

Stimulating Peripheral Activity to Relieve Conditions (SPARC) Material Sharing Policy

To catalyze scientific progress and maximize the value of the significant public investment in the SPARC Program, material generated from the SPARC consortium will be made freely available to the wider research community. This SPARC Material Sharing Policy outlines the requirements for sharing data, metadata, and resources that are developed and collected from or created by SPARC-funded initiatives. This Policy is consistent with the goals of the 22 February 2013 White House Office of Science and Technology Policy (OSTP) memorandum entitled “Increasing Access to the Results of Federally Funded Scientific Research”¹ and the National Institutes of Health’s (NIH) policy to make public access to digital scientific data the standard for all NIH-funded research².

“SPARC-generated material” is the term we use to describe any SPARC-funded investigator-derived material, such as data, metadata, digital resources, computational models, animal models, tools, techniques, procedures, methods, instruments, equipment, protocols, and documentation.

SPARC Data and Resource Center (DRC)

The SPARC DRC will assemble material derived from SPARC-funded investigators into a publicly accessible centralized location, and provide access for both human-friendly visualization tools and computational processing. The DRC will also run a clearinghouse for non-digital material (e.g. animal models, instrumentation, etc.), but will not serve as a biorepository. The DRC will follow best practices in managing heterogeneous data workflows and will implement mechanisms to share the material generated by the SPARC consortium. SPARC-funded investigators will closely coordinate with the DRC to integrate data into larger-scale maps and comparative visualizations, and to develop techniques that will allow the research community to interactively access these maps. Other associated activities may include, but are not limited to: development of informatics tools, development of ontology and provenance tools, development of data storage and communication protocols, curation of heterogeneous data, development or adaptation of common data elements, maintenance of documentation, tools to facilitate data upload, access control, and release, and protection of patient rights and data.

Until this centralized resource is established, and practices for its use have been articulated by the NIH SPARC team, interim plans to share data will include presentations at SPARC awardee meetings, deposition in public databases as appropriate, and anticipatory preparations for deposit into the DRC, such as creation of metadata and de-identification of patient data. We will establish standard practices to define when material is considered “shareable” and how soon after reaching a “shareable” state it must be submitted to the DRC. Once defined, these practices will first be published to the SPARC Consortium and then to the public after additional refinement, establishing a transparent baseline for

¹ White House Office of Science and Technology Policy memorandum entitled “Increasing Access to the Results of Federally Funded Scientific Research”

https://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf

² National Institutes of Health Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research <http://grants.nih.gov/grants/NIH-Public-Access-Plan.pdf>

³ Throughout this policy, DRC refers to the SPARC centralized online resource to be created as part of SPARC Component 4. The final name may differ from what appears here.

the expectations with regards to various types of material (e.g. electrophysiological recordings, anatomical maps).

Sharing within the SPARC Consortium

The SPARC Program aims to maximize the benefits of sharing, while protecting the intellectual property of the material producers. Prepublication sharing of data within the consortium will allow collaboration across initiatives and further the progress of the SPARC Program towards its goals and objectives. Therefore, the SPARC Program requires that data, metadata, and resources generated from SPARC funding be made available to other SPARC Consortium members immediately upon being considered “shareable”. When SPARC-generated material under embargo is shared within the SPARC Consortium, it will be considered confidential with the understanding that the information will not be used or disclosed by SPARC Consortium members unless explicitly agreed upon by the originator of the material under mutually acceptable terms. That is, Consortium members may not publish using material generated by other consortium members without a collaboration or other agreement, or until the material in question has been made available to the public (see “Sharing with the Public”, below). As such, SPARC investigators accessing embargoed material only available to members of the SPARC Consortium must sign a non-disclosure form agreeing to these terms.

Sharing with the Public

The SPARC Program requires timely submission to the DRC of SPARC-generated material. Within 30 days upon report of completion of a “shareable” data milestone, information about the data set (metadata) will be made available to the public. The data itself will then be made publicly available after a one-year moratorium from that date, or upon the date of publication in digital form, including advance online publication, whichever comes first (see Table 1 for a simple example). The one-year moratorium allows SPARC investigators sufficient time to publish first on generated material. Investigators may require public users to request access to SPARC-derived material if there are any terms, limitations, and or restrictions approved by the SPARC Program Manager. All public users must abide by the terms and conditions set forth by the DRC, including acknowledgement of SPARC Consortium-derived material.

