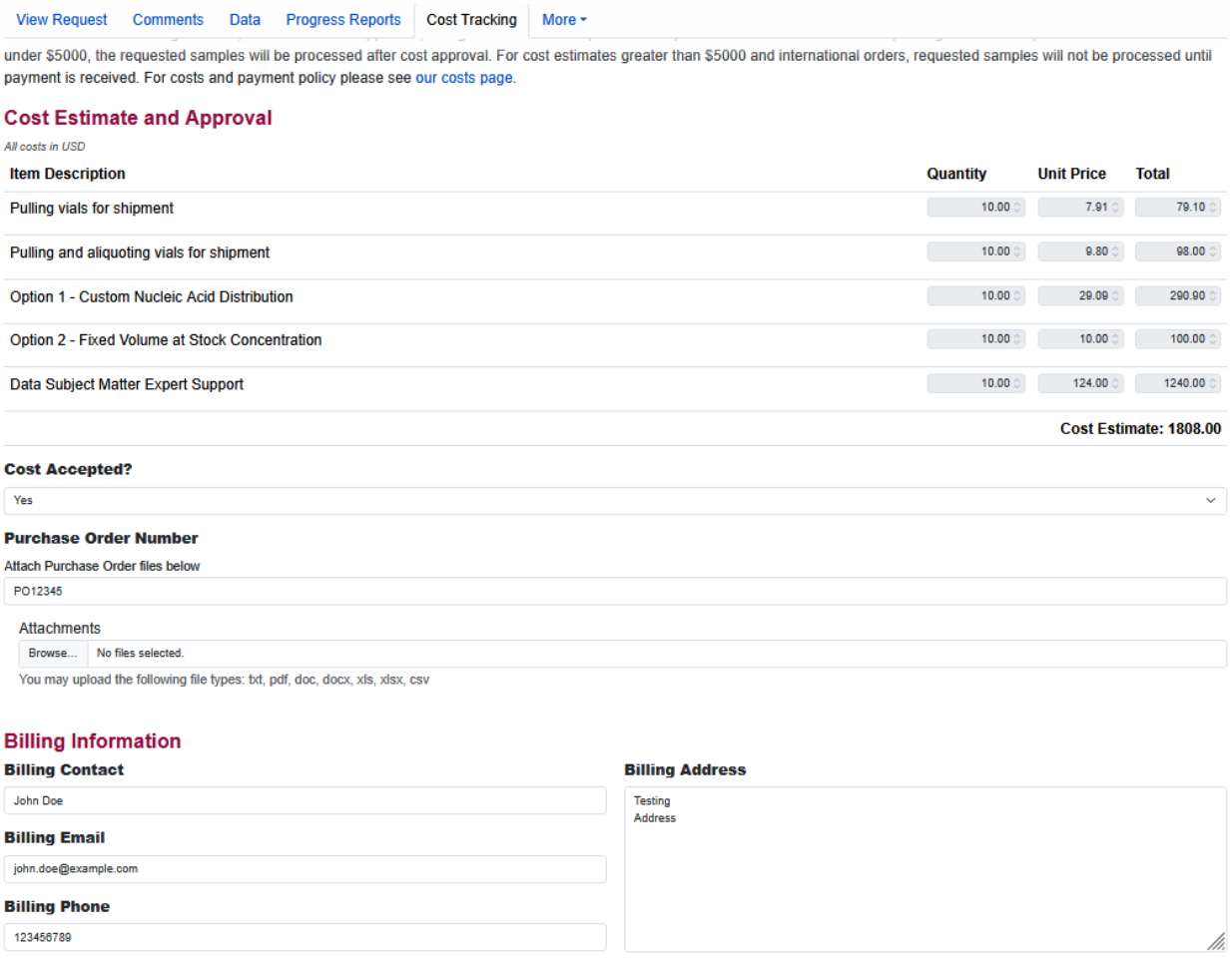
Destroyed box and upload a Certificate of Destruction, signed by your institutional signing officer, to this tab. Annual reminders to update the *Progress Report tab* will be sent until you have checked the Project Complete box and confirmed destruction of the data provided.

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.

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 Section 2.8 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 Section 2.12, 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 AgingResearchBiobank@imsweb.com. 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 AgingResearchBiobank@imsweb.com.
    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 Certificate of Destruction signed by the P.I. and their institutional signing official (SO) should be submitted via the *Progress Report tab* 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 Collaborator Attestation, 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.

