SCGE Phase 2 Consortium Data Sharing Policy (March 29, 2024)

Preamble

In Phase I of the Somatic Cell Genome Editing (SCGE) Consortium, a toolkit was developed to facilitate data sharing within the SCGE members, as well as the research community in general. In Phase II, an SCGE platform will serve to maintain Phase I data and to expand to the data, communications, guidelines, templates, and master protocols resulting from Phase II of the SCGE. Principal Investigators (PIs) are expected to deposit data and regulatory resources from their projects using the established tier paradigm 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 regulatory documents are redacted according to their team's internal requirements and that no copyright issues exist with journals or publishers. The Translational Coordination and Dissemination Center (TCDC) is free to use submitted documents, data, figures and/or images within the Platform within the appropriate Tiers (see below). For pre-publications, PIs should acknowledge the SCGE Platform (https://scge.mcw.edu/platform/) as a data resource.

Purpose

The SCGE Consortium aims to promote the sharing of data, technologies and regulatory 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, communications, guidelines, templates, regulatory agency interactions, and master protocols 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 FDA regulatory communications and regulatory documentation/resources into the SCGE Platform, which will be established, secured, and maintained by the SCGE TCDC. Protected or proprietary information can be redacted by the PI as needed. The PI will have the flexibility to submit both unredacted and redacted versions for release at selected tiers (see below). It is anticipated that SCGE investigators will also deposit resources, data, and information into public databases and repositories as required by the individual data-sharing plans or as agreed upon by the SCGE Consortium. Guidelines and requirements for deposition into the SCGE Platform 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 TCDC will provide the means for assigning data and resources to particular Tiers, and release/promote information 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 0** concerns preprocessing and quality control of regulatory documents and resources, data, technology and other materials between the submitter from an individual SCGE-funded team and the TCDC.
- **Tier 1** concerns regulatory documents and resources, data, technology and other materials sharing between members of individual SCGE-funded teams, as well as NIH program officers and the technical and data teams at the TCDC.

- **Tier 2** concerns sharing between a SCGE-funded team and other SCGE components beyond the TCDC.
- **Tier 3** concerns internal release across the entire SCGE Phase II consortium.
- **Tier 4** concerns external release to the broader scientific community and the public.

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 Disclosure Agreements (CDAs) and Material Transfer Agreements (MTAs) with others in the consortium 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 TCDC when executed CDAs have been established with other SCGE components. Moreover, if IP protection is needed before releasing data, the investigators have the freedom to redact protected information as needed at any tier. 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.

Types of Data to be Submitted

Required:

- Data and documents associated with milestones. Sequence and patient-specific data associated with milestones of specific programs will be addressed on a program-by-program basis.
- Data from publications supported and enabled by the SCGE Program.
- Oral presentations or posters presented at SCGE meetings.
- Interactions with regulatory agencies (e.g., FDA; includes meeting requests, communications to and from FDA, meeting packages)

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.
- Information pertaining to procurement/manufacture of gene editing reagents

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
Interactions with regulatory agencies (e.g., FDA)	Yes	1

Data, communications, guidelines, templates, and master protocol Tiers

Tier 0. When resources and data are first deposited into the SCGE Platform, they will be designated Tier 0, and access will be limited to the TCDC and those SCGE personnel who are members of the depositor's individual SCGE-funded team.

Purposes of Tier 0 sharing. Tier 0 access will (*i*) allow the TCDC to process and stage materials submitted by members of individual SCGE-funded teams; and (*ii*) enable materials to be reviewed and verified by the individual SCGE-funded submitter for further sharing in the appropriate tier.

Tier 1. After materials are verified in Tier 0, they will be designated Tier 1, and access will be limited to the TCDC, 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. Escalation to 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 TCDC; 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 TCDC. 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 Platform tools and interfaces provided by the TCDC. There is no specific requirement that all Tier 1 data be advanced to Tier 2+. The shared materials may be redacted as needed prior to progression 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.

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. Additional sharing can also be implemented beyond these specific examples, at the discretion of the data's owners. After initially advancing regulatory documents and resources, data, technology and other materials 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, communications, guidelines, templates, and master protocols that have been advanced from Tier 2 to Tier 3 are available to all participants in the SCGE Consortium with Platform access, for the benefit of the consortium's members and the program's research mission. The shared materials may be redacted as needed prior to progression to Tier 3. Progression from Tier 2 to Tier 3 will use SCGE Platform tools and interfaces provided by the TCDC. There is no specific requirement that all Tier 2 materials be advanced to Tier 3. Progression of deposited materials 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, communications, guidelines, templates, and master protocols 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 materials 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 materials 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.

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 PlatformURL is https://scge.mcw.edu/platform/.