

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF ADOPTED RULES

- 1) Heading of the Part: Spinal Cord Injury Paralysis Cure Research Code
- 2) Code Citation: 77 Ill. Adm. Code 570
- 3)

<u>Section Numbers:</u>	<u>Adopted Action:</u>
570.100	New
570.200	New
570.300	New
570.400	New
570.500	New
570.600	New
570.700	New
570.800	New
570.900	New
570.1000	New
570.1100	New
570.1200	New
570.1300	New
- 4) Statutory Authority: Section 6z-49 of the State Finance Act [30 ILCS 105/6z-49]
- 5) Effective Date of Rulemaking: January 20, 2012
- 6) Does this rulemaking contain an automatic repeal date? No
- 7) Does this rulemaking contain incorporations by reference? No
- 8) A copy of the adopted rulemaking, including any material incorporated by reference, is on file in the agency's principal office and is available for public inspection.
- 9) Notice of Proposed Rules Published in Illinois Register: October 7, 2011; 35 Ill. Reg. 15959
- 10) Has JCAR issued a Statement of Objection to this rulemaking? No
- 11) Differences between proposal and final version: No changes were made in response to comments received during the first notice or public comment period. Various typographical, grammatical, and form changes were made in response to the comments from JCAR.

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF ADOPTED RULES

- 12) Have all the changes agreed upon by the agency and JCAR been made as indicated in the agreements issued by JCAR? No agreements were necessary.
- 13) Will this rulemaking replace any emergency rulemaking currently in effect? No
- 14) Are there any amendments pending on this Part? No
- 15) Summary and Purpose of Rulemaking: The rules in Part 570 set forth the requirements for the Illinois Department of Public Health to award grants to medical research facilities located in Illinois to conduct research to find a cure for spinal cord injury paralysis. The rulemaking implements Public Act 91-737, which amended the State Finance Act to authorize the Department of Public Health to use moneys in the Spinal Cord Injury Paralysis Cure Research Trust Fund for this purpose.
- 16) Information and questions regarding this adopted rulemaking shall be directed to:

Susan Meister
Division of Legal Services
Department of Public Health
535 West Jefferson, 5th Floor
Springfield, Illinois 62761

e-mail: dph.rules@illinois.gov

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

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF ADOPTED RULES

TITLE 77: PUBLIC HEALTH
CHAPTER I: DEPARTMENT OF PUBLIC HEALTH
SUBCHAPTER f: EMERGENCY SERVICES AND HIGHWAY SAFETYPART 570
SPINAL CORD INJURY PARALYSIS CURE RESEARCH CODE

Section	
570.100	Definitions
570.200	Referenced Materials
570.300	Eligibility for Grants
570.400	Grant Requirements
570.500	Research Requirements
570.600	Application Requirements
570.700	Review of Applications
570.800	Grant Awards, Terms and Conditions
570.900	Use of Grant Funds
570.1000	Termination of the Grant Agreement
570.1100	Grant Funds Recovery
570.1200	Reporting
570.1300	Administrative Hearings

AUTHORITY: Implementing and authorized by Section 6z-49 of the State Finance Act [30 ILCS 105/6z-49].

SOURCE: Adopted at 36 Ill. Reg. 1736, effective January 20, 2012.

Section 570.100 Definitions

Act – the State Finance Act.

Applicant – an entity that applies for a grant under this Part *to conduct research to find a cure for spinal cord injury paralysis*. (Section 6z-49 of the Act)

Benefits – compensation that is in addition to direct wages or salary, including paid time off, pension, social security and insurance.

Business day – means any day, including Monday through Friday. It does not include a federal or State government declared holiday, Saturday or Sunday.

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF ADOPTED RULES

Calendar day – all days in a month or prescribed time frame. It includes weekends and federal or State government declared holidays.

Certified mail – mail for which proof of delivery is obtained.

Department – the Illinois Department of Public Health.

Director – the Director of the Illinois Department of Public Health.

Equipment cost – the cost of movable equipment, including movable medical equipment, and the cost of making this equipment operational (e.g., installation costs).

Fiscal year – the financial operating year of Illinois State government. It begins on July 1 and ends on June 30 of the next calendar year.

Fund – the Spinal Cord Injury Paralysis Cure Research Trust Fund in the State Treasury.

Grant agreement – the agreement entered into between the Department and any grant recipient for the use of grant funds under this Part.

Grant funds – public funds dispensed by the Department to any person or entity for obligation, expenditure or use for a specific purpose. (Section 2(b) of the Illinois Grant Funds Recovery Act)

Grant recipient – an entity that receives a grant under this Part *to conduct research to find a cure for spinal cord injury paralysis. (Section 6z.49 of the Act)*

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

Nonprofit medical research institution – 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.

