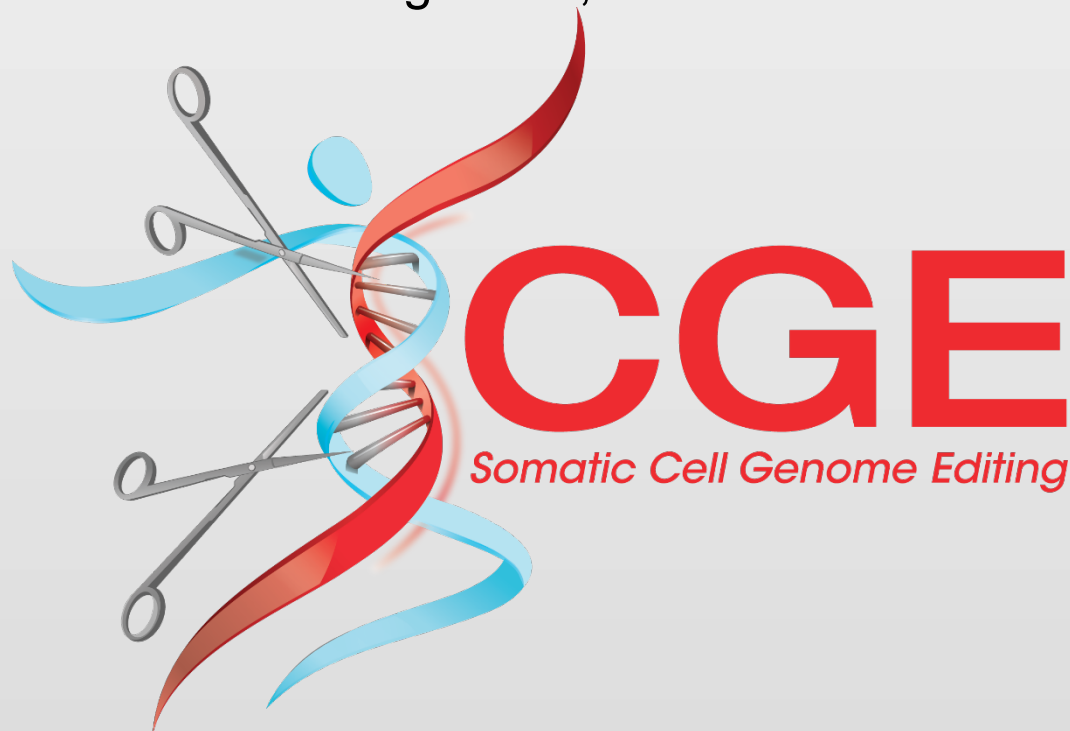


# NIH-Somatic Cell Genome Editing Applicant Webinar

August 14, 2018



*We will start @ 12:05 PM ET*



National Institutes of Health  
Office of Strategic Coordination - The Common Fund

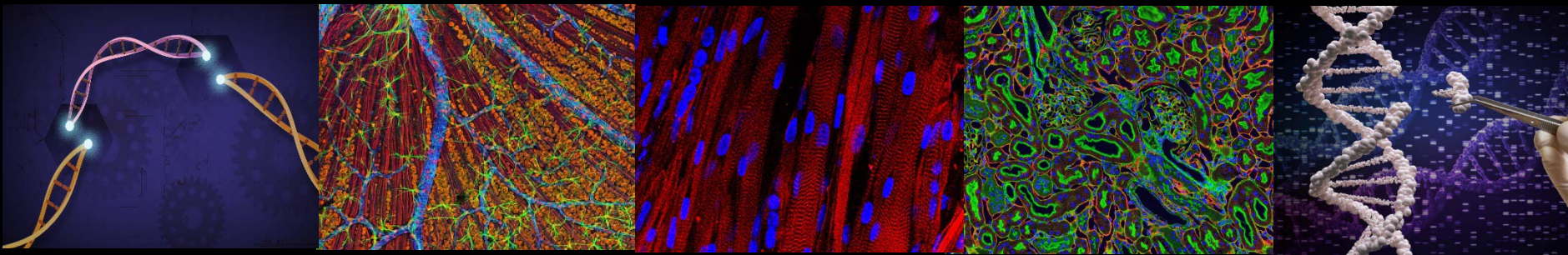
# Webinar Logistics

## WebEx

- We will not be recording and posting this webinar after, however the slide decks will be made available on the Common Fund Website:  
<https://commonfund.nih.gov/editing>
- All participants are muted until the Q&A session
  - These questions are intended for us to answer the group at large
  - If you have a specific question for a specific person, please reach out to them directly.
  - You can also submit questions during the talks to the SCGE mailbox, they will be answered during the Q&A: [SCGEprogram@nih.gov](mailto:SCGEprogram@nih.gov)
- A list of commonly asked FAQs are posted and will be updated on the Common Fund Website: <https://commonfund.nih.gov/editing/faq>

# Agenda

- **Introduction & WebEx overview** – 3 min; Kayla Valdes, NCATS
- **Program overview** – 5 min; Mary Perry, Common Fund, OD/OSC
- **Funding announcement overviews** – 5 min each; John Sheridan, NHLBI; PJ Brooks, NCATS; Betty Poon, NIAID;
- **Review procedure** – 5 min; PJ Brooks, NCATS
- **Cooperative agreement overview & application deadlines** – 5 min; PJ Brooks, NCATS
- **Q&A session** – 60 min



# SCGE Program Overview

Mary Ellen Perry, Ph.D.

