

**APPENDIX A-2**  
Empire State Stem Cell Board  
Contract Policy Statements and Conditions  
Rev. approved 10/10

**A. Ethical Considerations**

The Empire State Stem Cell Board (ESSCB) 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 Empire State Stem Cell 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 shall ensure that such research complies with New York State laws and regulations that would be applicable to such research if performed in New York State. The contracting organization will inform NYSTEM 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, and by submitting the annual HHS report form 6349, or equivalent, with the progress report. 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 stem cell biology. 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 commence unless it has been approved by an Institutional Review Board (IRB) and a copy of the current approval has been submitted to NYSTEM. Further, the following requirements shall be satisfied:

- The research study will comply with New York State Public Health Law (PHL) Article 24-A 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; and 21 CFR 812.
- The research study will comply with all other applicable federal and New York State laws, regulations and guidelines.

- If applicable, the applicant organization's IRB has received, reviewed, and accepted 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 NYSTEM 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 of the research study.

### *Vulnerable Populations*

Under Article 24-A of the New York State PHL, research which has no prospect of providing direct benefit and posing more than minimal risk to research participants 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 ESSCB unless it is demonstrated to the Board, and the Board determines, that all of 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 adult, each investigator must use IRB approved methodologies and procedures for initial capacity assessment of those individuals, 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.<sup>1</sup>

The Department 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.

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<sup>1</sup> 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.

## **C. Animal Use**

ESSCB requires that all individuals and institutions that conduct research using animals supported by the Empire State Stem Cell Fund adhere to all federal, state and local laws pertaining to humane care and use of animals for research purposes. Accordingly, no research study shall commence unless it has been reviewed and approved 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).

## **D. Other Compliance Requirements**

### *1. Human Tissue*

ESSCB will support research using human tissue and require that such research adhere to all federal, state and local laws and regulations pertaining to use of such tissue, including, but not limited to, 42 USC Section 289g *et seq.*; NYS PHL Article 43, sections 4301 to 4309; Article 43-B, sections 4360 to 4366; and 10 NYCRR Part 52. Any facility collecting, processing, storing, or distributing human tissue, even if for research purposes only, must seek and obtain an appropriate New York State tissue bank license. Accordingly, no research study shall commence unless such license is current.

### *2. Analytical Testing of Human Specimens*

Any facility performing analytical testing of specimens from tissue donors or donated tissues where donor identified test results are produced must seek and obtain the appropriate New York State Clinical Laboratory Permit in compliance with PHL Article 5, Title V, Sections 570 to 581, or verify that the facility performing the testing holds the appropriate permit. Accordingly, no research study shall commence unless such permit is current.

### *3. Recombinant DNA*

Any facility in possession of recombinant DNA or performing recombinant DNA activities must comply with relevant federal guidelines ([http://oba.od.nih.gov/oba/rac/guidelines.02/NIH\\_Guidelines\\_Apr02.htm](http://oba.od.nih.gov/oba/rac/guidelines.02/NIH_Guidelines_Apr02.htm)) and state statute and regulation, New York State PHL 32-A and 10 NYCRR 61. Accordingly, no research study shall commence unless it has been reviewed and approved by the appropriate institutional oversight committee.

## **E. Human Stem Cell Research**

1. *Scope.* The following types of research (“Human Stem Cell Research” or “HSC Research”) are subject to the requirements of this section.

Research involving:

- a) human embryonic stem cells;
  - b) human totipotent or pluripotent cells;
  - c) human pluripotent stem cell lines;
  - d) human neural and gonadal progenitor stem cells; or
  - e) other human somatic tissues for stem cell research (excluding cells that remain restricted in tissue potential and are not known to possess totipotent or pluripotent potential).
2. *National Academy of Science (NAS) and International Society of Stem Cell Research (ISSCR) Guidelines.* HSC Research must comply with either NAS or ISSCR Guidelines to the extent applicable, and must also comply with any additional or conflicting requirements of this Contract.
  3. *Embryonic Stem Cell Research Oversight (ESCRO) Committees.*
    - a) HSC Research must be approved by an Embryonic Stem Cell Research Oversight (ESCRO) Committee that meets the standards set forth in the NAS or ISSCR Guidelines and in paragraph (d) below. However, research permissible without ESCRO Committee review under Category 1 of the ISSCR Guidelines or Section 1.3 (a) of the NAS Guidelines shall not require ESCRO review if notification is provided to the ESCRO Committee.<sup>2</sup> Accordingly, no research

