Somatic Cell Genome Editing Program Manual of Operations

February 9, 2022

(Admin Update April 23, 2026)

Table of Contents

I. Consortium Overview and Governance

A. Consortium Overview

The Somatic Cell Genome Editing (SCGE) Consortium Phase 1 was established with two Small Animal Testing Centers, three Large Animal Production Centers, two Large Animal Testing Centers, twelve Biological Effects projects (eight Biological Systems and four *In Vivo* Cell Tracking), five Genome Editors projects, twenty Delivery Systems projects, and a Dissemination and Coordinating Center.

The Small Animal Testing Centers PIs and Institutions:

- Stephen Murray, Ph.D. and Cathleen Lutz, Ph.D. – Jackson Laboratory, Bar Harbor, ME
- Jason Heaney, Ph.D.; Mary Dickinson, Ph.D.; and William Lagor, Ph.D. – Baylor College of Medicine, Houston, TX

The Large Animals Production Centers PIs and Institutions:

- Daniel Carlson, Ph.D. – Recombinetics, Inc., Saint Paul, MN
- Guoping Feng, Ph.D. – Massachusetts Institute of Technology, Boston, MA
- Jon Hennebold, Ph.D. – Oregon Health Science University, Portland, OR

The Large Animals Testing Centers PIs and Institutions:

- Alice Tarantal, Ph.D.; David Segal, Ph.D.; and Dennis Hartigan-O'Connor M.D., Ph.D. – University of California, Davis, CA
- Kevin Wells, Ph.D.; and Randal Prather, Ph.D. – University of Missouri, Columbia, MO

The Biological Systems projects PIs and Institutions:

- Benjamin Freedman, Ph.D. – University of Washington, Seattle, WA
- Charles Gersbach, Ph.D.; Nenad Byrsac, Ph.D.; and George Truskey, Ph.D. – Duke University, Durham, NC
- John Travis Hinson, M.D. – University of Connecticut, Storrs, CT
- Samira Kiani, M.D. – Arizona State University, Tempe, AZ
- Bruce Conklin, Ph.D. – J. David Gladstone Institutes, San Francisco, CA
- Ryuji Morizane, M.D., Ph.D.; Jennifer Lewis, Ph.D.; and Venkata Sabbisetti, Ph.D. – Massachusetts General Hospital, Boston, MA
- Krishanu Saha, Ph.D.; David Gamm, M.D.; Sushmita Roy, Ph.D., and Melissa Skala, Ph.D. – University of Wisconsin, Madison, WI

- Shengdar Tsai, Ph.D. – St. Jude Children's Research Hospital, Memphis TN

The *In Vivo* Cell Tracking projects PIs and Institutions:

- Jeff Bulte, Ph.D. – John Hopkins University, Baltimore, MD
- John Ronald, Ph.D. – University of Western Ontario, London, Ontario, Canada
- Alice Tarantal, Ph.D.; and David Segal, Ph.D. – University of California, Davis, CA
- Moriel Vandsburger, Ph.D. – University of California, Berkeley, CA

The Delivery Systems projects PIs and Institutions:

- Aravind Asokan, Ph.D. – Duke University, Durham, NC
- Krystof Bankiewicz, M.D., Ph.D.; and Niren Murthy, Ph.D. – Ohio State University, Columbus, OH
- Gang Bao, Ph.D.; and William Lagor, Ph.D. – Rice University, Houston, TX
- James Dahlman, Ph.D.; and Philip Santangelo, Ph.D. – Georgia Tech, Atlanta, GA
- Benjamin Deverman, Ph.D. – Broad Institute, Cambridge, MA
- Zheng-Yi Chen, Ph.D.; David Liu, Ph.D.; and Qiaobing Xu, Ph.D. – Massachusetts Eye and Ear Infirmary, Boston, MA
- Elliot Chaikof, M.D, Ph.D. – Beth Israel Deaconess Medical Center, Boston, MA
- David Curiel, Ph.D. – Washington University, St. Louis, MO
- Guangping Gao, Ph.D.; Daniel Anderson, Ph.D.; and Wen Xue, Ph.D. – University of Massachusetts Medical School, Worcester, MA
- Ionita Ghiran, M.D. – Beth Israel Deaconess Medical Center, Boston, MA
- Shaoqin Gong, Ph.D.; Marina Emborg, M.D., Ph.D.; Jon Levine, Ph.D.; Subhojit Roy, M.D., Ph.D.; and Krishanu Saha, Ph.D. – University of Wisconsin, Madison, WI
- Kit Lam, Ph.D.; and R. Holland Cheng, Ph.D. – University of California, Davis, CA
- Kam Leong, Ph.D. – Columbia University, New York, NY
- Paul McCray, Jr., M.D. – University of Iowa, Iowa City, Iowa
- Mark Saltzman, Ph.D.; and Peter Glazer, M.D., Ph.D. – Yale University, New Haven, CT
- Erik Sontheimer, Ph.D.; Anastasia Khvorova, Ph.D.; Jonathan Watts, Ph.D.; and Scot Wolfe, Ph.D. – University of Massachusetts Medical School, Worcester, MA
- John Christian Tilton, Ph.D. – Case Western Reserve University, Cleveland, OH
- Ross Wilson, Ph.D.; and Jennifer Doudna, Ph.D. – University of California, Berkeley, CA
- Guohua Yi, Ph.D. – University of Texas Health Sciences Center, Tyler, TX

- Jiangbing Zhou, Ph.D. – Yale University, New Haven, CT

The Genome Editors projects PIs and Institutions:

- Jennifer Doudna, Ph.D.; and Jillian Banfield, Ph.D. – University of California, Berkeley, CA
- Stephen Ekker, Ph.D.; and Karl Clark, Ph.D. – Mayo Clinic, Rochester, MN
- Charles Gersbach, Ph.D. – Duke University, Durham, NC
- Peter Glazer, Ph.D.; Danith Ly, Ph.D.; and W. Mark Saltzman, Ph.D. – Yale University, New Haven, CT
- David Liu, Ph.D. – Broad Institute, Cambridge, MA

The SCGE Dissemination and Coordinating Center (SCGE DCC) PIs and Institution:

- Melinda Dwinell, Ph.D.– Medical College of Wisconsin

The purpose of this cooperative research Consortium is to accelerate the translation of genome editing technology into clinical applications. The deliverables of the SCGE program will be a collection of tools, reagents, methods, data, and best practices that will accelerate development and testing of new treatments for many diseases, i.e., the SCGE Toolkit for Therapeutic Genome Editing or SCGE Toolkit. The SCGE program will involve innovative and collaborative research by a partnership of genome editing experts, delivery systems experts, animal model experts, and assay developers to produce validated techniques and knowledge through exchange of expertise, information, and research tools. Awardees from all five SCGE program components form the Consortium, governed by a steering committee of investigators and NIH staff that will develop consensus policies and procedures for Consortium-wide activities such as data and resource sharing. It is expected that all awardees will collaborate to accelerate the translation of genome editing technologies into treatments for human disease.