Program Leader

Office of Strategic Coordination

Division of Program Coordination, Planning, and  
Strategic Initiatives

Office of the Director, NIH



# Origins of the Common Fund

2004: NIH Roadmap is launched

2006: Congress unanimously reauthorizes NIH



Establishes the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) within Office of the Director and the NIH Common Fund to provide a dedicated source of funding to enable *trans*-NIH research

## One Hundred Ninth Congress of the United States of America

AT THE SECOND SESSION

*Began and held at the City of Washington on Tuesday,  
the third day of January, two thousand and six*

### An Act

To amend title IV of the Public Health Service Act to revise and extend the authorities of the National Institutes of Health, and for other purposes.

*Be it enacted by the Senate and House of Representatives of  
the United States of America in Congress assembled,*

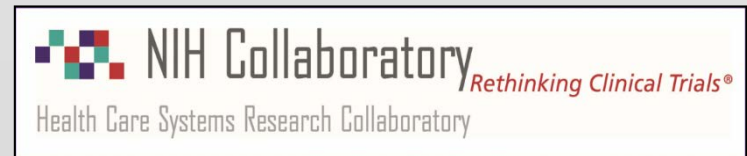
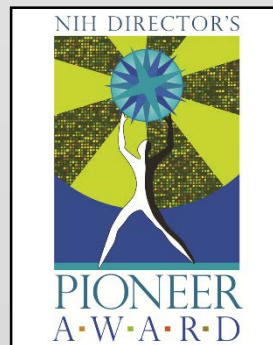
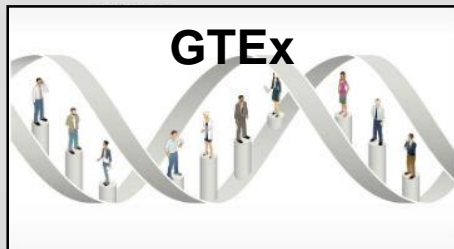
#### SECTION 1. SHORT TITLE.

This Act may be cited as the "National Institutes of Health Reform Act of 2006".

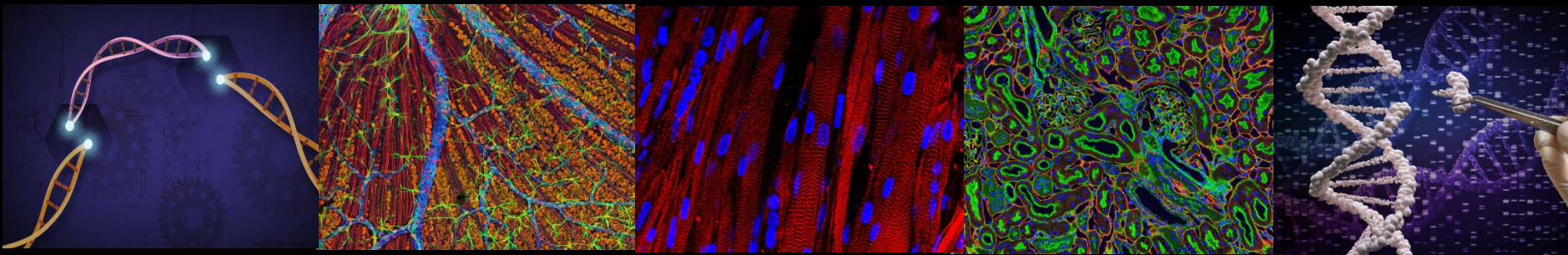
### TITLE I—NIH REFORM

# Criteria for Common Fund Programs

- **Transformative:** Must have high potential to dramatically affect biomedical and/or behavioral research over the next decade
- **Catalytic:** Must achieve a defined set of high impact goals within 5-10 years
- **Synergistic:** Outcomes must synergistically promote and advance individual missions of NIH Institutes and Centers to benefit health
- **Cross-cutting:** Program areas must cut across missions of multiple NIH Institutes and Centers, be relevant to multiple diseases or conditions, and be sufficiently complex to require a coordinated, trans-NIH approach
- **Unique:** Must be something no other entity is likely or able to do





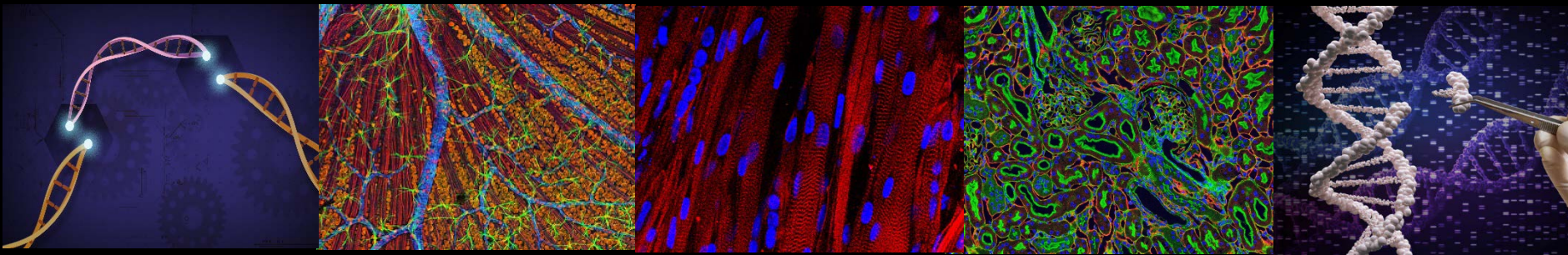


## NIH SCGE Working Group

Olivier Blondel, NIDDK  
Pj Brooks, NCATS  
Bonnie Burgess-Beusse, NIDDK  
Tom Cheever, NIAMS  
Colin Fletcher, NHGRI  
Maria Giovanni, NIAID  
Linda M. Griffith, NIAID  
Min He, NCI  
Keith Hoots, NHLBI  
Chamelli Jhappan, NCI  
Danuta Krotoski, NICHD  
Tim LaVaute, NINDS  
Jerry Li, NCI  
Nicole Lockhart, NHGRI

