Persons using assistive technology may not be able to fully access information in this file. For assistance, e-mail AgingResearchBiobank@imsweb.com. Include the website and filename in your message.

AgingResearchBiobank User's Guide

January 22, 2018

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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 and clinical 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. Aging research will be expanded through the use of such collections to address new promising scientific questions targeting the development of prognostics, markers, and therapeutics for conditions related to aging 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 significantly increases the value and power of future research findings from the resources offered by the AgingResearchBiobank.

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. The page has the following sections:

Login – A link to the registration system described in section 2.4 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.

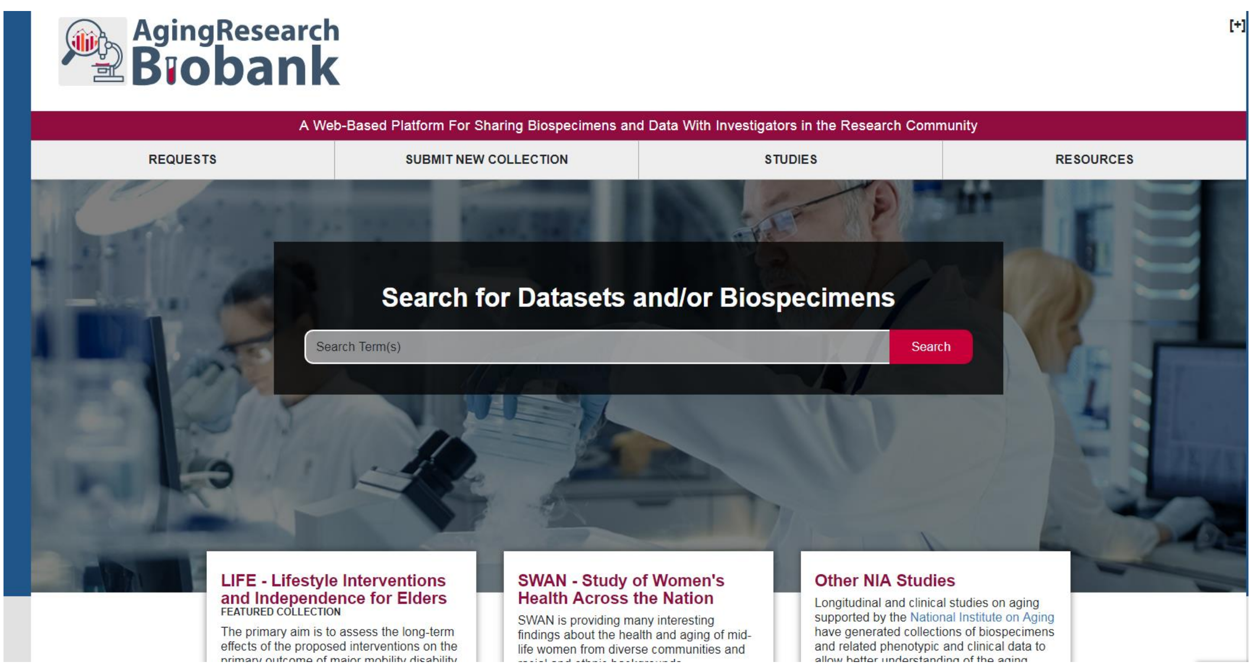
AgingResearchBiobank Logo – This logo can be used as a link back to the Home Page from anywhere in the site.

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

Search for Datasets and/or Biospecimens – A search box that will bring the user to the study search page discussed in section 2.3 below.

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

Figure 1.1 – The AgingResearchBiobank Homepage



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 on how to make a request
- Request Samples and Data – Create a request for specimens and data
- Request Data – Create a request for clinical data from a study
- Costs – A list of the current costs for requesting specimens and data

1.3.2 SUBMIT NEW COLLECTION

- Submit Datasets – Information on how to submit datasets
- Submit Biospecimens and Datasets – Information on how to submit a biospecimen and data collection

1.3.3 STUDIES

- Currently Available Collections – Contains a list of study collections available for request
- Other NIA-Supported Studies – Contains a list of other NIA-supported studies

1.3.4 RESOURCES

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

- FAQ – A list of frequently asked questions and their answers
- Glossary – A list of biorepository-related terms
- Forms –Opens a page containing helpful documents for submitting requests
- Other Resources –Opens a page containing links to other NIH repositories and informational sources related to the AgingResearchBiobank
- Contact Us – A form to submit questions to the AgingResearchBiobank

Chapter 2: How to Create a Request for Data

2.1 OVERVIEW

This Chapter provides information on the submission, review, and fulfillment of data requests via the AgingResearchBiobank Website. It describes the process by which investigators may identify the available data elements and apply for access to data archived from NIA-funded clinical trials and longitudinal/observational studies.

2.2 DEFINITIONS

- AgingResearchBiobank Staff – Personnel at the contractor level responsible for the maintenance of the data repository and AgingResearchBiobank Website

- NIA Contracting Officer's Representative (COR) – NIA personnel responsible for the administrative and scientific oversight of the AgingResearchBiobank as a whole. NIA Staff has expertise on biorepository issues and on specific NIA-funded studies included in the AgingResearchBiobank or relevant studies that have collections that may be kept somewhere else.

- Study – A particular clinical trial or longitudinal/observational 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

- Primary Investigator (PI) – 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 may also be the requestor noted above. This person must sign a transfer agreement to obtain access to AgingResearchBiobank's samples and/or data.

- Authorized Organization Representative (AOR) – Also known as the authorized signatory. The individual, named by the applicant organization, who is authorized to act for the requestor and to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to grant applications or grant awards. This official is equivalent to the Signing Official (SO) 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 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.

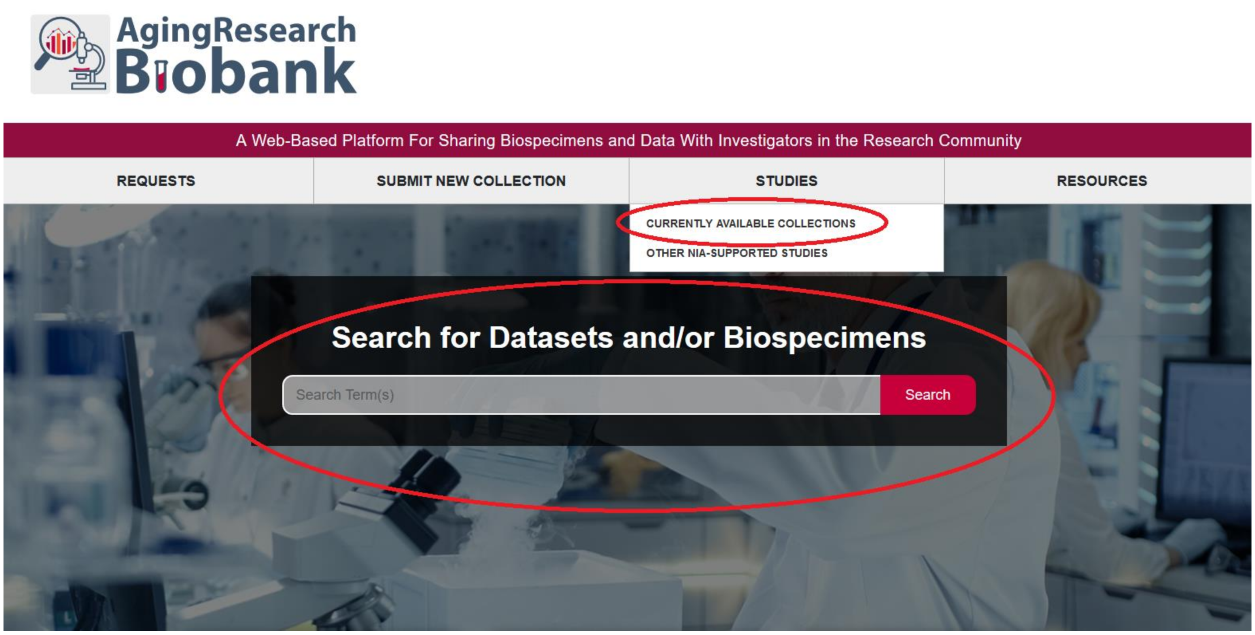
Institutional Review Board (IRB) – A body that reviews proposed research to ensure ethical guidelines are followed. When referred to in the context of the AgingResearchBiobank, this is the body overseeing the research proposed by the requestor. It may be affiliated with the requestor's institution or 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.

