



Request for Applications (RFA)

Proposals using Stored Biological Specimens for IMPAACT Network-Supported Investigations for Novel Research Relevant to IMPAACT's Scientific Agenda

I. Introduction

The US National Institutes of Health (NIH)-sponsored **International Maternal Pediatric Adolescent Clinical Trials (IMPAACT) Network** aims to increase investigator access to and use of stored biological specimens available at both the National Institute of Allergy and Infectious Diseases (NIAID) Biomedical Research Institute (BRI) repository and the Fisher Scientific repository, both in Rockville, Maryland, for new laboratory-based scientific investigations. Specimen types stored at these repositories include cerebrospinal fluid (CSF), cord blood, viable peripheral blood mononuclear cells (PBMCs), non-viable PBMCs, plasma, viable polymorphonuclear leukocytes, serum, whole blood, and whole blood pellets.

Investigators can use the interactive search tool at www.specimenrepository.org to learn about the types and numbers of specimens available, information about the studies for which they were collected, and publications associated with those studies. Priority will be given to investigations considered foundational for future clinical trials within the network's research agenda.

II. Purpose

The purpose of this RFA is to encourage collaboration with investigators and the IMPAACT Network by providing access to and funding support for use of pedigreed biological specimens in novel laboratory-based investigations. This funding opportunity is open to all qualified investigators, whether or not they are affiliated with the IMPAACT Network.

III. Background

To help facilitate access to approximately one million well-characterized specimens collected in clinical trials conducted by the IMPAACT Network, its predecessor (the Pediatric AIDS Clinical Trials Group (PACTG)), and the Adult AIDS Clinical Trials Group (ACTG), Frontier Science Foundation (the IMPAACT Data Management Center) was funded by NIH/DAIDS to create a public website, database, and search utility to enable investigators to identify specimens with specified characteristics for use in laboratory investigations. The studies in which these specimens were collected are now five years or more past the time of closure. The interactive public website at www.specimenrepository.org allows users to search for available specimens according to certain criteria such as material type, study characteristics, and participant characteristics. The search will generate a report that can be saved and used to complete a New Works Concept Sheet (NWCS), the mechanism through proposals for use of specimens are submitted and reviewed by the IMPAACT Network. The NWCS form accompanies this RFA and is available on the IMPAACT website under "Submit a

Proposal” (<http://impaaactnetwork.org/resources.htm>). Building on our open website resource, the IMPAACT Network has issued this RFA to stimulate interest in and provide support for laboratory-based investigations that will benefit from the use of these specimens.

IV. Funding Source and Mechanism

One to five awards (of \$50,000 in direct costs plus indirect costs; US dollars) for one year are anticipated. Investigator time, any facility and administrative costs, metadata required for the specimens as well as shipping of specimens from the repository to the testing laboratory, should be included in the total budget for each proposal.

V. Scope of Work

Investigators will propose laboratory-based studies using stored repository specimens to address an important question about the molecular epidemiology, viral pathogenesis, antiretroviral therapy, or immunology of HIV-1 and associated conditions.

VI. Limitations/Parameters:

- Investigations in which specimens from one or more of these studies will be used *in combination with* available specimens from studies outside the IMPAACT Network will be considered.
- Prior to release of study data and specimens, awardees will need to complete an IMPAACT Specimen and Data Use Agreement and obtain approval or a waiver for the research project from their institution’s Institutional Review Board/Ethics Committee (IRB/EC).

VII. Application Procedure and Requirements

Letter of Intent: Applicants should submit a brief letter of intent that includes the proposed PI’s name and institution and the names and institutional affiliations of all collaborating investigators by **15 September 2022** to facilitate selection of the review panel.

Applicant Package: Applicants are asked to submit a package including the following documents:

- Cover Page with the title of the proposed investigation and the names and institutional affiliations of the PI and collaborating investigators
- A completed New Works Concept Sheet (NWCS) in which the proposed investigation is to be described (no more than 10 pages exclusive of references)
 - the NWCS should clearly specify whether the proposing investigator will perform all the statistical work (listed below*) or if a statistical collaborator from the IMPAACT Statistical and Data Analysis Center (SDAC) will be needed to do some or all statistical work.
 - *Statistical work includes identifying specimens, cases and controls, matching if appropriate, creating analysis variables, performing the statistical analysis, and - if SDAC participates - collaborating as co-authors on the resulting manuscript.
- A Supplemental Research Proposal (no more than 2000 words) is allowed, but not required, to augment the information provided in the NWCS including the following:
 - Significance and innovation
 - Additional background and rationale
 - Description of any future plans for the data that will be generated through the proposed project and how the investigation may promote new collaborative research activities
 - A description of any assay validation or external quality assurance (EQA) proficiency results associated with the proposed laboratory testing
- Brief description of environment and statement of institutional support (200 words)

- NIH biographical sketch for the Principal Investigator and other key personnel
- Budget (format provided) and budget justification
 - For evaluation/illustrative purposes, please provide the budget and justification for the one-year funding period (total costs (direct (\$50,000) + indirect), beginning 1 December 2022.
 - Note any outside resources available to the investigator that may contribute to the success of the research project, e.g., institutional support, grant or foundation support.

VII. Evaluation Criteria, Review Process, and Scoring Scale

Proposals will be evaluated on the basis of originality, creativity, overall significance, and relevance to the HIV/AIDS or related fields. An independent review committee, comprised primarily of members from the network's scientific committees will score each application, using a scoring system of 1.00 to 5.00 as defined below:

1.00 = Outstanding:	Exceeds requirements for these criteria. Provides supporting information demonstrating substantial benefit and unique contribution to the HIV/AIDS field.
2.00 = Excellent:	Meets or exceeds requirements for these criteria. Supporting information reflects history of strong performance.
3.00 = Good:	Meets requirements. Supporting information is acceptable.
4.00 = Fair:	Only partially meets requirement. Marginal supporting information provided.
5.00 = Unacceptable:	Does not address or respond to criteria. No supporting information.

Specific review criteria will include:

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced?

Approach: Are the conceptual framework, design, methods, and analyses adequate and appropriate to the aims of the project?

Innovation: Does the project employ novel concepts, approaches or method? Are the aims original and innovative?

Investigators: Is the investigator appropriately trained and well suited to carry out this work? Are suitable collaborations in place to support the proposed laboratory work? Investigators internal and external to the IMPAACT network are eligible.

Environment: Does the scientific environment in which the laboratory work will be done contribute to the probability of success? Is there evidence of institutional support?

Feasibility: Is the study feasible given the duration of one year and the budget?

Potential for new research projects: Funded projects may aid in the development of the investigator by providing important data for a larger NIH (or other) funded study such as an R21 or R01.

VIII. Key Dates/Timeline

Letter of intent due date: 15 September 2022

Application due date: 1 October 2022

Review timeline: after 1 November 2022

Award issued: after 1 December 2022

IX. Contact Information

Address to which letters of intent and applications should be submitted:

IMPAACT.SpecimenRepRFA@frontierscience.org.

Inquiries regarding eligibility are encouraged prior to submission of applications. Questions may be submitted to IMPAACT.SpecimenRepRFA@frontierscience.org.

Frequently asked questions and answers will be posted on the IMPAACT [website](#).