

Crohn's & Colitis Foundation

Request for Proposals (RFP)

“Validation of Predictive Biomarkers for Crohn's Disease Using the NIH All of Us Research Resources”

Program Overview

The Crohn's & Colitis Foundation (the Foundation) invites applications from qualified academic investigators and multi-institutional research collaborations to conduct high-impact research utilizing biospecimens and data available through the National Institutes of Health (NIH) [All of Us Research Program Overview](#). Interested parties must FIRST apply to the NIH X01 mechanism AND get approval from All of Us for their proposed use of data and samples; [Search Results Detail | Grants.gov](#)

The purpose of this initiative is to facilitate the validation of biomarkers that can predict either of two scenarios:

1. risk of clinical Crohn's disease prior to clinical diagnosis
2. risk of developing fistula or strictures among patients with established Crohn's disease.

Projects must leverage existing access to the NIH All of Us repository and generate findings that advance development of biomarkers that could be used in clinical practice in screening individuals for Crohn's disease risk.

To further enhance proposal robustness, applicants can also request access to IBD Plexus research-ready datasets and/or biosamples at no-cost. Investigators interested in utilizing IBD Plexus resources must submit a project feasibility proposal to the IBD Plexus team after receiving notification of award from NIH X01 committee.

Background

Crohn's disease remains a heterogeneous condition with substantial variation in disease course, treatment response, and development of complications. Increasing evidence suggests that biological changes precede clinical diagnosis by years, creating opportunities for earlier identification, intervention, and potentially disease prevention.

At the same time, reliable predictors of stricturing, penetrating, and surgical complications remain limited.

The NIH All of Us Research Program (<https://allofus.nih.gov/article/program-overview>) offers a uniquely diverse national cohort with extensive electronic health record data, genomic information, survey data, and biospecimens. The Foundation seeks to leverage this resource to accelerate biomarker validation studies that can improve prediction, diagnosis, and management of Crohn's disease.

Research Objectives

Applicants must propose research addressing **one of the following two focus areas**:

Focus Area 1: Preclinical Crohn's Disease Biomarkers

Projects should validate biomarkers associated with future development of Crohn's disease prior to clinical diagnosis.

Examples include:

- Genomic risk markers
- Polygenic risk scores
- Proteomic biomarkers
- Metabolomic biomarkers
- Serologic markers
- Immune-cell signatures
- Multi-omic predictive models
- Digital or EHR-derived biomarkers
- Integrated biomarker algorithms

Priority will be given to studies demonstrating the potential to identify individuals at elevated risk before symptom onset, and include a development pathway to clinical use.

Focus Area 2: Biomarkers of Crohn's Disease Complications

Projects should validate biomarkers associated with clinically meaningful complications of Crohn's disease, including:

- Fibrostenotic disease
- Penetrating disease
- Fistulizing disease

Priority will be given to biomarkers with potential utility in patient stratification, risk prediction, and clinical decision-making.

Funding Available

The Foundation expects to commit up to:

\$400,000 in total costs

for this initiative.

Funding may be awarded as:

- One award up to \$400,000 total costs, or
- Two awards up to \$200,000 total costs.

Applicants may request:

- Up to **\$200,000 total costs per year**
- Maximum project duration: **2 years**
- No indirect costs will be provided beyond institutional policies established by the Foundation.

The Foundation reserves the right to fund fewer awards, partially fund proposals, or make no award if meritorious applications are not received. All funding must be utilized to analyze data and samples in the All of Us program. This is intended to validate existing biomarkers identified in prior studies, not to discover new potential biomarkers.

Eligibility

To be eligible, applicants must satisfy **all** of the following requirements:

Principal Investigator Eligibility

The Lead Principal Investigator must:

- Hold a faculty appointment at an accredited academic institution or research hospital.
- Be eligible to serve as Principal Investigator under institutional policies.
- Demonstrate expertise in IBD, epidemiology, biomarker discovery, bioinformatics, genomics, translational medicine, or a related discipline.