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 provided on the website. This documentation includes a listing of the available elements within the study's data and guidance as to the organization of the data. The study page also describes the population and interventions involved in the parent study. 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. Additional data not listed publicly is not available via the AgingResearchBiobank.

Figure 2.1 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 2.3.1 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 2.1 – Searching for Studies from the AgingResearchBiobank Homepage



2.3.1 THE STUDY SEARCH PAGE

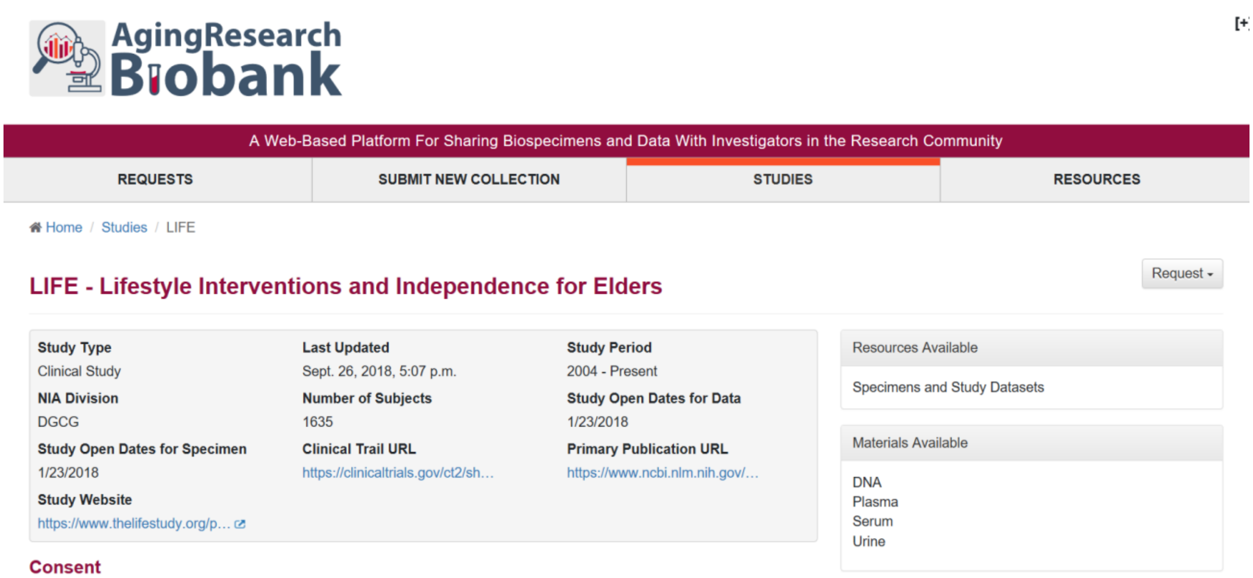
The study search page, as seen in Figure 2.2 below, is the interface through which a user can search for applicable studies with available materials. The search bar to the left of the page is used to search the study descriptions for the terms entered. The left side of the page contains a variety of 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 2.3.2 below.

Figure 2.2 – The Study Search Page

2.3.2 THE STUDY PAGE

As seen in the example in Figure 2.3 below, each requestable study within the AgingResearchBiobank has its own study page.

Figure 2.3 – An Example Study Page



The study page contains several sections:

- Quick facts about the study are found in the box at the top center of the page. These include the number of subjects in the data, type of study, area of research, etc. Links to additional study 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 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 this study. There are two options for most studies: Request Data and Request Samples and 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 2.3.3 below.

2.3.3 STUDY DOCUMENTS

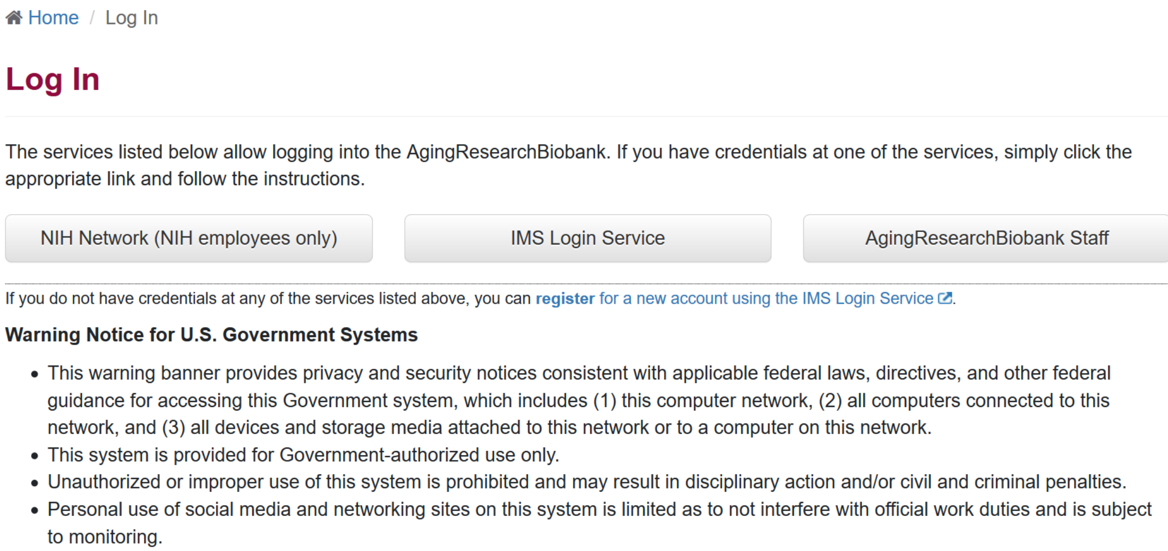
Contained within the Study Documents box described above are links to download the documentation provided by the study to the AgingResearchBiobank. Documents provided by each study vary in name and content, but generally fall into the following categories:

- 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.

2.4 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 2.4 below.

Figure 2.4 – The Login and Registration Page



There are two options for creating an account. NIH Staff can login using their existing credentials using their PIV card by clicking the leftmost button. When logging in for the first time via this method, users will be asked for some additional details. Users that are not NIH Staff should register via the IMS Login Service option by clicking the center button. On-screen prompts will guide the user through registration. E-mail confirmation is required to create an account. Note that only AgingResearchBiobank Website Staff use the rightmost button.