The major funders are:
The SCGE program is funded by the NIH Common Fund, which is managed by the Office of Strategic Coordination (OSC)/Division of Program Coordination, Planning and Strategic Initiatives (DPCPSI)/Office of the Director (OD).

B. Governance

B.1. Cooperative Agreement Responsibilities

The administrative and funding instrument used for the SCGE program is the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to support

and stimulate recipient activities by involvement in and otherwise 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. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the NIH as defined below.

NIH staff have substantial programmatic involvement that is above and beyond the normal stewardship role as described below:

The NIH SCGE Working Group consists of NIH programmatic staff from multiple Institutes and Centers of the NIH as well as the Office of the Director. It reports to OSC leadership for final funding decisions. The Working Group is Co-chaired by the Director of National Institute of Neurological Disorders and Stroke (NINDS), Walter Koroshetz, Ph.D. and by the Acting Director of the National Center for Advancing Translational Science (NCATS), Joni Rutter, Ph.D., who are responsible for overall scientific and managerial guidance to the SCGE program at the NIH level. The Working Group Coordinators, P.J. Brooks, Ph.D. and Tim LaVaute, Ph.D., provide high level management of the program on behalf of the Co-chairs, while the Common Fund Program Leader, Felicia Qashu, Ph.D., serves on the SCGE Working Group and provides guidance to the Working Group regarding Common Fund policies and requirements, and reports on these activities to OSC leadership. Additionally, the NIH SCGE Working Group has a dedicated group of Project Team Leaders that administer each of the program's research initiatives. The NIH SCGE Working Group will participate as members of the SCGE Program Steering Committee and will collectively have one vote.

Research Initiative(s)	Project Team Leader	Institute
Animal Production and Testing Centers	Oleg Mirochnitchenko, Ph.D.	ORIP
Biological Effects projects	Tatjana Atanasijevic, Ph.D.	NIBIB
Delivery Systems projects	P.J. Brooks, Ph.D.	NCATS
Genome Editors projects	Betty Poon, Ph.D.	NIAID
SCGE DCC	Colin Fletcher, Ph.D.	NHGRI

The NIH Project Scientist(s) will have substantial scientific and programmatic involvement during the conduct of this activity through technical assistance, advice, and coordination. However, the role of NIH staff will be to facilitate and not to direct the activities. The Project Scientist(s) will have the following substantial involvement:

- Participating with the other SCGE Program Steering Committee members in addressing issues that arise with SCGE planning, operation, assessment, and data analysis. The Project Scientist(s) will assist and facilitate the group process and not direct it.
- Serving as a liaison, helping to coordinate activities, including acting as a liaison to other NIH Institutes/Centers, and as an information resource for the awardees. The Project Scientist(s) will also help coordinate the efforts of the SCGE Consortium with other groups conducting similar efforts.
- Attending all SCGE Program Steering Committee meetings as a voting member, assisting in developing standard operating procedures, and consistent policies for dealing with situations that require coordinated action. The Project Scientist(s) will be responsible for working with the grantee as needed to manage the logistic aspects of the SCGE program.

- Reporting periodically on SCGE program progress to the NIH SCGE Working Group, and through it to the NIH Common Fund.
- Serving on subcommittees and working groups of the SCGE Program Steering Committee as appropriate.
- Assisting awardees in the development, if needed, of policies for dealing with situations that require coordinated action.
- Providing advice in the management and technical performance of the award.
- Assisting in promoting the availability of the data and related resources developed in the course of this program to the scientific community at large.
- Participating in data analyses, interpretations, and, where warranted, co-authorship of the publication of results of studies conducted through the program.
- Other NIH SCGE Working Group staff may assist the awardee as designated by the Program Official.

Additionally, an agency program official or IC program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice. The assigned Program Official may also serve as an NIH Working Group Project Scientist(s) to assist the awardee.

Areas of Joint Responsibility include:

Close interaction among the participating investigators will be required, as well as significant involvement from the NIH, to manage, assess, and disseminate the SCGE program. The awardees and the Project Scientist(s) will meet in person with the SCGE Program Steering Committee twice a year and on conference or Zoom calls as needed to share information on methodologies, analytical tools, and preliminary results. All members of a SCGE project/center are eligible to attend these meetings.

Cooperative agreement details specific to each RFA can be found at the following links:

- Small Animal Testing Centers: RFA-RM-18-012
- Large Animal Production Centers: RFA-RM-18-013
- Large Animal Testing Centers: RFA-RM-18-014
- Biological Systems: RFA-RM-18-015
- *In Vivo* Cell Tracking: RFA-RM-18-022
- Delivery Systems: RFA-RM-18-016 and RFA-RM-18-023
- Genome Editors: RFA-RM-18-017 and RFA-RM-18-024
- Dissemination and Coordinating Center: RFA-RM-18-018

B.2. Steering Committee Policies

Guideline: A Steering Committee composed of PIs from all projects and the NIH Project Scientist(s) is the decision-making body for SCGE responsible for the scientific direction of the program, and subject to oversight by the NIH SCGE Working Group as set forth in the FOAs RFA-RM-18-012-018 and RFA-RM-18-022-025. Awardees from all of the SCGE components form the SCGE Consortium. The Steering Committee governs the Consortium and will develop consensus policies and procedures for Consortium-wide activities.

Principles:

- The Steering Committee is responsible for policy decisions regarding the Consortium, and for the discussion and resolution of procedural issues that affect the operation and status of the network as a whole, including but not limited to the following:
    - Ensure that all projects contribute to input, design, and testing of the SCGE Toolkit.
    - Oversee compliance with program policies and procedures.
    - Approve significant modifications to approved protocols.
    - Make major decisions regarding publication policy, data sharing and data release to the public.
    - Approve significant modifications to approved milestones.
- The SCGE Steering Committee will be the operational group through which the NIH SCGE Working Group interacts with the SCGE Consortium.
- The Steering Committee will have monthly conference calls.
- The Steering Committee will meet in-person biannually. However, unforeseen circumstances may require these meetings to occur virtually.
- The minutes for all Steering Committee discussion will be documented and posted on SCGE DCC Google Drive (viewable to Steering Committee members).
- The voting members of the SCGE Steering Committee include the Principal Investigator(s) of each project/center and the collective NIH. Each project/center has one vote (multiple PIs may all be members of the Steering Committee, but collectively have one vote for their project/center) and the NIH SCGE Working Group collectively has one vote. Together, there are currently 46 voting members of the SCGE Steering Committee.
- Other government staff (e.g., DARPA, FDA, NIST) may attend the Steering Committee meetings as desired.

The SCGE Program Steering Committee may establish subcommittees and working groups as needed to address particular issues, which will include representatives from the program and the NIH and possibly other experts. The SCGE Program Steering Committee will have the overall responsibility of assessing and prioritizing the progress of the various subcommittees.