Aron Marquitz, OSC/OD  
Stephanie Morris, OSC/OD  
Oleg Mirochnitchenko, ORIP/OD  
Nasrin Nabavi, NIAID  
Lisa Neuhold, NEI  
Margaret Ochocinska, NHLBI  
David Panchision, NIMH  
Mary Perry, OSC/OD  
Betty Poon, NIAID  
David Rampulla, NIBIB  
John Satterlee, NIDA  
John Sheridan, NHLBI  
Jeff Struewing, NHGRI  
Kayla Valdes, NCATS  
Wendy Wang, NCI





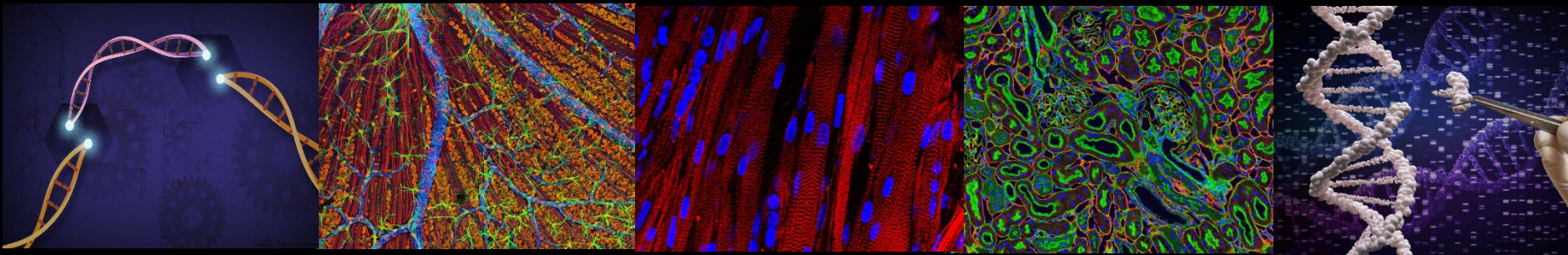
# The NIH SCGE Planning Workshop

July 24, 2017

## Major Gaps Identified:

- Relevant human and animal model systems for pre-clinical testing
- Cell- and tissue-specific delivery systems
- Error-free editing machinery (nuclease alternatives)
- Standardized assays for measuring genetic off-target effects
- Long-term cell tracking assays

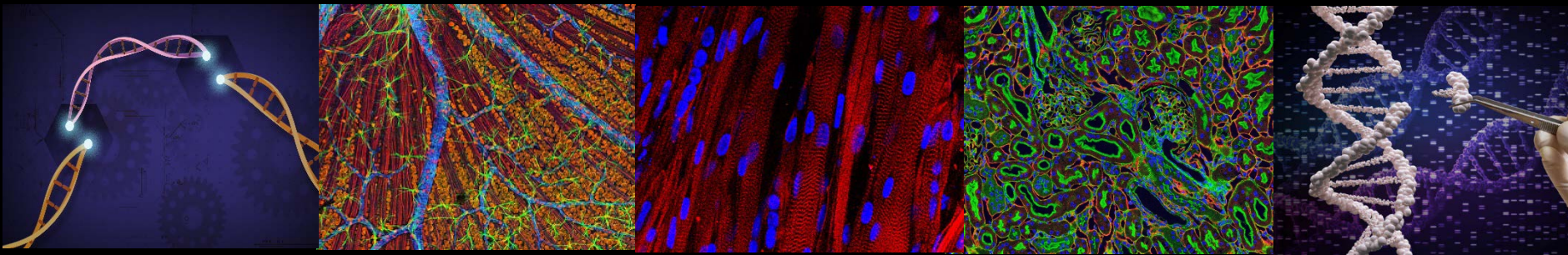




## SCGE Program Goals

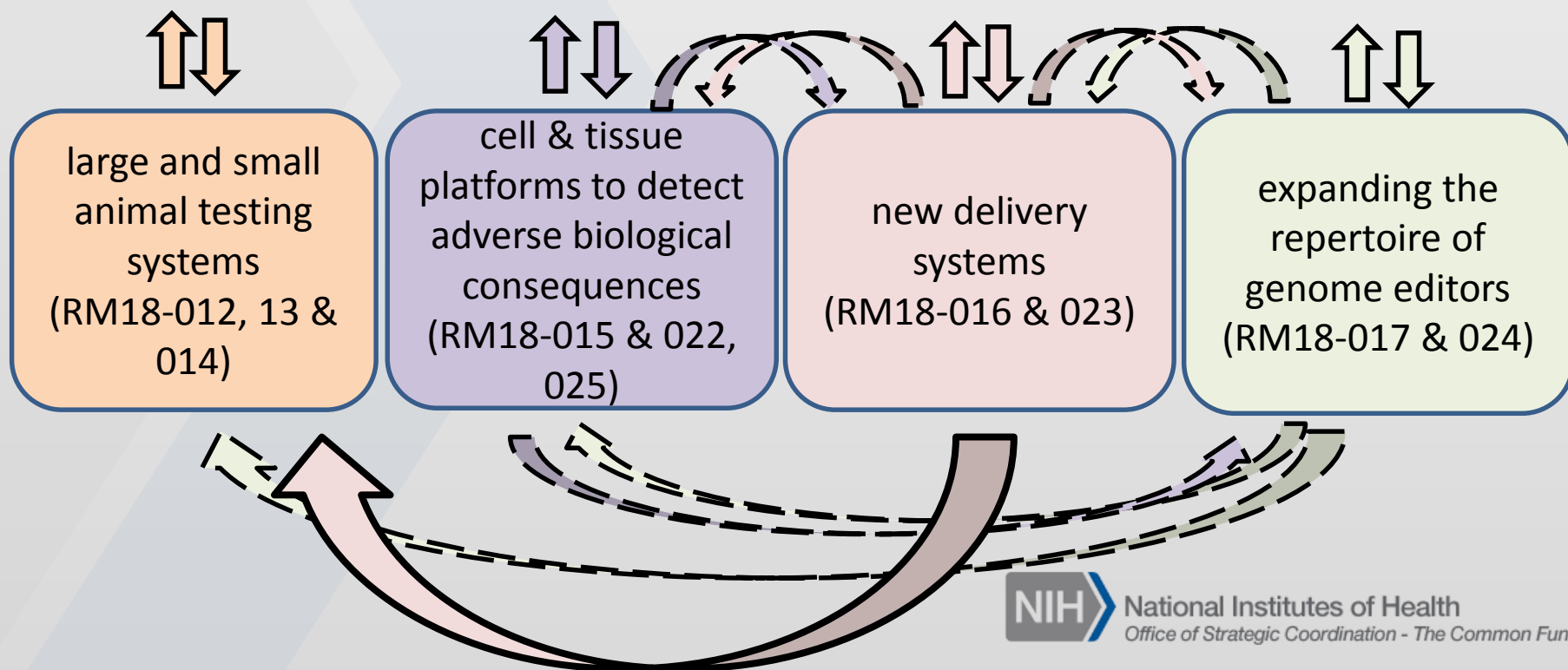
Lower the Barriers for New Genome Editing Therapies by:

- Testing Genome Editing Reagents and Delivery Systems in Better Animal Models
- Assessing Unintended Biological Effects
- Improving *In Vivo* Delivery of Genome Editing Machinery
- Expanding the Human Genome Engineering Toolkit
- Coordinating Partnerships and Disseminating Information



## SCGE Dissemination & Coordinating Center (RM18-018)

- Facilitate interactions and communication between consortium components
  - Disseminate a SCGE Toolkit to the research community





# SCGE Program Governance

Directors, OSC & DPCPSI

External Scientific  
Advisory Panel

NIH SCGE Working Group of  
Program Staff  
(Chair, NCATS Director)

Sub-committee on  
publications ?

Additional sub-  
committees as needed

Steering Committee of  
SCGE PIs

Sub-committee on data  
sharing ?

SCGE Consortium of Awardees

Sub-committee on  
common protocols ?



# Development of Cell and Tissue Platforms to Detect Adverse Consequences of Somatic Cell Genome Editing (U01 Clinical Trial Not Allowed)

**RFA-RM-18-022**

John Sheridan, NHLBI on behalf of  
the NIH Common Fund

([john.sheridan@nih.gov](mailto:john.sheridan@nih.gov))

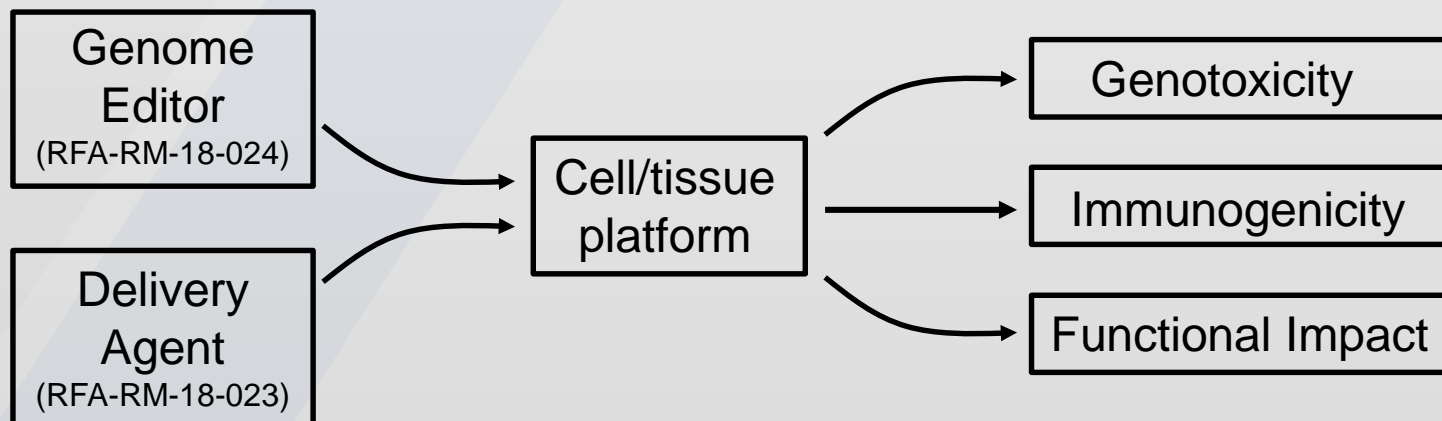


National Institutes of Health  
Office of Strategic Coordination - The Common Fund

## Program Objective

Goal: To support the development, validation, and testing of new and existing human tissue- and cell-based platforms that can provide information on the safety of genome editing technologies and delivery systems.

Does exposure to the editor or delivery agent have any adverse biological consequences in specific target cells?