2.5 SUBMITTING A DATA REQUEST

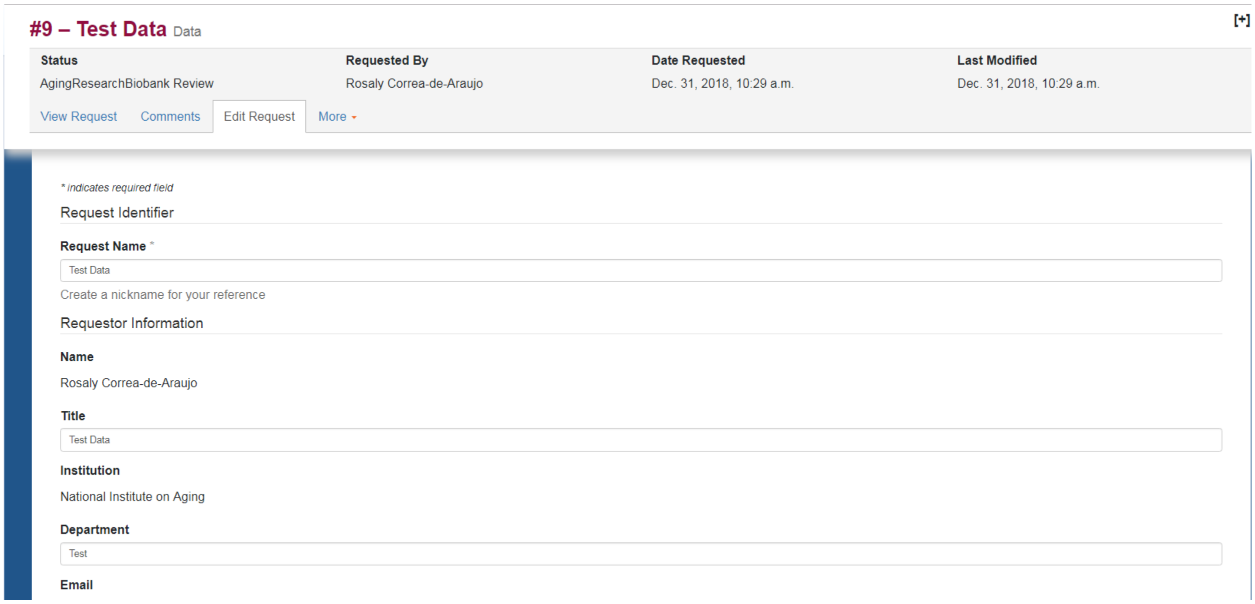
A Data Request may be submitted in two ways. The first is via the Request button on the study page seen in Figure 2.3, and selecting the type of request, if multiple types are available. To create a data request, the Data option should be selected. This brings up the request form and pre-selects the study from which the request was initiated.

The second way to submit a request is via the Request Data option from the Requests Menu. This brings up the data request form with no study pre-selected.

2.6 THE DATA REQUEST FORM

Upon initiating a data request via one of the methods described above, the user is brought to the data request form. The form is seen in Figure 2.5 below. Section 2.6.1 below describes the sections of the data request form, the required information and the functionality of the buttons on the form.

Figure 2.5 – The Data Request Form



2.6.1 DATA REQUEST FORM FIELDS AND FUNCTIONS

Request Identifier Section – The form begins with a section and field for the Request Name. This is the nickname by which a user can refer to a request. It is helpful for users submitting multiple requests to be descriptive, as this will show up in their list of requests (discussed in section 2.7 below).

Requestor Information Section – This section contains fields describing the requestor and Primary Investigator (PI). These may be the same person, but a separate user may also submit a request on behalf of the PI. Requestor information is partially auto-filled from the user's profile, but may be edited.

Support Information Section – This section contains questions characterizing the lead investigator as well as fields to describe the funding source. A federal grant may also be added if applicable.

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, 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.

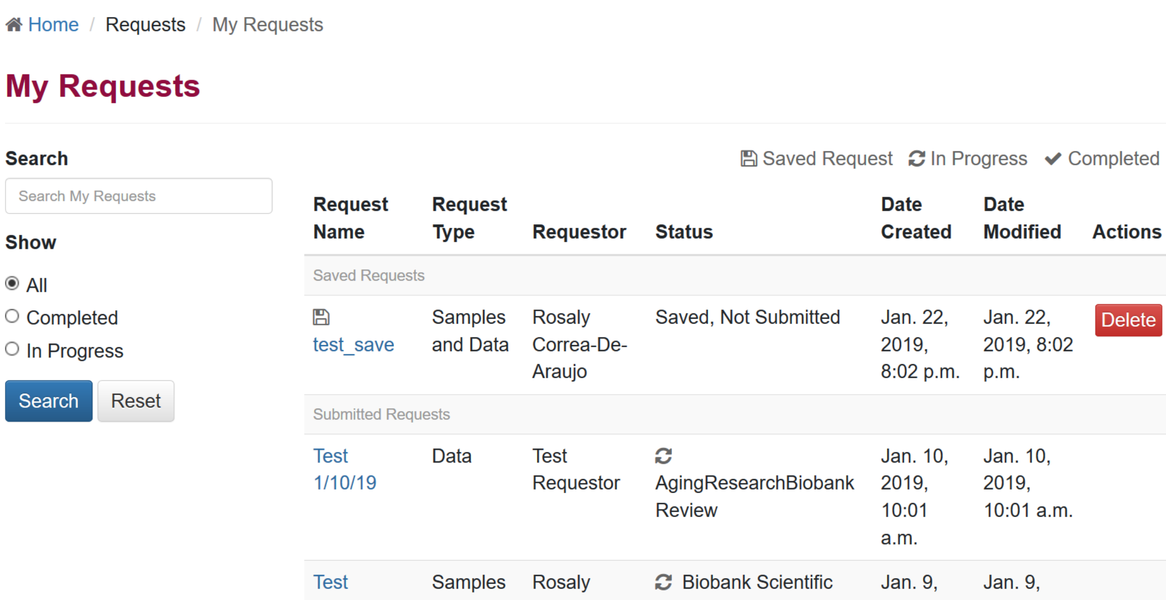
Attachments – This section allows the user to attach documents such as a full analysis protocol or IRB approval or exemption at the start of the request. IRB documentation is not required at submission, but will be required before the data are released.

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 2.7 below but not visible to the AgingResearchBiobank. This should only be used if the user intends to return and complete the form at a later time. Submitting the request saves the form and alerts AgingResearchBiobank Staff to review the input.