The SCGE awardee agrees to work collaboratively to:

- Provide for secure, accurate and timely data submission.
- Participate in presenting and publishing new processes and substantive findings.
- Assess and disseminate the SCGE Toolkit.
- Participate in the governance of the SCGE program as a member of the SCGE Program Steering Committee.
- Interact with other relevant NIH activities, as needed, to promote synergy and consistency among similar projects.

STEERING COMMITTEE
Co-Chairs: Charles Gersbach, Ph.D.; and Shengdar Tsai, Ph.D.

Voting Members:
Small Animal Testing Centers PIs (1 vote per center):
Stephen Murray, Ph.D. – Jackson Laboratory, Bar Harbor, ME

Jason Heaney, Ph.D. – Baylor College of Medicine, Houston, TX

Large Animals Production Centers PIs (1 vote per center):

Daniel Carlson, Ph.D. – Recombinetics, Inc., Saint Paul, MN

Guoping Feng, Ph.D. – Massachusetts Institute of Technology, Boston, MA

Jon Hennebold, Ph.D. – Oregon Health Science University, Portland, OR

Large Animals Testing Centers PIs (1 vote per center):

Alice Tarantal, Ph.D. – University of California, Davis, CA

Kevin Wells, Ph.D. – University of Missouri, Columbia, MO

Biological Systems projects (1 vote per project):

Benjamin Freedman, Ph.D. – University of Washington, Seattle, WA

Charles Gersbach, Ph.D. – Duke University, Durham, NC

John Travis Hinson, Ph.D. – University of Connecticut, Storrs, CT

Samira Kiani, Ph.D.– Arizona State University, Tempe, AZ

Bruce Conklin, Ph.D. – J. David Gladstone Institutes, San Francisco, CA

Ryuji Morizane, M.D., Ph.D. – Massachusetts General Hospital, Boston, MA

Krishanu Saha, Ph.D. – University of Wisconsin, Madison, WI

Shengdar Tsai, Ph.D. – St. Jude Children's Research Hospital, Memphis TN

In Vivo Cell Tracking projects (1 vote per project):

Jeff Bulte, Ph.D. – John Hopkins University, Baltimore, MD

John Ronald, Ph.D. – University of Western Ontario, London, Ontario, Canada

Alice Tarantal, Ph.D. – University of California, Davis, CA

Moriel Vandsburger, Ph.D. – University of California, Berkley, CA

Delivery projects (1 vote per project):

Aravind Asokan, Ph.D. – Duke University, Durham, NC

Krystof Bankiewicz, M.D., Ph.D. – Ohio State University, Columbus, OH

Zheng-Yi Chen, Ph.D. – Massachusetts Eye and Ear Infirmary, Boston, MA

Elliot Chaikof, Ph.D. – Beth Israel Deaconess Medical Center, Boston, MA

David Curiel, Ph.D. – Washington University, St. Louis, MO

James Dahlman, Ph.D. – Georgia Tech, Atlanta, GA

Benjamin Deverman, Ph.D. – Broad Institute, Cambridge, MA

Guangping Gao, Ph.D. – University of Massachusetts Medical School, Worcester, MA

Ionita Ghiran, Ph.D. – Beth Israel Deaconess Medical Center, Boston, MA

Shaoqin Gong, Ph.D. – University of Wisconsin, Madison, WI

William Lagor, Ph.D. – Rice University, Houston, TX

Kit Lam, Ph.D. – University of California, Davis, CA

Kam Leong, Ph.D. – Columbia University, New York, NY

Paul McCray, Ph.D. – University of Iowa, Iowa City, Iowa

Mark Saltzman, Ph.D. – Yale University, New Haven, CT

Erik Sontheimer, Ph.D. – University of Massachusetts Medical School, Worcester, MA

John Christian Tilton, Ph.D. – Case Western Reserve University, Cleveland, OH

Ross Wilson, Ph.D. – University of California, Berkeley, CA

Guohua Yi, Ph.D. – University of Texas Health Sciences Center, Tyler, TX

Jiangbing Zhou, Ph.D. – Yale University, New Haven, CT

Genome Editors projects (1 vote per project):

Karl Clark, Ph.D. – Mayo Clinic, Rochester, MN

Jennifer Doudna, Ph.D. – University of California, Berkeley, CA
Charles Gersbach, Ph.D. – Duke University, Durham, NC
Peter Glazer, Ph.D. – Yale University, New Haven, CT
David Liu, Ph.D. – Broad Institute, Cambridge, MA

SCGE DCC (1 vote per center):

Melinda Dwinell, Ph.D. – Medical College of Wisconsin, Milwaukee, WI

NIH SCGE WG – (1 vote total for NIH):

Colin Fletcher, Ph.D. (NHGRI)

B.3. Election of SCGE Steering Committee Co-Chairs

Guideline: The position of Chairperson of the SCGE Steering Committee will be filled by two Co-Chairs that serve staggered overlapping terms. The first set of Co-Chairs (Erik Sontheimer and Krishanu Saha) were selected by the NIH SCGE Working Group. Erik Sontheimer's (Delivery Systems) initial appointment was effective November 30, 2018, for approximately 18 months. Kris Saha's (Biological Effects) initial appointment was effective November 30, 2018, for 12 months. The SCGE DCC will request nominations for subsequent Co-Chairs from the Steering Committee. Nominations can be voiced during the Steering Committee meeting or via email to the DCC. Self-nominations are accepted. Current Steering Committee Co-Chair(s) will contact non-self-nominated individuals to confirm interest in the position. If multiple accepted nominations are received, the Co-Chair will be selected by a vote of the SCGE Steering Committee. Electronic ballots will be distributed by the DCC to Steering Committee voting members. The DCC will send frequent reminders prior to the voting deadline. Non-votes will count as abstentions. At least 50% of the voting members must vote to reach a quorum.

Principles:

1. The first set of Co-Chairs will have the opportunity to continue to serve if re-elected for a period of 12 months.
2. The subsequent term of the position of Co-Chair will be 12 months in duration.
3. The individuals holding the position of Co-Chair must be a voting member of the SCGE Steering Committee.
4. The Co-Chairs must be Principal Investigators of one of the Animal Testing or Production Centers, Delivery Systems projects, Genome Editors projects, or Biological Effects projects; the Principal Investigator of the SCGE DCC may not serve as a Co-Chair.
5. The Steering Committee Co-Chairs will be responsible for oversight of the SCGE program Steering Committee. Responsibilities of this role include, but are not limited to:
    a. Draft the agenda for the monthly Steering Committee meetings (in-person and teleconference).
    b. Oversee the SCGE Coordinating Committee (for more information see below).
    c. Assist in finalizing program governance documents developed by the SCGE Steering Committee.
    d. Keep track of key Steering Committee decisions and outcomes.