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF ADOPTED RULES

Spinal cord paralysis research by nonprofit medical institutions may include, but is not limited to, human, clinical, animal or laboratory research.

Personal services – costs associated with wages and salaries for individuals employed by the grantee.

Principal investigator – the person with primary responsibility for conducting a spinal cord injury paralysis research project.

Supplies – general purpose consumable items that have a shorter life span than equipment and that are stocked for recurring use.

Travel – the cost incurred by a grantee's employee to travel to fulfill specific job requirements. These costs could include, but not be limited to, air travel, local transportation, per diem, mileage allowance and lodging.

Section 570.200 Referenced Materials

The following materials are referenced in this Part:

- a) Illinois Statutes
 - 1) Illinois Grant Funds Recovery Act [30 ILCS 705]
 - 2) State Finance Act [30 ILCS 105]
- b) Illinois Administrative Rules
 - Practice and Procedure in Administrative Hearings (77 Ill. Adm. Code 100)
- c) Federal Statutes
 - 1) Internal Revenue Code (26 USC 501)
 - 2) Health Insurance Portability and Accountability Act of 1996 (42 USC 1320d-2)

Section 570.300 Eligibility for Grants

To be eligible to receive a grant from the Fund, the applicant shall:

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF ADOPTED RULES

- a) Be an Illinois non-profit medical *research* entity with *facilities located in Illinois*, with its principal place of business located in Illinois, and that conducts medical or clinical *research to find a cure for spinal cord injury paralysis*; and
- b) Demonstrate that the moneys from the fund will be used to *conduct research* dedicated to finding *a cure for spinal cord injury paralysis*. (Section 6z-49 of the Act)

Section 570.400 Grant Requirements

- a) Grant recipients shall comply with all applicable provisions of this Part.
- b) Grant recipients shall use the grant award *to conduct research to find a cure for spinal cord injury paralysis*. (Section 6z-49 of the Act)
- c) Grant recipients shall return a signed grant agreement to the Department in the specified time period and shall comply with the provisions of the grant agreement.
- d) All research funded by grants shall be conducted in Illinois.
- e) No grant funds shall be used for facility construction, lobbying, legal or accounting expenses, or utilities.

Section 570.500 Research Requirements

- a) All research shall at all times comply with all applicable federal laws, including, but not limited to, the Health Insurance Portability and Accountability Act. Grantees shall at all times ensure that the personal health information of participants in the research project is protected and kept confidential.
- b) Grantees shall obtain the written informed consent of all research participants.

Section 570.600 Application Requirements

- a) Applications shall be submitted to the Department through the website established for this purpose or at the following address:

Spinal Cord Injury Paralysis Cure Research Trust Fund Grants

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF ADOPTED RULES

Illinois Department of Public Health
Division of Emergency Medical Systems & Highway Safety
422 South 5th Street, 3th Floor
Springfield IL 62701

- b) Faxed and e-mailed applications will not be accepted.
- c) Applications shall be submitted on the form prescribed by the Department and shall include, at a minimum, the following:
 - 1) The legal name of the applicant;
 - 2) The applicant's address, telephone number, fax number, and e-mail address;
 - 3) The applicant's Federal Employer Identification Number (FEIN);
 - 4) The name, title and address of the applicant's corporate officers and key managers;
 - 5) The name, address, e-mail and phone number of the principal investigator and the secondary contact designated by the applicant to be responsible for administering the grant funds;
 - 6) A detailed description of the spinal cord injury paralysis research for which grant funding is requested, including:
 - A) A statement of the research question or hypothesis or a description of interventions or model programs on which the research will be based;
 - B) A prioritized listing of measurable objectives for the research during the time period of the grant;
 - C) Proposed activities for experiments, scientific rationale, and relevant reference to existing works;

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF ADOPTED RULES

- D) The evaluation methods to be used to measure progress in achieving objectives and a plan for monitoring the overall project; and
- E) The written guidelines under which the research will proceed;
- 7) An agreement by the applicant that, if awarded a grant, the grant will be used *to conduct research to find a cure for spinal cord injury paralysis* (Section 6z-49 of the Act);
- 8) The signature of the principal investigator and agency official authorized to certify the application;
- 9) An approximate timetable for research expenditures and completion;
- 10) Background data and information justifying the project;
- 11) A detailed budget for the period of the grant agreement, documenting sufficient resources to carry out the research. The budget shall list the total dollar amount needed for the project, including the amount to be provided by the applicant and other funding sources and the amount of funding requested through the grant. The applicant shall identify all revenue sources and amounts and provide budget estimates, including expenditures for the duration of the project. The budget shall include the following costs (if applicable):
 - A) Personal services, including salaries and hourly compensation for officers, directors, and key employees;
 - B) Benefits;
 - C) Travel;
 - D) Commodities/supplies;
 - E) Equipment costs;
 - F) Contractual services;

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF ADOPTED RULES

- G) Printing;
 - H) Telecommunications;
 - I) Patient/client care; and
 - J) Administrative costs;
- 12) Documentation of approval from the IRB of the project and the written guidelines under which the project will proceed.