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<sup>2</sup> Category 1 of the ISSCR Guidelines (Section 10.1) provides: “Experiments that are permissible after review under existing mandates and by existing local committees, and are determined to be exempt from full SCRO review. These will include experiments with pre-existing human embryonic stem cell lines that are confined to cell culture or involve routine and standard research practice, such as assays of teratoma formation in immune-deficient mice. We recommend that all institutions pursuing such research establish a mechanism capable of determining that a) these projects can be adequately reviewed by committees with jurisdiction over research on human tissues, animals, biosafety, radiation, etc. and b) that full review by a SCRO mechanism or body is not required. This mechanism should include a determination that the provenance of the human embryonic stem cell lines to be used has been scrutinized and deemed acceptable according to the principles outlined in this document, and that such research is in compliance with scientific, legal and ethical norms.”

Section 1.3(a) of the NAS Guidelines provides: “Purely in vitro hES cell research that uses previously derived hES cell lines is permissible provided that the ESCRO committee or equivalent body designated by the investigator’s institution (see Section 2.0) receives documentation of the provenance of the cell lines including (i) documentation of the use of an acceptable informed consent process that was approved by an Institutional Review Board (IRB) or foreign equivalent for their derivation (consistent with Section 3.6); and (ii) documentation of compliance with any additional required review by an Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), or other institutionally mandated review.”

study shall commence unless it is demonstrated that research protocols have been reviewed and approved by the ESCRO committee.

- b) The ESCRO Committee shall be responsible for the initial and ongoing review and oversight of the research at the institution where the research is being conducted.
- c) The ESCRO Committee shall ensure that research complies with either NAS or ISSCR Guidelines to the extent such Guidelines are applicable, and also complies with any additional or conflicting requirements of this Contract.
- d) The ESCRO Committee shall create and follow written policies that include the following standards:
  - i) Committee Membership: The membership of the ESCRO Committee responsible for oversight for the contracting institution should have sufficient diversity among its members, including consideration of race, gender and background, and should be sensitive to such issues as community attitudes, to promote respect for its advice and counsel. The ESCRO Committee should be composed of qualified persons of both sexes. The members present at a meeting in which research funded under this contract is approved by the ESCRO Committee must include at least one scientist with relevant expertise and one ethicist. The purpose of diverse membership on the ESCRO Committee is to ensure that different perspectives are given a voice; the ESCRO Committee should encourage different perspectives and voices in its discussion of protocols and in its minutes.
  - ii) Conflict of Interest Policies: The policies shall address conflicts of interest in a manner that is in alignment with other institutional conflict of interest policies, including, but not limited to, those governing the activities of the IRB. Such policies shall preclude a member from participating in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the ESCRO Committee.
  - iii) Recordkeeping: The policies shall address recordkeeping requirements for the activities of the ESCRO Committee and for research reviewed by the Committee that are in alignment with the policies developed by the institution's IRB in accordance with the requirements of 45 CFR Part 46 and guidance issued by the Office for Human Research Protections. In addition, the ESCRO Committee shall develop and adhere to policies for maintaining records relating to the provenance of all stem cell lines used in funded research, consent of gamete donors, applicable ethical research standards, and reports of adverse or unexpected outcomes that pose a threat to the health or safety of any individual or raise new ethical issues. Records relating to the activities and review of the ESCRO Committee and to the research conducted shall be retained for at least six years after completion of the research. All records shall be accessible for

inspection and copying by authorized representatives of the Department at reasonable times and in a reasonable manner.

