

APPENDIX A-2

New York State Spinal Cord Injury Research Board Contract Policy Statement and Conditions Rev. approved 10/08

A. Ethical Considerations

The Spinal Cord Injury Research Board (SCIRB) stipulates that each awarded grant contract satisfy the following requirements:

In accepting an award from the New York State Department of Health for support from the Spinal Cord Injury Research Trust Fund, the contracting organization shall ensure that each project investigator agrees to conform strictly to the codes of practice, regulations and laws governing ethical conduct of scientific research in his/her own laboratory/institution. He/she shall be solely responsible for any violation of these standards. If experimental procedures conducted pursuant to this project are performed in another state or country, either directly by the principal investigator (PI) and any co-investigators, or in collaboration with other persons, the PI and contracting organization agree to ensure that such research does not violate New York State laws and regulations applicable to such research if performed in New York State. Representatives of the contracting organization will inform SCIRB Program administrators of any and all instances of actual or potential lapses in scientific integrity by any project participant as soon as this information becomes known to the contracting entity. The contracting organization is fully responsible for investigation of these instances.

B. Human Subjects Research

Human subjects research is essential to the continued advancement of scientific knowledge concerning spinal cord injury and the health of such injured persons. In carrying out such research, the rights and welfare of all individual research participants are of critical importance. Furthermore, additional safeguards must protect especially vulnerable research subjects, including minors, mentally disabled adults who lack capacity to provide informed consent to research participation, and prisoners.

Accordingly, no research study shall be approved for funding recommendation by SCIRB unless it is demonstrated that all the following requirements are satisfied:

- The research study will comply with New York State Public Health Law (PHL) Article 24-A, Sections 2440 to 2446, unless the research is subject to, and in compliance with, policies and regulations promulgated by any agency of the federal government for the protection of human subjects.
- The research study will comply with 45 CFR Part 46 (unless exempt from the requirements of this Part) and, if applicable, 21 CFR Parts 50 and 56; 21 CFR 312; 21 CFR 361; 21 CFR 812.
- The research study will comply with all other applicable federal and New York State laws, regulations and guidelines.
- The research study has been approved by an Institutional Review Board (IRB).

- If applicable, the applicant organization's IRB has received and reviewed written approval from an authorized representative of each site where the study will take place.
- The IRB has determined that the investigator will immediately withdraw a subject from the research study if continued participation would be detrimental to the subject's well-being.
- The IRB will communicate to SCIRB program administrators (i) any unanticipated problems involving risks to subjects, (ii) any serious or continuing noncompliance with IRB policy or requirements; and (iii) any suspension or termination of IRB approval.

Vulnerable Populations

Under New York State law (Article 24-A of the Public Health Law), research with no prospect of direct benefit and posing more than minimal risk is prohibited for research participants who are minors, mentally disabled adults who lack capacity to provide informed consent to research participation, or prisoners. No research study in which any research participant is a minor, a mentally disabled adult who lacks capacity to provide informed consent to research participation or a prisoner shall be approved by SCIRB unless it is demonstrated to the Board, and the Board determines, that all the following requirements, in addition to the requirements set forth above, are satisfied:

- The IRB has determined that the research study constitutes either: research with a prospect of direct benefit to research participants; or research with no prospect of direct benefit to research participants that presents minimal risk.
- If the research involves one or more mentally disabled adults, each investigator must use IRB approved methodologies and procedures for initial capacity assessment, including: procedures for notice to a prospective subject that his/her capacity to consent to research is under consideration; notice to a prospective subject of a determination that he/she lacks the capacity to consent to research; and the opportunity for a prospective subject to contest such a determination of incapacity through a second opinion and a judicial proceeding prior to enrollment in the research.
- The IRB has determined that, prior to involving in a research study a minor, a mentally disabled adult who lacks the capacity to provide informed consent to research participation, or a prisoner, each investigator will obtain such individual's assent to research participation.¹

The Department of Health reserves the right to revise or expand requirements applicable to human subjects research as part of negotiation of any contract arising from this request for applications.