Section 570.700 Review of Applications

- a) The grant cycle runs from July 1-June 30.
- b) The Department will review applications for compliance with the requirements of this Part. During the course of its review, the Department may contact the applicant for additional information if the information provided is incomplete, inconsistent or unclear.
- c) Once the Department determines that applications are complete, grant proposals will be forwarded to the Medical Director of the Office of Preparedness and Response for review and oversight of the review process. If needed, the Department may consult an advisory committee of experts in medical or spinal cord paralysis research.
- d) After review by the Office of Preparedness and Response, the Department's Grant Review Committee will review the applications. The Grant Review Committee will review and rank the applications using 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;

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF ADOPTED RULES

- 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 spinal cord injury research project has the greatest potential, based on the information presented in the application, for therapies and cures;
- 10) The research is likely to lead to new therapies, treatments or cures for spinal cord injury paralysis, based on the information presented in the application;
- 11) The research will lead to patents, articles in peer-reviewed journals or additional grant funding;
- 12) The research project will develop or refine the understanding of any ethical, legal or social issues raised by spinal cord injury paralysis research;
- 13) The project proposes novel ideas and approaches to develop the ideas;
- 14) The project proposes spinal cord injury paralysis research that may attract venture capital for biotechnology start-up companies in Illinois;
- 15) The research is likely to accelerate the pace at which basic and preclinical findings are translated into clinical benefits;

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF ADOPTED RULES

- 16) The project proposes collaborative and interdisciplinary research among investigators, whether at the same or different institutions; and
 - 17) Funding the project will increase awareness and understanding of spinal cord injury paralysis research.
- e) Upon completion of the grant review process, the Department will award grants to the applicant or applicants that best meet all of the requirements of the Act and this Part.
 - f) Applicants whom the Department determines not to be eligible for grant funds will be notified in writing of this decision.
 - g) Distribution of grants is dependent on available funding. The amount of the award will be based on the amount requested by the applicant, the recommendation of the Grant Review Committee and the amount available in the Fund for distribution. The amount awarded will not exceed the amount requested by the applicant.
 - 1) The Grant Review Committee will set forth its analyses and recommendations concerning the grant applications, the rank order of the applications, and the amount of the grant, if any. The Committee may approve part of an application and recommend partial funding (see Section 570.800)
 - 2) After the Grant Review Committee ranks the applications, the Committee will decide which applications to fund, based on the review criteria 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.
 - h) Applicants shall submit a new application each State fiscal year to be considered for funding. Applications are applicable only to the State fiscal year in which the applications are received, with the exception of multiple year grants.

Section 570.800 Grant Awards, Terms and Conditions

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF ADOPTED RULES

To issue a grant award, the Department and grantee will enter into a grant agreement. This agreement will describe the requirements the grantee must fulfill, based on the goals and objectives in the application, and how the grantee will ensure compliance with all applicable stipulations and conditions.

- a) The Grant Review 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 570.700, should not be funded or should be partially funded; and
 - 4) Whether the requested funding exceeds the described activities of the research project, based on the review process in Section 570.700.
- 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 570.700 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) Applicants whom the Department determines not to be eligible for grant funds will be notified in writing of this decision.
- e) The grant agreement will contain, at a minimum, the following:
 - 1) Identifying information of the grantee, including name, mailing address, phone number, fax number and e-mail address;
 - 2) A description of the grant's purpose;

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF ADOPTED RULES

- 3) Information on how quarterly payments to the grantee will be made;
 - 4) A detailed budget of permissible expenditure of grant funds;
 - 5) Reporting requirements applicable to the grant, including the filing of quarterly reports, at a minimum, that describe the project's progress and a detailed report of funds expended, according to the budget;
 - 6) The time period of the grant; and
 - 7) Certification that the grantee will comply with all applicable provisions of the Illinois Grant Funds Recovery Act.
- f) Grant funds that the grantee does not expend or obligate by the end of the grant agreement shall be returned to the Department within 45 calendar days (see Section 4(b)(5) of the Illinois Grant Funds Recovery Act). The 45-calendar-day time frame begins the day after the grant agreement expires. Returned funds will be deposited into the fund from which the original grant disbursement to the grantee was made.
- g) Grantees are required to keep complete and accurate accounting records of all grant funds received from the Department.
- h) If a grantee dispenses part or all of the grant funds to another person or entity for obligation or expenditure, those dispensed funds shall be viewed and treated as grant funds. Thus, the person or entity that receives the grant funds from the grantee will be subject to all applicable Sections of this Part (see Section 12 of the Illinois Grant Funds Recovery Act).