2.7 THE MY REQUESTS PAGE

The My Requests screen is the hub for accessing saved and submitted requests. It is available to users that have logged in to the AgingResearchBiobank Website and is visible in the Requests section of the main menu at the top of all pages. As seen in Figure 2.6 below, the page will contain a table of 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 2.6 – My Requests Page



2.8 REQUEST TABS

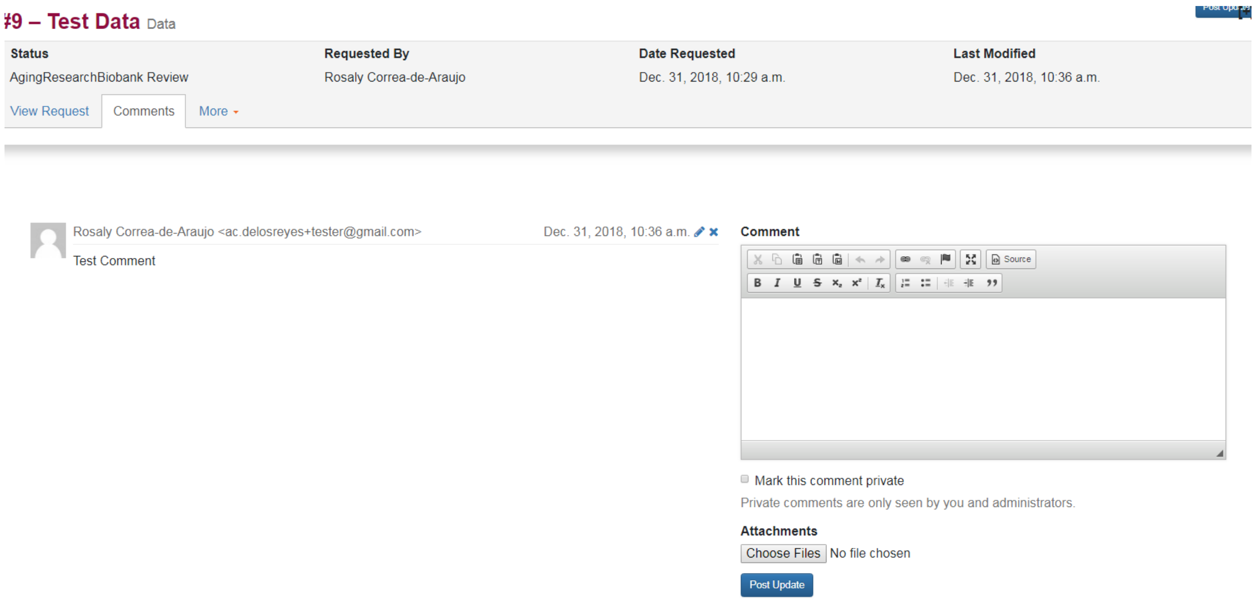
When a request is accessed via the My Requests page, there are four tabs accessible to the user. These are located below the header, which contains the most important information regarding the request. The tabs are:

View Request and Edit Request – These tabs allow the user to view and edit the information from the request form, respectively. The edit page has the same functionality as the request form described above. The view page is a locked version for reference.

Comments – The Comments tab, seen in Figure 2.7 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 to the AgingResearchBiobank. As described below, comments by AgingResearchBiobank Staff will generate an email with a link to this page.

Datasets – The Datasets tab will appear after a request has been approved. It contains links to download the approved data packages.

Figure 2.7 – The Comments Tab



2.9 REQUEST ACTIONS

Within the header of the request, seen in Figure 2.79 above, there is a tab called More, listing certain actions the requestor can take. The following actions are available:

Edit Request – Opens the Edit tab described above.

Add Approved Users – Opens a page where additional registered users can be provided access to 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. The requestor also has the option to share dataset access or restrict access to only the online request. Current approved users are displayed below the interface to add new users.

Generate PDF – Generates a PDF of the request form.

2.10 DATA REQUEST PROCESS

After submitting the request form described in section 2.6 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 issues that require input from the requestor, the request will be set to a status of “Pending Requestor Input”. The requestor will receive an email indicating that the request has been updated and a direct link to the Comments Tab will be included. When the requestor responds, AgingResearchBiobank Staff will review the input again and respond as appropriate.
3. If the request form is complete, AgingResearchBiobank Staff will post a comment providing the requestor with an agreement for the PI and an institutional representative to sign. If an IRB approval has already been attached the status of the request will be set to “Pending Requestor Agreement Signature”. If an IRB approval has not been attached the request will be set to a status of “Pending Requestor Documentation”. The requestor will receive an email indicating that the request has been updated and a direct link to the Comments Tab will be included.
4. The requestor will return a signed copy of the agreement (and IRB approval if not previously attached) to the Comments Tab. The agreement must be signed by the PI and AOR.
5. AgingResearchBiobank Staff will review the signed agreement. If complete, the request will be assigned to NIA Staff for review, setting the status of the request to NIA Staff Review. If incomplete, AgingResearchBiobank Staff will post a comment explaining what is needed and set the request to the appropriate status. The requestor will receive an email indicating that the request has been updated and a direct link to the Comments Tab will be included.
6. NIA Staff will review the request for appropriateness and feasibility.
7. If NIA staff do not approve, AgingResearchBiobank Staff will relay their concerns to the requestor 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. A requestor may address the concerns or choose to abandon the request.
8. If NIA Staff approve, AgingResearchBiobank Staff will inform the requestor via the Comments Tab and a link to the Datasets tab will become visible. The data package for each study will be available via a link on the Datasets 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.
9. 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 and set the request to a status of “Fulfilled”. The requestor will receive an email indicating that the request has been updated and a direct link to the Comments Tab will be included.
10. If the requestor has questions regarding the data they may post them in the Comments tab. 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. The requestor will receive an email indicating that the request has been updated and a direct link to the Comments Tab will be included.

2.11 AGREEMENT EXPIRATIONS AND RENEWALS

Agreements are valid for three years from the date of execution. As expiration approaches, AgingResearchBiobank Staff will send an email to the requestor and PI informing that expiration is approaching. If the data are no longer needed, they should be removed from local systems. This will be noted by AgingResearchBiobank Staff and the date of destruction noted through the request.

If the data are still in use, the requestor or PI should submit an extension letter. The letter must be signed by the PI and an authorized representative of the institution in the same manner as the original agreement. The extension letter should be posted to the Comments tab. AgingResearchBiobank Staff will receive a notification that this has been posted and send an acknowledgement. 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 PI leave the institution whose AOR 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 AOR.

Chapter 3: How to Create a Request for Samples and Data

3.1 OVERVIEW

This Chapter provides information on the submission, review and fulfillment of Samples and Data Requests via the AgingResearchBiobank Website. It describes the process by which investigators may determine the available materials and apply for access to samples and data archived from NIA-funded clinical trials and longitudinal/observational studies.

The process of applying for samples takes place over a period of time. First, the requestor seeks out materials appropriate for their research and receives a statement on their availability from the AgingResearchBiobank. If the requestor has already obtained funding for the research, AgingResearchBiobank Staff will obtain additional information and submit the request for review by the Biobank Scientific Review Committee (BSRC) and approval by the NIA COR. If the requestor does not have funding, this statement may be included in any application for funding to use the materials. If the grant application is approved, the requestor should upload a copy of the approval to the Comments tab of their request to continue the request process. AgingResearchBiobank Staff will then obtain additional information from the requestor and submit the request for review by the BSRC and approval by the NIA COR.

3.2 DEFINITIONS

- AgingResearchBiobank Staff – Personnel at the contractor level responsible for the maintenance of the data repository and AgingResearchBiobank Website.

- NIA Contracting Officer's Representative (COR) – NIA personnel responsible for the administrative and scientific oversight of the AgingResearchBiobank as a whole. NIA Staff has expertise on biorepository issues and on specific NIA-funded studies included in the AgingResearchBiobank or relevant studies that have collections that may be kept somewhere else.

