

UNITED  
MITOCHONDRIAL  
DISEASE  
FOUNDATION.

VIRTUAL SEMINAR

# Bench-to-Bedside



*National Institutes of Health  
(NIH) and Department of  
Defense (DOD) Funding  
Mechanisms in the  
Mitochondrial Disease Space*

February 15, 2022

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11:00 AM Eastern



# MITO U

## Mito University

Resources and videos about mito,  
providing answers 24-7

[https://umdf-  
mitou.teachable.com/](https://umdf-mitou.teachable.com/)



# Mitochondrial Medicine Phoenix

**June 8-11, 2022**

Connect | Learn | Inspire

For more information, visit  
[www.umdf.org/symposium](http://www.umdf.org/symposium)





# Advancing Research



## UMDF Annual Grant Cycle

*accelerators* Post-doctoral Fellow Award - \$50,000

Deadline: March 7, 2022

<https://umdf.smapply.org/>

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## Clinical Trials Finder

A user-friendly tool on UMDF's website to help find trials  
right for you      [www.umdf.org/clinical-trials](http://www.umdf.org/clinical-trials)

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## Pilot Genetic Testing Program

Helping patients and families find answers on the diagnostic  
journey      [www.umdf.org/testing](http://www.umdf.org/testing)

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On the Roadmap to a Cure, every step matters.



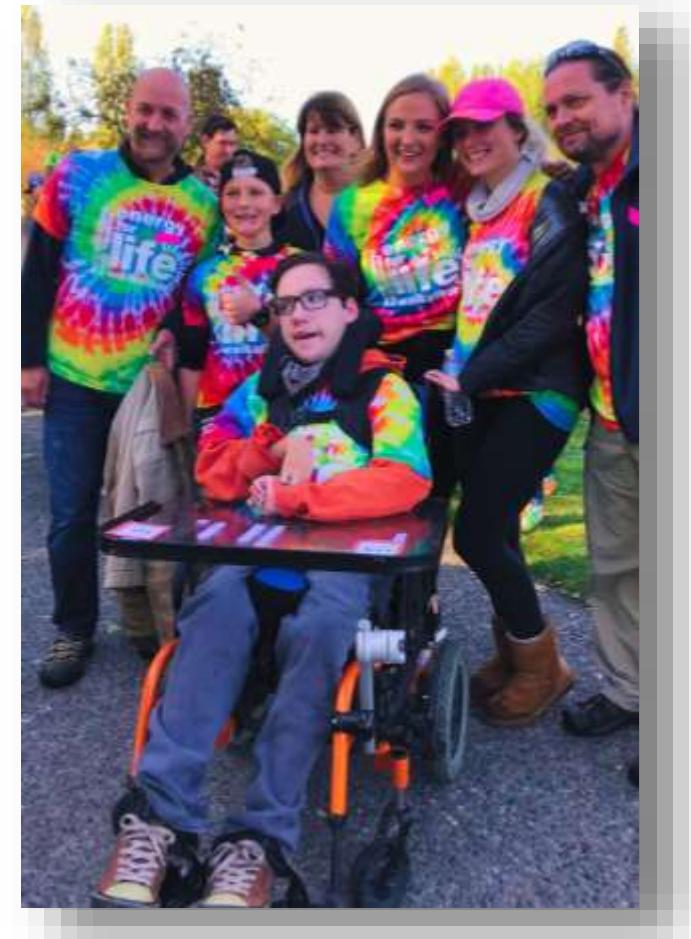


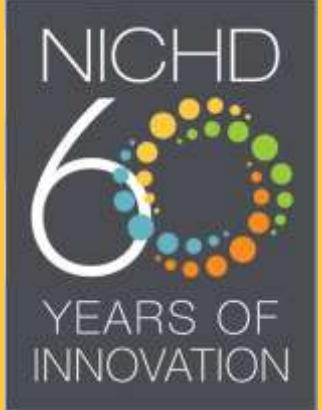
# Energy for Life

## Walkathon

Raising awareness and  
dollars that make a  
difference.

Find a walk near you at  
[energyforlifewalk.org](http://energyforlifewalk.org)





# Mitochondrial disease research and funding opportunities at the NIH and NICHD

Mollie Minear, PhD

Program Officer

Intellectual and Developmental Disabilities Branch, NICHD



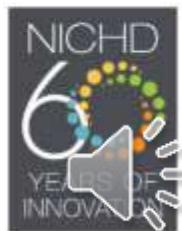
Eunice Kennedy Shriver National Institute  
of Child Health and Human Development





## Talk Outline

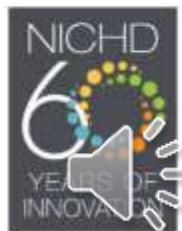
- NIH updates
- NIH resources and mitochondrial disease research funding opportunities
- NICHD support for mitochondrial disease research
  - Clinical Genome Resource (ClinGen)
  - Hunter Kelly Newborn Screening Research Program





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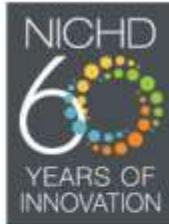
# NIH funding guidelines

- Operating under a continuing resolution through February 18, 2022 (NOT-OD-22-045)  
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-045.html>
  - Funding decisions for new awards are extremely conservative during this period
  - Non-competing research grant awards may be issued at a level below that indicated on the most recent Notice of Award
  - Upward adjustments to awarded levels will be considered after FY 2022 appropriations are enacted
- NICHD funding strategies page for FY 2022 (will be updated):  
<https://www.nichd.nih.gov/grants-contracts/process-strategies/strategies/2022>
  - E.g., R01, R03, and R21 non-competing funding levels under the continuing resolution will be at 90%



