DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED RULES

1) Heading of the Part: Illinois Regenerative Medicine Institute Code

2) Code Citation: 77 Ill. Adm. Code 995

3)

Section Numbers:	Proposed Action:
995.10	New
995.15	New
995.60	New
995.70	New
995.80	New
995.90	New
995.100	New
995.110	New
995.130	New
995.140	New
995.150	New
995.160	New

4) Statutory Authority: Department of Public Health Powers and Duties Law of the Civil Administrative Code of Illinois [20 ILCS 2310] and the Stem Cell Research and Human Cloning Prohibition Act [410 ILCS 110]

5) A Complete Description of the Subjects and Issues Involved: Part 995 administers the Stem Cell Research and Human Cloning Prohibition Act [410 ILCS 110], which established the Illinois Regenerative Medicine Institute within the Illinois Department of Public Health to provide for the awarding of grants to Illinois medical research institutions. The Act states that the purposes of the grant programs are: 1) to improve the health of the citizens of Illinois through stem cell research; 2) to support scientific research in Illinois for which funding from the U.S. government might be restricted; 3) to improve the national competitive position of Illinois in the field of regenerative medicine; and 4) to promote the translation of stem cell research into clinical practice and the transfer of technology to biomedical and technological industry. The rules include: definitions; incorporated and referenced materials; types of grant programs; eligibility for grants; conditions on use and disbursement of grant funds; research requirements and limitations; applications; application review process; grant awards; grant agreements; post-grant monitoring and compliance; and suspension, termination and recovery of grant awards.

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The economic effect of this proposed rulemaking is unknown. Therefore, the Department requests any information that would assist in calculating this effect.

The Department anticipates adoption of this rulemaking approximately six to nine months after publication of the Notice in the Illinois Register.

6) Published studies or reports, and sources of underlying data, used to compose this rulemaking: None

7) Will this rulemaking replace any emergency rulemaking currently in effect? No

8) Does this rulemaking contain an automatic repeal date? No

9) Does this rulemaking contain incorporations by reference? Yes

10) Are there any other proposed rulemakings pending on this Part? No

11) Statement of Statewide Policy Objectives: This rulemaking does not create or expand a State mandate.

12) Time, Place and Manner in which interested persons may comment on this proposed rulemaking:

Interested persons may present their comments concerning this rulemaking within 45 days after the publication of this issue of the *Illinois Register* to:

Susan Meister
Division of Legal Services
Illinois Department of Public Health
535 W. Jefferson St., 5th floor
Springfield, Illinois 62761

217/782-2043
e-mail: dph.rules@illinois.gov

13) Initial Regulatory Flexibility Analysis:

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A) Types of small businesses, small municipalities and not for profit corporations affected: Nonprofit medical research institutions with their principal place of business located in Illinois.

B) Reporting, bookkeeping or other procedures required for compliance: Applicants are to submit a letter of intent and a complete application. Grant recipients: 1) must submit written reports of progress toward achieving objectives at six months, one year and within one month after completion; 2) will be subject to periodic on-site inspections by IRMI representatives and oral presentations to clarify the status or the end of project report for the benefit of the peer review panel or other formally recognized audiences; 3) must establish and maintain the necessary processes to monitor their compliance and that of their employees and contractors; take appropriate action to meet the stated objectives; and inform IRMI of any problems or concerns; and 4) are responsible for the actions of their employees and other research collaborators, including third parties involved in the project.

C) Types of professional skills necessary for compliance: The Act requires the Illinois Regenerative Medicine Institute Oversight Committee [410 ILCS 110] to include individuals from professional medical organizations, voluntary health organizations, and for-profit biomedical or biotechnology industry.

The proposed rules require the Embryonic Stem Cell Research Oversight (ESCRO) committee to include individuals with legal and ethical expertise in developmental biology, stem cell research, molecular biology, assisted reproduction, or ethical and legal issues in embryonic stem cell research.

The proposed rules require the members of the Scientific Review Panel (Panel) (77 Ill. Adm. Code 995) to have:

Demonstrated scientific research and experience in the derivation and use of human embryonic stem cells, human embryonic germ cells or human adult stem cells; or

Demonstrated knowledge and understanding of the ethical and medical implications of the derivation and use of human embryonic stem cells, human embryonic germ cells and human adult stem cells.

14) Regulatory Agenda on which this rulemaking was summarized: January 2009

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The full text of the Proposed Rules begins on the next page:

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NOTICE OF PROPOSED RULES

TITLE 77: PUBLIC HEALTH
CHAPTER I: DEPARTMENT OF PUBLIC HEALTH
SUBCHAPTER u: MISCELLANEOUS PROGRAMS AND SERVICES

PART 995
ILLINOIS REGENERATIVE MEDICINE INSTITUTE CODE

Section

AUTHORITY: Implementing and authorized by the Department of Public Health Powers and Duties Law of the Civil Administrative Code of Illinois [20 ILCS 2310] and the Stem Cell Research and Human Cloning Prohibition Act [410 ILCS 110].

SOURCE: Adopted at 34 Ill. Reg._____, effective _____.

Section 995.10 Definitions

"Androgenetic human embryos" means embryos created from a male spermatozoon without genetic contribution from a female.

