

# Request for Applications: The Human Tissues and Organs for Research Resource Pilot Award Program Fall 2024 Program Announcement

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## 1 Overview

### 1.1 Funder Overview

The National Disease Research Interchange (NDRI) is a 501(c)(3), not-for-profit with a mission to provide human biospecimens to researchers worldwide for the purpose of advancing biomedical/bioscience research and development and supporting education in the life sciences. Importantly, we serve as the Human Tissue and Organ for Research Resource (HTORR), as the National Institutes of Health (NIH) has supported our work for more than 30 consecutive years. Our unparalleled tissue recovery network includes over 130 partners comprised of organ procurement organizations, eye banks, tissue banks and hospitals, and our biorepository facility is accredited by the College of American Pathologists (CAP). Utilizing the expertise of NDRI staff and that of our recovery partners, we provide anatomical structures, organs, and tissues with annotated data to support research across the full spectrum of disease and disability.

Since our founding, we have been committed to expanding the horizons of medical knowledge. We continue to do so today, with an array of programs designed to provide human tissues and organs to meet critical research needs. We are grateful for the support we receive from the National Institutes of Health and other public and private funding sources, from our expansive nationwide network of recovery partners, and through the generosity of patients and families who want to contribute to finding answers to today's most pressing biomedical challenges.

### 1.2 Funding Opportunity in Brief

**Title:** The Human Tissues and Organs for Research Resource Pilot Award Program

**Award:** This award will cover all costs associated with obtaining up to ~10 human biospecimens to be used in a pilot study, including tissue preservation reagents and shipping costs, for an award period of up to 24 months. **The preliminary data generated through the completed Pilot Award study is expected to be used in at least one subsequent grant application by the end of the 2-year project period to at least one of the following NIH Institutes:** National Institute of Allergy and Infectious Diseases (**NIAID**), the National Heart, Lung, and Blood Institute (**NHLBI**), the National Eye Institute (**NEI**), the National Institute of Diabetes and Digestive and Kidney Diseases (**NIDDK**), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (**NIAMS**), or the Office of Research Infrastructure Programs (**ORIP**).

### 1.3 Key Dates

**Request for Applications Open:** June 1, 2024

**Application Deadline:** October 1, 2024, 5 p.m. US EST

**Anticipated Award Decision:** December 2024

**Anticipated Earliest Start Date:** January 2025

All required documentation must be completed within 60 days of the award offer. Otherwise, we reserve the right to rescind the award offer and redirect the funds to other projects.

## 2 Full Announcement

### 2.1 Funding Opportunity Description

#### 2.1.1 Program Overview

Primary diseased and control human tissue samples are a vital resource for starting new programs focusing on human disease research, but they can be both expensive and difficult for investigators to obtain, especially before securing a grant. **The Human Tissues and Organs for Research Resource Pilot Award Program (PAP) seeks to enable the completion of pilot studies necessary for an investigator to obtain subsequent funding.** Specifically, we are planning to support individuals that meet at least one of the following three high priority areas: 1) individuals from underrepresented populations in the U.S. biomedical workforce, including women, minorities, persons with disabilities, and persons from disadvantaged backgrounds, 2) early-stage investigators that are within 10 years of a terminal degree or completion of clinical residency, and 3) established investigators that are transitioning to using human biospecimens. These 2-year awards provide up to ~10 biological samples per awarded investigator, covering all costs associated with obtaining the biospecimens, including tissue preservation reagents and shipping costs. Pilot Award Program awardees will also receive additional technical support for tissue procurement protocol design to help bolster rigor and reproducibility in their experimental data and analysis.

Importantly, as this Pilot Award is intended to generate the preliminary data necessary for an investigator to obtain subsequent funding, a stipulation of this award is that **the data generated through the completed Pilot Award study is expected to be used in at least one subsequent grant application to at least one of the following NIH Institutes by the end of the 2-year project period:** National Institute of Allergy and Infectious Diseases (**NIAID**), the National Heart, Lung, and Blood Institute (**NHLBI**), the National Eye Institute (**NEI**), the National Institute of Diabetes and Digestive and Kidney Diseases (**NIDDK**), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (**NIAMS**), or the Office of Research Infrastructure Programs (**ORIP**).