# NIH policy updates

## Effective January 25, 2022

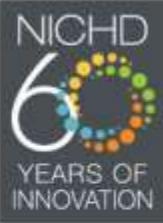


- Must now use new FORMS-G application package for all grant applications
  - Published as [NOT-OD-21-169](#)
  - See these links for more information:
    - High level summary of form changes: <https://grants.nih.gov/grants/electronicreceipt/files/high-level-form-change-summary-FORMS-G.pdf>
    - How to tell if you have the right form version:  
[https://grants.nih.gov/grants/electronicreceipt/files/right\\_forms.pdf](https://grants.nih.gov/grants/electronicreceipt/files/right_forms.pdf)
- New Biographical Sketch and Other Support format pages
  - Access here (non-fellowship blank format page): <https://grants.nih.gov/grants/forms/biosketch-blank-format-rev-10-2021.docx>
  - See these links for more information:
    - [NOT-OD-21-073](#), [NOT-OD-21-110](#), and [NOT-OD-21-122](#)
    - <https://grants.nih.gov/grants/forms/biosketch.htm>
    - <https://grants.nih.gov/faqs#/biosketches.htm>



# New NIH Policy for Data Management and Sharing

## *Effective January 25, 2023*



- Published as [NOT-OD-21-013](#)
- Researchers required to prospectively plan for how scientific data will be preserved and shared through submission of a Data Management and Sharing Plan (DMS Plan)
  - Plan will be required as part of Budget Justification section of applications
  - How data generated by research project will be managed and which of the data and accompanying metadata will be shared
  - Institutes and Centers may have additional requirements for their awards
- Resources:
  - NIH Office of Science Policy (OSP) page on new DMS Policy: <https://osp.od.nih.gov/scientific-sharing/nih-data-management-and-sharing-activities-related-to-public-access-and-open-science/>
  - OSP Frequently Asked Questions: <https://osp.od.nih.gov/scientific-sharing/nih-policy-for-data-management-and-sharing-faq/>
  - Elements of a DMS Plan: [NOT-OD-21-014](#)
  - Allowable costs for data management and sharing: [NOT-OD-21-015](#)
  - Selecting a repository for data resulting from NIH-supported research: [NOT-OD-21-016](#)



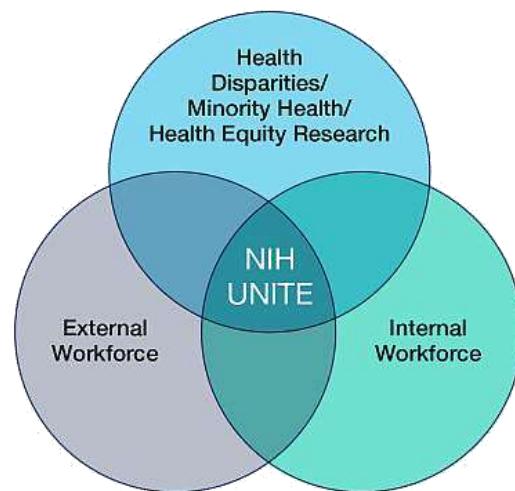


# NIH's UNITE Initiative

The UNITE initiative was established to:

- Identify and **address structural racism** within the NIH-supported and the greater scientific community
- Establish an **equitable and civil culture** within the biomedical research enterprise and **reduce barriers to racial equity** in the biomedical research workforce
- Identify opportunities, make recommendations, and develop and implement strategies to **increase inclusivity and diversity in science**

Learn more at: <https://www.nih.gov/ending-structural-racism/unite>



NIH has issued a **Request for Information (RFI)** inviting comments and suggestions on a framework for the NIH-wide strategic plan for diversity, equity, inclusion, and accessibility. **Responses are due April 3.** See NOT-OD-22-061: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-061.html>

Understanding stakeholder experiences through listening and learning; New research on health disparities/ minority health, and health equities; Improving the NIH Culture and Structure for equity, inclusion and excellence; Transparency, communication and accountability with our internal and external stakeholders; and the Extramural Research Ecosystem: Changing Policy, Culture, and Structure to Promote Workforce Diversity



# NICHD's STRIVE Initiative (STrategies to EnRich Inclusion and AchieVe Equity)



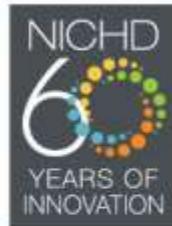
- NICHD launched STRIVE to improve equity, diversity, and inclusion in all aspects of its research and workforce; implemented over next 5 years
- Led by NICHD's Office of Health Equity and coordinated with NIH's UNITE initiative
- STRIVE committees addressing:
  - Equity, Diversity, and Inclusion in NICHD's Workforce
  - Extramural Scientific Workforce
  - Health Disparities Research
- 2021 NICHD STRIVE for Change Workshop Series:  
<https://www.nichd.nih.gov/about/org/strive/engagement>



<https://www.nichd.nih.gov/about/org/strive>



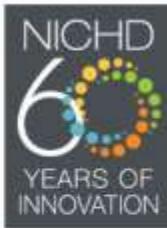
# NIH workshop on *Gene-Targeted Therapies:* *Early Diagnosis and Equitable Delivery* (June 2021)