Institutional Eligibility

Eligible institutions include:

- Public nonprofit organizations
- Private nonprofit organizations
- Academic medical centers
- Government research institutions

Multi-institutional collaborations are strongly encouraged.

Required All of Us Access

At the time of submission:

- The Principal Investigator or investigative team **must already possess NIH approval through the X01 mechanism (or equivalent NIH-approved process) granting access to the All of Us Research Program repository and associated biospecimens/data resources:**
- <https://www.grants.gov/search-results-detail/361104>
- Documentation of approval must be included with the application.

Applications lacking evidence of approved access will be administratively withdrawn.

Scope of Work

Projects may utilize:

- Electronic health records
- Whole genome sequencing data
- Genotyping data
- Survey data
- Physical measurements
- Biospecimens
- Linked clinical outcomes
- Multi-omic datasets available within All of Us
- Optional: IBD Plexus data / biosamples

Projects should emphasize:

- Biomarker validation rather than initial discovery
- Biomarker performance measurements to be evaluated, including sensitivity, specificity, positive predictive value, negative predictive value, receiver operating characteristics curve (ROC), area under the curve (AUC).

- Power calculation for sample size determination
- Rationale for the use of analytical algorithms including artificial intelligence classifiers
- Reproducibility
- Statistical rigor
- Clinical applicability
- Diversity and health equity considerations
- Generalizability across populations

The Foundation highly encourages analyses that capitalize on the demographic diversity of the All of Us cohort.

Expected Deliverables

Awardees will be expected to provide:

Scientific Deliverables

- Validated biomarker performance metrics
- Replication and validation analyses
- Statistical analysis plans
- Final study report

Translation Deliverables

- Assessment of clinical utility
- Pathway toward external validation
- Recommendations for future implementation studies

Dissemination Deliverables

- Presentation of findings at Foundation-sponsored scientific meetings, if requested
 - Submission of manuscripts to peer-reviewed journals
 - Executive summary suitable for Foundation stakeholders
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Review Criteria

Applications will be evaluated by an independent scientific review committee.

Review criteria include:

1. Scientific Merit (30%)

- Significance of the research question
- High-performance metrics of the biomarker(s) that will be validated
- Clear description of the biomarker context of use (e.g. susceptibility, prognostic)
- Innovation
- Overall impact

2. Biomarker Validation Strategy (25%)

- Strength of validation approach
- Statistical rigor
- Reproducibility

3. Feasibility (20%)

- Appropriate use of All of Us resources
- Adequate sample size and power
- Realistic timeline

4. Investigator and Team Expertise (15%)

- Relevant publications
- Prior accomplishments
- Collaborative strength

5. Clinical and Translational Impact (10%)

- Potential to improve prediction, diagnosis, prevention, or management of Crohn's disease
- Type of diagnostic test that can be developed based on the validated biomarker

Only applicants with NIH X01 approval may submit a full proposal.

Full Proposal Requirements

Invited applicants must submit:

1. Full NIH X01 application
 2. Documentation of X01 approval
 3. Letters of collaboration (if applicable)
 4. IBD Plexus resources feasibility status (if applicable)
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Reporting Requirements

Awardees must submit:

- Semiannual scientific progress reports
- Annual financial reports
- Final scientific report within 90 days of project completion

Continuation of funding is contingent upon satisfactory progress.

Key Dates (Illustrative)

Activity	Date
RFP Released	September 2026
NIH X01 Application Due	October 30 th 2026
Full Proposal Application Opens	February 15 th 2027
Full Proposal Due	April 9 th 2027
Peer Review	May 2027
Funding Decisions	June 2027
Earliest Start Date	July 2027

Mission Alignment

This initiative seeks to advance the Foundation's mission to cure Crohn's disease and improve the lives of patients by accelerating the development of validated biomarkers capable of identifying disease earlier and predicting clinically important outcomes. Consistent with the Foundation's research priorities, this RFP emphasizes translational science, biomarker validation, and the use of large-scale patient-centered datasets to advance precision medicine in IBD.

Questions regarding this RFP should be directed to the Crohn's & Colitis Foundation Research & Scientific Programs Department.

Email: grant@crohnscolitisfoundation.org