B.4. Coordinating Committee

The Coordinating Committee consists of the two Co-Chairs of the Steering Committee, the NIH SCGE Working Group Coordinator, the PI(s) of the SCGE DCC, the PI representatives of any initiatives unrepresented by the SCGE DCC and Co-Chairs, and the Program Officer of the SCGE DCC. Each of the five SCGE components will be represented by at least one member on the Coordinating Committee. The first set of initiative representatives to the Coordinating Committee include Erik Sontheimer (Steering Committee Co-Chair and Delivery Systems Initiative), Kris Saha (Steering Committee Co-Chair and Biological Effects Initiative, Steve Murray (Animal Reporter and Testing Center Initiative), Karl Clark (Genome Editors Initiative), and Mindy Dwinell (DCC) were selected by the NIH SCGE Working Group. Shengdar Tsai

(Biological Effects Initiative) has since replaced Erik Sontheimer as Steering Committee Co-Chair. Erik Sontheimer has remained on as the representative of the Delivery Systems Initiative. Charlie Gersbach (Biological Effects Initiative and Genome Editors Initiative) has since replaced Kris Saha as Steering Committee Co-Chair. Kris Saha has remained on as the representative of the Biological Effects Initiative.

Current representatives to the Coordinating Committee include Shengdar Tsai (Steering Committee Co-Chair and Biological Effects Initiative), Charlie Gersbach (Steering Committee Co-Chair, Biological Effects Initiative, and Genome Editors Initiative), Karl Clark (Genome Editors Initiative), Steve Murray (Animal Reporter and Testing Center Initiative), Erik Sontheimer (Delivery Systems Initiative), Kris Saha (Biological Effects Initiative), and Mindy Dwinell (DCC). The Coordinating Committee supports the Steering Committee and its decision-making process by planning, priority setting, and tracking progress of the SCGE program.

Principles:

1. Assist in Steering Committee agenda development.
2. Review updates from Working Groups and Subcommittees.
3. Provide input on global guidelines for adherence to deliverables and timelines, dissemination of data to DCC and/or repositories.
4. Identify issues to be brought forward to the Steering Committee and NIH for further discussion.

Operations: The DCC is responsible for scheduling meetings, distributing agendas and materials at least 2 business days before the Coordinating Committee meeting, and recording and posting minutes. Draft Coordinating Committee minutes should be ready for review within 5 business days and approved by the Coordinating Committee the following month.

Development of the Coordinating Committee agenda will be by the following process:

1. 1.5 weeks before the Coordinating Committee meeting, the DCC will contact the Steering Committee co-chairs for agenda items and documents to be brought to the attention of the Coordinating Committee. The standard request could include a request for the documents still under development and their timelines. The Steering Committee co-chairs will have 2 business days to respond.
2. The DCC assembles a draft Coordinating Committee agenda and shares it with the Steering Committee co-chairs and NIH members for editing at least 3 business days before the Coordinating Committee meeting.
3. After NIH input is received, the Steering Committee co-chairs should review and finalize the meeting agenda.
4. The DCC distributes the Coordinating Committee agenda (with any documents) to the Coordinating Committee members 2 business days in advance of its meeting. Late breaking items can be added by Coordinating Committee members with Steering Committee co-chairs approval.

5. The DCC assembles draft Coordinating Committee minutes directly after the Coordinating Committee meeting and shares it with the Coordinating Committee members.

B.5. Working Groups and Subcommittees

Guideline: The Steering Committee may establish Working Groups and Subcommittees as needed to address particular issues, which will include representatives from the program and NIH, and possibly other experts. The SCGE Steering Committee will have the overall responsibility of assessing and prioritizing the progress of the various Working Groups and Subcommittees.

Principles:

- Any individual or group proposing a new SCGE Working Group/Subcommittee will present their idea to the SCGE Steering Committee. A formal vote of the SCGE Steering Committee is needed to create a new standing Working Group/Subcommittee. However, a formal vote is not necessary for new *ad hoc* Working Groups.
- Volunteers for Chair or Co-Chairs of the new Working Group/Subcommittee will be solicited when the new Working Group/Subcommittee is proposed. A formal vote of the SCGE Steering Committee is needed to confirm the Chair or Co-Chairs if multiple nominations for a single position are received.
- At least 50% of the voting members must vote to reach quorum. For electronic votes, non-votes will count as abstentions.
- Co-chairs are not required for *ad hoc* Working Groups but may be recommended by the SCGE Steering Committee.
- Working Group/Subcommittee Co-Chairs are not prohibited from coming from the same project.
- Working Group Chairs and Co-Chairs are not required to be PIs of a SCGE project/center. Working Group Co-Chairs work with the DCC to create the monthly meeting agenda. The Co-Chairs facilitate the monthly meetings, ask questions following presentations, make suggestions, and ensures participants remain on topic. They are responsible for communicating updates to Subcommittee Co-chairs and Steering Committee Co-chairs.
- If there are no volunteers for Chair or Co-Chair, or only one, the SCGE Steering Committee may recommend a project or type of project that may be a good fit for the Working Group/Subcommittee and one of the SCGE Steering Committee Co-Chairs will solicit the project(s) for a recommended chair.
- Individuals can be members of more than one Working Group/Subcommittee.
- All Working Groups/Subcommittees will make their meeting agendas and minutes available to other Working Groups/Subcommittees.
- Progress reports on Working Group/Subcommittees activities will be presented at the bi-annual meetings and made available to other Working Groups/Subcommittees.
- Any SCGE Working Group/Subcommittee (excluding *ad hoc* Working Groups) proposing to close will present its idea to the SCGE Steering Committee. A formal vote of the SCGE Steering Committee is needed to close a standing Working Group/Subcommittee.

Working Groups and Subcommittees:

Data, Technology and Resource Sharing Subcommittee: Nick Anderson (Large Animal Testing Center) and Jeff De Pons (DCC)

Outreach Subcommittee: Reka Lorincz and Paul Boucher (Delivery Systems)

Animal Reporters and Testing Centers Working Group: Kathy Snow (Small Animal Testing Center)

Biological Effects Working Group: Benjamin Freedman and Samira Kiani (Biological Effects)

Delivery Systems Working Group: Zheng-Yi Chen and Ross Wilson (Delivery Systems)

Genome Editors Working Group: Gabe Butterfield Ankit Sabharwal (Genome Editors)

B.6. Implementing and Revising the SCGE Manual of Operations

- Subcommittees may be tasked with development of chapters for the SCGE Manual of Operations.
- Changes to the Manual of Operations will be ratified by the SCGE Steering Committee via vote.
- Working Groups or Subcommittees that would like to recommend: 1) a change to a ratified Manual of Operations chapter that affects network-wide operations, or 2) addition of a new chapter, should recommend the change to the SCGE Coordinating Committee for review prior to Steering Committee ratification.
- Subcommittees will have the authority to make decisions regarding implementation of ratified chapters of the Manual of Operations that are assigned to the Working Group for implementation.
- If a Working Group cannot resolve an implementation decision internally, the SCGE Steering Committee will be consulted.
- Working Groups will consult with other relevant Working Groups on implementation decisions that involve multiple areas of expertise. A cross-Working Group liaison may be assigned to facilitate these interactions.