- Day 1 defined who could benefit from gene-targeted therapies, what novel approaches are needed to enable development of these therapies, and when to optimally identify individuals who could benefit from these therapies
- Day 2 identified existing systems that can be leveraged or adapted to bring treatments to the individuals who can benefit from them
- Day 3 focused on identifying gaps that need to be addressed to facilitate the effective dissemination of treatments in an equitable manner
- Website: [https://events-support.com/events/GeneTargeted\\_Therapies\\_June\\_2021/](https://events-support.com/events/GeneTargeted_Therapies_June_2021/)
- NIH VideoCast links to watch live/recorded workshop sessions:
  - Day 1: <https://videocast.nih.gov/watch=41968>
  - Day 2: <https://videocast.nih.gov/watch=41969>
  - Day 3: <https://videocast.nih.gov/watch=41970>

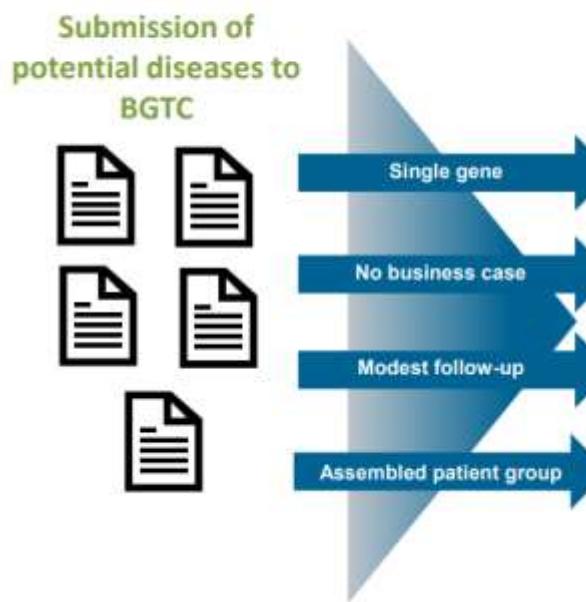


# Accelerating Medicines Partnership® Bespoke Gene Therapy Consortium (BGTC)

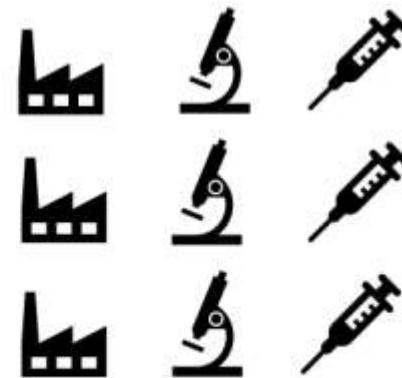


- Using public-private partnerships to streamline Adeno-Associated Virus (AAV) manufacturing and regulatory frameworks to increase accessibility of gene therapies for rare diseases
- Seeking information on rare diseases that could be candidates for AAV gene therapy trials
  - Will select 4-6 monogenic conditions for pilot trials to standardize vector generation, harmonize manufacturing practices, and streamline regulatory pathways
  - Disease Nomination forms are due February 18, 2022

Conducting AAV clinical trials in order to develop repeatable, optimized processes that can be used broadly



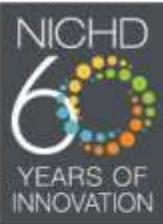
Standardize manufacturing, pre-clinical characterization and clinical trials conducted using the same processes



<https://fnih.org/our-programs/AMP/BGTC>



# NIH Common Fund



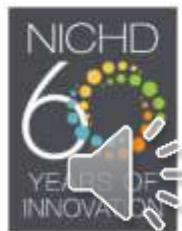
- Emerging scientific opportunities and pressing challenges in biomedical research that no one NIH Institute or Center can address on its own
  - Programs must be transformative, catalytic, synergistic, cross-cutting, and unique
- Selected Common Fund programs:
  - Somatic Cell Genome Editing (SCGE): Improve efficacy and specificity of gene editing approaches for somatic cells, <https://commonfund.nih.gov/editing>
  - Somatic Mosaicism Across Human Tissues (SMaHT): Transform understanding of how somatic mosaicism in human cells influences biology and disease, <https://commonfund.nih.gov/smaht/members>
- Common Fund programs can stimulate follow-up initiatives
  - Developmental Gene-Tissue Expression (dGTEx) program (NICHD and NHGRI, co-funded by NIMH and NINDS) expands the Common Fund GTEx program into children: <https://www.genome.gov/Funded-Programs-Projects/Developmental-Genotype-Tissue-Expression>





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# NIH Guide for Grants and Contracts

## Find Grant Funding

### NIH Guide for Grants and Contracts

The NIH Guide for Grants and Contracts is NIH's official publication of notices of grant policies, guidelines and funding opportunity announcements (FOAs).

We publish daily and issue a [table of contents](#) weekly. Learn more [about the NIH Guide](#) and [subscribe to receive updates today!](#)

Organizations

Issuing Only
  All
  DHHS
  NIH

Active Funding Opportunities and Notices

mitochondrial

[Advanced Search](#)

[Clear Search Query](#)
Displaying: 1 to 25 of 31 results
Results Per Page

25

Title	FOA/Notice Number	Issuing Organization	Release Date	Expiration Date	Activity Code
Notice of Special Interest (NOSI): Promoting Fundamental Research on <b>Mitochondrial</b> Involvement in Lung Diseases and Sleep Disorders	NOT-HL-22-003	NHLBI	Dec 22, 2021	Apr 5, 2025	R01
Notice To Announce Continued Funding and Updated Research Objectives for PAS-16-033 "Stimulating Hematology Investigation: New Endeavors (SHINE) (R01)	NOT-DK-17-002	NIDDK	Nov 23, 2016	N/A	N/A
Notice of the National Human Genome Research Institutes Interest in Receiving Applications to Analyze and Develop Methods for X Chromosome Genome-wide Association (GWA) Data	NOT-HG-11-021	NHGRI	Jun 2, 2011	N/A	N/A
Request for Proposals (RFP) Notice: In Vitro	NOT-DA-	NIDA	May 2	N/A	N/A