Successful applications will include strong and compelling data supporting the biological rationale for the proposed pilot experiment(s) as well as a detailed explanation of how the proposed pilot experiment(s) will support at least one subsequent grant application with a clear timeline outlining both the proposed project and subsequent grant submissions.

#### 2.1.2 Topics of Interest

HTORR is supported by a U42 grant funded through the Office of Research Infrastructure Programs (**ORIP**), with co-funding institutes of the National Institute of Allergy and Infectious Diseases (**NIAID**), the National Heart, Lung, and Blood Institute (**NHLBI**), the National Eye Institute (**NEI**), the National Institute of Diabetes and Digestive and Kidney Diseases (**NIDDK**), and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (**NIAMS**). **Therefore, only applicants whose work aligns with the current mission of these specified institutes will be reviewed.**

#### 2.1.3 Topics Not Supported by This Funding Opportunity

The following are **not appropriate** for this funding opportunity, and applications focusing on these topics will be administratively withdrawn:

- Clinical trials
- Research using fetal tissue
- Applications that do not align with the mission of at least one HTORR co-funding institute

## 2.2 Award Information

### 2.2.1 Anticipated Number of Awards

- A maximum of fourteen (14) total awards can be funded per program year.

### 2.2.2 Award Budget

- Awards will provide up to ~10 biological samples per awarded investigator, covering all costs associated with obtaining the biospecimens, including tissue preservation reagents and shipping costs.

### 2.2.3 Award Period of Performance:

- The maximum period of performance is 2 years, unless prior written approval for an extension is obtained from HTORR.

## 2.3 Eligibility

### 2.3.1 Eligible Individuals

Eligible individuals must hold a faculty position with the title of assistant professor, instructor, research assistant professor, professor, or the equivalent at an academic, medical, or research institution and meet at least one of the following three high priority areas:

- Belong to group(s) that has (have) been shown to be traditionally excluded in the sciences workforce
  - These groups can include women, persons with disabilities, persons from disadvantaged backgrounds (as defined by the NIH [here](#)), and minorities such as Black or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians and other Pacific Islanders. It is recognized that the traditionally excluded group(s) can vary from setting to setting and individuals from underrepresented groups not listed above may also be eligible to apply for this program. Please contact [Grants@ndriresource.org](mailto:Grants@ndriresource.org) for additional information.
- Early-stage investigators that are within 10 years of a terminal degree or completion of clinical residency
- Established investigators that are transitioning to using human biospecimens

### 2.3.2 Eligible Organizations

- U.S. public and private non-profit entities, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government.

## 2.4 Content and Review of Applications

It is **highly encouraged** that all applicants fill out and submit the Requested Tissue Information Form to NDRI **at least 2 weeks prior to submitting a full application**. This will allow us to evaluate and provide feedback about the feasibility of procuring the proposed tissues to researchers to aid in the development of successful applications and prevent the decline of applications due to non-feasible tissue requests. Submit forms to [Grants@ndriresource.org](mailto:Grants@ndriresource.org).

## 2.4.1 Application

### 2.4.1.1 Content - General

In summary, the application must include:

- Requested Tissue Information Form
- Administrative Information Form
- Personal Statement (*2 pages maximum*)
- Lay Summary (*500 words maximum*)
- Scientific Abstract (*500 words maximum*)
- Specific Aims (*1 page maximum*)
- Research Plan (*6 pages maximum*)
  - Background
  - Preliminary/Supporting Data
  - Experimental Plan
  - Timeline
    - Must include experimental milestones and planned grant application submissions.
- References
- Letters of Recommendation (*minimum of 2, maximum of 3*)
- Additional Attachments
  - Applicant Biosketch
  - Biosketches for Collaborators (*if applicable*)
  - Letters of Collaboration (*if applicable*)
- Signed HTORR Pilot Award Program Application Checklist

### 2.4.1.2 Content – Specific

Requested Tissue Information Form: This form will include basic project information including a Public Health Relevance Statement (50 words or less) and a Short Project Description (150 words or less), along with specific tissue request information including tissue type, disease state, sample size, preservation method, and donor criteria.