"Applicant" means an eligible institution that has submitted an application for an award of a grant pursuant to this Part for the purpose of conducting stem cell research in Illinois.

"Biotechnology start-up company" means a new company that makes use of microorganisms to achieve a result.

"Blastocyst" means a preimplantation embryo of 30-100 cells. The blastocyst consists of a sphere made up of an outer layer of cells (the trophectoderm), a fluid-filled cavity (the blastocoel), and a cluster of cells on the interior (the inner cell mass).

"Cell division" means a method by which a single cell divides to create two cells. This continuous process allows a population of cells to increase in number or maintain its numbers.

"Chimera" means an organism derived from more than one fertilized cell.

"Department" means the Illinois Department of Public Health.

"Differentiated cell" means a cell in which the level of organization or complexity has developed into a specialized function.

"Embryo" means a fertilized ovum from the time of fertilization until the end of the eighth week of gestation.

"Embryonic stem cell research" means research on embryonic stem cells.

"Embryonic stem cells" means pluripotent stem cells derived from the inner cell mass of a blastocyst that have the potential to become a wide variety of specialized cell types.

"ESCRO committee" means the Embryonic Stem Cell Research Oversight committee that provides ethical and legal oversight at institutions working with human embryonic stem cell lines.

"Experiment" means a test under controlled conditions that is made to demonstrate a known truth, to examine the validity of a hypothesis, or to determine the efficacy of something previously untried.

"FDA" means the United States Food and Drug Administration.

"Gamete" means a sperm or oocyte.

"Grant" means the award of funds under the Illinois Regenerative Medicine Institute (IRMI) program to an eligible applicant to conduct stem cell research in Illinois.

"Grant agreement" means the agreement entered into between the Department and a grantee setting forth the terms and conditions of a grant award.

"Grantee" means an institution receiving a grant.

"HIPAA" means the Health Insurance Portability and Accountability Act of 1996 and the Standards for Privacy of Individually Identified Health Information (Privacy Rule).

"Human embryonic stem cells" means embryonic stem cells derived from a human blastocyst.

"Human subject" means a living individual from whom an investigator, whether professional or student, conducting research obtains data or tissue through either intervention or interaction with the individual, or identifiable private information.

"Illinois Regenerative Medicine Institute" or "IRMI" or the "Institute" means a program of the Department to award research grants.

"Illinois Regenerative Medicine Institute Oversight Committee" or "Committee" means the group that determines the awards of the Institute's grant program, among other duties.

"Institution" means a corporation, association, partnership, nonprofit organization, governmental entity or other legal entity that conducts stem cell research.

"Institutional Animal Care and Use Committee" or "IACUC" means the committee providing oversight at an institution that uses animals as part of federally funded laboratory research.

"Institutional Research Committee" or "IRC" means the committee appointed by an institution to provide continuing oversight of the activities of an IRMI funded project.

"Institutional Review Board" or "IRB" means any board, committee or other group formally designated by an institution to conduct an initial review of, to approve the initiation of, and to conduct periodic review of all biomedical research involving human subjects.

"Intellectual property" means a creation of the mind that is unique, novel and unobvious, and has commercial value.

"Investigator" means a person conducting or assisting in the performance of stem cell research.

"In vitro" means a process or reaction occurring in an artificial environment such as a test tube or culture medium.

"In vitro fertilization" means a procedure in which fertilization of an egg with a sperm is accomplished outside the living organism.

"Lobbying" means any communication with the Governor, Lieutenant Governor, Secretary of State, Attorney General, State Treasurer or State Comptroller, their chiefs of staff, their cabinet members including Directors, Assistant Directors and Chief Legal Counsels or General Counsels, or Members of the General Assembly for the ultimate purpose of influencing executive, legislative or administrative action.

"Medical research" means basic or applied research conducted to aid the body of knowledge in the field of medicine.

"Nonprofit" means an institution exempt from taxation under section 501(c)(3) of the Internal Revenue Code.

"Nonprofit medical research institution" means a corporation, association, partnership, nonprofit organization, governmental entity or other legal entity that is exempt from taxation under section 501(c)(3) of the Internal Revenue Code and conducts basic or applied research to aid the body of knowledge in the field of medicine.

"Parthenogenetic human embryos" means embryos created soley from a female oocyte without genetic contribution from a male.

"Pluripotent" means the ability of a single stem cell to develop into many different cell types of the body.

"Principal investigator" means the person with primary responsibility for conducting a stem cell research project.

"Progenitor cell" means an early descendant of a stem cell that can differentiate, but cannot renew itself as a stem cell can.

"Project period" means the period in which a research project funded by a grant is to be completed.

"Reproductive cloning" means somatic cell nuclear transfer used for the production of a fetus and delivery of a live offspring that is genetically identical to the donor of the somatic cell DNA.

"Request for applications" or "RFA" means the announcement of the details of the application process for stem cell grants.

"Research donor" means an individual who donates to research any number of blastocysts that remain after clinical care at the time of the original harvesting.

"Scientific Review Panel" or "Panel" means a group of stem cell researchers from outside Illinois, chosen by the Department.

"Somatic cell nuclear transfer" means a technique in which the nucleus of a somatic cell is injected or transferred into an egg that has had its nucleus removed.