- [https://grants.nih.gov/funding/search\\_guide/index.html#/](https://grants.nih.gov/funding/search_guide/index.html#/)
  - New funding opportunities, grants policies, and guidelines are published daily
  - Subscribe to receive regular updates:  
[https://grants.nih.gov/grants/guide/listserv\\_dev.htm](https://grants.nih.gov/grants/guide/listserv_dev.htm)
    - Weekly table of contents
    - Can customize and save your search and receive notifications when new funding opportunities or notices that match your search are published



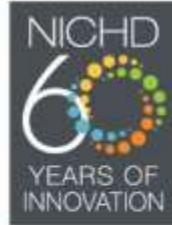
# Selected active funding opportunities

- **Mitochondrial involvement in lung diseases and sleep disorders** (R01s, clinical trial required or not allowed)
  - [NOT-HL-22-003\\*](#): open 2-5-22 through 4-5-25
- **Opportunities for Collaborative Research at the NIH Clinical Center** (X02 and U01, clinical trial optional)
  - PAR-21-342: <https://grants.nih.gov/grants/guide/pa-files/PAR-21-342.html> (X02 pre-application, recommended before applying to U01)
  - PAR-21-343: <https://grants.nih.gov/grants/guide/pa-files/PAR-21-343.html> (U01)
- **Administrative supplements for data science\*\*** (AI readiness, repository support, AI ethics, software)
  - [NOT-OD-22-067\\*](#): Collaborations to Improve the AI/ML-Readiness of NIH-Supported Data – due 3-17-22
  - [NOT-OD-22-069\\*](#): Support for existing data repositories to align with FAIR and TRUST principles and evaluate usage, utility, and impact – due 3-22-22
  - [NOT-OD-22-065\\*](#): Advancing the Ethical Development and Use of AI/ML in Biomedical and Behavioral Sciences – due 3-31-22
  - [NOT-OD-22-068\\*](#): Enhancing Software Tools for Open Science – due 4-12-22
- **Administrative supplements for bioethics research\*\***
  - [NOT-OD-22-026\\*](#), Applications due March 17, 2022

\*For all Notices of Special Interest (NOSIs), you must place the **notice number in box 4B** of SF424 R&R form to be considered

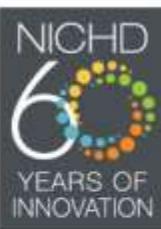
\*\*Administrative supplements are not standalone awards – they require a parent grant that is currently funded by NIH

# NINDS common data elements (CDEs) for mitochondrial disease research



- <https://www.commondataelements.ninds.nih.gov/Mitochondrial%20Disease>
- Common definitions and metadata sets so that data are consistently captured and recorded across studies
- Data standards include CDEs, case report form (CRF) modules, and guidelines
- Defines data elements in domains of:
  - Biomarkers
  - Cognitive/Behavioral/Psychological
  - Endocrinology/Diabetes/GI/Nutrition
  - Exercise Physiology
  - Genetics
  - Imaging
  - Neurological Assessments
  - Patient Reported Outcomes/Quality of Life
  - Vision





# Center for Scientific Review Assisted Referral Tool (ART)

- <https://art.csr.nih.gov/ART/>
- Developed by NIH Center for Scientific Review (CSR) to recommend potentially appropriate study sections, based on the scientific content of a user's grant application
- Uses natural language processing and large-scale machine learning technology to make recommendations

**NIH** Center for Scientific Review

## Assisted Referral Tool (ART)

Please make a selection:

**Recommend study sections directly**  
You will be given a list of the best matching of the 175 active SRG panels.

**Recommend SBIR/STTR Special Emphasis Panels**  
If you are applying for a SBIR/STTR grant, select this option.

**Animal Usage?**  
If your research involves animals, check this optional checkbox.

**NIH** Center for Scientific Review

## Assisted Referral Tool (ART)

[Help](#) | [Disclaimer](#) | [User Guide](#)

[ART Home](#) >> SRG  Animal Usage?

Enter application text and hit the Submit button to get a list of relevant study sections in two groups, "Strong" and "Possible". Within a group, study sections are listed alphabetically by the SRG acronym

Title  Optional but strongly recommended, as title concepts receive full weight in the models

Enter your application text here. Entering both Abstract and Specific Aims is recommended. Section subheaders and delimiters (e.g. 'Abstract') will be ignored. At least 10 scientific concepts from the RCDC Thesaurus must be detected for ART to submit your job.

Terms will be weighted by frequency of appearance in the text above. The process is automated and confidential. ART does not track or store submitted text. For more information consult the [User Guide](#).