## Research Scope

There are several highlighted areas of interest applicable to this FOA:

- Replicate critical aspects of normal human physiology
- Amenable to sequencing-based approaches to monitor off-target editing
  - DNA sequencing, RNA-seq, other “omics”-based approaches
- Development of assays to monitor other unintended biological effects
  - Biological function, genotoxicity, immunogenicity, etc.
- Bioinformatics and computational techniques should be implemented in combination with the cell/tissue platform

Examples of activities that will not be considered responsive:

- Platforms that use non-human cells/tissues or immortalized human cell lines
- Development of new sequencing-based approaches for the detection of off-target genome editing alone, without biological system

# Tissue Types of Interest

- Cell types of interest include but are not limited to disease-relevant cells, especially endogenous stem cells and cell types of origin for cancer, in the following organs or systems:
  - Lung
  - Nervous system
  - Cardiovascular system, including hematopoietic and immune cells
  - Sensory organs
  - Kidney
  - Muscle
  - Bone
  - Endocrine systems
  - Gastrointestinal tract
  - Liver

\*\*\*Applications focused on other cell types should include a justification of disease relevance

## **Applications Instructions Specific to RFA-RM-18-022 (Section IV):**

The complete application instructions can be found in section IV of the FOA

Important instructions to keep in mind:

Describe novel concepts, approaches, or methodologies to be developed or used to establish and/or validate the platform. Explain refinements, improvements, adaptations, or new applications of existing technologies or platforms to be implemented in the project.

Describe the overall strategy and methodology to be used to establish feasibility and for making the platform sufficiently selective and sensitive to evaluate adverse biological consequences of genome editing. Provide a plan for validating the platform and describe in detail the potential functional outputs of the associated assays.

A timeline (Gantt chart) that includes milestones is required for all studies

## Review Criteria Specific to RFA-RM-18-022 (Section V):

Investigator: Does the application provide sufficient evidence that the PD/PI(s) and key personnel have the necessary expertise to design and validate a platform to evaluate adverse effects of genome editing?

Innovation: How appropriate are the proposed concepts, approaches, or methodologies to establish and/or validate the cell- or tissue-based platform to evaluate adverse effects of genome editing?

Approach: Are the overall strategy, methodology, and analytical approaches adequately developed, well-integrated, and appropriate to establish feasibility of the platform? How strong is the evidence that the platform will be sufficiently selective, sensitive, or otherwise appropriate to evaluate adverse biological consequences of genome editing? Is the validation of the platform adequate and appropriate and are the outputs sufficiently described in detail?

### Additional Review Considerations

Milestones: How strongly do the milestone address the specific aims of the project? Are the listed milestones appropriate for the goals of the project?

# Program Timeline and Budget

## Proof of Concept

- Establish the platform and accompanying assays
- Demonstrate capacity to identify adverse effects of genome editing

## Collaborate and Optimize

- Refine the platform and assays
- Expand the capacity of the system
- Test additional consortium-generated editors and delivery agents

Year 1

Year 2

Year 3

Year 4

Milestones: quantitative milestones should be proposed for each year of the award and describe how the objectives will be achieved

Award Budget: \$410K direct costs per year in FY19-22



# Innovative Technologies to Deliver Genome Editing Machinery to Disease- Relevant Cells and Tissues (UG3/UH3 Clinical Trial Not Allowed)

**RFA-RM-18-023**

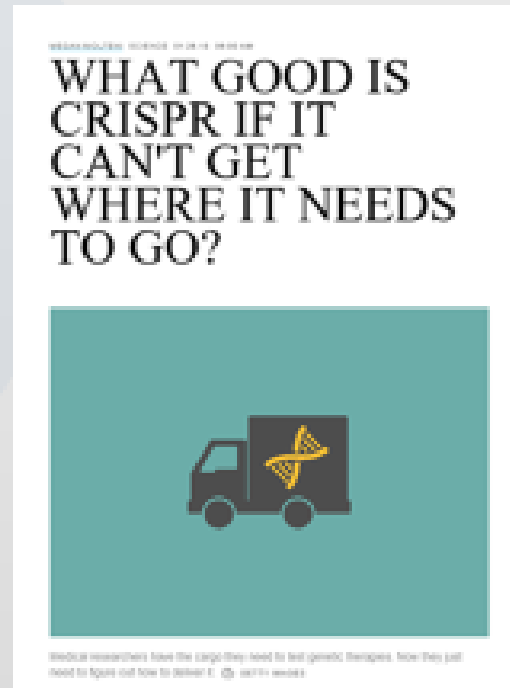
PJ Brooks, NCATS on behalf of the  
NIH Common Fund  
([pj.brooks@nih.gov](mailto:pj.brooks@nih.gov))



National Institutes of Health  
Office of Strategic Coordination - The Common Fund

## Program Objective

Goal: To support the development and evaluation of innovative approaches to deliver genome editing machinery into somatic cells, with the ultimate goal of accelerating the development of genome editing therapeutics to treat human disease.



# Research Scope

- Cell types of interest include but are not limited to endogenous stem cells and cell types of origin for cancer in any organ, and disease relevant cells in the:
  - Nervous system
  - Cardiovascular system, including hematopoietic and immune cells in vivo
  - Sensory organs
  - Kidney
  - Muscle
  - Bone
  - Endocrine system
  - Lymphatic organs
  - Gastrointestinal tract
- Emphasis on organs/cell types that have no effective delivery technologies.
- For organs and cell types currently accessible to genome editing; emphasis on substantial qualitative improvements in clinical application.
  - Slight modifications or incremental advances will not be considered responsive
- Improvements that would substantially enhance clinical utility include but are not limited to:
  - Greater capacity and versatility in size or type of genome editing machinery delivered
  - Support of transient or regulatable expression of genome editors
  - Reduced immunogenicity
  - Avoidance of pre-existing immunity
  - Improved or expanded cell-type targeting
  - Simplification or increased scalability of production
  - Less invasive mode of administration

## Research Scope (cont'd)

- Non-viral technologies could include but are not limited to:
  - Nanoparticles
  - Liposomes
  - Physical delivery methods (devices)
  - Prokaryotic systems
  - Human cells modified to deliver genome editing machinery in vivo
  - ??????
- Projects can focus on a single cell type, or multiple cell types
- Screening approaches welcome
- Deliver genome editors as:
  - DNA
  - mRNA
  - Protein
- Viral technologies
  - Applications proposing to incorporate genome editors into currently known AAV serotypes not responsive

# Program Timeline and Budget : UG3 / UH3 Mechanism

## Proof of Concept

- Establish and optimize the delivery technology
- Demonstrate genome editing *in vivo* in target cell types (by end of year 2).