- Study – A particular clinical trial or longitudinal/observational 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

- Primary Investigator (PI) – 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 may also be the requestor noted above. This person must sign a transfer agreement to obtain access to the AgingResearchBiobank's samples and/or data.

- Authorized Organization Representative (AOR) – Also known as the authorized signatory. The individual, named by the applicant organization, who is authorized to act for the requestor and to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to grant applications or grant awards. This official is equivalent to the Signing Official (SO) 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 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.

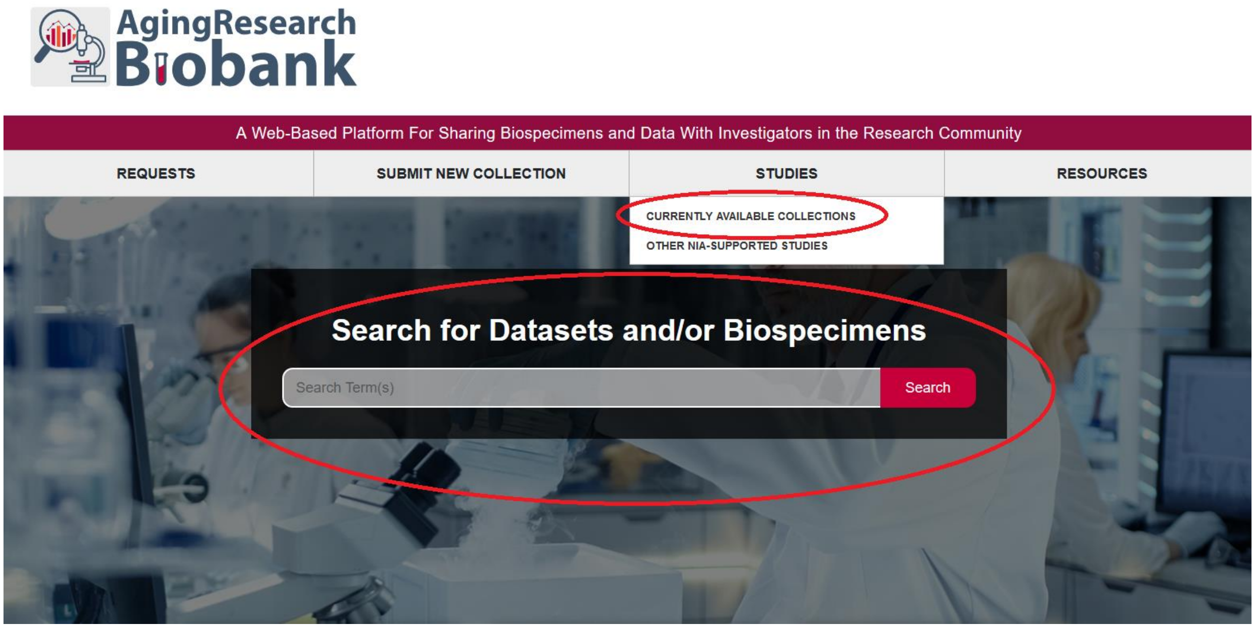
Institutional Review Board (IRB) – A body that reviews proposed research to ensure ethical guidelines are followed. When referred to in the context of the AgingResearchBiobank, this is the body overseeing the research proposed by the requestor. It may be affiliated with the requestor's institution or independent. 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.

3.3 FINDING AVAILABLE MATERIALS AND STUDIES

Prior to the submission of a request to the AgingResearchBiobank, investigators are encouraged to examine the information provided on the AgingResearchBiobank Website. The website includes the available material types, documentation of the available data elements and an overview of the study's design. 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. Additional data not listed publicly is not available via the AgingResearchBiobank. Some study samples may likewise be unavailable due to prior use or exclusion from the AgingResearchBiobank. Investigators should ensure that appropriate materials and data are available from a study before submitting an availability request.

Figure 3.1 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 3.3.1 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 3.1 – Searching for Studies from the AgingResearchBiobank Homepage



3.3.1 THE STUDY SEARCH PAGE

The study search page, as seen in Figure 3.2 below, is the interface through which a user can search for applicable studies with available materials. The search bar at the top 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 studies to those with material available and those with a population or intervention of interest.

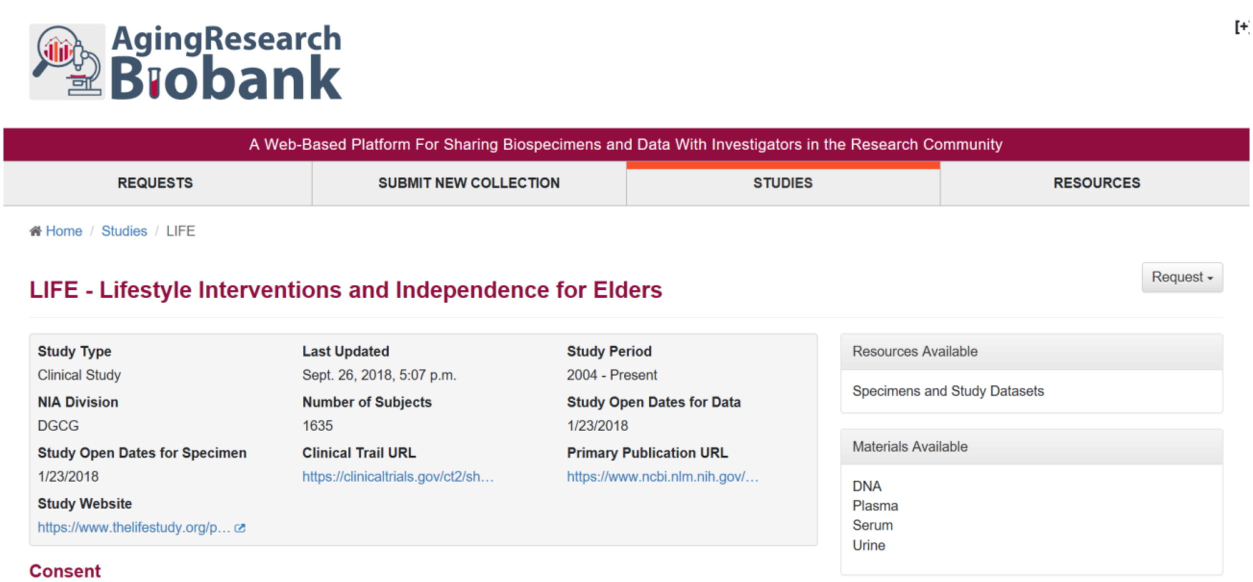
When a filter is applied, the matching studies will be displayed within the table on the center of the page. Clicking on the name of the study brings the user to the study page, described in section 3.2 below.

Figure 3.2 – The Study Search Page

3.3.2 THE STUDY PAGE

As seen in the example in Figure 3.3 below, each requestable study within the AgingResearchBiobank has its own study page.

Figure 3.3 – An Example Study Page



The study page contains several sections:

- Quick facts about the study are found in the box at the top center of the page. These include the number of subjects in the data, type of study, area of research, etc. Links to additional study 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 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 this study. There are two options for most studies: Request Data and Request Samples and 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 samples that may be available from the study.
- Below "Resources Available" is a box for Study Documents. The available documents vary by study and several common types are described in section 3.3.3 below.