# Tips for preparing a successful NIH application

- Read the funding opportunity announcement closely
  - Specific instructions or application requirements, receipt dates, extra review criteria, which Institutes and Centers participate
- Make the specific aims realistic, don't be overly ambitious or make aims too dependent
- Don't be shy about contacting a program officer for help!
  - Guidance about proposed specific aims, alignment with Institute's current scientific priorities, and suggestions on study sections
  - Be persistent and send follow-up emails
- Make your specific aims page clear and compelling – this may be the only part of your application that most reviewers read
- If resubmitting, responsiveness is important – address all reviewer concerns
- Increasing emphasis on diverse participants and researcher teams
- Read the funding opportunity announcement closely



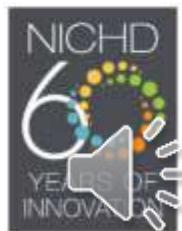
# NIH grant writing resources

Website	URL
NIH regional seminars on program funding and grants administration <ul style="list-style-type: none"><li>• <i>2021 seminar presentations</i></li></ul>	<a href="https://grants.nih.gov/news/contact-in-person/seminars.htm">https://grants.nih.gov/news/contact-in-person/seminars.htm</a>
How to Apply – Application Guide (NIH)	<a href="https://grants.nih.gov/grants/how-to-apply-application-guide.html">https://grants.nih.gov/grants/how-to-apply-application-guide.html</a>
<b>Apply for a Grant (NIAID)</b> <ul style="list-style-type: none"><li>• <i>Lots of helpful grant writing tips and sample applications</i></li></ul>	<a href="https://www.niaid.nih.gov/grants-contracts/apply-grant">https://www.niaid.nih.gov/grants-contracts/apply-grant</a>
Grant Writing and Approval Process (NIMH) <ul style="list-style-type: none"><li>• <i>Common mistakes in writing applications</i></li></ul>	<a href="https://www.nimh.nih.gov/funding/grant-writing-and-application-process">https://www.nimh.nih.gov/funding/grant-writing-and-application-process</a> <ul style="list-style-type: none"><li>• <a href="https://www.nimh.nih.gov/funding/grant-writing-and-application-process/common-mistakes-in-writing-applications">https://www.nimh.nih.gov/funding/grant-writing-and-application-process/common-mistakes-in-writing-applications</a></li></ul>
Quick guide for grant applications (NCCIH) <ul style="list-style-type: none"><li>• <i>Last updated in 2010 but still has good general advice</i></li></ul>	<a href="https://www.nccih.nih.gov/grants/tips-for-new-nih-research-grant-applicants">https://www.nccih.nih.gov/grants/tips-for-new-nih-research-grant-applicants</a>