Section 570.900 Use of Grant Funds

- a) The entire amount of the grant award shall be used for *research to find a cure for spinal cord injury paralysis* as set forth in the grant agreement and budget. (Section 6z-49 of the Act)
- b) Any research facilities located in Illinois applying for the grant under this Part shall not receive more than one grant from the Fund each fiscal year.

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF ADOPTED RULES

- c) The grantee shall assure that the investigators fulfill the grant requirements and the requirements for the fiscal and legal management of a research 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.

Section 570.1000 Termination of the Grant Agreement

The agreement may be terminated immediately without recourse or further payment being required if the General Assembly fails to appropriate or otherwise make available sufficient funds for the award, or if sufficient funds are not available in the Spinal Cord Injury Paralysis Cure Research Trust Fund, a special fund in the State Treasury. A denial or termination due to the General Assembly's failure to appropriate funds is not subject to the notice and hearing requirements of this Part.

Section 570.1100 Grant Funds Recovery

Grants made under this Part are subject to the provisions of the Illinois Grant Funds Recovery Act. If a provision of this Part conflicts with a provision of that Act, then the provision of the Illinois Grant Funds Recovery Act controls.

- 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) If the Department believes that a grant should be suspended, revoked or recovered because of 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.
- c) If, based on the outcome of the informal hearing, the Department believes that a grant should be suspended, revoked or recovered because of a grantee's failure to comply with this Part or the terms of the grant agreement, 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 calendar days after

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF ADOPTED RULES

the receipt of the notice to request a formal hearing (see 77 Ill. Adm. Code 100) to show why the action is not justified or proper.

- d) If a grantee requests a hearing pursuant to subsection (c), the Department shall hold a hearing at which the grantee or the grantee's attorney is permitted to present evidence and witnesses to show why the action should not be taken.
- e) 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.
- f) The Department may suspend payment of grants at any time for failure to comply with Section 570.1200 or in any situation that constitutes a threat to the public health, safety or welfare. Notice of opportunity for hearing will be provided with the notice of suspension. If a grantee requests a hearing pursuant to subsection (c), the Department may not take any action of recovery until at least 35 calendar days after the Department has issued a final recovery order pursuant to subsection (e). If a grantee does not request a hearing, the Department may proceed with recovery of the grant funds identified in the notice at any time after the expiration of the 35 calendar day request period established in subsection (c).
- g) Any notice or mailing required or permitted by this Part shall be deemed received five business days after the notice or mailing is deposited in the U.S. mail, properly addressed with the grantee's current business address and with sufficient U.S. postage affixed.

Section 570.1200 Reporting

Failure of a grantee to comply with the requirements of this Section shall result in the Department's withholding future grant funds to the grantee (see Section 4.1 of the Illinois Grant Funds Recovery Act).

- a) Quarterly Progress Report. Each grantee shall submit (at a minimum) written progress reports to the Department every three months. The reports are due within 10 calendar days after the quarterly reporting period has expired (see Section 4(b)(2) of the Illinois Grant Funds Recovery Act).
- b) The quarterly progress reports and annual reports shall include the following information:

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF ADOPTED RULES

- 1) Current status of the research project;
 - 2) Project components finished and project components yet to be finished;
 - 3) Costs incurred to date and an itemized listing of the total current estimated project costs compared to the approved amounts;
 - 4) Signature of an authorized official of the grantee stating that this is a true and complete report on the project's status; and
 - 5) A detailed report of how grant funds were expended.
- c) Final Report. Grantees shall submit a final report within 60 calendar days after the conclusion of the grant period. The degree to which each objective in the grant proposal has been met shall be fully addressed in this report. The final report shall contain the following information:
- 1) A brief narrative summarizing project accomplishments;
 - 2) A description of any problems that developed and how they were addressed;
 - 3) A listing of all project costs and sources of funds for the grant period.
 - 4) A certification, in the form of a notarized statement signed by an authorized representative of the grantee, attesting that:
 - A) All funds attributed to the grant have been expended;
 - B) The costs reported are the final costs required to complete the research project and there are no additional or associated costs; and
 - C) Funds used for the project were approved by the Department.
 - 5) A grantee's failure to comply with the requirements of this Section will be considered a material breach of the performance required by the grant agreement and shall be the basis to initiate proceedings to recover all grant funds disbursed to the grantee.

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF ADOPTED RULES

Section 570.1300 Administrative Hearings

The Department's rules titled Practice and Procedure in Administrative Hearings apply to proceedings conducted under this Part. Where the terms "license" and "licensing" are used in those rules, the definitions of those terms shall be expanded to include a grant applicant, a grantee awarded funds, and a grant agreement executed under this Part.