Chapter 3: Submitting a New Collection of Phenotypic & Clinical Data with or without Images and/or Biospecimens

3.1 OVERVIEW

This Chapter provides information on the submission of requests to include data, images, and/or biospecimens in the AgingResearchBiobank for secondary use by approved requestors. In addition, the preparation of datasets, images, and biospecimens prior to the transfer of these materials to the Biobank is covered starting in Section 3.6.

3.2 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, and priority research topics on aging and aging-related conditions (e.g., chronic conditions, multimorbidity, biomarkers, secondary analyses, etc.)
- **Study Collection** – A particular clinical trial, longitudinal/observational study, or animal study that has been funded by NIA and which is requesting to submit materials to the AgingResearchBiobank.
- **Study Principal Investigator (P.I.)** – The person responsible for oversight of the original study requesting inclusion in the AgingResearchBiobank. This person must sign a transfer agreement to transfer custodianship of the data, images, and/or biospecimens to the AgingResearchBiobank.
- **Institutional Review Board (IRB)** – A body that reviews the restrictions, if any, on sharing the original study's data, images, and/or biospecimens with secondary researchers. It is usually affiliated with the P.I.'s institution. 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 applicant'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.

- **Study Data** - Information collected and recorded from study participants through periodic examinations; measurements from biospecimens; quantitative results from procedures such as imaging studies, exercise tests, lung function assessments, etc.; clinical event surveillance and follow-up contacts.
- **Study Documentation** – Descriptive information regarding the conduct of the study and collection of data. Study documentation may include study protocol; manual of operations or manual of procedures; annotated data collection forms; codebooks or data dictionary; algorithms for calculated or derived data elements; and descriptions of data derived from procedures or biospecimens.
- **Biospecimens** – Biological material collected according to the Study Protocol for the purposes of research. These samples may be original material, derivatives, or extracted material. Examples include: urine, whole blood, plasma, serum, DNA, RNA, etc.
- **Images** – Individual images or groups of images such as MRIs or X-rays collected from participants throughout the course of a study.
- **NIH Data Sharing Policies**

  NIH 2003 Policy on Data-Sharing:
  https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm
  NIH Genomic Data Sharing Policy
  https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html
  NIH Model Organism Sharing Policy
  https://grants.nih.gov/grants/policy/model_organism/
  NIA Alzheimer's Disease Genomics Sharing Plan
  https://www.nia.nih.gov/research/dn/alzheimers-disease-genomics-sharing-plan

3.3 BENEFITS OF TRANSFERING CUSTODIANSHIP

A Request to include data, images, and/or biospecimens in the AgingResearchBiobank, if approved, results in the transfer of custodianship of the Study's collection of data, images, and/or biospecimens to the NIA, including relocating biospecimens and the clinical study data (including images) to the AgingResearchBiobank. In this role, the NIA becomes the caretaker and assumes responsibility for maintaining the collection. In addition, custodianship also includes the right to determine conditions under which the biospecimens are accessed, used, and retained.

Key benefits of transferring custodianship to the NIA include

1. Long term storage in an established facility, at no cost to the study
2. Biospecimens are inventoried and tracked in a secure centralized database and made available online through the AgingResearchBiobank
3. All requests undergo a scientific and technical review
4. The original Study is acknowledged in publications

Only quality study collections from NIA-funded clinical and epidemiological studies with potential scientific utility and that can meet the requirements below will be considered for transfer to the AgingResearchBiobank:

- An Institutional Review Board (IRB) has reviewed and verified that submission of the collection to the AgingResearchBiobank for subsequent sharing with non-study investigators for research purposes is consistent with the informed consent of study participants.
- A data file in SAS or Excel/CSV format can be provided electronically of the current biospecimen inventory. This file should include the variables described in the Incoming Biospecimen Collection Questionnaire available here and should be included in the initial collection application.
- The Parent Study PI(s) will sign an Incoming Human Materials Transfer Agreement (IHMTA) prior to shipment of data, images, and/or biospecimens to the AgingResearchBiobank.
- The Parent Study acknowledges that biospecimen collections in the AgingResearchBiobank are subject to periodic utilization assessments and possible reduction, pending evaluation of the collection's value, including results from further analyses, clinical applicability of results, and trends in the research field.