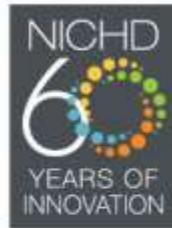


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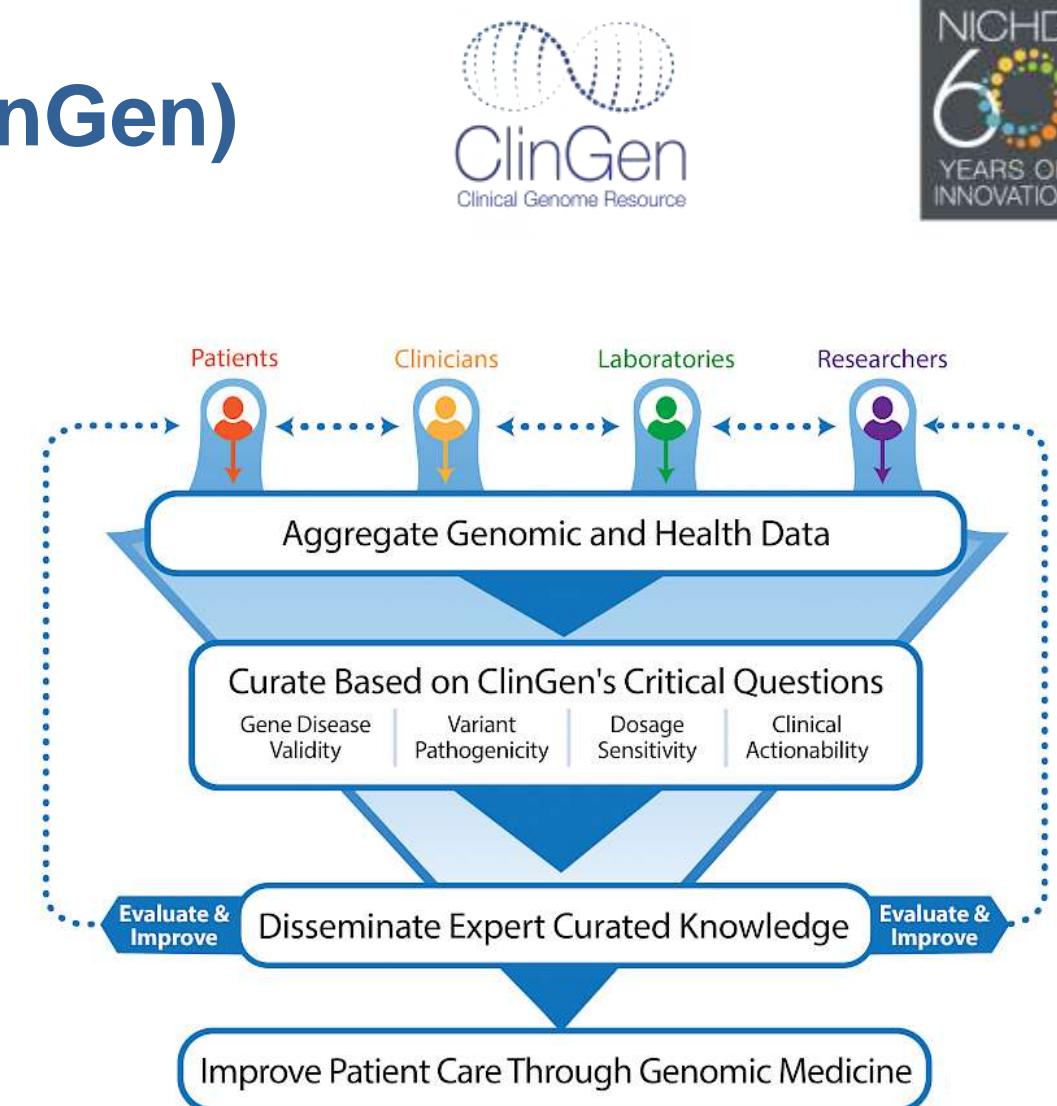
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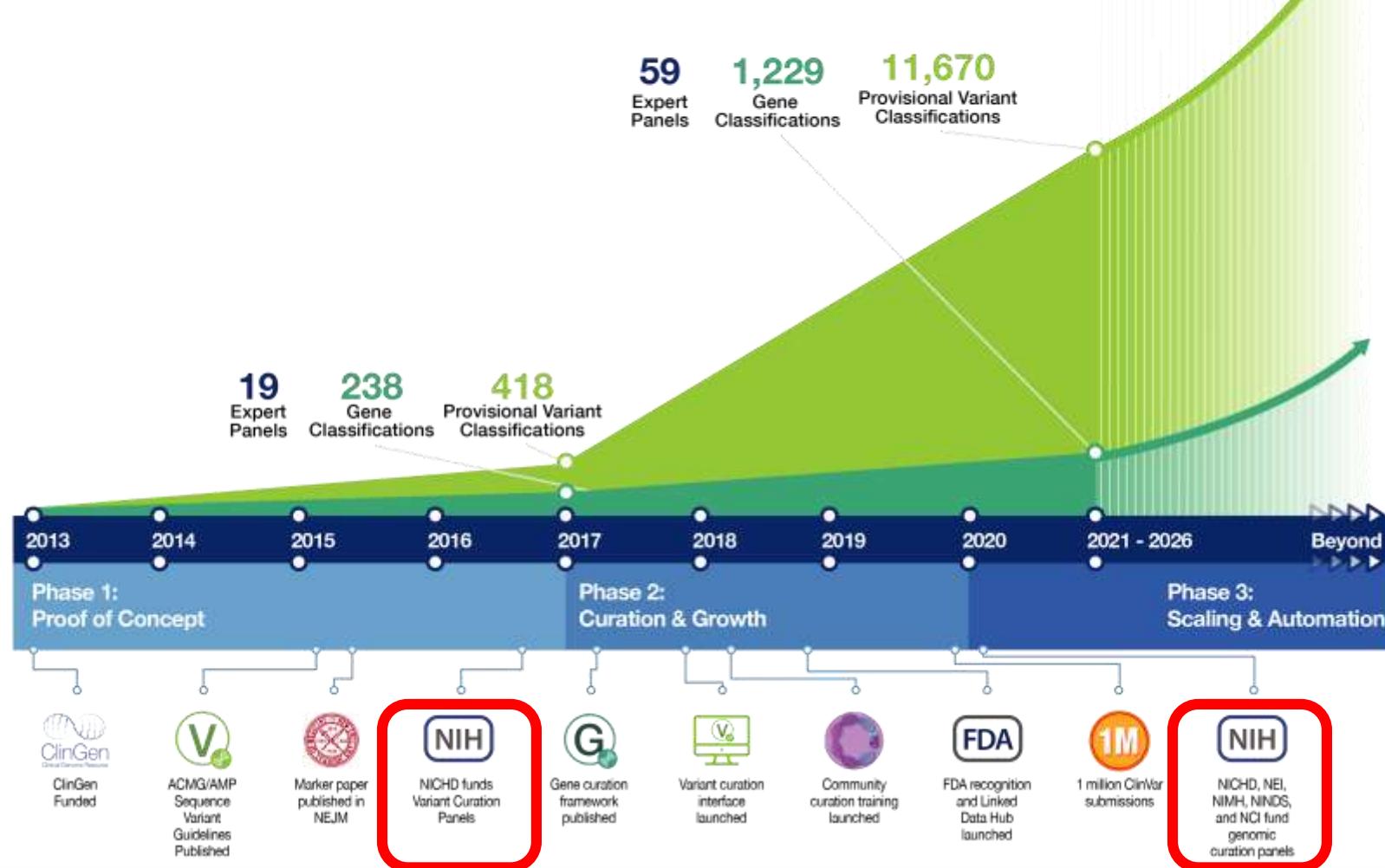
# Clinical Genome Resource (ClinGen)



- Authoritative central resource that defines the clinical relevance of genes and variants for use in precision medicine and research
  - Over 1700 contributors from over 40 countries
- Mission: build an expert-curated, public genomic knowledge base to improve patient care
- Experts manually review evidence to answer curation questions, such as:
  - Is this gene associated with a disease, and by which mechanisms do variation cause this disease?
  - Is this variant causative?
  - Will this information affect medical management?



# NIH-supported expert panels in ClinGen



# NICHD-led funding of ClinGen expert panels

- NICHD first published as RFA (Request for Applications) in 2017
- [PAR-20-101](#) (updated with [NOT-HD-21-028](#)) reissued as PAR (Program Announcement with Review) in 2020
  - 5 Institutes currently participate: NICHD, NCI, NEI, NIMH, NINDS
  - Final receipt date is May 27, 2022 – please help spread the word to investigators who might be interested in submitting an application in May!
- Mitochondrial disease curation activities supported through U24HD093483, led by Marni Falk and Xiaowu Gai
  - Inborn Errors of Metabolism clinical domain working group
  - Gene curation: <https://clinicalgenome.org/affiliation/40027/>
  - Variant curation: <https://clinicalgenome.org/affiliation/50027/>