"Somatic stem cell", also called adult stem cell, means an undifferentiated cell that can become a specialized cell type of the tissue from which it came.

"Stem cell" means a cell with the ability to divide for indefinite periods in culture and to give rise to specialized cells, and includes, without limitation, somatic stem cells, cord blood stem cells, pluripotent stem cells, totipotent stem cells, progenitor cells, the product of somatic cell nuclear transfer, and any combination of these cells.

"Stem cell line" means a family of constantly dividing cells, the product of a single parent group of stem cells.

"Stem cell research" means scientific investigation and study into the nature and properties of stem cells, the transformation of stem cells into specialized cells, the development of stem cell lines, the growth of stem cells in vitro, or the possible uses of stem cells to cure or reduce the effects of disease, disabilities or physical conditions or maladies.

"TIN" means the nine-digit federal taxpayer identification number assigned to an institution by the Internal Revenue Service, also known as the federal employer identification number or governmental unit code.

"Totipotent stem cell" means a cell that can give rise to all cell types that are found in an embryo, fetus or developed organism, including the embryonic components of the trophoblast and placenta required to support development and birth. The zygote and the cells at the very early stages following fertilization are considered totipotent.

"Undifferentiated cell" means a cell in which the level of organization or complexity has not yet developed into a specialized function.

Section 995.15 Incorporated and Referenced Materials

a) The following federal statutes are referenced in this Part:

1) Americans With Disabilities Act of 1990 (42 USC 126)

2) Animal Welfare Act (7 USC 2131-56)

3) Davis-Bacon Act (40 USC 276a)

4) Health Insurance Portability and Accountability Act of 1996 (42 USC 1320d-2)

5) Internal Revenue Code (26 USC 501)

6) Occupational Health and Safety Act of 1970 (29 USC 15)

b) The following federal regulations are incorporated in this Part:

1) Attending Veterinarian and Adequate Veterinarian Care, United States Department of Agriculture (9 CFR 2.33), January 1, 2008

2) Institutional Animal Care and Use Committee (IACUC), United States Department of Agriculture (9 CFR 2.31), January 1, 2008

3) Protection of Human Subjects, United States Department of Health and Human Services (21 CFR 50), April 1, 2008

4) Standards for Privacy of Individually Identified Health Information (Privacy Rule), United States Department of Health and Human Services (45 CFR 160 and 164), October 1, 2007

c) The following federal guidelines are incorporated in this Part:

1) The following guidelines, which are available from the National Academies of Science at The National Academies Press, 500 Fifth Street NW, Lockbox 285, Washington DC 20055 or on-line at: http://www.nap.edu/catalog.php?record_id=12553

A) Guidelines for Human Embryonic Stem Cell Research (2005)

B) 2007 Amendments to the Guidelines for Human Embryonic Stem Cell Research

C) 2008 Amendments to the Guidelines for Human Embryonic Stem Cell Research

2) Public Health Service Policy on Humane Care and Use of Laboratory Animals (2002), available from the National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892

d) All incorporations by reference of federal regulations and guidelines in this Part refer to the regulations and guidelines on the date specified and do not include any amendments or editions subsequent to the date specified.

e) The following Illinois statutes and administrative rules are referenced in this Part:

1) Administrative Review Law [735 ILCS 5/Art. III]

2) Drug Free Workplace Act [30 ILCS 580]

3) Illinois Grant Funds Recovery Act [30 ILCS 705]

4) Illinois Human Rights Act [775 ILCS 2]

5) Department of Public Health's Rules of Practice and Procedure in Administrative Hearings (77 Ill. Adm. Code 100)

Section 995.60 Grant Programs

a) Grants shall be made from funds appropriated by the General Assembly for the purpose of stem cell research. Unless the General Assembly designates funds for specific types of research or grants, the Committee will award grants including, but not limited to, those for single projects, multiple projects, and projects that support early and conceptual stages of innovative ideas. The Committee may award extensions or continuations to previous grantees in accordance with Section 995.70.

b) As funds are made available for a specific type of grant, the Institute will solicit applications for those grants by posting a request for applications (RFA) notice of the availability on the Department's web site and by sending notices to Illinois colleges, universities and research institutions. The RFA will include key dates, eligibility, types of grants, amount of grants, amount of permitted indirect cost, a summary of the review process, and the criteria used for the evaluation of the applications as indicated in Section 995.110(d).

Section 995.70 Eligibility for Grants

a) Applicants shall be nonprofit medical research institutions with their principal place of business located in Illinois.

b) All research funded by grants shall be conducted in Illinois.

c) Each applicant involved in human embryonic stem cell research funded by IRMI shall establish an Embryonic Stem Cell Research Oversight (ESCRO) committee,

in accordance with the Guidelines for Human Embryonic Stem Cell Research. The ESCRO committee shall include representatives of the public and persons with legal and ethical expertise in developmental biology, stem cell research, molecular biology, assisted reproduction, or ethical and legal issues in embryonic stem cell research. The ESCRO committee shall conduct its own review, including, where necessary, management of various other reviews required for a particular protocol. This provision does not preclude the establishment of a joint ESCRO committee that would assume oversight responsibilities for two or more research institutions, provided that the ESCRO committee has oversight authority for each institution consistent with the requirements of this Part.

