SCGE Consortium Data, Technology and Resource Sharing Policy (February 13, 2020)

The Somatic Cell Genome Editing (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 Dissemination and Coordinating Center (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, etc, see Tier 4 below]). Guidelines and requirements for deposition into the SCGE Toolkit will be determined by the SCGE Consortium. For example, the consortium will define what data elements and metadata to include, when material is considered "shareable," and how soon after reaching a shareable state it should be promoted to a higher tier. The specific schedule for data/resource deposition will be established by the NIH Program Officer (PO) for each award in consultation with the Principal Investigator(s) (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 PIs.

- **Tier 1** concerns data, technology and resource sharing between members of individual SCGE-funded teams, as well as the technical and data teams at 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.

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 ATCs, 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.

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 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 all 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, according to the individual project's scientific timeline and the needs of other SCGE components (e.g., ATCs).

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 ATCs. It is essential for SCGE investigators to provide the ATCs with all data, technology, and information that may be necessary for the ATCs to conduct the required tests in a manner that ensures regulatory (e.g., IACUC) compliance, 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 ATC 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 (COF). 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 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, 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 such as Addgene (plasmids), NIH-supported national repositories (e.g., Mutant Mouse Resource and Research Centers, MMRRC; National Swine Resource and Research Center, NSRRC; and National Primate Research Centers, NPRCs for distribution of the reporter animals), Github (computer code), or similar mechanisms.

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

The link to the SCGE Toolkit will be provided here when the Toolkit becomes available.