Version 1
01-Mar-2024

Guidance for use of the Population and Data Sciences Core (PDSC)

The PDSC is a Core facility within the CU Anschutz Division of Rheumatology's overarching P30 Center for Mucosal Immunobiology and Rheumatic Disease Pathogenesis (CMIR)

I. Background

The Population and Data Sciences Core (PDSC) has been created over many years of dedicated clinical research in the area of Rheumatoid Arthritis (RA), pre-clinical RA and other rheumatic and autoimmune diseases. The PDSC is housed in the Division of Rheumatology in the Department of Medicine.

The PDSC was formally established in 2021 and houses samples and data collected from 2005 and is continuing to collect new data and biospecimens through many large cohort studies with a particular focus on pre-clinical RA and RA.

The goal of the PDSC is to provide consultative support for studies in rheumatic disease pathogenesis as well as allow access to valuable key samples that would be difficult to attain for researchers to help advance the understanding of pre-clinical RA and the development of RA.

Funding for the development of the Rheumatology Data & Biospecimen Core was provided by NIHP30 **P30 AR079369** grant which allowed for a service center to be created to allow these samples to be readily available to researchers.

II. Consultative services and data and biologic sample repository services and access

Consultative services on study design and analysis are available through the PDSC. An initial consult meeting might include refining research questions and identifying analytic resources available on campus.

In addition, a variety of samples and data are available on 1000+ subjects and 5,000+ timepoints. These include materials from individuals with established diseases as well as controls. There is a focus on materials from individuals with RA, pre-clinical RA, and those who have transitioned to RA; however, other disease states are also available.

The following data and biospecimen resources are available:

- Patient-reported assessments
    - Demographics
    - Medical History
        - Autoimmune diseases
        - Medications
        - Immunization history
    - Substance Use
        - Alcohol use
        - Tobacco use
        - Cannabis use
    - General Health
        - Physical activity
        - MDHAQ

    - Self-reported joint symptoms
    - PROMIS
    - Vitamin and supplement use
- Clinical assessments
    - Including joint examination data, and in subsets of individuals joint imaging, lung imaging or other diagnostic study results including a range of biomarkers (e.g. autoantibody testing).
- Biological samples

Serum, plasma, red blood cells, DNA, RNA (PAXgene), PBMCs, sputum, and stool

III. Requests for Use of Consultative Services and/or Data and Biological Samples

If Consultative services are requested without data or biological samples, please email the PDSC at: PDS.Core@cuanschtuz.edu

Researchers interested in accessing data and samples from the PDSC are asked to complete an online submission:
https://ucdenverdata.formstack.com/forms/population_and_data_sciences_core_request_form

Once submitted, the PDSC Leadership Team will review and determine whether to approve or reject a proposal as written or request additional information before a final decision is made. The criteria for approving applications will include:

- Scientific merit of the proposal
- Potential impact of the findings
- Experience and training of investigators (with emphasis on the proposed methodology)
- Availability of sufficient PDSC resources to perform the proposed study
- Quantity of the repository resource requested (e.g. serum volume, PBMC count)
- Regulatory approval and compliance
- Funding

The PDSC Leadership Team is composed of the following members:

- Kevin D. Deane, MD, PhD – Director
- Jill Norris, PhD – Co-Director
- Brandie Wagner, PhD – Biostatistics specialist
- Laura Moss, BS – Data Manager
- Marie Feser, MSPH – Project Manager

If investigators propose similar projects, the PDSC will encourage collaboration if possible. If members of the CMIR Leadership Team submit requests for use of data or samples, they will be asked to recuse themselves from the discussion and the vote for or against approval of those requests. Similarly, if there are requests from collaborators or competitors of members of the Leadership Team, they may be asked to recuse themselves to avoid the appearance of conflict of interest.

Availability of biologic materials is not infinite, and requests may not completed based on availability of materials or volume of biospecimens requested is unavailable. In the event we cannot provide the samples requested, we will discuss further with applying teams regarding other opportunities.

Distribution of the dataset(s) and/or biologic samples to investigators will occur after approval of the project/request. Please note that all materials are provided with no personal health identifiers (PHI); in addition, in some cases, data and biologic material may be blinded to health-status of a subject until experiments are complete. Before any information or samples are distributed, a copy of the IRB approval for the project, as well as completion of any additional regulatory documents (e.g. Materials Transfer Agreements, Data Use Agreements) must be received by the PDSC Team.

IV. Authorship Policy

Investigators utilizing specimens and data from the PDSC are encouraged to publish their findings.

Authorship guidelines related to the PDSC are as follows:

- Investigators using resources (including consultation, data and biospecimens) from the PDSC will be required to contact the PDSC Team by emailing (PDS.Core@cuanschtuz.edu) for review of the manuscript and determination of authorship inclusion based on the project and what team members were involved in the design and execution of the project. Of note, the PDSC may include non-PDSC Team members as authors if these individuals participated in the original collection of relevant data and materials that was used in a project.
- All publications will be required to attribute the work to the P30 grant **P30 AR079369** (see below for details).