Section 995.80 Conditions on Use and Disbursement of Grant Funds

a) The grantee is responsible for assuring that the investigators fulfill the grant requirements and the requirements for the fiscal and legal management of a project that is funded with a grant.

b) All grants shall be subject to all requirements and limitations imposed by Illinois law, including, without limitation, the Illinois Grant Funds Recovery Act.

c) Each institution receiving a grant shall establish an IRC to review the institution's activities during the grant period. The IRC shall meet at least quarterly and hear reports from the institution's projects. The IRC shall include scientists, ethicists and community representatives, including organizations supporting medical conditions likely to be investigated by stem cell research.

d) Project funds shall be used for the direct cost of administering, operating and maintaining a project and for an amount of indirect costs as announced by the Department in its RFA. The direct costs permitted include, but are not limited to:

1) Personal services costs, including gross salaries and employer-paid benefits for full-time and part-time employees on the project;

2) Contractual services costs, including, but not limited to, fees for consultants and specialists, exclusive of consultant services for patient care; conference registration fees; repair and maintenance of furniture and equipment; postage and postal services; subscriptions to periodicals; training and education costs; software; and telecommunications costs;

3) Travel costs, which are the expenses for transportation, lodging and subsistence for personnel who are on travel status on official business related to the IRMI grant. Out-of-state travel requires prior written approval of the Department;

4) Supplies/commodities as required in the operation of the project that are directly related to its operation. Supplies include, but are not limited to, office, medical and educational supplies; equipment items costing less than $100 each; printing; and paper; and

5) Equipment directly related to the operation of the project. Equipment is defined as items costing over $100 each, with a useful life of more than one year. Equipment costs shall include all freight and installation costs. Purchase of equipment items, other than those included in the approved budget, requires prior written approval from the Department.

e) No grant funds shall be used for facility construction or lobbying.

f) No grant funds shall be awarded to any person who knowingly purchases or sells embryonic or cadaveric fetal tissue for research purposes. Funds may be used to pay customary medical charges for the removal, processing, disposal, preservation, quality control, storage, transplantation or implantation of the tissue.

g) Payments for the purchase of stem cells and stem lines for the purpose of research under this Part shall be limited to payment for removal, processing, disposal, preservation, quality control, storage, transplantation, implantation and legal transaction and other administrative costs associated with these medical procedures and shall specifically include any required payments for medical or scientific technologies, products and processes for royalties, patents, licensing fees and other costs for intellectual property.

h) Requests for budget adjustments shall be submitted to the Department in writing no later than 45 calendar days before the end of the grant agreement period.

i) No grant funds shall be disbursed for costs incurred more than two years after the start of the project period. Any grant funds not expended or legally obligated by the end of the project period shall be returned to the Department within 45 days after the end of the project period, if the funds are not already on deposit with the

Department or the State Treasurer. Returned funds shall be deposited into the fund from which the original grant disbursement to the grantee was made.

j) Grant funds shall not be provided for:

1) Research involving the reproductive cloning of a human being;

2) Research involving fetuses from induced abortions; and

3) Research involving the creation of embryos through the combination of gametes solely for the purpose of research.

Section 995.90 Research Requirements and Limitations

All grantees shall comply with the following requirements in the course of performing stem cell research funded by a grant under this Part:

a) All research shall be undertaken according to the National Academies of Science Guidelines for Human Embryonic Stem Cell Research. The research shall be approved by the ESCRO committee and submitted with the application. Any changes from the National Academies of Science Guidelines for Human Embryonic Stem Cell Research shall be submitted to the Department prior to implementation to assure compliance with this Part and the grant agreement. Any use of human embryonic stem cells shall be consistent with the National Academies of Science Guidelines for Human Embryonic Stem Cell Research.

b) All research shall at all times comply with all applicable federal laws, including, but not limited to, the Occupational Health and Safety Act and HIPAA, and the following federal regulations: Institutional Animal Care and Use Committee (IACUC) and Attending Veterinarian and Adequate Veterinarian Care. Grantees shall comply with the U.S. Department of Health and Human Services regulations titled Protection of Human Subjects and the U.S. Department of Agriculture regulations titled Attending Veterinarian and Adequate Veterinarian Care and Institutional Animal Care and Use committee (IACUC) (see Section 995.15).

c) Grantees shall be responsible for supervising their investigators to ensure that they conduct themselves in accordance with the grant agreement and professional standards.

d) The project period shall be up to 24 months.

e) Grantees shall obtain the informed consent of all research donors, patients and participants, including a new consent from individuals who had indicated their intent to donate to research any blastocysts that remain after clinical care at the time of the original harvesting. Donors shall be informed that they retain the right to withdraw consent until the blastocysts are actually used in cell line derivation. A research project's informed consent procedures shall satisfy each of the following requirements:

1) In seeking informed consent, the following information shall be provided to each research donor:

A) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

B) A description of any reasonably foreseeable risks or discomforts to the donor;

C) A description of any benefits to the donor or to others that may reasonably be expected from the research;

D) A disclosure of appropriate alternative options pertaining to use of the embryos;

E) A statement describing the extent, if any, to which confidentiality of records identifying the donor will be maintained;

F) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

G) An explanation of whom to contact for answers to pertinent questions about the research and research donors' rights, and whom to contact in the event of a research-related injury to the donor; and

H) A statement that participation or donation is voluntary; that refusal to participate and/or donate will involve no penalty or loss of benefits to which the donor is otherwise entitled; and that the donor may discontinue participation at any time without penalty or loss of benefits to which the donor is otherwise entitled.