3.4 PLANNING AND TIMING

Preparing to transition a collection from the Study Collection's use to an "open" scientific resource requires considerable planning to curate the Study documentation and data, assess the scientific utility of the collection, and complete all the activities necessary to transfer the data (including images) and any biospecimens. This process can take several months or longer. Study Principal Investigators (PIs) and/or the NIA Program Officials (POs) responsible for Study oversight should initiate discussions with the NIA Official with oversight of the Biobank's scientific and business operations regarding the transfer of the custodianship of the collection to the NIA at least 18 months before the anticipated transfer date of the data (including images) and any biospecimens.

To be eligible for inclusion in the AgingResearchBiobank, the Study must demonstrate that the collection is of interest to the scientific community, that it has been collected in a rigorous and well documented manner, that data (including images) and biospecimens can be shared with non-Study investigators, that the Study data can be linked to the appropriate biospecimen vials in the collection, that an electronic inventory with the location of each vial is available, and that the Study will sign a Material Transfer Agreement (MTA).

Requestors should be aware that biospecimens cannot be transferred to the Biobank until the Study data have been submitted to, and accepted by, the Biobank. In addition, the collection will be available for secondary research requests immediately following a quality Control (QC) of both the data (including images) and any biospecimens. Storage of collections for Study investigator use only is not provided.

3.5 SUBMITTING AN APPLICATION TO TRANSFER A STUDY COLLECTION

All applications to transfer a collection to the AgingResearchBiobank undergo a rigorous assessment for potential scientific utility and, if applicable, biospecimen quality. The reviews assess the completeness and quality of the Study data and documentation, the ability to link each biospecimen and any images to their corresponding Study data, the integrity of the biospecimens based on the Study procedures, and the collection's potential scientific future use.

Given that unanticipated delays frequently occur, applications should be submitted at least 18 months before the proposed transfer date. The time to complete the assessment depends on the ability of the Study to submit the required documents and to respond promptly to review questions.

3.5.1 INITIATE A REQUEST TO SUBMIT A STUDY COLLECTION

The request is initiated by submitting a Request to Submit the Study Collection (see Figure 3.1).

Figure 3.1: Submit Request to Deposit Your Study

Submit Request to Deposit Your Study (Data Only)

If you are interested in registering a collection of data to the AgingResearchBiobank, fill out and submit the form below and an AgingResearchBiobank staff member will contact you within 7-10 days. The following checklists and forms are provided to assist with the curation and submission of Study data to the AgingResearchBiobank Data Repository. Preparation and Submission of Datasets and Documentation (PDF - 1,200 KB) provides additional information on preparing and submitting datasets and documentation to the NIA.

- Data Submission Worksheet (DOCX - 88.8 KB)
- Informed Data Consent Questionnaire (DOCX - 82.7 KB)

The Study should contact their NIA Program Official for specific submission requirements and timelines.

All fields are required.

Study Information

Name of Study

Study Acronym

Create an acronym for your study. This acronym will be your reference for this study registration.

Was this study funded by the NIA?

- Yes
- No

Email

Institution

Please use the full legal name of the institution. Do not abbreviate.

Requesting Institution Type

Title

e.g., Professor

e.g., PhD, MD, etc.

Number of Years in Scientific Research

Approximately how many years has the lead investigator been involved in scientific research?

Phone

Address of Institution

(include street address, city, state, zip code. Complete information is required.)

Country where Institution is Located

Add Additional

Have you discussed the transfer of this study to the AgingResearchBiobank with the PI?

- Yes
- No

Study Start Date

Please provide an estimated start date for this study (MM/YYYY).

Study End Date

Please provide an estimated end date for study specimen collections (MM/YYYY).