## Validation

- Send delivery reagents to SCGE testing center (RM-18-12) for independent validation
- Collaboration with other SCGE Awardees

- Scale-up and testing in large animals
- Working with SCGE Large Animal Testing Center (RFA-RM-18-014)
- Collaboration with other SCGE Awardees

Year 1

Year 2

Year 3

UG3: \$500K direct costs per year

Year 4

UH3: Up to \$1,000,000  
(new Award)

## UG3/UH3 transition:

- Programmatic review by NIH
- Based on negotiated milestones
  - e.g. % of target cells edited *in vivo*
- ***Independent validation essential***



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## **Application instructions specific to RFA-RM-18-016 (Section IV):**

### ***Overall***

Both the UG3 and UH3 phases should be described in the Research Strategy section,  
**12 pages total**

A timeline (Gantt chart) that includes milestones is required. Milestones must include clear and quantitative criteria (e.g. % of target cells edited).

### ***Added Review Criteria***

**Significance :** Has the PD/PI provided a convincing therapeutic rationale for genome editing in the chosen target cell population?

**Approach:** If the investigators are proposing a project involving modifications of currently available vector(s), have they provided a convincing explanation of how the approach would substantially enhance clinical utility?

Have they included adequate plans to assess whether the proposed technologies will deliver genome editing machinery to human cells in vitro, if appropriate human cell systems are available?

# Expanding the Human Genome Editing Repertoire (U01 Clinical Trial Not Allowed)

**RFA RM-18-024**

Betty Poon, NIAID on behalf of the NIH  
Common Fund

([poonb@niaid.nih.gov](mailto:poonb@niaid.nih.gov))



# RFA RM-18-024 Expanding the Human Genome Editing Repertoire

## Program Objective

- The objective of this FOA is to support research aiming to develop innovative genome editing systems with improved specificity, efficiency, or functionality over currently available systems.
- Genome editing technology supported by the SCGE Consortium is defined broadly, extending beyond nuclease-dependent activities for manipulating DNA. Thus the platforms may also include, but not be limited to, nuclease-independent targeted editing, epigenetic modifiers, transcriptional repression and activation approaches, and RNA editors.
- Furthermore, the scope includes more than a single editor type (e.g., CRISPR-Cas).

# RFA RM-18-024 Expanding the Human Genome Editing Repertoire

## Research Scope:

Design and optimization strategies to enhance genome editing capabilities in human cells can include but is not limited to:

- Rational screening, directed evolution, and selection methodologies to guide the identification of complexes with novel enzymatic activities and substrate specificities.
- Epigenome reprogramming technologies to alter the epigenetic composition of the genome at any given genomic location.
- Strategies for manipulation of normally inaccessible genomes or genomic regions that are relevant to the treatment of certain diseases.
- Approaches to increase the frequency of HDR within target regions, while reducing non-specific events.
- In silico computational design, including software tools, to improve or alter the activity of existing genome editing platforms. Modeling and simulation results should complement experimental studies that quantify the genome editing system efficacy and characterize both on-target and off-target system activities.
- Modifications of existing nucleases may be proposed, but should represent a significant enhancement compared to present nucleases, such as improved delivery or packaging in viral or non-viral vectors, short-term or regulatable expression or activity, higher fidelity with reduced off-target activity, and decreased immunogenicity.

# RFA RM-18-024 Expanding the Human Genome Editing Repertoire

## **Application Instructions specific for this FOA (section IV):**

Under Research Strategy: All projects should include plans for comprehensive evaluation of efficiency and accuracy of the proposed genome editing platforms. If modifications of existing nucleases are proposed, applicants should clearly articulate the expected improvements in platform performance. These improvements they aim to achieve should be significant and be stated as a quantitative comparison to the state of the art.

A timeline (Gantt chart) that includes milestones is required for all studies

## **Specific Review Criteria for RFA-RM-18-024 (section V):**

Under Approach: Are the plans for evaluating the efficiency and accuracy of the proposed genome editing platforms well described, comprehensive, and appropriate to establish the feasibility of the platform? If modifications of existing nucleases are proposed, are the improvements quantitative and do the modifications provide significant improvements over current genome nuclease-mediated editing strategies?



## Program Timeline and Budget

### Proof of Concept

- Demonstrate the editing capacity of the new or optimized editor(s)
- In vitro molecular or cell model testing systems chosen by the awardee

### Optimize

- Continue to refine the genome editing platform(s)
- Contribute expertise to help guide SCGE animal model development, delivery technologies, and biological systems

### Collaborate as appropriate

- For example, share editors with delivery awardees. Work together to optimize packaging and delivery in vivo



Milestones are used to assess the progress made towards each aim. They should be scientifically justified, well defined for each year of the project, and based on the proposed specific aims.

Award Budget: \$250K direct costs per year in FY19-22

# Innovative Technologies to Non-Invasively Monitor Genome Edited Cells In Vivo (UH2/UH3 Clinical Trial Not Allowed)

**RFA-RM-18-025**

John Sheridan, NHLBI on behalf of  
the NIH Common Fund  
([john.sheridan@nih.gov](mailto:john.sheridan@nih.gov))



National Institutes of Health  
Office of Strategic Coordination - The Common Fund

## Program Objective

Goal: To support the development of tools and technologies that will enable monitoring and tracking of genome edited cells in humans to better assess the safety and efficacy of genome editing therapies.

In vivo tracking of genome edited cells will provide information on the fate, turnover, and distribution of cells, notably in solid tissues or those that are difficult to sample, to better evaluate therapeutic efficacy and monitor adverse effects.