2) When appropriate, the following additional elements of information shall also be provided to each research donor:

A) Anticipated circumstances under which the donor's participation in the research may be terminated without the donor's consent;

B) The consequences of the donor's decision to withdraw from the research, and procedures for the donor's orderly termination of participation; or

C) Significant new findings developed during the course of the research that may relate to the donor's willingness to continue participation.

3) The grantee shall develop the precise form of the informed consent specifically for the particular study protocol or procedure for which the consent is being sought, and the informed consent form shall be approved by the grantee's ESCRO committee.

4) The language in the informed consent shall be clear and understandable.

5) When donor gametes have been used in the in vitro fertilization process, resulting blastocysts shall not be used for research without consent of all gamete donors.

6) The informed consent shall otherwise conform to the requirements for research funded by the National Institutes of Health and be consistent with the Guidelines for Human Embryonic Stem Cell Research published by the National Academies of Science (see Section 995.15).

f) Financial Incentives Prohibited

1) Financial incentives in the solicitation or donation of blastocysts, gametes or somatic cells for research purposes are prohibited.

2) No cash or in-kind payments shall be provided for donating blastocysts in excess of clinical need for research purposes.

3) No cash or in-kind payments shall be provided for donating oocytes for research purposes.

4) No payments shall be made for donations of sperm for research purposes or of somatic cells for use in nuclear transfer.

g) Standards of Clinical Care

1) Consenting or refusing to donate gametes or blastocysts for research shall not affect or alter in any way the quality of care provided to prospective donors. Clinical staff shall provide care to patients without prejudice regarding their decisions about disposition of their embryos.

2) Researchers shall not ask members of the infertility treatment team to generate more oocytes than necessary for the optimal chance of reproductive success. An infertility clinic or other third party responsible for obtaining consent or collecting materials is not to pay for or be paid for the material obtained (except for specifically defined cost-based reimbursements and payments for professional services).

h) Privacy and Confidentiality

1) Grantees shall at all times ensure that donors' personal health information is protected and kept confidential. Investigators and institutions shall comply with applicable laws, including, but not limited to, HIPAA.

2) Grantees shall ensure that authorizations are received from donors, as required by HIPAA, for the confidential transmission of personal health information to repositories or to investigators who are using embryonic stem cell lines derived from donated materials.

3) When the FDA requires that the identity of the donor source be preserved, investigators and institutions shall ensure that the confidentiality of the

donor is protected; that the donor understands that the donor's identity will be maintained; and that, where applicable, human subject protections as defined in HIPAA are followed.

i) Derivation of Stem Cell Lines

1) Requests from the investigators to the ESCRO committee for permission to attempt derivation of new embryonic stem cell lines from donated embryos or blastocysts or from any other source or by another procedure not previously approved by the IRB shall include the IRB's written approval of the procurement process.

2) The investigator shall present the scientific rationale for the need to generate new embryonic stem cell lines, by whatever means, to the ESCRO committee, and the investigators shall justify the basis for the numbers of embryos and blastocysts needed.

3) Blastocysts made using nuclear transfer (whether produced with human or nonhuman oocytes) and parthenogenetic or androgenetic human embryos shall not be transferred to a human or nonhuman uterus and shall not be cultured as intact embryos in vitro.

4) Cells shall not be extracted from blastocysts more than 12 days after cell division begins, not counting any time during which the blastocysts or cells have been stored frozen.

5) Investigators shall document how they will characterize, validate, store and distribute the new embryonic stem cell lines and how they will maintain the confidentiality of any coded or identifiable information associated with the lines.

j) Storage and Distribution of Stem Cell Lines

1) Cell lines derived or modified in any way with IRMI grant funds shall be deposited in a bank in a timely manner as defined in the grant agreement. Grantees shall allow stem cell lines to be shared with other investigators.

2) Grantees that are banking or plan to bank embryonic stem cell lines shall establish uniform guidelines to ensure that records are maintained about

all aspects of cell culture, and shall establish uniform tracking systems and common guidelines for distribution of cells.

3) Grantees engaged in obtaining and storing embryonic cell lines shall:

A) Create a committee for policy and oversight purposes and create clear and standardized protocols for banking and withdrawals.

B) Establish documentation requirements for investigators and sites that deposit cell lines, including:

i) Providing a copy of the donor consent form;

ii) Providing proof of written approval of the procurement process by the depositor's IRB and the grantee's IRB;

iii) Providing available medical information on the donors, including results of infectious disease screening;

iv) Providing available clinical, observational or diagnostic information about the donors;

v) Providing critical information about culture conditions (such as media, cell passage and safety information); and

vi) Providing available cell lines characterization (such as karyotype and genetic markers).