C. Animal Use

SCIRB requires that all individuals and institutions that conduct research using animals supported by the Spinal Cord Injury Research Trust Fund adhere to all federal, state and local laws pertaining to humane care and use of animals for research purposes. Research applications submitted to the Board for consideration are expected to be reviewed by an Institutional Animal Care and Use Committee (IACUC) whose guidelines are in compliance with the U.S. Public Health Service's *Policy on Humane Care and Use of Laboratory Animals*, and *Guide for the Care and Use of Laboratory Animals*, as well as any other federal, state and local laws or regulations (e.g., the federal Animal Welfare Act and its implementing regulations; and PHL Article 5, Title I, Sections 504 and 505-a).

¹ A minor's objection need not be honored if an independent physician determines that the research intervention or procedure holds out a prospect of direct benefit that is important to the health or well-being of the minor, and is available only within the context of the research.

D. Tissue

SCIRB will support research using human tissue and require that such research adhere to all federal, state and local laws, regulations and guidelines pertaining to use of such tissue, including, but not limited to, 42 USC Section 289g et seq.; Public Health Law Article 5, Title V, sections 570 to 581; Article 24-A, sections 2440 to 2446; Article 43, sections 4301 to 4309; Article 43-B, sections 4360 to 4366; and 10 NYCRR Part 52. Research proposing to use pluripotent stem cells requires appropriate and rigorous legal and ethical oversight.

E. Publication and Intellectual Property Rights

1. It is SCIRB's intent that the results of research it supports through its sponsorship be disseminated and made easily available to the research community and the lay public. Manuscript submission for publication of research funded by the Spinal Cord Injury Research Trust Fund shall not be delayed by investigators or their research institutions for more than 60 days after the manuscript is completed. Research results are to be submitted promptly for publication in internationally recognized scientific journals. Publication should not be delayed for commercial or other reasons beyond the editorial period needed to ensure scientific accuracy and presentation.
 - a. All publications reporting research supported by SCIRB funds published in peer reviewed journals must be deposited in the National Institutes of Health National Library of Medicine's PubMed Central (PMC). SCIRB encourages investigators to sign copyright agreements that specifically allow the published manuscript to be deposited for public posting on PMC. As investigators are encouraged to publish SCIRB-funded research findings as "open access" publications, contract funds may be used to cover costs required for such "open access" publication.
 - b. An electronic copy of each such publication must be filed with the progress report pursuant to the contract.
 - c. Within 60 days of publication, the investigator must submit to SCIRB Program administrators a 500 word abstract of the publication suitable for the general public, highlighting the research findings. A full literature citation and a brief biographical sketch of the SCIRB-funded Principal Investigator must also be submitted. This information will be made available to the public through the SCIRB website.
 - d. Support by the Spinal Cord Injury Research Trust Fund shall be acknowledged in all publications, presentations and products of research in a form consistent with the publication's guidelines, e.g.,: "supported by the Spinal Cord Injury Research Trust Fund through New York State Department of Health Contract # <<>>. Opinions expressed here are solely those of the author and do not necessarily reflect those of the Spinal Cord Injury Research Board, the New York State Department of Health, or the State of New York."
2. It is SCIRB's intent that the resources, materials and methods created through its sponsorship be disseminated and made easily available to the research community. All such materials described in invention disclosures, publications, or other public forums shall be made available to requesting investigators. The contractor may collect reasonable costs for provision of such resources and may require execution of appropriate material transfer agreements, licenses, or confidentiality agreements (see paragraph #4, below).
3. With regard to SCIRB funded research, where the grantee organization has not made reasonable efforts to protect the property interests or because the grantee has failed to share the research developments, the State shall retain march-in rights. The State shall have a perpetual royalty-free, non-exclusive and irrevocable right to reproduce, publish or otherwise use, and to authorize others to use, for research and governmental purposes only, any

published or otherwise reproducible material, device, invention, technique, material, or methodology developed under or in the course of performing this funded research, dealing with any aspect of the research activity, or of the results and accomplishments attained from the research.

4. The contractor must have written agreements with researchers requiring prompt disclosure of inventions made in the performance of SCIRB-funded research. Within 60 days of such disclosure the contractor shall notify SCIRB Program staff of the invention disclosure. The contractor shall notify SCIRB Program staff upon the filing of any patent application in the progress report pursuant to the contract. The contractor shall provide SCIRB Program staff with advance written notice of any assignment or transfer of intellectual property rights generated as a result of research supported by the Spinal Cord Injury Research Trust Fund. Any such assignment or transfer must acknowledge, and be subject to the rights retained by the State pursuant to the above paragraph #2.