II. Data Sharing Policy

SCGE Consortium approved policy on 9/3/2021.

Preamble: The Somatic Cell Genome Editing (SCGE) Toolkit will launch to the public in 2022. Therefore, the data generated from SCGE funded projects needs to be made available through the toolkit to other members of the consortium, as well as the research community in general, as soon as it is reasonable. Principal Investigators (PIs) are expected to deposit data and move it forward through the tiers as efficiently as possible to accomplish broad dissemination of this information. PIs will work with their respective Program Officers (POs) if exceptions to the public release of the data are necessary. PIs are responsible for ensuring that no copyright issues exist with journals or publishers. The Dissemination and Coordinating Center (DCC) Toolkit is free to use submitted data, figures, and/or images within the Toolkit. For pre-publications, PIs should acknowledge the SCGE Toolkit (https://scge.mcw.edu/toolkit/) as a data resource.

Purpose: The SCGE Consortium aims to promote the sharing of data, technologies, and resources as broadly and expeditiously as possible, while respecting the obligations, interests, and prerogatives of consortium investigators and their institutions. The SCGE's sharing principles are consistent with the goals of the NIH Data Sharing Policy (https://grants.nih.gov/grants/policy/data_sharing/) and with the Resource Sharing Plan guidelines stated in the original SCGE funding announcements (https://commonfund.nih.gov/editing/fundingopportunities). This document describes the SCGE Consortium policy for sharing and releasing data, technologies, and resources at multiple levels: within specific components of the SCGE, across the SCGE, to the broader scientific community, and to the public. SCGE sharing and release policies augment but do not replace general NIH policies that concern data, technology and resource access and sharing. These policies also augment but do not supersede sharing requirements described in the Terms and Conditions of SCGE awards.

To facilitate sharing, SCGE investigators will deposit data, descriptions of the methods used to generate the data, operating procedures, and other information into the SCGE Toolkit, which will be established and maintained by the SCGE DCC. It is anticipated that SCGE investigators will also deposit resources, data, and information into public databases and repositories agreed upon by the SCGE Consortium (e.g., Mouse Genome Database, see Tier 4 below). Guidelines and requirements for deposition into the SCGE Toolkit will be determined by the SCGE Consortium. The specific schedule for data/resource deposition will be established by the NIH PO for each award in consultation with the PIs. The DCC will provide the means for assigning data to particular Tiers, and release/promote data according to established plans. This SCGE sharing policy distinguishes four sharing and release tiers. For the purposes of this policy, "individual SCGE-funded teams" refers to personnel supported by a single SCGE award, as specified by that team's PI(s).

- **Tier 1** concerns data, technology, and resource sharing between members of individual SCGE-funded teams, as well as the technical and data teams at the DCC.
- **Tier 2** concerns sharing between a SCGE-funded team and other SCGE components beyond the DCC.
- **Tier 3** concerns internal release across the entire SCGE Consortium.

- **Tier 4** concerns external release to the broader scientific community and the public.

A. General Considerations

The SCGE acknowledges that investigators and their research institutions could have intellectual property (IP)-related obligations and interests that result from SCGE-funded research, and that SCGE policy should be consistent with such obligations and interests. It is the responsibility of investigators and their institutions to manage their own IP protection. Furthermore, given that data, technology, and resource sharing may be necessary or desirable in advance of IP filing (e.g., to meet testing-related program milestones), SCGE investigators have the ability and (if needed) the responsibility to establish Confidentiality and Disclosure Agreements (CDAs) and Material Transfer Agreements (MTAs) with others in the consortium, such as the Small Animal and Large Animal Testing Centers, who are the recipients of proprietary data, technology, and resources. The SCGE provides CDA and MTA examples and templates to program personnel as shared documents, but the final executed content of any such agreements is the responsibility of the specific parties involved. Members of the SCGE Consortium must notify the DCC when executed CDAs have been established with other SCGE components. Moreover, if IP protection is needed before releasing data, the investigators can request from their PO a six-month extension to the to-be-determined data deposition dates. In general, if the terms of a CDA are inconsistent with data sharing that would otherwise align with SCGE Consortium policies or priorities, the parties to the CDA will work with their respective POs to identify an equitable solution.

A.1. Types of Data to be Submitted

Required:

- Data associated with milestones.
- Data from publications supported and enabled by the SCGE Program.
- Oral presentations or posters presented at SCGE meetings.
- Negative/disappointing data associated with reporter allele validation and delivery system testing milestones.

Encouraged:

- Relevant data in SCGE-supported publications but not funded by the SCGE.
- Preliminary data that leads to the development of the final product but not published.
- Negative results not planned for publication.
- Detailed protocols for generating and/or analyzing data relevant to SCGE projects.

Summary Table:

Data Type	Required?	Entry Tier
Milestone Associated	Yes	1
Published, SCGE Funded	Yes	4
Negative Results	No	1
Preliminary/Development Work	No	1
Published, Not SCGE Funded	No	4*
Non-data Information		
Presentation at SCGE Meetings	Yes	3
Detailed Protocols Associated with Milestones	No	1

*Open access requirements must be followed.

A.2. Data, Resource and Technology Tiers

Tier 1. When data, technologies and resources are first deposited into the SCGE Toolkit, they will be designated Tier 1, and access will be limited to the DCC, to those SCGE personnel who are members of the depositor's individual SCGE-funded team, and to the PO associated with that team's SCGE award. Deposition of data, technology and resources into Tier 1 should be done as early as possible, according to the individual project's scientific timeline and the PO-established specific schedule for data/resource deposition.

Purposes of Tier 1 sharing. Tier 1 access will (*i*) allow data, technology, and resources to be shared among members of individual SCGE-funded teams, their PO, and the DCC; and (*ii*) enable data to be subjected to quality control and confirmation in preparation for further sharing.

Tier 2. Tier 2 data, technologies, and resources will be shared between specific consortium components beyond the individual SCGE-funded teams, that team's PO, and the DCC. SCGE components and personnel with access to Tier 2 data will be specified by the data's owners within individual SCGE-funded teams, using SCGE Toolkit tools and interfaces provided by the DCC. There is no specific requirement that <u>all</u> Tier 1 data be advanced to Tier 2. Progression of deposited data, technology, and resources from Tier 1 to Tier 2 should be done as early as possible, and according to the individual project's scientific timeline and the needs of other SCGE components (e.g., Small and Large Animal Testing Centers).