C) Establish a secure system for protecting the privacy of donors when materials retain information that could lead to the identification of the patient, including, but not limited to:

i) A schema for maintaining confidentiality, such as a coding system;

ii) A system for a secure audit trail from primary cell lines to those submitted to the repository, which identifies all individuals who have accessed the information; and

iii) A policy governing whether and how to deliver clinically significant information to donors.

D) Establish the following standard practices:

i) A process for assignment of a unique identifier to each sample;

ii) A process for characterizing cell lines;

iii) A process for expanding, maintaining and storing cell lines;

iv) A system for quality assurance and control;

v) A website that contains specific descriptions and data related to the cell lines available;

vi) A procedure for reviewing applications for cell lines;

vii) A process for tracking disbursed cell lines and recording their status when shipped, including number of times the stem cell line has been subcultured or transferred;

viii) A system for auditing compliance;

ix) A schedule of charges;

x) A statement of intellectual property policies;

xi) A process to create a material transfer agreement or user agreement;

xii) A liability statement; and

xiii) A system for disposal of material.

E) Establish clear criteria for distribution of cell lines, including, but not limited to, written approval of the research by the ESCRO committee or equivalent body at the recipient institution.

k) Research Use of Stem Cell Lines

1) Once stem cell lines have been derived, investigators and grantees shall monitor their use in research.

2) Grantees shall require documentation of the source of all stem cell lines, including whether the cells were imported into the institution or generated locally. The investigator's notice to the institution shall include evidence of written IRB approval of the procurement process, and adherence to Guidelines for Human Embryonic Stem Cell Research. In the case of lines imported from another institution, documentation that these criteria were met at the times of derivation will suffice.

3) Each grantee shall maintain a registry of its investigators who are conducting stem cell research.

4) The investigators shall submit all protocols involving the combination of embryonic stem cells with nonhuman embryos, fetuses or adult animals to the ESCRO committee for consideration of the consequences of the human contributions to the resulting chimeras.

5) The ESCRO committee shall review experiments in which embryonic stem cells, their derivatives or other pluripotent cells are introduced into nonhuman fetuses and allowed to develop into adult chimeras, including consideration of any major functional contributions to the brain.

6) The IRB shall review use of existing stem cells when the research involves introduction of the stem cells or their derivatives into patients or the possibility that the identity of the donors of the blastocysts, gametes or somatic cells is readily ascertainable or might become known to the investigator. Documentation of the IRB's review shall be included with the grant application (see Section 995.100(c)(17)).

l) Research involving nonhuman mammals

1) Standards for the review of research involving nonhuman mammals shall be based on the requirements of the Animal Welfare Act and the Public Health Service Policy on Humane Care and Use of Laboratory Animals

(see Section 995.15). All research involving nonhuman animals shall be approved by the institution's IACUC.

2) Introduction of embryonic stem cells into nonhuman mammalian blastocysts shall be considered by investigators and approved by the ESCRO committee only under circumstances in which no other experiment can provide the information needed.

3) Animal embryonic stem cells shall not be transplanted into a human blastocyst.

4) Human embryonic stem cells shall not be transplanted into nonhuman primates.

Section 995.100 Application for Grant

a) The Department shall provide written application instructions and forms to potential applicants.

b) The Department will request a letter of intent from prospective applicants approximately one month before applications are due. A letter of intent is not binding on the prospective applicant. A letter of intent shall include the descriptive title of the proposed research; the name, address and telephone number of the principal investigator; the names of other key personnel; the names of participating institutions; and, if applicable, the type of grant for which the application is being submitted.

c) All applications shall include the following:

1) The name, address and telephone, FAX and teletypewriter (TTY) numbers, if available, of the institution applying for the grant.

2) The principal investigator's name, address and telephone, FAX and TTY numbers, if available.

3) The curriculum vitae of the principal investigator or principal investigators.

4) A one-page nontechnical abstract that describes the significance of the applicant's project for stem cell research.

5) The applicant's TIN or the Governmental Unit Code assigned by the Illinois Comptroller.

6) The signature of the principal investigator and agency official authorized to certify the application.

7) An approximate timetable for project expenditures and completion.

8) Background data and information justifying the project.

9) A detailed budget for the project period, documenting sufficient resources to carry out the project. The budget shall be by line item category and shall provide sufficient detail to justify the use of grant funds to support project activities. The applicant shall indicate the total cost of conducting the project; the anticipated funding request for each year of the project period; the source of other funds in hand supporting the research project; other grants or funds awarded, denied or pending; and the amount of support requested from the Department.

10) A Statement of Assurances, signed by a responsible official, indicating compliance with applicable State and federal requirements.

11) A statement of the type of grant being requested (see Section 995.60(a)).

12) A statement of the research question or hypothesis or a description of interventions or model programs on which the research will be based.

13) A prioritized listing of measurable objectives for the project period.

14) Proposed activities for experiments, scientific rationale and relevant reference to existing works.

15) The evaluation methods to be used to measure progress in achieving objectives and a plan for monitoring the overall project.

16) A sample informed consent document (with patient identifier information removed) and a description of the informed consent process that meets the criteria for informed consent set forth in this Part (see Section 995.90(e)).