4. *Consent to Donation of Biological Materials:* Contractors must ensure that the procurement of biological materials used in research funded pursuant to this contract complies with the informed consent provisions in either the NAS or ISSCR Guidelines, modified as follows:
- a) *Obtaining Informed Consent:* Obtaining a person's fully informed, voluntary consent to a donation<sup>3</sup> must be accomplished through a dynamic process - *i.e.*, a dialogue that encourages the potential donor to ask questions, and prompts the potential donor to confirm his or her understanding of the information being disclosed. Accordingly, the informed consent process must adhere to the introductory paragraph of ISSCR Guideline 11.3<sup>4</sup> and all of ISSCR 11.6.<sup>5</sup>
  - b) *Donation of Embryos in Excess of Clinical Need:* ESCRO Committees shall review available documentation to ensure that there was a clear separation between the prospective donor(s)'s decision to create human embryos for reproductive purposes and the prospective donor(s)'s decision to donate the embryos for research purposes. Providing a general authorization for research donation when providing consent for reproductive treatment does not violate this provision, so long as specific consent to the research donation is obtained at the time of donation for research purposes.
  - c) *Re-consent:* Consent to donation shall be obtained at the time of the proposed transfer of the materials to the research team. With respect to obtaining re-consent to donation, ESCRO Committees should apply the standards set forth in ISSCR Guideline 11.2,<sup>6</sup> or may choose to use the stricter standards set forth in NAS Guideline 3.2.<sup>7</sup>

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<sup>3</sup> References to "donors" or "donations" in this paragraph apply to donations of all biological materials – gametes, embryos and somatic cells – to stem cell research, except where otherwise noted.

<sup>4</sup> ISSCR 11.3 - Informed consent: Researchers should exercise care in communicating the concept of "informed consent" to ensure that such consent has actually been obtained. The informed consent process should take into account language barriers and the educational level of the subjects themselves....

<sup>5</sup> ISSCR 11.6 - Steps to enhance the procurement process: Attempts should be made to improve the informed consent process for human materials procurement. The informed consent document is but one aspect of this process. The purpose of the informed consent document is to record that all the ethically relevant information has been discussed. The informed consent document alone can never take the place of an interactive dialogue between research staff and providers of human materials. Researchers are thus encouraged to focus on enriching the informed consent process itself, in addition to ensuring that the informed consent document includes all of the ethically relevant information. The informed consent process can be enhanced in the following ways:

- i) Whenever possible, the person conducting the informed consent dialogue should have no vested interest in the research protocol. If members of the research team participate in the informed consent process, their role must be disclosed and care must be taken to ensure that information is provided in a transparent and accurate manner.
- ii) Empirical research has shown that informed consent is most effective as a dynamic, interactive, and evolving process as opposed to a static, one-time disclosure event. Thus, researchers should provide ample opportunities for providers of human materials to discuss their involvement in the research protocol.
- iii) Counseling services should be made available upon request to any providers of human materials prior to procurement.
- iv) Procurement procedures should be revised in light of a) ongoing studies of the long-term risks associated with oocyte retrieval; and b) research on informed consent for all types of human biological materials procurement.
- v) Researchers should consider on a regular basis, subject to annual review, the possible use of alternatives to hormonally induced oocytes procured solely for stem cell research, such as oocytes derived from pluripotent stem cells, in vitro maturation of oocytes from ovariectomy samples, and egg sharing programs offered through infertility clinics.

<sup>6</sup> ISSCR 11.2 - Contemporaneous consent for donation: Consent for donation of materials for research should be obtained at the time of proposed transfer of materials to the research team. Only after a rigorous review by a SCRO mechanism or body can

- d) *No Affect on Medical Care:* Policies and procedures shall be in place, and donors shall be so informed, that providing or declining to provide consent to donate biological materials to research will not affect the quality of care provided to the donor.
- e) *Withdrawal of Consent:* Donors shall be informed that they retain the right to withdraw consent until the biological materials are actually used in research, in compliance with ISSCR Guideline 11.2,<sup>8</sup> or until information which could link the identity of the donor(s) with the biological material is no longer retained (if applicable).
- f) *Restrictions on the Initial Use of Donated Materials:* Donors must be informed of the intended use of their biological materials to the extent such use is known, and that cell lines derived from the biological materials may be disseminated to other institutions or researchers, and/or may be stored in a tissue bank. Donors should be encouraged to provide their biological materials free of restrictions on use, but must be offered the opportunity to impose restrictions on the types of research in which their materials initially might be used (e.g., somatic cell nuclear transfer) prior to, or in conjunction with, derivation of a cell line. Donors must be informed that adherence to restrictions beyond initial-use restrictions cannot be guaranteed, and that researchers may decline to use their biological materials or cell lines derived therefrom if such restrictions are imposed.
- g) *Options for Disposition:* Donors shall be advised that there are alternatives to donating their gametes or embryos to research, and shall be provided with an explanation of what the alternatives are, including, but not limited to, all of the options available at the health care facility where the reproductive treatment was sought, embryo adoption, donation for fertility treatment, and discarding.
- h) *Financial Disclosures:* Donors must be provided with information that complies with financial disclosure provisions of ISSCR Guidelines 11.3(a)(viii) and (ix).<sup>9</sup>
- i) *Reimbursement for Costs of Research-Related Injuries:* Contractors shall be responsible for donors' medical costs, including the costs of treating injuries, that arise directly and proximately from the act[s] of donating.