Purposes of Tier 2 sharing. The SCGE aims to maximize collaboration and sharing across the consortium, and Tier 2 access can be used to enable sharing in a manner that individual SCGE-funded teams can manage and control. Furthermore, the SCGE Program requires many of its investigators to deliver their technologies and reagents for testing by the Small and Large Animal Testing Centers. It is essential for SCGE investigators to provide the Testing Centers with all data, technology, and information that may be necessary to conduct the required tests in a manner that ensures regulatory compliance (e.g., IACUC, biological use authorizations), and that is consistent with SCGE milestones. Because some of this sharing will occur relatively early in the SCGE project period, potentially in advance of non-provisional IP filings, Tier 2 will allow restricted Testing Center access to the necessary investigator-provided data, technology, and resources, but without public disclosure. Tier 2 data can also be used for sharing between groups jointly supported by the SCGE Collaboration Opportunity Fund Projects. Additional sharing can also be implemented beyond these specific examples, at the discretion of the data's owners. After initially advancing data, technology, and resources from Tier 1 to Tier 2, investigators can expand access to additional SCGE groups as needed while still keeping the shared material at Tier 2.

Tier 3. Data, technologies, and resources that have been advanced from Tier 2 to Tier 3 are available to all participants in the SCGE Consortium with Toolkit access, for the benefit of the consortium's members and the program's research mission. Progression from Tier 2 to Tier 3 will use SCGE Toolkit tools and interfaces provided by the DCC. There is no

specific requirement that all Tier 2 data be advanced to Tier 3. Progression of deposited data, technology, and resources from Tier 2 to Tier 3 should be done as early as possible, according to the individual project's scientific timeline, forthcoming SCGE Consortium policies and the potential value of the shared materials to the SCGE Consortium.

Purposes of Tier 3 sharing. The SCGE Program aims to maximize collaboration and sharing across the consortium, and Tier 3 access can be used to enable such consortium-wide sharing.

Tier 4. Data, technologies, and resources that have been advanced from Tier 3 to Tier 4 are available to the scientific community and to the public. It is expected that shareable data presented publicly (e.g., in public presentations, preprint deposition into *BioRxiv*, and publication) will be made broadly available via Tier 4 sharing. There is no specific requirement that all Tier 3 data be advanced to Tier 4. Progression of deposited data, technology, and resources from Tier 3 to Tier 4 should be done as early as possible, consistent with the timelines for scientific milestones and forthcoming SCGE Consortium policies; but no later than the time those data are included in posted preprints or publications or are made broadly available through other public databases or repositories.

Resources such as plasmids, animal reporters (initially validated, bred, and provided to the greater research community via the Small and Large Animal Testing Centers), and original software that were developed in the course of generating Tier 4 data should be made freely available to the scientific community via distribution venues including post-SCGE Consortium activities. These include Addgene (e.g., plasmids), NIH-supported national repositories (e.g., Mutant Mouse Resource and Research Centers; National Swine Resource and Research Center; and National Primate Research Centers for distribution of reporter animals), Github (computer code), or similar mechanisms.

Purposes of Tier 4 sharing. The SCGE aims to advance SCGE technologies and resources for the benefit of the research community and the general public. Tier 4 access enables such sharing.

The SCGE Toolkit URL is https://scge.mcw.edu/toolkit/.

III. Project Management

This section includes policies and procedures to meet program milestones and coordinate collaboration.

A. Program milestones

The SCGE DCC monitors major program milestones, especially as they relate to the completion of key elements to be included in the SCGE Toolkit. Milestones vary by SCGE Initiative but include the development and testing of reporter animal models, *in vitro* and *in vivo* validation of delivery and gene editing techniques, proof-of-concept that cell/tissue platforms can identify biological consequences of genome editing, the development of new or optimized editors, and the sharing of verified reagents. Metrics and milestones were established by the funding agency. These metrics are not modifiable except through negotiation with the funding agency.

B. Collaboration Opportunity Fund

This subsection contains guidelines and principles for the selection and use of the Collaboration Opportunity Fund (COF) by the SCGE Program.

Guidelines: The COF is intended to promote the exchange, cross-testing, and evaluation of the improved technologies within the SCGE Consortium. The COF will support new and pilot research projects led by SCGE-supported investigators. Investigators that have an interest in establishing cutting-edge scientific collaborations within the Consortium are invited to submit applications. While the scope of the collaborations are not limited to the scope of the parent awards, the contributions of each COF collaborator should be related to the focus on the COF collaborator's parent award. Collaborations across initiatives are highly encouraged. It is expected that several awards will be made under this funding opportunity to support these collaborative projects.

Principles:

- A single COF of approximately $3,000,000 per year in fiscal years 2020-2022 will be established. Subawards will be issued from the Medical College of Wisconsin (MCW) to each of the awardees. Each collaborating partner will be issued a separate subaward from MCW unless the collaborating partners are at the same institution.
- The distribution of COF awards will be based on scientific merit, budget justifications, and availability of funds. It is anticipated that between 8-10 COF awards will be made each year with total costs anticipated to be between $100,000-$500,000, with the maximum combined budget not to exceed $500,000 total costs. Application budgets need to reflect the actual needs of the proposed projects.
- Awards will be for no more than 1 year.
- Applicants must discuss their COF plans with their respective Program Officers to confirm that there is no overlap with the parent award.
- The following will be considered non-responsive, primarily due to existing funding through primary award:
    - Animal Testing Centers proposing to test delivery vehicles included as part of the primary award.

    - Biological systems proposing to extend testing of editors and delivery agents included in primary award.
- Collaborative applications must not propose what is currently funded in the parent projects. Examples of the types of collaborations that will be considered responsive to the COF request for applications are:
    - Delivery Systems could request new collaborations with Biological Systems and Genome Editors or an additional Large Animal Testing Center.
    - Genome Editors could initiate new collaborations with Delivery Systems, Biological Systems, or Animal Testing Centers to test new editors in new delivery vehicles in either animals or biological platforms.
    - Small Animal Testing Centers could create additional reporter animals in collaboration with novel editors (Genome Editing).
    - Large Animal Testing Centers could collaborate with Genome Editors to accommodate novel genome editing and engineering systems.
- The applications for collaboration support will be reviewed by an appropriate review group convened by the SCGE DCC. Applications deemed to have scientific and technical merit will be recommended to the NIH SCGE Working Group for final approval.
- Multiple applications per applicant are allowed; however, each application must be scientifically distinct. Collaborations must be among currently funded SCGE awardees.

IV. Data Validation

A. Validation

This Validation component of the Manual of Operations provides preliminary protocols and operating guidelines that will define an initial framework for common approaches to validation protocol development and data collection and serve as a basis for further refinement by SCGE investigators.

B. Data Standards

B.1. Background

The success of the SCGE depends on the collection and subsequent sharing of well-described genome editing data. In order for the SCGE data to be comparable and maximally useful, information about biodistribution and editing efficiency must be captured in a uniform way. To assist in depositing data to the SCGE Toolkit in a uniform manner while capturing established data standards, a metadata form has been developed and distributed to projects prior to data submission. Well-established standards that have already been adopted by the genome editing community will be adopted by the SCGE and will be described in the first part of this section; those described are well-established standards for other relevant data types generated by the SCGE Consortium. The second part of the section describes the standard processes and data that are needed in order to track project progress through the SCGE.