17) The written guidelines under which the research will proceed and documentation of approval from the IRB, and, if the grant activities require, from the ESCRO committee and IACUC.

Section 995.110 Application Review Process

a) At the end of an application period, the Department will conduct a screening review to confirm that each application is complete. The screening review will confirm that:

1) All required questions in the application have been answered;

2) All required forms and materials have been submitted;

3) All ethical and legal guidelines applicable to the research project have received appropriate approvals, including any required approvals by the institution's IRB, ESCRO committee or IACUC, or that the appropriate approvals have been applied for and are pending. No monies shall be spent on an activity without appropriate approvals;

4) The description of the research project and its objectives, protocols and ethical and legal guidelines is clear and concise. Applications that exceed the maximum length permitted in the written instructions for applicants shall be returned without consideration; and

5) All of the necessary parties have signed the application.

b) The Scientific Review Panel will have 10 to 20 members appointed by the Director to serve a term of two years. If a vacancy occurs, the Director will appoint a replacement to serve the remainder of the term. Panel members will:

1) Not be residents of Illinois;

2) Not be employed by a medical research institution with its principal place of business in Illinois;

3) Not be members of the Committee; and

4) Have demonstrated at least one of the following:

A) Scientific research and experience in the derivation and use of human embryonic stem cells, human embryonic germ cells or human adult stem cells;

B) Knowledge and understanding of the ethical and medical implications of the derivation and use of human embryonic stem cells, human embryonic germ cells and human adult stem cells.

c) The Panel will:

1) Establish guidelines for scoring applications, which shall adhere to the National Academies of Science Guidelines for Human Embryonic Stem Cell Research, 2007 Amendments to the National Academies of Science Guidelines for Human Embryonic Stem Cell Research, and 2008 Amendments to the National Academies of Science Guidelines for Human Embryonic Stem Cell Research.

2) Review complete applications submitted by eligible institutions and make recommendations to the Committee with respect to the scientific and ethical merit of the applications reviewed.

3) Review progress and final reports prepared by awardees as required in grant agreements with the Department.

d) Two members of the Panel will review and evaluate each complete application and present their evaluations to the entire Panel. The Panel will review and study the application, rate the scientific and technical merit of the application, and propose terms for the grant agreement. The Panel will review and rank the quality of the research project under the following criteria:

1) The activities identified by the applicant will lead to achievement of the research objectives;

2) The project objectives are achievable in the stated time frame;

3) The evaluation methods measure progress toward the identified objectives;

4) The budget provides sufficient resources that include, but are not limited to, staff, equipment and supplies, and justifies the need for funds to carry out the project;

5) The investigators, especially the principal investigator, have a history of conducting and completing scientific research on time, on budget and as planned;

6) The investigators, especially the principal investigator, have significant expertise in biotechnology and have a reputation for innovation and for developing practical applications for biotechnology;

7) The applicant has the facilities and resources to complete the research project as described;

8) The research leads to or involves clinical trials;

9) The stem cell research project has the greatest potential, based on the information presented in the application and the Panel's knowledge and experience, for therapies and cures and cannot receive or is unlikely to receive sufficient federal funding;

10) The research is likely to lead to new therapies, treatment or cures for debilitating diseases and injuries, based on the information presented in the application and the Panel's knowledge and experience;

11) The research will lead to patents, articles in peer-reviewed journals or additional grant funding;

12) The research proposes projects of established researchers to undertake stem cell research, of junior investigators to develop stem cell research projects, or of researchers in human embryonic stem cells;

13) The research project will develop or refine the understanding of the ethical, legal and social issues raised by stem cell research;

14) The project proposes novel ideas and approaches to develop the ideas;

15) The project proposes human embryonic stem cell research that may attract venture capital for biotechnology start-up companies in Illinois;

16) The research that is likely to accelerate the pace at which basic and preclinical findings are translated into clinical benefits;

17) The project proposes collaborative and interdisciplinary research among investigators, whether at the same or different institutions; and

18) Funding the project will increase awareness and understanding of stem cell research.

e) The Panel will prepare a report for the Committee, setting forth its analyses, impressions and recommendations on the application, the rank order of the projects and the amount of the grant recommended, if any. The Panel may approve part of an application and recommend partial funding (see Section 995.130).

f) After the Panel ranks the approved applications in order and submits the list to the Committee, the Committee will decide which applications to fund based on the reviewers' recommendations and the criteria listed in this Section. If the amount of recommended funding exceeds the total amount for awards, the Committee may approve reduced funding for one or more applicants. Those applicants offered reduced funding may decline; if they accept, they shall submit a revised budget for the reduced amount within 10 days after acceptance.

Section 995.130 Award of Grants

a) The Committee may award all of the requested funds to the applicants that are selected for funding, or may award reduced funding for one or more applicants. The Committee's decision will include, but not be limited to, the following:

1) The total amount of grant funds available;

2) The number of grant proposals selected for funding;

3) Whether a selected project contains elements that the Committee determines, based on the review process in Section 995.110, should not be funded or should be partially funded; and

4) Whether the requested funding exceeds the described activities of the project, based on the review process in Section 995.110.

b) If the Committee determines that the number of selected projects must be reduced to accommodate the amount of grants funds available, the criteria in Section 995.110 will be used to reduce the number of projects.

c) The Department will prepare award transmittal letters and a grant agreement for approved projects. Mailing of the transmittal letter and grant agreement to the applicant for acceptance shall constitute notification of award.

d) The Department will notify in writing those applicants whose research projects are not accepted for IRMI funding.