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permission be granted to use materials for which prior consent exists but for which re-consent is prohibitively difficult. Consent must be obtained from all gamete donors for use of embryos in research.

<sup>7</sup> NAS 3.2 - Consent for donation should be obtained from each donor at the time of donation. Even people who have given prior indication of their intent to donate to research any blastocysts that remain after clinical care should nonetheless give informed consent at the time of donation....

<sup>8</sup> ISSCR 11.2 - Donors should be informed that they retain the right to withdraw consent until the materials are actually used in research.

<sup>9</sup> ISSCR 11.3(a) - The informed consent document and process should cover, at a minimum, the following statements:...

- viii) disclosure of the possibility that any resulting cells or cell lines may have commercial potential, and whether the donor will or will not receive financial benefits from any future commercial development.
- ix) disclosure of any present or potential future financial benefits to the investigator and the institution related to or arising from proposed research.

- j) *Genetic and Medical Information:* Donors must be informed that any resulting cells or cell lines derived from their biological materials will carry some or all of the DNA of the donor, and therefore, could be partially or completely genetically matched to the donor. Donors must also be provided with the disclosures mandated by ISSCR Guideline 11.3(a) (vii).<sup>10</sup>
- k) *Counseling Services:* Donors shall be advised of the availability of counseling services pursuant to ISSCR Guideline 11.6(iii),<sup>11</sup> which preferably shall be made available to the donor free of charge.
- l) *Donation of Oocytes Solely for the Purpose of Research:* The informed consent process must assure compliance with the provisions of ISSCR Guideline 11.5(b).<sup>12</sup> Special care must be taken to disclose both the short- and long-term health risks arising out of the oocyte donation process in a manner that reflects the most current scientific knowledge of such risks.
- m) *Application:* The standards set forth in this subsection shall apply to research funded pursuant to this contract involving the derivation of new stem cell lines. Contractors may use biological materials obtained prior to the execution of this contract and/or cell lines derived without the use of funds provided under this contract so long as the informed consent obtained from the donor(s) adhered to the provisions of the NAS or ISSCR Guidelines. In addition, grantees may use

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<sup>10</sup> ISSCR 11.3(a) - The informed consent document and process should cover, at a minimum, the following statements:...

- vii) disclosure of what donor medical or other information and what potential donor identifiers will be retained; specific steps taken to protect donor privacy and the confidentiality of retained information; and whether the identity of the donor will be readily ascertainable to those who derive or work with the resulting stem cell lines, or any other entity or person, including specifically any oversight bodies and government agencies.

<sup>11</sup> ISSCR 11.6 (iii) - Counseling services should be made available upon request to any providers of human materials prior to procurement.

<sup>12</sup> ISSCR 11.5(b) - *For provision of oocytes for research, when oocytes are collected outside the course of clinical treatment.* In locales where oocyte donation for stem cell research is allowed, the SCRO mechanism or body is responsible for conducting rigorous review of any protocol to ensure the safety and the free and informed choice of oocyte providers, according to the following principles:

- i) There must be monitoring of recruitment practices to ensure that no vulnerable populations, for example, economically disadvantaged women, are disproportionately encouraged to participate as oocyte providers for research.
- ii) In locales where reimbursement for research, participation is allowed, there must be a detailed and rigorous review to ensure that reimbursement of direct expenses or financial considerations of any kind do not constitute an undue inducement.
- iii) At no time should financial considerations of any kind be given for the number or quality of the oocytes themselves that are to be provided for research.
- iv) Oocyte procurement must be performed only by medically qualified and experienced physicians, and nonaggressive hormone stimulation cycles and frequent monitoring must be used to reduce the risk of ovarian hyperstimulation syndrome (OHSS).
- v) Due to the unknown long-term effects of ovulation induction, women should not undergo an excessive number of hormonally induced ovarian stimulation cycles in a lifetime, regardless of whether they are induced for research or assisted reproduction. The limits should be determined by thoughtful review during the SCRO process, which should be informed by the latest available scientific information about the health risks.
- vi) There should be a provision to pay for the cost of any medical care required as a direct and proximate result of a woman's provision of oocytes for research.
- vii) An infertility clinic or other third party responsible for obtaining consent or collecting materials should not be paid specifically for the material obtained, but rather for specifically defined cost-based reimbursements and payments for professional services.