Contact Information

Study Contact

Organization

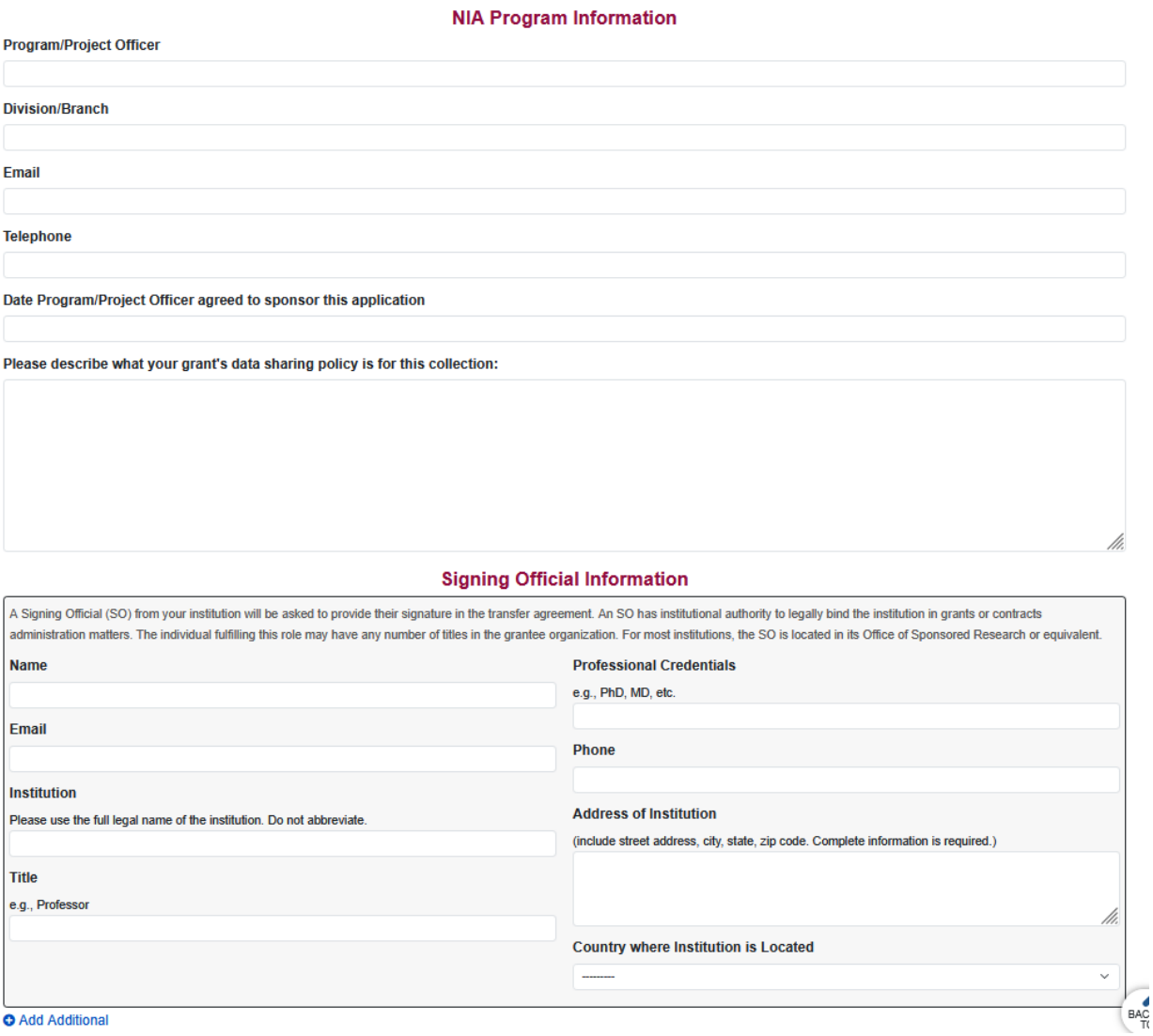
Email

Telephone

Group Email

Confirm Primary Contact

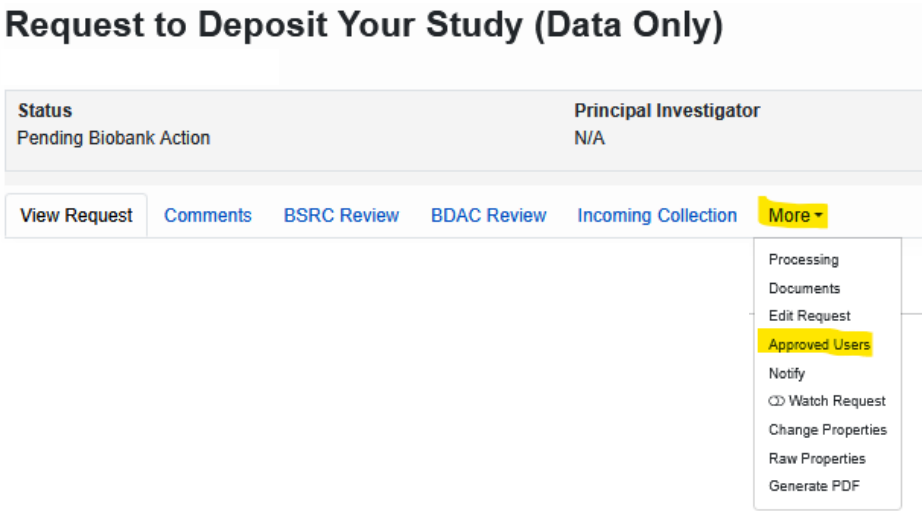
Please confirm that by registering this collection you agree to become the primary contact for this study.