B.2. Data Standards

Ontologies and standardized vocabularies will be used by the SCGE Toolkit when available. These include ontologies such as Gene Ontology, Cell Ontology, and UBERON. Uniform identifiers for model organisms, genes, genomes, public repository, resource, RRID, and others will be applied as appropriate. Unique SCGE IDs will be assigned to objects included in data submissions for both objects with uniform identifiers and data objects not currently under discussion for standard format identifiers.

V. Publications

SCGE Consortium approved policy on 10/24/2020.

One parameter of SCGE success will be the number and quality of its publications and presentations. The purpose of this document is to define the role of the SCGE Outreach Subcommittee and establish a framework for SCGE manuscripts that facilitates the submission of Concept Sheets for consortium and collaborative manuscripts. The SCGE Outreach Subcommittee will oversee the activities set out herein on behalf of the SCGE Steering Committee, and report to it. Changes to the policy described herein, which are expected from time to time, must be approved by the SCGE Steering Committee. The publication policy applies to publications for which the work supporting that publication is the product of NIH SCGE funding.

A. Scope of Outreach Subcommittee Oversight

A. To review and make recommendations on Concept Sheets for SCGE Consortium and collaborative manuscripts (See Section A.2. for definitions).
B. To maintain confidentiality prior to IP filings and/or publication. Information related to manuscript preparation and submission will not be shared outside of the SCGE Consortium. It is the primary responsibility of SCGE Consortium Investigators to take appropriate steps to protect any IP rights to their work and to follow any relevant rules of their institution and of the NIH.
C. To advise the SCGE DCC in management and population of the database of concepts, presentations, abstracts, and publications submitted, finished and in progress.
D. To provide timely input to the SCGE DCC of all SCGE Consortium presentations, abstracts, preprints (if applicable), and publications, including consortium, collaborative, and individual project publications. The SCGE DCC is responsible for tracking of activities and materials, including manuscript submissions of consortium and collaborative manuscripts, acceptance of all NIH SCGE-funded publications, and SCGE presentations.
E. To ensure accurate, uniform, timely, and high-quality reporting of SCGE activities and results, including publications, presentations, and abstracts of work supported by NIH SCGE funding.

B. SCGE Consortium Manuscript Types

A. Consortium – represent major, cross-project/center publications (e.g., marker paper, SCGE data trends analysis).
B. Collaborative – represent cross-project/center publications involving a small number of SCGE projects/centers (e.g., experimental protocol development, new methods, research outcomes, review/commentary articles). Policies below describing manuscript proposals and their pre-submission review by the consortium (e.g., see section A.3.1 below) ***do not*** apply to this category.
C. Individual project/center – represent publications of new methods, protocols, research outcomes, or reviews/commentaries driven by a single project/center. Policies below describing manuscript proposals and their pre-submission review by the consortium (e.g., see section A.3.1. below) ***do not*** apply to this category; publications or research

results from individual projects/centers will be at the discretion of the PIs, as is generally the case for NIH-funded research.

C. SCGE Manuscript Guidelines (Consortium, Collaborative, and Individual project/center)

A. It is encouraged although not mandated that manuscripts be shared with the public via an appropriate public preprint server (e.g., *bioRxiv*, *arXiv*, *ChemRxiv*) prior to or concurrent with the time of submission to a journal. Authors are requested to notify the DCC of any SCGE *bioRxiv* postings so that such manuscripts can be included in the SCGE *bioRxiv* channel.
B. All SCGE manuscripts must acknowledge the SCGE Consortium. The Acknowledgements should include a statement such as "This work was supported by the National Institutes of Health (NIH) Common Fund Program, Somatic Cell Genome Editing, through an award administered by the [Institute, Center or Office name] [(Institute, Center or Office abbreviation)] [(grant number)]; PIs: [PI names])." Manuscripts acknowledging SCGE funding should be a direct outcome of the supported work.
C. If there is an NIH co-author, the NIH co-author must seek appropriate NIH approval.
D. It is expected that the DCC will be informed of all SCGE manuscript acceptances and provide the expected publication date.

C.1. SCGE Consortium Manuscript Guidelines (e.g., Marker Paper)

The SCGE Consortium, led by the Steering Committee, will develop a manuscript (or multiple manuscripts) that will describe, define, and introduce the SCGE Consortium, or components of the Consortium, to the medical and scientific community.

1. Authors (First, Middle and Senior) will be determined by common agreement based upon the type, scope, and site of project (see concept sheet below). The first author(s) will take primary responsibility for the manuscript. Given the nature of the SCGE Consortium's collaborative work, shared first or last authors should be considered as an option.
2. The SCGE Consortium will be acknowledged at the end of the author list, as "Members of SCGE".
3. Generally, it is expected that authors would make contributions to any or all of the following, including but not limited to the conception, design, acquisition, and analysis of data, drafting of the manuscript, and editing and revision of the manuscript.
4. The Outreach Subcommittee will take a role in resolving all authorship disagreements for SCGE Consortium manuscripts on behalf of the SCGE Steering Committee and report to the Steering Committee any resolution or recommendations for resolution.

C.1.1. Consortium Manuscript Proposal-Submission of Concept Sheet

A. To initiate the process that will lead to a SCGE Consortium publication, the proposed lead (first) author submits a completed Manuscript Concept Sheet (see section C.1.1.C)

to the DCC, which timestamps the Concept Sheet and sends it to the Outreach Subcommittee for review. The Outreach Subcommittee makes a recommendation to the SCGE Steering Committee whether to accept the Concept. A voting member of the Steering Committee must endorse the Concept. If more than one person submits the same or similar topic, the Outreach Subcommittee will help decide who will assume the project lead. Other groups or investigators can contribute to the Concept Sheet, but the original submitter of the sheet will take the lead. Please note that the Concept Sheet has an **expiration date** of **6 months** but can be extended for an additional 6 months if needed upon submission of an updated Concept Sheet

B. It is expected that the approval process will not take more than four weeks.

C. Manuscript Concept Sheet (Google doc available here https://docs.google.com/document/d/1nJZEbKk1sy15Bgxh_Gh-eGZj2eiHvIaVYeEh3YxeGmk/edit?usp=sharing)

Concept submission date	
Manuscript title (tentative)	
First author (tentative)	
Senior Author (tentative)	
SCGE Project Sites	
Overall outline	
Tentative Journal	
Target date for journal submission	

C.2. SCGE Collaborative Project Manuscript Guidelines

Cross-project/center manuscript development does not require submission, review, and approval by the SCGE Steering Committee of a Manuscript Concept Sheet, although it is encouraged that a Manuscript Concept Sheet is made available to members of the SCGE Consortium to encourage collaboration.