While this component is a required part of the full application package, it is **highly encouraged** that all applicants fill out and submit the Requested Tissue Information Form to NDRI **at least 2 weeks prior to submitting a full application**. This will allow us to evaluate and provide feedback about the feasibility of procuring the proposed tissues to researchers to aid in the development of successful applications and prevent the decline of applications due to non-feasible tissue requests. Submit forms to [Grants@ndriresource.org](mailto:Grants@ndriresource.org).

The final version of the Requested Tissue Information Form must be included in the full application package even if previously submitted to NDRI in advance of the submission deadline.

Administrative Information Form: This form will include basic applicant information, project information, and contact information for letter writers. A minimum of two (2) letters of recommendation are required, with a maximum of three (3) letters.

Personal Statement (*2 pages maximum*): The personal statement should include personal and relevant background that clearly identifies at least one high priority

area indicated in the eligibility section (2.3), along with pertinent scientific experience and specific future career goals.

Lay Summary (500 words maximum): If you are a selected awardee, this summary will be made available to the public on the NDRI website. It should be written for the general, non-scientific public and address the relevant public health implications of the project.

Scientific Abstract (500 words maximum): The abstract should succinctly and comprehensively summarize the proposed pilot project and subsequent grant project(s).

Specific Aims (1 page maximum): The specific aims should outline the significance of the project and the specific steps necessary to address the identified gap in knowledge. Consider reviewing the tips from NINDS on Writing Specific Aims (linked [here](#)).

Research Plan (6 pages maximum): The research plan should provide adequate background information to support the rationale of the project, along with any available preliminary or supporting data. An explicit experimental plan should be included, addressing how the pilot experiment directly supports the proposed subsequent grant proposals. **A timeline is also a required portion of the Research Plan. The timeline should detail specific experimental milestones as well as planned grant application writing and submission deadlines by the end of the 2-year project period to a grant opportunity from at least one of the HTORR co-funding institutes, with the specific NIH institute clearly identified.**

References: References should be appropriately cited throughout the application in APA style.

Letters of Recommendation: A minimum of two (2) letters of recommendation (maximum of 3) are requested. Letter writers should be former mentors or collaborators who have worked directly with the applicant and can speak to their ability and expertise. Letters should be sent to [Grants@ndriresource.org](mailto:Grants@ndriresource.org) directly by the writer.

Additional Attachments: Please include the most up-to-date version of the NIH-formatted biosketch for the applicant. If the proposed research includes collaborators who are necessary to complete the described experiments, please provide the biosketch of each collaborator as well as Letter(s) of Collaboration that explain the support (technical expertise, access to specific equipment, etc.).

#### 2.4.1.3 Review Criteria

Because the primary objective of this Pilot Award Program is to support our awardees on their path to independent funding, each award will be reviewed through the lens of the NIH Institute that will receive the subsequent grant applications from that awardee. Specifically, each application will be reviewed for:

- **Fit**: Does the project fall within the mission and capabilities of HTORR/NDRI? Does the proposed research fall within the scope of **at least one of the**

**following NIH Institutes:**

- National Institute of Allergy and Infectious Diseases (**NIAID**)
  - National Heart, Lung, and Blood Institute (**NHLBI**)
  - National Eye Institute (**NEI**)
  - National Institute of Diabetes and Digestive and Kidney Diseases (**NIDDK**)
  - National Institute of Arthritis and Musculoskeletal and Skin Diseases (**NIAMS**)
  - Office of Research Infrastructure Programs (**ORIP**)
- **Scientific Merit:** What are the strengths and weaknesses of the proposed project? Do the preliminary/supporting data justify the proposed project? Will the subsequent projects be highly valued by the Institute the applicant will be applying to? Is the design of the project adequately developed and appropriate for the aims of the study? Have potential problem areas been acknowledged and alternative tactics been considered? Are the milestones and timelines feasible?
  - **Potential:** If the project is successful, how will the data that is generated fit into the proposed future grant applications? Will the proposed project generate enough data to support a grant application? If not, does the applicant have other data or ability to generate data that will support a successful application?