Material Submission

The SPARC Program requires investigators to submit all relevant SPARC-derived material to the DRC. The initial terms of (e.g. submission of raw and/or processed data) and timelines for material submission will be established by the SPARC Program Manager and SPARC investigators at the time of the award, and will be revised as necessary, in coordination with the DRC. The terms will be based on the nature of the material and project milestones. Investigators will work with DRC investigators and analysts to ensure data are of sufficient quality, are described with rich metadata, and to ensure that data and metadata are searchable (i.e. data and metadata are registered or indexed). Once the appropriate material and embargo access restrictions meet the standards for submission, the DRC will manage access to the data, as described above under “Sharing within the SPARC Consortium” and “Sharing with the Public”.

Sharing Model Organisms

Unique model organism resources generated from NIH funding are expected to be shared and accessible so that other researchers can benefit from these resources³. Model organisms include, but are not restricted to: mammalian models, such as the mouse and rat; and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains. Upon development, these resources should be made readily available to SPARC Consortium members. Strains of all transgenic animals generated from SPARC funding will be deposited into an NIH supported repository⁴ upon the date of publication in digital form, including advance online publication, whichever comes first. NIH supported repositories cryopreserve embryos or sperm and distribute the frozen embryos or animals to biomedical researchers.

Publication and Authorship

The SPARC program will organize and maintain a publication and authorship committee, composed of members from the SPARC Consortium and an NIH SPARC working group. The SPARC Publication and Authorship Committee will be responsible for ensuring that SPARC Consortium members are being properly attributed for their work in all publications using material that is shared within the Consortium (see section above, "Sharing Within the SPARC Consortium"). In addition, the Committee will ensure appropriate acknowledgement of SPARC data and resources. As such, SPARC investigators are required to submit final drafts of peer-reviewed manuscripts for review and approval by the SPARC Publication and Authorship Committee prior to submission to a journal for publication. The Committee will evaluate manuscripts from the point-of-view of assigning proper attribution, rather than evaluation of scientific merit. The SPARC Steering Committee, composed of SPARC Project Directors/Principal Investigators, will govern adherence to this publication review requirement and determine repercussions for non-compliance.

Additional Considerations

All investigators must comply with relevant statutes, and are encouraged to factor in the following two considerations:

- *Intellectual Property Protection:* There may be times when the sharing of intellectual property and other forms of proprietary information might affect certain data and may need to be restricted or delayed in order to foster innovation and investment. The rights of awardees to elect and retain title to subject inventions developed with federal funding pursuant to the Bayh-Dole Act⁵ are specified in the Funding Opportunity Announcement. For more information, see the Office of Extramural Research, Division of Extramural Inventions & Technology Resources (DEITR), Intellectual Property Policy page: <http://grants.nih.gov/grants/intell-property.htm>. Awardees are responsible for filing for appropriate protection of intellectual property as

³ NIH Policy on Sharing of Model Organisms for Biomedical Research <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>

⁴ NIH Model Organisms for Biomedical Research <http://modelorganisms.nih.gov/>

⁵ Bayh-Dole Act of 1980 (Public Law 96-517; 35 U.S.C. 200-212)

required by the Bayh-Dole Act to avoid unnecessary delays in data release to the DRC, the SPARC consortium, and to the public.

- Human Subjects Protection:* NIH-funded researchers are subject to applicable rules governing the privacy of research participants, including in some cases the HIPAA Privacy Rule⁶ and in all cases Department of Health and Human Services regulations governing the protection of human subjects⁷. The rights and privacy of individuals who participate in NIH-sponsored research must be protected at all times, and participants must be informed of the SPARC Material Sharing Policy and their rights when consenting to participate. Thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects. Investigators must exercise great care to ensure that resources involving human cells or tissues do not identify original donors or subjects, directly or through identifiers such as codes linked to the donors or subjects.

Table 1. Example Data Sharing Timeline

Event	Sharing clock
Shareable data generation milestone reported complete in quarterly report	Clock starts – day 0
Existence and nature of data set (“metadata”) posted to DRC Public Area	Day 30
Data shared to SPARC Consortium (potentially via DRC Consortium Area)	Day 30
Data shared to public	Day 365 or online publication of a paper using the data, whichever comes first

⁶ <http://www.hhs.gov/hipaa/for-professionals/privacy/index.html>

⁷ <http://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html>