Assignment and ownership allocation of intellectual and industrial property rights generated from research supported by the Fund is to be determined by the parties concerned (researchers, and their research organizations or institutions), consistent with organizational policies. Prior to execution of a negotiated contract, appropriate arrangements (existing or proposed) regarding intellectual and industrial property rights must be made by the contracting organization and communicated to SCIRB Program administrators. Such arrangements may include: provisions about dissemination of information such as disclosure and methods of publication, and provisions regarding ownership and exploitation of the results arising from the research supported by the Fund. However, to protect the State's interests and to streamline invention reporting procedures, contracts between the New York State Department of Health and the contracting institution will, except to the extent inconsistent with this paragraph, incorporate the provisions of 37 CFR 401.14 with the following modifications throughout: *Federal or Government* will refer to New York State, and *agency* will refer to the Department of Health.

5. Contractor agrees, pursuant to the provisions of the New York State Administrative Procedure Act relating to access to data, added by Chapter 647 of the Laws of 1999, and Chapter 229 of the Laws of 2000, to provide the Department with the study, any data supporting that study, and the identity of the principal person or persons who performed such study. If such study is used as the basis for the promulgation, amendment, or repeal of a rule, regulation, or guideline used in enforcement of a statute, rule, or regulation, the study, any data supporting that study, and the identity of the principal person or persons who performed the study shall be subject to disclosure in accordance with the law.

F. Reporting Requirements

Scientific/Technical and Financial Reports shall be submitted as provided in Appendix C.

G. Equipment

Requests for purchase of equipment may be granted if strongly justified as essential to the proposed project; a current price quote should be included in the application appendix. During the course of the contract term, prior approval will be required for all equipment that was not detailed in the application and its appendix.

Equipment may not be purchased within ninety (90) days of contract termination.

Upon satisfactory completion of the contract, as determined by the State Department of Health, all equipment purchased hereunder may be retained by the contractor.

H. Other Information

1. Documents submitted to the Department of Health on behalf of the SCIRB program will not be returned to the applicant.
2. Appendix B (Budget) may be reviewed and revised each year, depending on research progress and the availability of funds.
3. The New York State Department of Health may require reimbursement of all or a part of the award if ineligible expenses have been incurred or false accounting statements have been submitted.
4. Neither the Department of Health nor the State of New York will assume any responsibility for any damage or injuries caused or resulting from research conducted with the financial support of the Fund.
5. Recipient entities accept auditing of their expenditures by an appointed representative of the SCIRB research program at any time.
6. Assurances and Certifications. The New York State SCIRB has adopted the following federal regulatory mechanisms to ensure responsible administration of its awards and to preserve the integrity of the research enterprise it supports. By signing this Grant Contract, the authorized representative of the organization certifies that, in addition to all applicable state and local statutes and regulations, the applicant organization will comply with applicable federal regulations and statutes, including but not limited to:
 - a. *Vertebrate Animals:*
 - Animal Welfare Act as amended (7 USC 2131 et sec.), if applicable, and other federal statutes and regulations relating to animal care and use.
 - b. *Research Misconduct:*
 - 42 CFR Part 50, Subpart A, "Responsibilities for PHS awardees and applicant institutions for dealing with and reporting possible misconduct in science."
 - 42 CFR 94, "Public Health Service standards for the protection of research misconduct whistleblowers" (effective on the date set forth in the final rule).
 - Each covered institution must certify that it will comply with the above policies and the requirements of the Final Rule.
 - A copy of the institution's Annual Report on Possible Research Misconduct (Form 6349), routinely sent to all PHS awardees by the Office of Research Integrity, shall be forwarded to SCIRB program administrators.
 - c. *Conflict of Interest*
 - 42 CFR 50, Subpart F, "Responsibility of applicants for promoting objectivity in research for which PHS funding is sought."
7. The Department of Health reserves the right to revise or expand the requirements applicable to research conduct, as well as legal and administrative oversight.

8. Fees related to patient care costs are not reimbursable expenses. Tuition reimbursement is not an allowable expense for the CART, IDEA and Postdoctoral Fellowship awards.