FDA released new guidance on “[Long Term Follow-Up After Administration of Human Gene Therapy Products](#)”

“The LTFU (long term follow-up) protocol for GT (gene therapy) trials is primarily designed to capture delayed adverse events in study subjects as well as to understand the persistence of the GT product”

# Research Scope

- This program will support the discovery, development and evaluation of specific, sensitive and ideally clinically-relevant approaches to non-invasively monitor and track genome edited cells *in vivo*
- The FOA is open to technologies at various stages of development, from the initial discovery of a novel approach to the development and adaptation of pre-existing technologies
- Approaches that are likely to have clinical utility are preferred. However, approaches that may not have clinical utility (i.e. involving the use of GFP or other exogenous reporter genes) but that are being applied for discovery purposes aimed at identifying endogenous ligands, validating assays, or developing other means to specifically label and detect edited cells may also be proposed
- The proposed monitoring assays must have the capacity to be performed *in vivo*.
- Applicants must propose studies to validate the technology in a small animal model (mice or rats)
- Approaches that would involve invasive procedures or destruction of edited cells/tissues are not responsive to this FOA.

# Application Instructions Specific to RFA-RM-18-025 (Section IV):

The complete application instructions can be found in section IV of the FOA

## Background and Significance:

- Outline the main characteristics and applicability of the proposed technology. Provide a rationale for the method of delivery, route of administration, and cell/tissue to target. Explain and justify the potential of the proposed technology for clinical use beyond the UH3 project.

## Approach:

- Sub-divided into two sections, describing activities for each phase (UH2 and UH3).
- All applications should address plans for assessing potential clinical utility and feasibility.
- As appropriate for each phase, provide a plan to develop, evaluate, and optimize the technology, including:
  - Approaches to evaluate feasibility of the technology to detect genome edited cells *in vivo*
  - The strategy to non-invasively monitor labeled cells longitudinally
  - The route of administration
  - Experiments to evaluate safety and toxicity of the technology *in vivo*
  - Methods to evaluate and optimize the sensitivity of the technology *in vivo*

## Milestones and timeline:

- A timeline (Gantt chart) that includes milestones is required for all studies.
- Quantitative go/no-go decision points, and timelines for assessing progress in both the UH2 and UH3 phases must be proposed.
- The UH2/UH3 transition milestone should be specific, quantifiable, and scientifically justified.

## Review Criteria Specific to RFA-RM-18-025 (Section V):

Significance: How strong is the potential of the proposed technology for monitoring genome edited cells in vivo in humans?

Investigator: How strong is the evidence that the PD/PI(s) and key personnel have the necessary expertise to develop and test the technology?

Approach: How well has the application demonstrated that the overall strategy, methodology, and analytical approaches are adequately developed and appropriate to establish the feasibility of the technology?

### Additional Review Considerations

Milestones: How strongly do the milestone address the specific aims of the project? Are the listed milestones appropriate for the goals of the project?



# Program Timeline and Budget: UH2/UH3 Mechanism

## Proof of Concept

- Evaluate the feasibility of detecting and monitoring genome edited cells
- In vivo evaluation of the monitoring technology in a small animal may begin in the UH2 portion

Year 1

Year 2

UH2: \$150K direct costs per year in FY19-20

## Develop

- Optimize delivery and detection
- Evaluate safety of technology *in vivo*
- Refine detection assays
- Improve sensitivity of the monitoring methodology *in vivo*

Year 3

Year 4

UH3: \$300K direct costs per year in FY21-22

## UH2/UH3 Transition

- Programmatic review by NIH
- Successful achievement of negotiated milestones



Center for  
Scientific Review

# Overview of Scientific Review Process

PJ Brooks, Ph.D. on behalf of  
Elena Smirnova, Ph.D.

Acting Chief, Genes, Genomes and Genetics IRG

# Review – who will review my application?

- Reviewed in Center for Scientific Review (CSR)
- Special Emphasis Panels (SEP) – no need to look up and request a standing study section. One-time panels held to review applications on special topics.
- Include only temporary members
- Meeting rosters will be posted online 30 days before the review meeting -  
<https://public.csr.nih.gov/StudySections/SpecialEmphasis/>

## Review Information

- Refer to Section V of the FOA – “Application Review Information”
- Read Criteria.
- Pay special attention and address “Specific to this FOA” review questions.

## Overall Impact and Review Criteria

- **Overall Impact:** The reviewers will assess the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria (as applicable for the project proposed).
- Five Scored Review criteria: Significance, Investigator(s), Innovation, Approach, Environment
- Additional Review Criteria: Protections for Human Subjects, Vertebrate Animals, Biohazards

# Overview of Cooperative Agreements and Multi-phase Milestone Applications (UH2/UH3; UG3/UH3)

PJ Brooks

([pj.brooks@nih.gov](mailto:pj.brooks@nih.gov))



National Institutes of Health  
Office of Strategic Coordination - The Common Fund



# Cooperative Agreements: U Mechanism

- Used when **substantial programmatic involvement is anticipated between the Federal agency and the recipient** during performance of the assisted activity.
- Supports and stimulates the recipients' activities by involvement in and working jointly with the award recipients in a **partnership role**; it is not to assume direction, prime responsibility, or a dominant role in the activities. **The dominant role and prime responsibility reside with the awardees** of the project as a whole.
- The Cooperative Agreement Terms and Conditions of Award in each FOA clearly outlines the roles and expectations of the PD/PI and NIH Program Staff.
- This information will also be in the Notice of Award (NoA)

# Multi-phase Applications

- Applications must be written in a multi-phased manner with clear, quantitative milestones
- Milestones are goals that create go/no-go decision points and must include clear and quantitative criteria for success.
- At a minimum, there should be one defined milestone for each year of requested support.
- Milestones are included in the Type 1 application and are sometimes re-negotiated in the pre-award stage.
- **RM18-023:** Phase I (UG3) will be three years in length, and Phase II (UH3) is an additional one year in length, for a total project length of four years.
- **RM18-025:** Phase I (UH2) will be two years in length, and Phase II (UH3) is an additional two years in length, for a total project length of four years.