3.3.3 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:

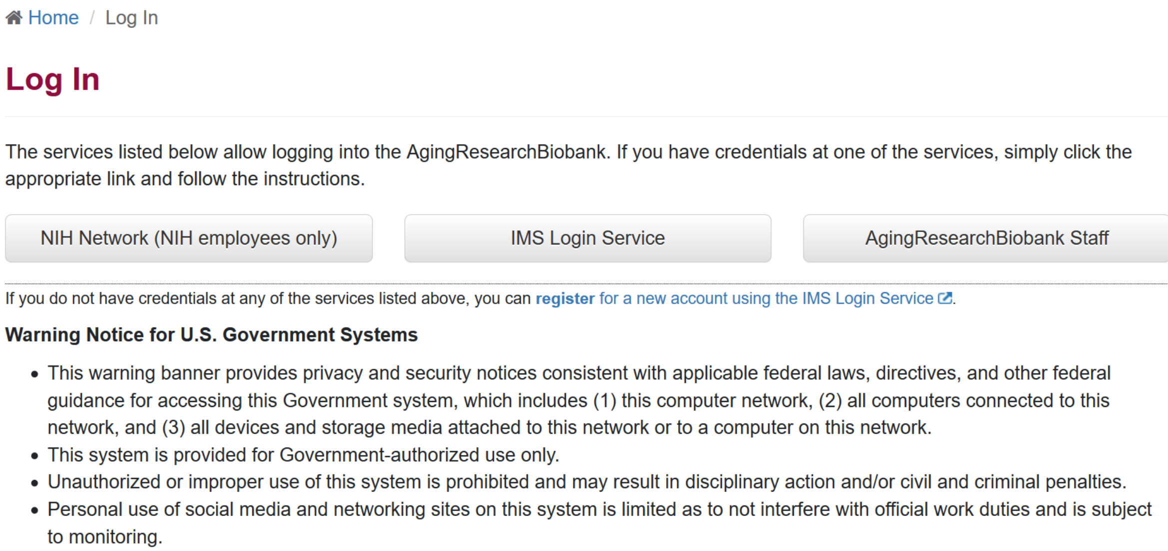
- Data Dictionary – A document listing the variable labels and descriptions. These are organized according to the datasets provided by the study. Forms – The forms used to generate portions of the data. Can be used in conjunction with the data dictionary to see the details of a particular variable's 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.

3.4 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 AgingResearchBiobank Website. The Login page is shown in Figure 3.4 below.

There are two options for creating an account. NIH Staff can login using their existing credentials using their PIV card by clicking the leftmost button. When logging in for the first time via this method, users will be asked for some additional details. Users that are not NIH Staff should register via the IMS Login Service option by clicking the center button. On-screen prompts will guide the user through registration. E-mail confirmation is required to create an account. Note that only AgingResearchBiobank Website Staff use the rightmost button.

Figure 3.4 – The Login and Registration Page



3.5 SUBMITTING A REQUEST FOR SAMPLES AND DATA

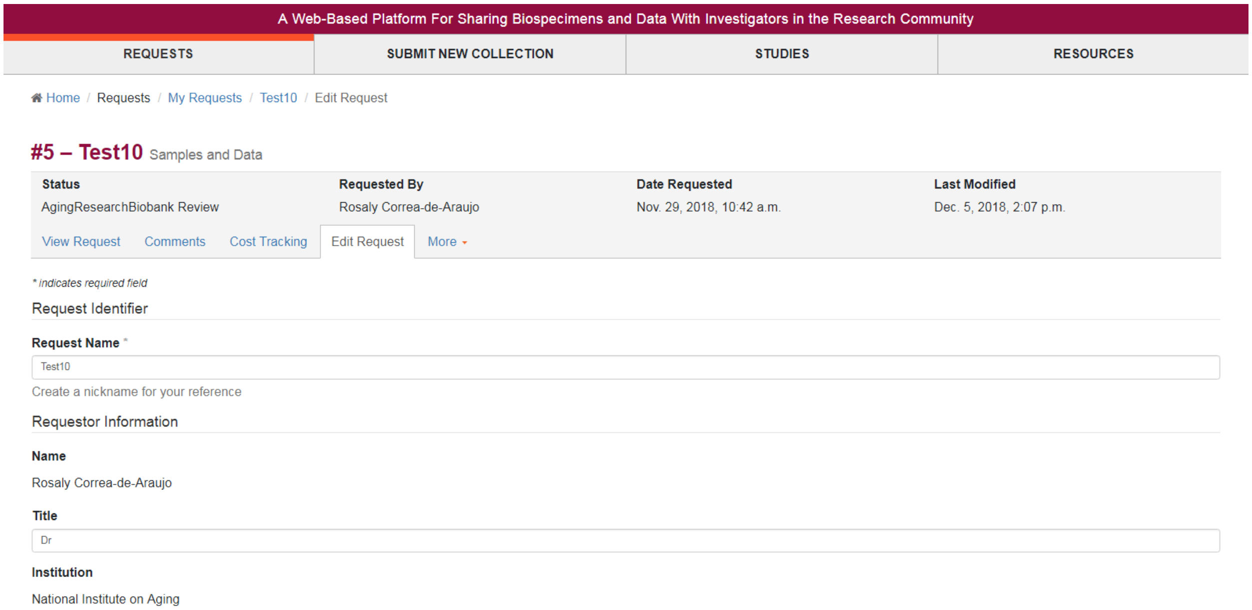
A request for Samples and Data may be submitted in two ways. The first is via the Request button on the study page seen in Figure 3.3, and selecting the type of request, if multiple types are available. To create a request for Samples and Data, the Samples and Data option should be selected. This brings 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 Samples and Data option from the Requests Menu. This brings up the request form with no study pre-selected.

3.6 THE INITIAL SAMPLES AND DATA REQUEST FORM

Upon initiating a request for Samples and Data via one of the methods described above, the user is brought to the request form. The form is seen in Figure 3.5 below. Section 3.6.1 below describes the sections of the form, the required information and the functionality of the buttons on the form.

Figure 3.5 – The Samples and Data Request Form



3.6.1 SAMPLES AND DATA REQUEST FORM FIELDS AND FUNCTIONS

Request Identifier Section – The form begins with a field for the Request Name. This is the nickname by which a user can refer to a request. It is helpful for users submitting multiple requests to be descriptive, as this will show up in their list of requests (discussed in section 3.7 below).

Requestor Information Section – This section contains fields describing the requestor and Primary Investigator (PI). These may be the same person, but a separate user may also submit a request on behalf of the PI. Requestor information is partially auto-filled from the user's profile, but may be edited.

Support Information Section – This section contains questions characterizing the lead investigator as well as fields to describe the funding source. A federal grant may also be added if applicable.

Request Details – 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 samples 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 samples. 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 samples from specific visits. Requestors should also indicate whether samples 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 samples fields provide a space for the requestor to list an estimate of the total number of samples 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 samples requested will be considered as part of the request's review for approval.
- 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.