V. Investigator/Study Team Responsibilities

A. Materials Transfer/Data Use Agreements: Applicants may be asked to complete a Materials Transfer Agreement (MTA) and/or Data Use Agreement with the University of Colorado, which will include specific information about intellectual property and related issues consonant with any inter-institutional subcontracts and agreements with CU policy. The need for an MTA/DUA will be determined by PDSC Team on review of the application. If an MTA/DUA is required, the data or materials will be distributed only after the Agreement is fully executed. The investigator will agree to abide by the responsibilities as outlined in this document. No materials may be transferred from the approved investigator to any other investigators without the written consent of CU officials.

B. Secondary Research Protocol: All projects will be required to have a secondary research protocol at the University of Colorado. This will be developed by the investigator(s) requesting samples/data with input from the PDSC Team. The applying investigator(s) will also need to ensure appropriate approvals are in place at their institution, if applicable.

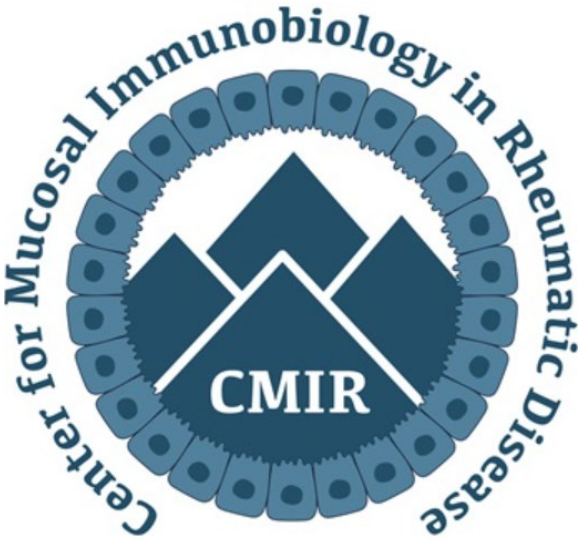
C. Fees: See statement of fees (Appendix A). During the application and project development process these fees will be discussed and final costs determined. Transfer of funds will be managed through the PDSC's Service Center.

D. Progress Report: Applicants may be requested to report their research progress and to submit reprints of their publications. In addition, projects may be asked to provide data from their experiments to be included in the PDSC datasets for future use (see below under 'Results reporting' for details); this will be determined on a case-by-case basis during application review. If data inclusion in the RBDC database is required, that will be included in any MTA/DUAs that are executed for the project.

E. Publications: Applicants are required to receive prior approval from the PDSC of all manuscripts, abstracts, posters, and presentations. These must be provided to the PDSC Team a minimum of two

weeks prior to submission. Publications will include acknowledgement/attribution to the P30 grant with grant number **P30 AR079369** using the following language: This project was supported by the NIH/NIAMS P30 AR079369 funded Center for Mucosal Immunobiology in Rheumatic Disease (CMIR).

F. Presentations: Presentations will include reference to CMIR and the P30 grant in their acknowledgement slides using the following language: This project was supported by the NIH/NIAMS P30 AR079369 funded Center for Mucosal Immunobiology in Rheumatic Disease (CMIR). In addition, presentations may use the following logo:



G. Results reporting: All data generated by applicant investigators may be requested to be made available for inclusion in the PDSC's database. If data is to be included in the PDSC database, there will be a one-year grace period from the time that the data/samples are received to allow the investigator to publish his/her work. After that one-year period, data generated by the applicant investigator needs to be submitted for inclusion to the database and may be made available for additional users of the RBDC or for general public use at that time in keeping with NIH policies and procedures. This will be determined on a case-by-case basis during application review. If data inclusion in the RBDC database is required, that will be included in any MTA/DUAs that are executed for the project.

H. Biological materials remaining after experiments are complete: DNA, RNA, serum, or plasma remaining after the proposed studies are performed must be returned, unless other arrangements are made in the MTA.

VI. Application Instructions and Forms

Requests should be made here:
https://ucdenverdata.formstack.com/forms/population_and_data_sciences_core_request_form

If there are questions about available resources or applications, please contact:
PDS.Core@cuanschtuz.edu

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APPENDIX A

SCHOOL OF MEDICINE
Division of Rheumatology
UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS

Rheumatology Data & Biospecimen Core

Internal Customer Pricing FY23

Service	**A**	Sputum Supernatant	**Cost per sample** $92.30
Service	**B**	Serum specimen	**Cost per sample** $43.98
Service	**C**	EDTA plasma specimen	**Cost per sample** $43.98
Service	**D**	Stool specimen	**Cost per sample** $72.46
Service	**E**	PBMC specimen	**Cost per sample** $140.59
Service	**F**	Data/Regulatory services	**Cost per hour** $87.56