The information collected in this request includes basic identifiers such as the Study name and acronym, and contact information for the Study P.I.(s) and NIA PO(s). Note that all parties must list their institutional email address. In the case of multiple collaborating institutions, a Signing Official from each institution must be listed and will be required to sign an MTA.

A list of additional Study contacts who are essential to the maintenance of the collection or to the transfer of the data (including images) and biospecimens must be provided. The NIA PO(s), the Study P.I.(s) listed on the registration form, and the additional contacts MUST be added as users on the request to ensure they receive correspondence. These individuals will first need to register for an account (see Section 2.6). Then, the P.I. can add colleagues to the request by using the “More” tab in the application header, selecting “Approved Users”, and searching for and adding registered users based on their e-mail addresses. (see Figure 3.2) Once added, Approved Users can view and comment on the request, add information and documents, and will be included on subsequent update notifications.

Figure 3.2: Add Approved Users



The Request to Submit a Collection can be saved if the user intends to return and complete the form at a later time. A saved form is available to the user via My Requests, (see Section 2.9) but is not visible to the AgingResearchBiobank and Approved Users cannot be added. 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.

The Request can be submitted before all required information has been entered in full. If additional information will be added later or by other team members, type "TBD" in that field. Submitting the request saves the form, alerts AgingResearchBiobank Staff to review the input, and allows the P.I. to add Approved Users who can assist in adding information and documents. After submission, the Request will be listed on the My Requests page (see Section 2.9) visible to the P.I. and each Approved User.

Upon request, AgingResearchBiobank will schedule a call to review the registration and application process.

3.5.2 SUBMITTING REQUIRED DOCUMENTS

After submission, the remaining required information must be uploaded to the request. These materials are essential to completing the initial scientific and technical review of the biospecimens and data, and incomplete submissions will not be reviewed. Studies will be informed of the status of their submission through their AgingResearchBiobank website account.

The required application documents and files include:

- Study protocol (most current version)
- The names and contact information for Study staff (data coordinating center and laboratory) are essential to the maintenance of the collection
- The Data Submission Worksheet
- The Informed Consent Questionnaire
- Study informed consent template(s)

- A summary of the informed consent documents used at the collection sites to collect the biospecimens with information on:
    - restrictions on use by non-Study investigators
    - restrictions on use by research topic (e.g., disease or organ-specific), genetic use restrictions, commercial entities, etc., if applicable
    - changes to the restrictions over time, including the effective date(s)
    - site-specific changes to the Study informed consent related to biospecimens and data use (including images) by secondary investigators

3.5.3 CERTIFICATE OF CONFIDENTIALITY

Answering the following questions on the Request form will help the AgingResearchBiobank determine whether the data to be submitted should be covered by a Certificate of Confidentiality (CoC).

Does the information to be submitted include identifiable, sensitive information?

□Yes □No

IMPORTANT: Research in which identifiable, sensitive information is collected or used includes research that:

- Meets the definition of human subjects' research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46)), including exempt research except for human subjects' research in which participant information cannot be identified or their identity cannot readily be ascertained, directly or through identifiers;
- Is collecting or using human biospecimens that are identifiable or that have at least a very small risk of being used to deduce the identity of an individual;
- Involves the generation or use of individual level human genomic data from biospecimens, regardless of identifiability; or
- Involves any other information where there is at least a very small risk that a person could be identified.

Is the identifiable, sensitive information to be submitted covered by a Certificate of Confidentiality?