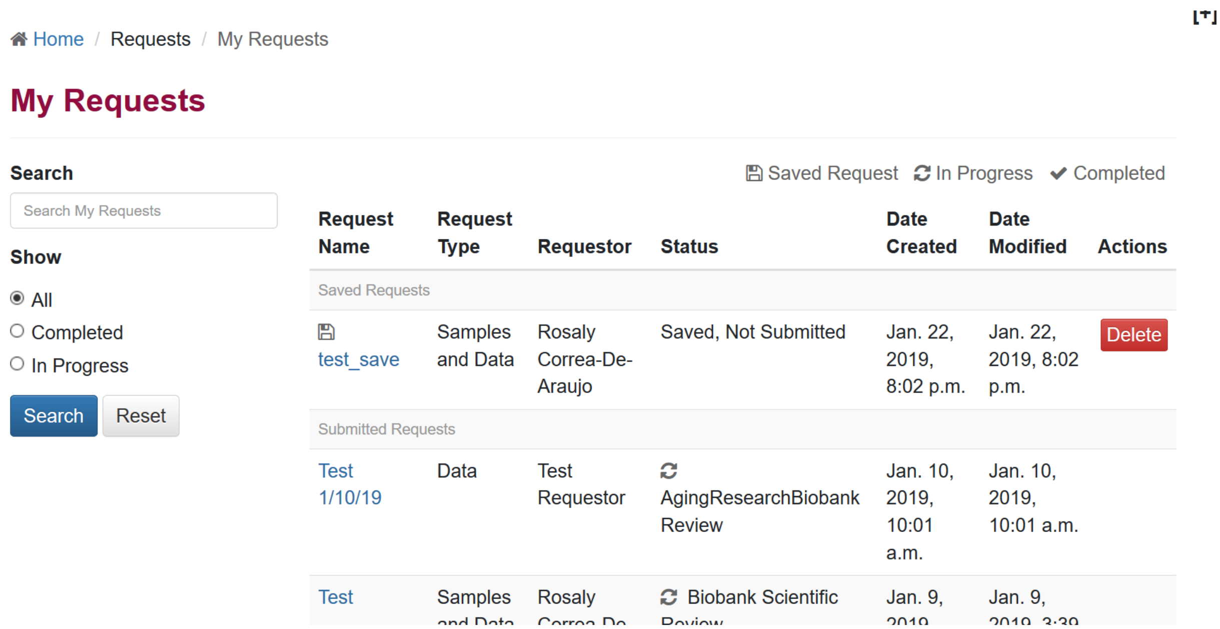
Attachments – This section allows the user to attach any supporting documentation such as a full protocol, proof of funding, or IRB documentation they may have and wish to share. No attachments are required for submission.

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 3.7 below but not visible to the AgingResearchBiobank. This should only be used if the user intends to return and complete the form at a later time. Submitting the request saves the form and alerts AgingResearchBiobank Staff to review the input.

3.7 THE MY REQUESTS PAGE

The My Requests screen is the hub for accessing saved and submitted requests. It is available to users that have logged in to the AgingResearchBiobank site and is visible in the Requests menu at the top of all pages. As seen in Figure 3.7 below, the page will contain a table of requests with pertinent information. Requests are accessed by clicking on the row within the table. There are sections for saved and submitted requests.

Figure 3.7 – My Requests Page



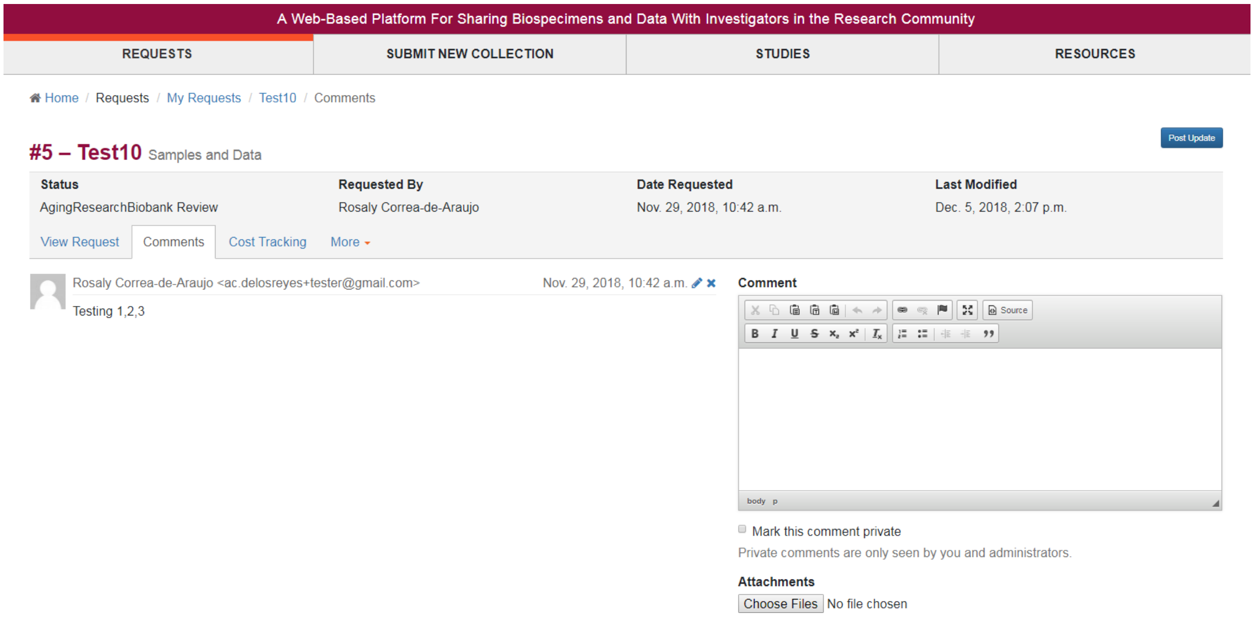
3.8 REQUEST TABS

When a request is accessed via the My Requests page, there are 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 and Edit Request – These tabs allows the user to view and edit the information from the request form, respectively. The edit page has the same functionality as the request form described above. The view page is a locked version for reference.