# Cooperative Agreements Terms and Conditions of Awards

- Acceptance of the Notice of Award (NoA) indicates the recipients' willingness to work with NIH Program staff during the course of the award.
- To participate in semi-annual meetings and in regular conference calls with NIH program staff and other SCGE grantees.
- To actively seek input from NIH regarding resource needs or expertise needs that may arise during the performance of the project.
- To work within a consortium agreement to meet the goals of the Program.

# Transition Phases

The transition from one phase to the next (UH2/UG3 to UH3 phase) is gauged on the achievement of the negotiated milestones during an administrative review. Some of the following are general points that are considered:

- Potential for meeting the goals of the Initiative
- Ability to work within a Consortium arrangement with other awardees to meet the goals of the program
- The availability of funds
- Program priorities
- Successful achievement of the defined milestones for the UG3/UH2 Phase of the project
- Independent validation of the delivery of genome editing machinery in target cells in vivo. (**ONLY for RM-18-023**)
  - Milestones and details of independent validation criteria will be included in the Notice of Award

# Resources

- NIH Grants Policy Statement:  
<https://grants.nih.gov/grants/policy/nihgps/HTML5/introduction.htm>
- SF424 (R&R) General Instructions for NIH and other PHS Agencies:  
<https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf>
- Funding Opportunity Announcements:
  - NHLBI RFA (*U01 mechanism*): RFA-RM-18-022
  - NCATS RFA (*UG3/UH3 mechanism*): RFA-RM-18-023
  - NIAID RFA (*U01 mechanism*): RFA-RM-18-024
  - NHLBI RFA (*UH2/UH3 mechanism*): RFA-RM-18-025

# Important Contacts

## Scientific/Research Contact(s)

- **RFA-RM-18-022 & -025**

- John Sheridan, Ph.D.; NHLBI
- Tel.: 301-435-0202
- Email: [john.sheridan@nih.gov](mailto:john.sheridan@nih.gov)

- **RFA-RM-18-023**

- Phillip J. ("Pj") Brooks, Ph.D., NCATS
- Tel: 301-443-0513
- Email: [PJ.Brooks@nih.gov](mailto:PJ.Brooks@nih.gov)

- **RFA-RM-18-024**

- Betty Poon, Ph.D., NIAID
- Tel: 240-669-5024
- Email: [poonb@niaid.nih.gov](mailto:poonb@niaid.nih.gov)

- **Peer Review Contact**

- Elena Smirnova, Ph.D.; CSR
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- Email: [smirnove@csr.nih.gov](mailto:smirnove@csr.nih.gov)

- **Grants Management\*\***

- Gloria Velez; NCATS
- Tel: 301-435-0846
- E-mail: [gloria.velez@nih.gov](mailto:gloria.velez@nih.gov)

- **Common Fund**

- Mary Perry, Ph.D., OD/OSC
- Tel: 301-435-5082
- E-mail: [perry@mail.nih.gov](mailto:perry@mail.nih.gov)

\*\*Please check FOA for specific GM contact

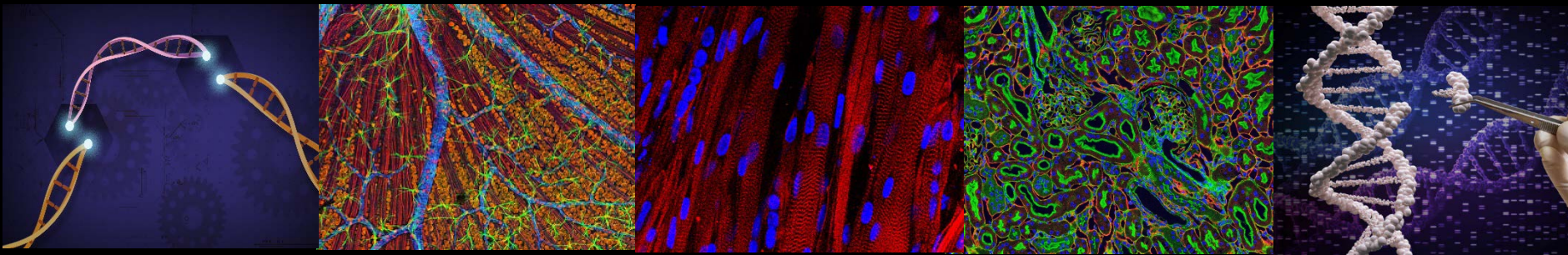


# Questions?

- Please submit using the **chat box**
- All questions submitted to the SCGE email during the webinar will be answered in the order they were received.



National Institutes of Health  
Office of Strategic Coordination - The Common Fund



# Instructions for NIH IRP Applicants

Instructions for IRP applicants are in the Common Fund Handbook (NIH access only):

[https://osc.cf.cit.nih.gov/CommonFundHandbook/Pages/Chapter 6 Section C Intramural Involvement in Common Fund Programs.aspx](https://osc.cf.cit.nih.gov/CommonFundHandbook/Pages/Chapter_6_Section_C_Intramural_Involvement_in_Common_Fund_Programs.aspx)

Some highlights:

IC Scientific Director needs to sign application

IRP can request funds only for project activities – not to support federal staff

If acting as a collaborator, the IRP PI gives a budget request to the ERP PI that gets submitted with the application

The IRP funds go directly from the CF to the IRP as an interagency agreement, not from the CF to the ERP and then to the IRP.