□Yes □No

IMPORTANT: Note that research subject to the NIH Certificates of Confidentiality Policy that involves the generation, collection, or use of identifiable, sensitive information that is funded in whole or in part by NIH and that was on-going on or after December 13, 2016, is automatically deemed to be issued a Certificate of Confidentiality (CoC). For more information, see the NIH Certificates of Confidentiality webpage. (https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects/coc)

For research that does not meet these criteria, a CoC may be requested through NIH. (https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects/coc/request-certificate)

The following information needs to be provided when requesting a CoC:

1. Project details, including research title, start date, projected end date, and description.
2. Institution and performance site (if applicable) details, including institution and performance site(s) names and addresses, and institutional official name, email address, and phone number.

3. Principal Investigator name, phone number, email address, degree, position.
4. Key personnel names, degrees, and positions.
5. Name(s) of drugs that will be administered, route of administration, and dosage.
6. If applicable, a copy of the DEA certificate(s)/registration for studies in which a controlled substance will be administered.

3.6 PREPARATION OF DATA

Checklists and forms to assist studies in the curation and submission of study data are available on the AgingResearchBiobank website (https://agingresearchbiobank.nia.nih.gov/submit-datasets/). These are intended to provide guidance in the preparation of the study data, and are to be submitted as part of an incoming data package. The dataset preparation and submission process essentially involves three steps:

- **Step 1** - Includes the assembly of study data and documents as well as the procurement of institutional certification for the sharing of redacted study data.
- **Step 2** - Includes the development of a data redaction plan for the creation of shared study datasets and the application of that plan to the study data. (see Preparation and Submission of Datasets and Documentation)
- **Step 3** - Includes the submission of these redacted data, their associated documentation, and a description of the redactions as applied.

Parent study coordinating centers which have not previously prepared dataset packages for the AgingResearchBiobank are asked to submit the following prior to preparing their data for submission:

1. The institutional certification permitting the sharing of study data
2. Draft data redaction plan for review by the AgingResearchBiobank expert staff and feedback prior to finalizing the approach. AgingResearchBiobank may be contacted for questions and guidance at: agingresearchbiobank@imsweb.com
3. Key documentation including annotated forms, data dictionaries, documentation for calculated variables

Study documentation, not including documentation of pre-redacted (private) study datasets but including documentation of datasets to be shared, will be used to describe the study on the AgingResearchBiobank website. Examples include Forms, Data Dictionaries, Descriptive Statistics, and the Study Protocol.

All documents posted on the AgingResearchBiobank website will need to be accessible to those with disabilities according to section 508 of the Rehabilitation Act. Links to resources on creating and checking accessibility can be found on the HHS website on 508 issues (http://www.hhs.gov/web/508/index.html).

Finally, the Parent study shall provide documentation certifying that the study data were collected in a manner consistent with DHHS 45 C.F.R. Part 46, Protection of Human Subjects, and that submission of data to the AgingResearchBiobank and subsequent sharing for research purposes are not inconsistent with the informed consent of study participants from whom the data were obtained.

3.6.1 RESPONSIBILITIES IN PREPARING DATASETS

Investigators conducting NIA studies subject to the NIH/NIA Policy for Data Sharing from Clinical Trials and Epidemiological Studies may be required as part of the terms and conditions of their awards to prepare and deliver to the NIA datasets that satisfy NIA requirements. This includes measures to reduce the likelihood that any individual participant can be identified, such as the elimination of personal identifiers. These measures safeguard privacy and honor the informed consent of research participants. Additional requirements include the provision of documentation and key study documents (protocol, data collection forms, manuals of procedures, etc.) that will enable the use of prepared datasets by outside investigators.

Datasets and associated documentation must be provided in electronic form to the AgingResearchBiobank. In addition, if a tiered consent was utilized by the study, investigators must provide the AgingResearchBiobank with a list of participant identification numbers with data fields indicating:

- Participants who asked that their data not be shared beyond the initial study investigators (if applicable)
- Participants who asked that their data not be used for commercial purposes (if applicable)
- Participants who asked that use of their data be restricted to specific types of research activities (if applicable)

Investigators conducting ancillary studies based on ongoing (parent) studies that are subject to the NIAH/NIA Data Sharing Policy must also submit ancillary study data to the NIA through the parent study coordinating center or data submission process established by the parent study.