## 2.4.2 Peer Review and Selection Process

- Proposals will be peer reviewed by a Scientific Review Committee made up of internal and external experts. Based on the applications received, additional experts may be invited to participate to ensure thorough and unbiased reviews.
- The Scientific Review Committee will utilize a scoring rubric that specifically evaluates fit, scientific merit, and potential to assess each application and assign a priority score.
- Reviewer comments will be made available to each applicant. Priority scores will be provided only to the NDRI Internal Selection Committee for final application decisions.
- For applications selected for awards, approval may be contingent on agreement from the PI to reasonably integrate specific recommendations suggested by the reviewers.
- Application status notifications and other award-related correspondence will come from [Grants@ndriresource.org](mailto:Grants@ndriresource.org). Applicants are advised to add this address to their safe sender list to ensure notifications are not directed to their spam folder.

## 2.5 Application and Submission Information

### 2.5.1 Format of Submissions

- It is **highly encouraged** that all applicants fill out and submit the Requested Tissue Information Form to NDRI **at least 2 weeks prior to submitting a full application**. This will allow us to evaluate and provide feedback about the feasibility of procuring the proposed tissues to researchers to aid in the development of successful applications and prevent the decline of applications due to non-feasible tissue requests. Submit forms to [Grants@ndriresource.org](mailto:Grants@ndriresource.org).
- All application materials must be consolidated into a single PDF file and submitted as a single file, **with filename**: ApplicantLastName\_PAP\_[Fall/Spring]Year.pdf
- Files should be concatenated in the order specified in 2.4.1.1 “Content”.
- Upon receipt, application materials will be evaluated for completeness and compliance with application instructions and a receipt confirmation will be sent via email. Application materials that are incomplete and/or non-compliant will not be reviewed.

## 2.5.2 Funding Restrictions

All awards are subject to the terms and conditions described in the Applicant’s Agreement and Research Grant Agreement, which are required upon receipt of award.

- Awards will provide up to ~10 biological samples per awarded investigator, covering all costs associated with obtaining the biospecimens, including tissue preservation reagents and shipping costs.

## 2.6 Award Administration

### 2.6.1 Award Agreement

- A formal notification in the form of an HTORR-PAP Award Agreement (Agreement) is the authorizing document and will be provided to the applicant organization for successful applicants.
- The Agreement, signed by the applicant’s authorized organizational representative (AOR), PI, and NDRI, will include the negotiated terms and conditions of the award.

### 2.6.2 Administrative Requirements

- The grantee is expected to utilize the tissues provided through this award in the proposed pilot experiment(s), with the goal of using the generated preliminary data to apply for independent funding at **one of the following NIH Institutes by the end of the 2-year project period**: National Institute of Allergy and Infectious Diseases (**NIAID**), the National Heart, Lung, and Blood Institute (**NHLBI**), the National Eye Institute (**NEI**), the National Institute of Diabetes and Digestive and Kidney Diseases (**NIDDK**), or the National Institute of Arthritis and Musculoskeletal and Skin Diseases (**NIAMS**).

### 2.6.3 Reporting Requirements

- The grantee will be required to submit semi-annual research progress reports during the period of the award unless otherwise noted in the Agreement.
- Future tissue procurements both for the awarded pilot project as well as for any



subsequent projects are contingent upon the grantee's submission of and the acceptance of the report(s) by NDRI.

- Final closeout reports (i.e., final research progress, publications (meeting abstracts and journal articles), grant submissions, and milestone reports) are due within 90 days following the termination date of the Agreement.
- The awardees will complete an online annual survey for seven years after grant completion to support the ongoing assessment of the long-term impacts of the program.
- HTORR must be acknowledged in publications (meeting abstracts and journal articles) arising from research using human biospecimens supplied through the HTORR PAP.

## 2.7 NDRI Contacts

We encourage inquiries concerning this research program and welcome the opportunity to answer questions from potential applicants. Please direct all correspondence to [Grants@ndriresource.org](mailto:Grants@ndriresource.org).