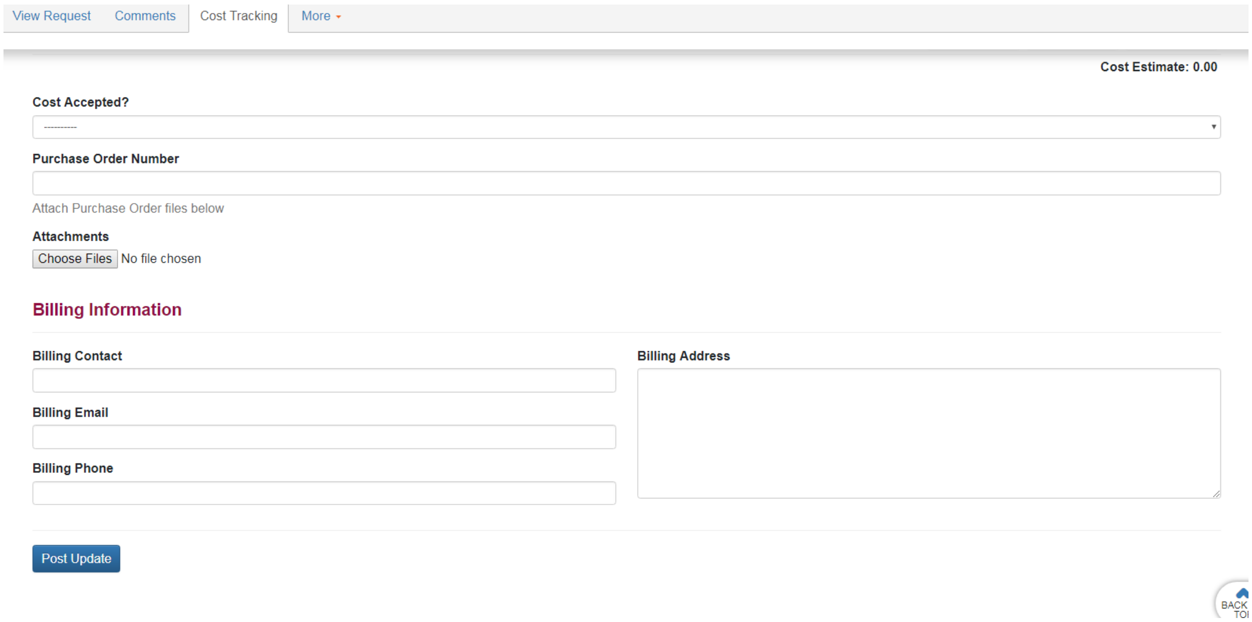
Comments – The Comments tab, seen in Figure 3.8 below, provides a space for AgingResearchBiobank Staff and requestors to interact and share files. All communication should take place through this tab and emails should not be sent to the AgingResearchBiobank. If needed for a grant application, an availability report will be posted on this tab. As described below, comments by AgingResearchBiobank Staff will generate an email with a link to this page.

Figure 3.8 – The Comments Tab



Cost Tracking – Once a request is approved by NIA, the Cost Tracking tab provides a location where AgingResearchBiobank Staff will post a cost estimate for processing the samples 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 samples. An example of the Cost Tracking tab with a cost estimate is shown in Figure 3.9 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 3.9 – The Cost Tracking Tab



Datasets – The Datasets tab will appear after a request has been approved. It contains links to download the approved data packages.

3.9 REQUEST ACTIONS

Within the header of the request, seen in Figure 3.8 above, there is a tab called More, listing certain actions the requestor can take. The following actions are available:

Edit Request – Opens the Edit tab described above to edit a request once it has been submitted

Add Approved Users – Opens a page where additional registered users can be provided access to 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. The requestor also has the option to share dataset access or restrict access to only the online request. Current approved users are displayed below the interface.

Generate PDF – Generates a PDF of the request form

3.10 SAMPLES AND DATA REQUEST PROCESS

After submitting the request form described in section 3.6.1 the following will occur:

1. AgingResearchBiobank Staff will review the requestor's input in light of the available materials within the AgingResearchBiobank.
2. If the request form does not contain sufficient information for a search of the AgingResearchBiobank's inventory or if the input is unclear, 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. When the requestor responds in sufficient detail, the

request will proceed to the next step. The requestor will receive an email indicating that the request has been updated and a direct link to the Comments Tab will be included.

3. If the request criteria is complete and AgingResearchBiobank Staff have sufficient information to perform a query, they will acknowledge to the requestor that a search has begun.
4. Upon successful completion of a search, AgingResearchBiobank Staff will post an impact report to 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. The requestor will review this report 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 statement of availability will be posted to the Comments tab and can be submitted with any grant for funding.
7. If funding has already been obtained, NIA Staff will review the request for appropriateness and feasibility.
8. If NIA staff do not approve, AgingResearchBiobank Staff will relay their concerns to the requestor 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. A requestor may address the concerns or choose to abandon the request.
9. If NIA Staff approve, AgingResearchBiobank Staff will inform the requestor 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.
10. Once approved, the following additional fields should be completed to proceed:

    Specimen Shipping Information Section – This section contains a field for the shipping address and email address of the user that will be receiving the samples. 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.

11. AgingResearchBiobank Staff will post a comment providing the requestor with an agreement for the PI and an institutional representative to sign. If an IRB approval has already been attached it will be included in this agreement and the status of the request will be set to “Pending Requestor Agreement Signature”. If an IRB approval has not been attached the request will be set to a status of “Pending Requestor Documentation”. The requestor will receive an email indicating that the request has been updated and a direct link to the Comments Tab will be included.
12. The requestor will return a signed copy of the agreement (and IRB approval if not previously attached) to the Comments Tab. The agreement must be signed by the PI and AOR.
13. AgingResearchBiobank Staff will review the signed agreement. If complete, the request will be assigned to NIA Staff for their signature, setting the status of the request to NIA Staff Review. If incomplete, AgingResearchBiobank Staff will post a comment explaining what is needed and set the request to the appropriate status. The requestor will receive an email

indicating that the request has been updated and a direct link to the Comments Tab will be included.

14. AgingResearchBiobank Staff will inform the requestor via the Comments Tab that a link to the Datasets tab has become visible. The data package for each study will be available via a link on that 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.
15. 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.
16. After providing a link to the data, AgingResearchBiobank Staff will provide a cost estimate for processing the samples via the Cost Tracking tab.
17. 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 request is set to a status of "Pending Cost Approval". 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.
    a. If the requestor is based in the United States and the cost is under $5000, AgingResearchBiobank Staff will proceed to the next step.
    b. If the requestor is based outside of the United States or the cost is over $5000, AgingResearchBiobank Staff will invoice, as described in the next section, and await payment before proceeding to the next step.
18. Upon cost approval or payment, AgingResearchBiobank Staff will submit the samples to the Biorepository for processing and set the request to "Biorepository Processing Samples".
19. When the samples are ready for shipment, the shipping contact will be emailed to arrange a receipt date. Samples will be shipped to the specified address.
20. After shipment and receipt is confirmed by the biorepository, the shipment date and number of samples shipped will appear in the request header. A file linking the samples to the data provided previously will also be added to the Comments tab. Prepaid requests will be set to a status of "Fulfilled" while those that have yet to pay will be set to a status of "Awaiting Payment" with invoicing proceeding as described in the next section.

3.11 INVOICING

When a request requires payment for the processing of the samples, AgingResearchBiobank Staff will send an invoice to the contacts provided via the Cost Tracking tab at the time of cost approval. Invoices are sent as a PDF via e-mail from the address AgingResearchBiobank@imsweb.com. They are sent to the billing contact, PI and requestor (if not the PI). A purchase order will be referenced and included as an attachment if it was provided to the AgingResearchBiobank.

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.

3.12 AGREEMENT EXPIRATIONS AND RENEWALS

Agreements are valid for three years from the date of execution. As expiration approaches, AgingResearchBiobank Staff will send an email to the requestor and PI informing that expiration is approaching. If the data are no longer needed, they should be removed from local systems. This will be noted by AgingResearchBiobank Staff and the date of destruction noted through the request.

If the data or samples are still in use, the requestor or PI should submit an extension letter for the agreement. The letter must be signed by the PI and an authorized representative of the institution (AOR) in the same manner as the original agreement. The extension letter should be posted to the Comments tab. AgingResearchBiobank Staff will receive a notification that this has been posted and send an acknowledgement. Extension letters will be archived on the Comments tab and the date of expiration updated to reflect the extension of the agreement for another three year.

If at any time during the tenure of the agreement or extension the requestor or the PI leave the institution whose AOR 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 AOR.