3.6.2 TYPES OF DATA TO BE INCLUDED IN SUBMITTED DATASETS

Clinical Trials – datasets should include baseline, interim visit(s), ancillary data, procedural based data, and outcome data, along with laboratory measurements not otherwise summarized.

Longitudinal/Observational Epidemiology Studies – datasets should include all of the examination data obtained in each examination cycle, ancillary data, and/or all of the follow-up information available up to the last follow-up cycle cutoff date.

Data from scored or procedural assessments (e.g., food item data, psycho-social questionnaires, individual electrocardiographic lead scores, etc.) should include for each participant both raw data elements and summary information where feasible.

Pre-redacted (private) final analytic master files from which the redacted data files will be derived are required in the following circumstances: 1) Studies also submitting specimens to the AgingResearchBiobank and 2) Studies funded under NIA contract mechanisms.

Submission of pre-redacted final analytic files is optional but preferred for data-only studies funded by grants or cooperative agreements, as they are useful for the AgingResearchBiobank to verify the study's redaction process.

3.7 PREPARATION OF IMAGES

For Studies applying to transfer images to the AgingResearchBiobank, appropriate clinical and phenotypic data that can be linked to the images must also be submitted following the guidance in Section 3.6.

All images must be deidentified by masking or removing any identifiable or sensitive information, such as names, medical record numbers, dates of birth, etc. from the image files and their filenames. Commercial products are available to assist with this redaction. No images with PII or PHI will be accepted by the Biobank.

Image files should be named with the patient's Study ID or an Image ID that can be linked via a separate linking file to the Study ID. Image filenames may additionally contain the type of image (e.g. CT, MRI) and visit number. It may be helpful to store the images in a folder structure that organizes the type of image and the visits for ease of finding specific images for review.

For a collection that includes images, the following additional files must be submitted:

- A SAS or Excel/CVS data file(s) that represents an inventory of all images, including file sizes. The inventory files should be separated by type of image.
- A file that links Image IDs to IDs used for the clinical/phenotypic data (if they differ)
- A summary documentation file, providing an overview of the submitted image types, the number of images of each type, the approximate total amount of storage needed for all images to be transferred, the number of subjects and visits these images represent, and an example of how the images will be organized in folders for transfer and retrieval.
- An example of each type of image file
- Examples of possible or existing research using these images

3.8 PREPARATION OF BIOSPECIMENS

For Studies applying to transfer a biospecimen collection to the AgingResearchBiobank, the physical transfer of biospecimens will not be scheduled until all datasets and documents described in Section 3.6 and Section 3.6.2 are submitted to and reviewed by the AgingResearchBiobank.

For a Biospecimen collection, the following additional documents are also required:

- The AgingResearchBiobank Incoming Biospecimen Collection Questionnaire:

  This document includes detailed information regarding the scientific value and technical quality of the collection.

- A SAS or Excel/CVS data file and data dictionary that includes represents the physical biospecimen inventory and contains the variables listed in Section H #8 of the AgingResearchBiobank Incoming Biospecimen Collection Questionnaire.

  The data file should be structured to list one observation for each individual biospecimen sample in the inventory and include all the samples that the Study proposes to send. The data dictionary should include a description of the variables and their formats. For variables that are not captured electronically, the data dictionary should indicate if this information is captured non-electronically and, if it is, where and what data are captured.

- A data file which clearly links each biospecimen with their clinical and/or laboratory data.

  Biospecimens that cannot be linked to data or which were collected from subjects who did not agree to make their specimens available for wider use will not be accepted and should not be included in the inventory data file above, nor should they be sent to the AgingResearchBiobank if the application is approved.

- The Study document(s) with the procedures used to:
  - o collect, process, label, aliquot, track, store, and ship each biospecimen type
  - o validate and monitor the biospecimen collection throughout the Study
  - o perform the laboratory assays performed on fresh and frozen biospecimens

Additional information on building a biospecimen collection suitable for sharing with secondary researchers can be found here: New Biospecimen Collection Guide

Additional information on preparing and submitting a biospecimen collection to be included in the AgingResearchBiobank can be found here: Preparation and Submission of Biospecimen Collections

3.9 SIGNING THE MATERIAL TRANSFER AGREEMENT

The Study must complete a Materials Transfer Agreement (MTA) prior to uploading or shipping their study materials.