# ClinGen curation for mitochondrial disorders

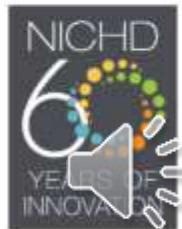
- Uses international Mitochondrial Disease Sequence Data Resource (MSeqDR) consortium to organize and curate mitochondrial disease genomic knowledge
- First phase (2017-2020): Expert curation of pediatric mitochondrial Leigh-like syndrome genes and variants
  - Curate Leigh syndrome spectrum disorders for gene-disease association
  - Establish variant curation guidelines for actionable nuclear genes
  - Address the unique challenges of curating mtDNA variant pathogenicity, including creation of consensus guideline revisions for mtDNA variant specification
- Second phase (2021-2024): Primary mitochondrial disease expert curation panel
  - Co-funded by NICHD and NINDS
  - Expand from syndromic and organ-focused phenotype curation efforts to all primary mitochondrial diseases
- Published “Mitochondrial Disease Genes Compendium” in 2020





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# Newborn screening (NBS)

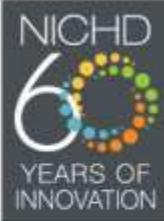
- Newborn screening (NBS) programs screen > 4 M infants per year to identify infants at risk for congenital disorders
  - Early interventions and treatments can reduce morbidity and mortality
- A federal advisory committee (Advisory Committee on Heritable Disorders in Newborns and Children; **ACHDNC**) recommends conventional newborn screening for at least 35 core and 26 secondary conditions, part of the Recommended Uniform Newborn Screening Panel (**RUSP**)





# NICHD's Hunter Kelly NBS Research Program

*Legislatively mandated by the Newborn Screening Saves Lives  
Act of 2007 and its 2014 reauthorization*



Identify, develop and test the most promising **new screening technologies**



Provide **research findings** and data for newborn conditions under review by the ACHDNC to be added to the RUSP

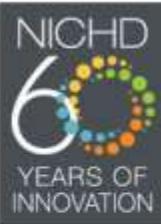


Develop experimental **treatments and management strategies** for conditions that could be detected through NBS



Conduct **pilot studies** on conditions recommended by the ACHDNC





# NBS research supported by NICHD

- **Investigator-initiated research projects:** Includes funding opportunity announcements (FOAs) for NBS-related proposals
  - Innovative Screening Approaches and Therapies for Screenable Disorders in Newborns (R01/R03/R21, Clinical Trial Optional):
    - PAR-21-353, R01: <https://grants.nih.gov/grants/guide/pa-files/PAR-21-353.html>
    - PAR-21-354, R03: <https://grants.nih.gov/grants/guide/pa-files/PAR-21-354.html>
    - PAR-21-355, R21: <https://grants.nih.gov/grants/guide/pa-files/PAR-21-355.html>
  - Natural History of Disorders Screenable in the Newborn Period (R01, Clinical Trial Optional)
    - PAR-21-115: <https://grants.nih.gov/grants/guide/pa-files/PAR-21-115.html>



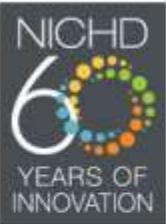
# NBS research supported by NICHD

- Investigator-initiated research projects
- **Newborn Screening Translational Research Network (NBSTRN):** facilitates research on genetic or congenital disorders through an infrastructure that provides the research community access to robust NBS resources
  - Serves as a “Coordinating Center” for NBS research
  - Infrastructure support for data sharing, curated literature resources, and state-level policy map (e.g., conditions screened, consent for research)