cell lines registered on the National Institutes of Health (“NIH”) Registry,<sup>13</sup> and cell lines in existence on or prior to August 9, 2001 that were approved by the NIH for use in federally-funded research prior to initiation of the NIH Registry. Nothing in this paragraph shall preclude an ESCRO from reviewing, if it so chooses, the procurement or derivation of such cell lines for compliance with additional ethical standards, such as those set forth in this contract, or by NAS and ISSCR.

5. *Payments to Gamete Donors:*

- a) Contractors may conduct research involving the use of stem cell lines, or deriving new stem cell lines, in which women donating oocytes solely for research purposes have been, or are being, reimbursed for out-of-pocket expenses, including payments for travel, housing, medical care, child care and similar expenses incurred as a result of the donation of the oocytes for research purposes and compensated for the time, inconvenience and burden associated with the donation in a manner consistent with the New York standards applicable to women who donate oocytes for reproductive purposes in an amount not to exceed the payments permitted by the guidelines of the American Society of Reproductive Medicine. Payments made to oocyte donors in accordance with the provisions of this section are an allowable expense under this contract.
- b) If reimbursement for oocyte donation is provided, there must be a detailed and rigorous review by the ESCRO Committee, and the IRB, if required, to ensure that reimbursement of direct expenses and/or other compensation do not constitute an undue inducement.
- c) At no time should financial consideration of any kind be given for the number or quality of the oocytes themselves that are provided for research.
- d) The ESCRO Committee should review information, where available, regarding the payment to donors who produced gametes originally for reproductive purposes to ensure compliance with the ISSCR Guideline 11.5(a). Where no such information is reasonably available, the ESCRO Committee need not ensure that payment history complies with either NAS or ISSCR Guidelines.

**F. Publication and Intellectual Property Rights**

1. It is ESSCB’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 Fund shall not be delayed by investigators or their research institutions. 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.

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<sup>13</sup> See National Institutes of Health Guidelines on Human Stem Cell Research, §§ II.B - D (2009), available at <http://stemcells.nih.gov/policy/2009guidelines.htm>.

- a. All publications reporting research supported by NYSTEM funds published in peer reviewed journals must be deposited in the National Institutes of Health National Library of Medicine's PubMed Central (PMC). NYSTEM 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 NYSTEM-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. Support by the Empire State Stem Cell 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 Empire State Stem Cell 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 Empire State Stem Cell Board, the New York State Department of Health, or the State of New York."
2. It is ESSCB'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 NYSTEM funded research, where the awarded organization has not made reasonable efforts to protect the property interests or because the awardee has failed to share the research developments, the State shall retain march-in rights. The State shall have the right to 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 ESSCB-funded research. The contractor shall notify NYSTEM of the invention disclosures and the filing of any patent application in the progress report pursuant to the contract. The contractor shall also provide NYSTEM with written notice of any assignment or transfer of intellectual property rights generated as a result of research supported by the Fund. Any such assignment or transfer must acknowledge, and be subject to the rights retained by the State pursuant to the above paragraph 3, *supra*.

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. 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 Department 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.

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.

#### **G. Reporting Requirements**

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

#### **H. Equipment**

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

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

#### **I. Other Information**

1. Documents submitted to the Department on behalf of NYSTEM 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 Department may require reimbursement of all or a part of the award if ineligible expenses have been incurred or inaccurate accounting statements have been submitted.
4. Neither the Department 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 contract expenditures by an appointed representative of NYSTEM at any reasonable time.

6. Assurances and Certifications. The ESSCB 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 seq.*), 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 NYSTEM 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 reserves the right to revise or expand the requirements applicable to research conduct, as well as legal and administrative oversight.