The institution or corporation, through the Institutional Signing Official, and the Submitting Investigator, are each signatories to the Incoming MTA and agree the data are appropriate to share. The Signing Official and Submitting Investigator must certify:

- That the data was collected in a manner consistent with all applicable national, Tribal, and state laws and regulations as well as relevant institutional policies.

- That submission of the data is consistent with applicable national, Tribal, and state laws and regulations as well as relevant institutional policies.

- That expectations with explicit limitations on subsequent use, such as those imposed by laws, regulations, policies, informed consent, and agreements, as applicable, or as otherwise determined by the Submitting Institution, will be delineated at submission.

- That metadata and supporting information, materials, and documentation to adequately describe and facilitate interpretation will be submitted to NIH controlled-access data repositories at submission.

- That different offices or components of an institution with appropriate roles and expertise (such as an Institutional Review Board (IRB), Privacy Board, Human Research Protection Program (HRPP), or equivalent body) has reviewed the investigator's proposal for data submission and assures that:

  - Submission for subsequent sharing and use of the data for research purposes is consistent with explicit limitations on subsequent use, such as those imposed by laws, regulations, policies, informed consent, and agreements, or as otherwise determined by the Submitting Institution.

- The submitted data has been de-identified to the extent required by the NIH controlled-access data repository, applicable laws, regulations, and NIH policies.
- Consideration has been given to risks to individual participants and their families associated with data submitted to NIH controlled-access data repositories and subsequent sharing.
- Consideration has been given to risks to groups or populations associated with submitting datasets to NIH controlled-access data repositories and subsequent sharing.

The MTA is generated by NIA using information already provided through the AgingResearchBiobank website account. The study will be instructed to obtain the appropriate signatures and send the signed MTA back to NIA. Materials cannot be transferred to the AgingResearchBiobank until the MTA has been signed by the appropriate study signatories and the NIA Official with Oversight of the AgingResearchBiobank's Scientific and Business Operations. The fully executed MTA will be posted in the study application.

3.10 REVIEW OF STUDY MATERIALS

AgingResearchBiobank staff will conduct a review of all materials submitted to ensure that the data, images, and/or biospecimens are complete and ready for use by approved requestors.

3.10.1 REVIEW OF STUDY DATA

All data files and accompanying documentation will be reviewed by AgingResearchBiobank staff to confirm that the documentation provided is adequate for use by secondary researchers unfamiliar with the Study data, that all fields are present in the documentation and labeled in the data, and that all identifying and sensitive information has been appropriately redacted.

Any significant deviations from the redaction plan or lack of adequate documentation will be referred to the Study for resolution.

3.10.2 REVIEW OF IMAGES

AgingResearchBiobank staff will review the images and accompanying documentation to ensure that clinical/phenotypic data can be linked to the submitted images, that the images have been appropriately redacted, and that all images in the inventory have been transferred.

Any concerns will be referred to the Study for resolution.

3.10.3 REVIEW OF BIOSPECIMENS

AgingResearchBiobank staff will review the materials provided to ensure that the subject ID, race, gender, tiered consent (if applicable), and visit (if applicable) can be linked to biospecimen data found in the associated inventory as part of the application to transfer the biospecimen collection. Any Studies that have a tiered consent should have a variable in the data that details which level of consent each subject gave for use of their data and biospecimens.

The AgingResearchBiobank will prepare a report that summarizes an assessment of the quality of the data and the ability to link the data to biospecimens. This report will be included in the materials provided to the NIA during the biospecimen application review process.

Once the biospecimens have been transferred, AgingResearchBiobank Biorepository staff will conduct a thorough assessment of the biospecimens using the inventory file provided. This assessment will confirm the existence and location of each vial, information on the vial labels, apparent material in the vials, and estimated volume in each vial. Any discrepancies will be sent to the Study for resolution.

3.11 PREPARE THE STUDY DESCRIPTION

AgingResearchBiobank staff will collaborate on a description of the study that includes study type, study period, number of subjects, primary publication, and a short description of the study to be posted on the Study's page on the AgingResearchBiobank website. Examples can be found at https://agingresearchbiobank.nia.nih.gov/studies/

3.12 STUDY MADE AVAILABLE FOR REQUEST

Once all of the steps above are completed, the study's materials will be made publicly available for request by secondary researchers in the greater scientific community. The request process is described in Chapter 2 of this document.