<https://nbstrn.org/>



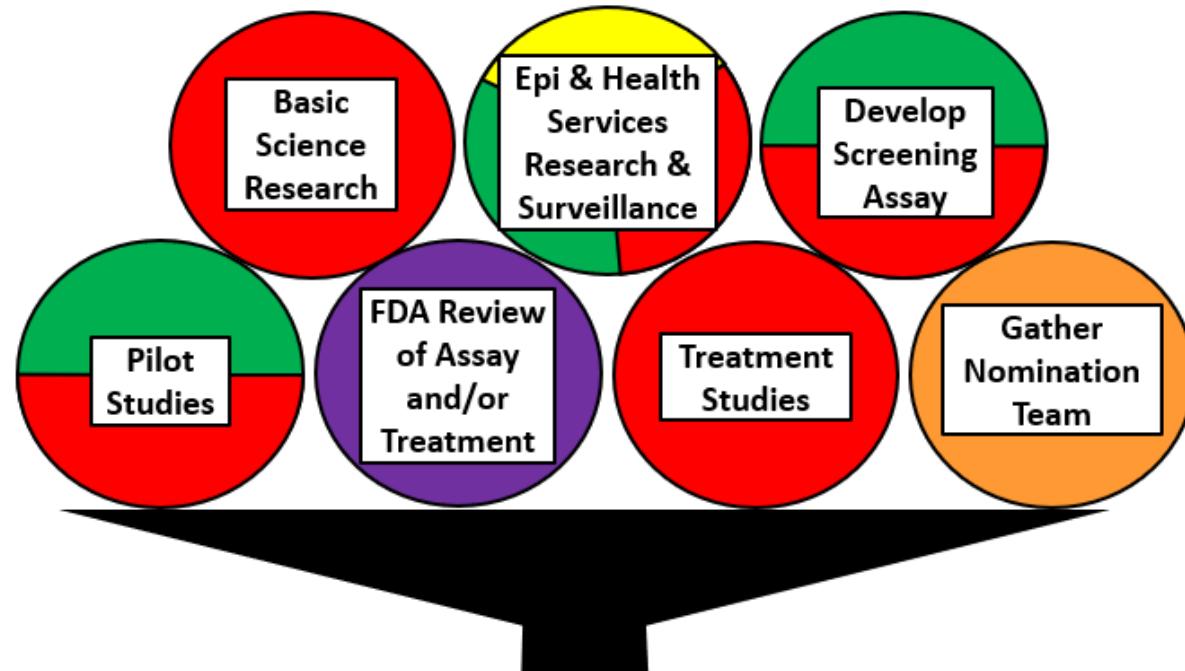


# NBS research supported by NICHD

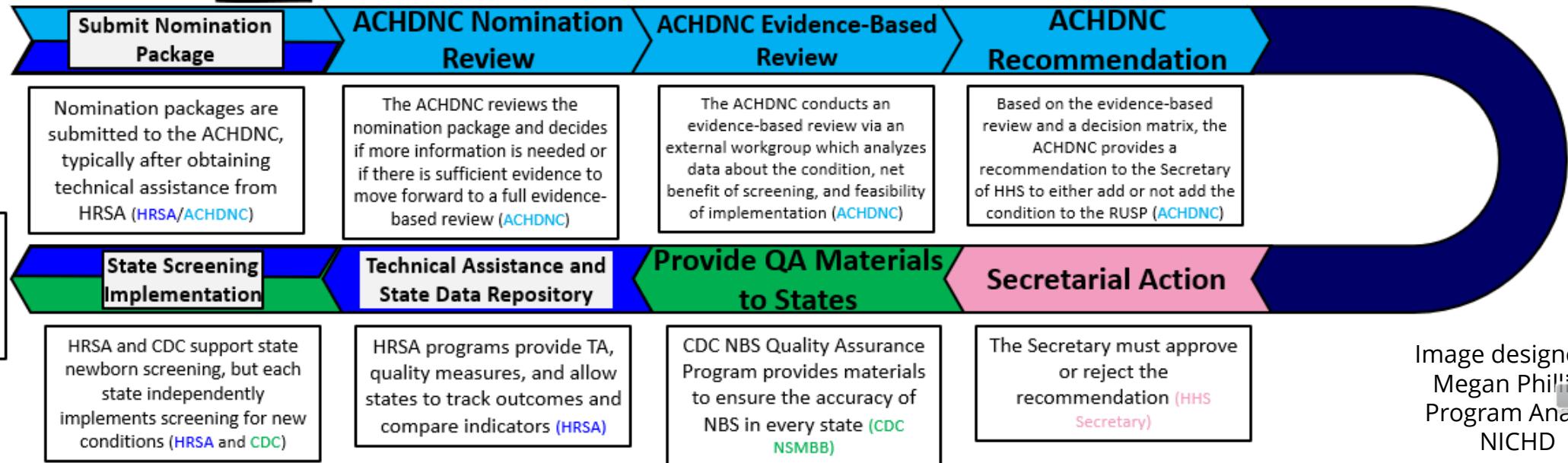
- Investigator-initiated research projects
- Newborn Screening Translational Research Network (NBSTRN)
- **Newborn Screening Pilot Studies:** for conditions recently added to or recommended for the Recommended Uniform Screening Panel (RUSP) to ensure these conditions are ready for nationwide implementation
  - Pool of contractors who run pilot studies for conditions selected by NICHD
    - High-throughput NBS laboratories (state or private)
    - Capacity to screen at least 100,000 newborns within 2 years
    - Ability to develop, implement, and demonstrate proof-of-concept for new NBS technologies



# Road to the RUSP: Adding a Condition to Newborn Screening

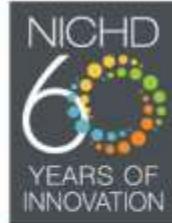


Legend	
<span style="color:red;">■</span>	NIH
<span style="color:blue;">■</span>	HRSA
<span style="color:green;">■</span>	CDC
<span style="color:purple;">■</span>	FDA
<span style="color:yellow;">■</span>	AHRQ
<span style="color:pink;">■</span>	HHS
<span style="color:orange;">■</span>	Advocacy Groups, Experts, Others
<span style="color:teal;">■</span>	ACHDNC



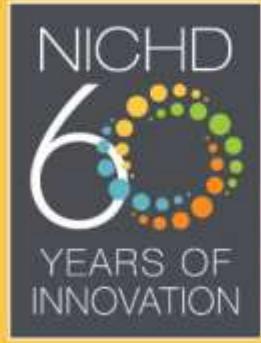
# Nominating a condition to be added to the RUSP

<https://www.hrsa.gov/advisory-committees/heritable-disorders/rusp/nominate.html>



- Requires submission of a nomination package to the ACHDNC:  
<https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/heritable-disorders/rusp/Nominate-condition/enhanced-nomination-form.pdf>
- Rigorous evidence-based review of nominations:
  - What are the clinical effects of early detection and treatment for the condition?
  - How would newborn screening for the condition affect the population?
  - How would adding newborn screening services for the condition affect the public health system?
- For assistance with preparing a nomination, please contact the participating federal agencies (HRSA, CDC, NIH/NICHD, etc.)
  - NBSTRN is available to assist with nomination packages





# Questions?

[mollie.minear@nih.gov](mailto:mollie.minear@nih.gov)



David Lenz, "Rare Halo Display: A Portrait of Eunice Kennedy Shriver"

NICHD is turning 60! Mark your calendar for our 60<sup>th</sup> Anniversary Symposium on October 17, 2022, and learn more at:

<https://www.nichd.nih.gov/60years>





# UPCOMING

[www.umdf.org/seminars](http://www.umdf.org/seminars)



SCAN ME

# Bench-to-Bedside



## Ocular Mitochondrial Disease

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March 15, 2022  
11:00 AM Eastern