Section 995.140 Grant Agreements

a) No award to an applicant shall be final until the applicant and the Department have executed and delivered a grant agreement setting forth the terms and conditions of the grant, including the requirements set forth in this Section. The Department will retract the award of a grant if an agreement cannot be reached on the terms of the grant agreement.

b) The grant and the grant agreement shall not be sold, assigned or transferred in any manner. Any actual or attempted sale, assignment or transfer shall render the grant agreement null, void and of no further effect. If the grantee, for whatever reason, ceases operation, the grant agreement shall be terminated.

c) All projects shall begin and end on the date specified in the grant agreement. The project period shall be for 24 months. Requests for a no-cost extension shall be submitted to the Committee no later than 45 calendar days before the end of the project period.

d) Pursuant to the Grant Funds Recovery Act, the grant agreement shall contain the following terms:

1) The grant agreement shall describe the purpose of the grant and be signed by the Department and all grantees;

2) The grant agreement shall specify how payments will be made, what constitutes permissible expenditure of the grant funds, and the financial controls applicable to the grant;

3) The grant agreement shall specify the project period; and

4) The grant agreement shall contain a provision that all grant funds remaining at the end of the project period shall be returned to the State within 45 days.

Section 995.150 Post-Grant Monitoring and Compliance

a) The Department will monitor all grants awarded.

b) Grantees shall submit written reports of progress toward achieving objectives at:

1) Six months into the grant agreement period;

2) One year into the grant agreement period; and

3) Within a month after the conclusion of the project period.

c) The reports shall include the following:

1) A description of the current status of the project in accordance with the proposed time frames in the application;

2) Documentation on the progress in meeting each project objective in accordance with the proposed time frames in the application;

3) Rationale for any revisions in the evaluation methods or the monitoring plan;

4) A comparison of actual expenses to the budget projections and time frames in the application;

5) A projection of methods and time frames involved to accomplish the pending objectives within the time frame remaining (except for the end of the project summary report); and

6) A summary at the close of the project period of the achievements and ultimate conclusions derived as a result of the project.

d) The Department and one or more members of the Panel will review reports submitted by grantees.

e) Grantees shall be subject to periodic on-site inspections by IRMI representatives.

f) IRMI may request an oral presentation to clarify the status or the end of project report for the benefit of the peer review panel or other formally recognized audiences.

g) Grantees shall establish and maintain the necessary processes to monitor their compliance and that of their employees and contractors; take appropriate action to meet the stated objectives; and inform IRMI of any problems or concerns.

h) Grantees are responsible for the actions of their employees and other research collaborators, including third parties involved in the project.

Section 995.160 Suspension, Termination and Recovery of Grant Awards

a) If a grantee fails to comply with this Part or the terms of the grant agreement, the Department, after notice and opportunity for hearing, shall suspend or revoke the grant or recover any grant funds previously disbursed to the grantee.

b) Hearings will be conducted in accordance with the Department's Rules of Practice and Procedure in Administrative Hearings.

c) Pursuant to the Grant Funds Recovery Act, any grant funds that are misspent or are being improperly held may be recovered by the Department, after notice and opportunity for hearing, or alternatively by the Illinois Attorney General (see Section 995.80).

d) If the Department believes that a grant should be suspended, terminated or recovered due to a grantee's failure to comply with this Part or the terms of the

grant agreement, the grantee shall have the opportunity for at least one informal hearing before the Department or the Department's designee to determine the facts and issues and to resolve any conflicts as amicably as possible before any formal recovery action is taken.

e) If, based on the outcome of the informal hearing, the Department believes that a grant should be suspended, terminated or recovered due to a grantee's failure to comply with this Part or the terms of the grant agreement, then written notice of the proposed action shall be given to the grantee identifying the action to be taken and specific facts that permit the action. The grantee shall have 35 days after the receipt of the notice to request a hearing to show why recovery is not justified or proper.

f) If a grantee requests a hearing pursuant to subsection (d) of this Section, then:

1) The Department shall hold a hearing at which the grantee (or the grantee's representative) is permitted to present evidence and witnesses to show why the action should not be taken; and

2) After the conclusion of the hearing, the Department shall issue a written final order setting forth its findings of fact and decision. A copy of the order shall be sent to the grantee.

g) A grantee may seek judicial review of any final order pursuant to the provisions of the Administrative Review Law.

h) The Department may suspend payment of grants at any time. If a grantee requests a hearing pursuant to subsection (d), the Department may not take any action of recovery until at least 35 days after the Department has issued a final recovery order pursuant to subsection (e). If a grantee does not request a hearing as permitted in subsection (d), the Department may proceed with recovery of the grant funds identified in the notice at any time after the expiration of the 35-day request period established in subsection (e).

i) Any notice or mailing required or permitted by this Part shall be deemed received five days after the notice or mailing is deposited in the United States mail, properly addressed with the grantee's current business address and with sufficient U.S. postage affixed.