A. Authors (First, Middle and Senior) and order will be determined by PI/MPIs involved in the SCGE project(s). Generally, the first author will take primary responsibility for the manuscript. Given the nature of the SCGE Consortium's collaborative work, shared first or last authors should be considered as an option.
B. Generally, it is expected that authors would make contributions to any or all of the following, including but not limited to the conception, design, acquisition, and analysis of data, drafting of the manuscript, and editing and revision of the manuscript.

D. Abstracts and Presentations

A. Abstract submissions for consortium-wide activities require submission to the Outreach Subcommittee for review and recommendation to the SCGE Steering Committee. Abstract submissions for Collaborative projects are encouraged to submit the abstract to the Outreach Subcommittee for review and reporting to the SCGE Steering Committee prior to submission. Abstracts prepared by Individual projects/centers will not require review by the Outreach Subcommittee.
B. All authors on abstracts and presentations must be made aware and confirm their authorship prior to submission or presentation.
C. Abstracts and presentations should mention SCGE NIH SCGE Common Fund support as well as the appropriate SCGE grant number(s).
D. To assist the SCGE DCC in tracking SCGE Consortium member presentations, information (presenter, project PI(s), title, conference, location, date) for all invited and oral/poster presentations submitted to conferences should be submitted to the SCGE Outreach Subcommittee. The SCGE Outreach Subcommittee will share conference participation and abstract citations with the SCGE DCC. Please submit to scge@mcw.edu
E. If there is an NIH co-author, the NIH co-author must seek the appropriate NIH approval.

VI. Outreach

SCGE Consortium approved policy on 1/26/2021.

Overview: The SCGE Consortium Outreach Policy is the foundation in which the SCGE will build all outreach initiatives to create and maintain a unified public-facing web and social media presence to inform interested members of the public and scientific community about the SCGE and gene editing research. Outreach initiatives consists of original material developed by the SCGE Consortium to explain (a) concepts in somatic cell genome editing, including its promise for treating rare and common diseases, (b) research conducted by SCGE Investigators, (c) key challenges in the field, and (d) the objectives of the SCGE Consortium. Outreach initiatives will also highlight updates on gene editing research performed by SCGE PIs that is outside of their SCGE Consortium research but is similar work. The SCGE Outreach Subcommittee will not endorse explanatory information on somatic cell genome editing generated outside of the SCGE Consortium but retains the right to follow and repost appropriate pages commenting when appropriate. Additionally, the Outreach Subcommittee will not take stands on scientific or ethical controversies by advocating for a specific policy but may comment for informational and educational purposes on advances within the gene editing field, including highlighting commentaries by SCGE Principal Investigators or affiliated NIH leadership with appropriate disclaimers. SCGE Consortium outreach efforts will not include the moderation of any online or offline debates on gene editing. The main platforms through which the SCGE Outreach Subcommittee will disseminate information is a public-facing **website** and **Twitter** account.

A. Website and Social Media

A.1. Outreach Content on Website

The SCGE Consortium will have a public-facing website, which will be created and maintained by the SCGE DCC, with directional input from the SCGE Steering Committee and the SCGE Outreach Subcommittee. Content that may be included, but is not limited to, are success stories, descriptions of the project sites, an annual summary of SCGE progress, publications, a portal to the SCGE Toolkit, and additional information for researchers.

All members of the SCGE Consortium are invited to submit content suggestions for the website. Outreach-focused content for the website will be screened by members of the SCGE Outreach Subcommittee prior to being posted or linked to.

The SCGE website will not contain commentaries on gene editing, unless authored by consortium members with appropriate disclaimers. This website may link to the lab websites of SCGE-funded investigators and news articles highlighting SCGE-funded work.

A.2. Outreach Content on Twitter

The SCGE DCC will cultivate a social media presence that will begin with a Twitter account and may expand to other social media platforms. The Twitter biography must at all times state (a) the grant's source of funding, (b) the account is run by the SCGE Outreach Subcommittee, and (c) retweets are not endorsements. The biography can be changed at any time provided the content in (a), (b), and (c) remains the same.

The Twitter profile picture will be a version of the most current SCGE logo and cannot be a picture of a specific individual or group of individuals. In accordance with NIH policy, the handle for the account is @SomaticEditing, and does not contain the letters “NIH.” All photos used to display as the cover or profile picture must be affiliated with the SCGE Consortium, either owned by the SCGE or contain the SCGE logo. Photos can be changed at any time as long as they follow the listed guidelines.

This Twitter account will be accessible by one DCC staff member. The Outreach Subcommittee Slack channel will be used to post suggested tweets for approval. Tweets are not required to be approved but can be posted for input and suggestions before posting publicly. The DCC staff member will also provide a monthly review of analytics to the Outreach Subcommittee. The tone of voice used to post from this account will be an institutional tone and special care is to be taken to ensure that the account does not read as a personal tone. Active voice should be avoided, if possible, along with the utilization of personal pronouns to refer to the SCGE.

A.3. Posting Content on Twitter

This Twitter account will feature similar content as the website and will link out to the website when appropriate. Outreach information on somatic cell gene editing generated by the members of the Outreach Subcommittee should be linked out by using this account. Achievements made by SCGE PIs, and SCGE research updates will be highlighted by the account in addition to relevant gene editing-related work outside of the SCGE that may be interesting and educational to members of the public and scientific community. The account will also highlight SCGE PI participation in providing their input on research and ethics surrounding gene editing topics at conferences, interviews, and the like. While SCGE research is disease-agnostic, the account retains the right to post about gene editing and translational work being done working towards the goal of eventual therapeutic and clinical use. The account may retweet with or without comment any tweets directly mentioning or referencing the SCGE and SCGE-funded research posted by NIH institutes, NIH employees affiliated with the SCGE, SCGE-funded investigators, SCGE-funded trainees, and SCGE-affiliated institutions. The account may retweet with or without comment any tweets highlighting relevant gene editing research not directly related to the SCGE, but related to SCGE-like research, including research done by SCGE PIs outside of the SCGE, but related work. The account may not retweet any tweets not directly mentioning or referencing the SCGE, and tweets not related to genome editing. The same guidelines apply for liking content on Twitter.

A.4. Following on Twitter

This Twitter account will follow accounts relevant to the SCGE, including, but not limited to, SCGE-funded investigators, other somatic cell genome editing researchers relevant to NIH, NSF, and DoE initiatives, institutes or companies related to gene editing, SCGE-funded trainees, journals, journal editors, and advocacy organizations.

VII. Ethical Legal and Social Implications

The DCC team includes members with expertise in ethical, legal, and social implications (ELSI). These members serve as a resource within the Consortium for potential issues related to somatic cell genome editing. These members will lead discussions as emerging challenges arise, especially related to somatic cell genome editing therapies. As needed, the DCC ELSI experts will provide workshops or tutorials for SCGE Consortium members as needed.