

TITLE 183, NEBRASKA ADMINISTRATIVE CODE, CHAPTER 7

NEBRASKA DEPARTMENT OF HEALTH

RULES AND REGULATIONS GOVERNING GRANTS AND CONTRACTS FOR RESEARCH
TO THE UNIVERSITY OF NEBRASKA MEDICAL CENTER AND EPPLEY
INSTITUTE, AND OTHER POSTSECONDARY EDUCATIONAL INSTITUTIONS
HAVING COLLEGES OF MEDICINE

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TITLE 183 - NEBRASKA DEPARTMENT OF HEALTH/FINANCIAL ASSISTANCE/REGULATIONS

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001 SCOPE OF REGULATIONS. These regulations govern grants and contracts for research on cancer and smoking diseases with the University of Nebraska Medical Center and the University of Nebraska Eppley Institute for Research in Cancer and Allied Diseases and other postsecondary institutions having colleges of medicine located in the State of Nebraska to be funded with two cents of the cigarette tax imposed by Neb. Rev. Stat. Section 77-2602. The regulations implement Neb. Rev. Stat. Sections 81-637, 81-638(2)(3), and 81-639 to 81-640.01 by establishing (1) an application process for grants and contracts; (2) criteria for programs in order to receive funding; (3) criteria as to the rates and amounts of funding; and (4) other procedures necessary for the proper administration of the authorizing statutes.

002 DEFINITIONS. As used in these regulations, unless the context otherwise requires:

002.01 Cancer means all malignant neoplasm regardless of the tissue of origin, including malignant lymphoma and leukemia;

002.02 Department means the Nebraska Department of Health;

002.03 Director means the Director of Health;

002.04 Smoking disease means diseases whose causes are linked to smoking including, but not limited to, cardiovascular, pulmonary, and gastrointestinal diseases.

003 ELIGIBLE APPLICANTS. The following institutions are eligible to apply for contracts and grants.

003.01 The University of Nebraska Medical Center and the University of Nebraska Eppley Institute for Research in Cancer and Allied Diseases; and

003.02 Other postsecondary educational institutions having colleges of medicine located in Nebraska which have cancer research programs for the purpose of conducting research in cancer and allied diseases.

004 PROJECT ELIGIBILITY. This section describes the categories and duration of projects which are eligible for funding. Joint projects by eligible applicants are encouraged to the extent practical and feasible in order to maximize the use of funds and strengthen existing cancer research programs and prevent duplication of research efforts.

004.01 The following categories of projects are eligible for funding:

004.01A Core facilities. This category is centralized shared resources and services which are less directly identified with the conduct of individual research projects. Core facilities must be used primarily by peer-reviewed projects which must have priority access to the core facilities. Core facilities cannot support research activities dedicated to one or a few project-specific functions.

Resources and services funded under this category must be closely connected to the conduct of the research. If the resources and services are not closely connected to the conduct of research, they must be highly specialized to the types of research described in the proposal, but such resources and services are eligible for funding only if they are not normally provided by the applicant to departments or other comparable organizational components of the institution.

004.01A1 Examples of resources and services which are closely connected to the conduct of the research include, but are not limited to:

- 004.01A1(a) Centralized shared equipment facilities;
- 004.01A1(b) Biostatistical services;
- 004.01A1(c) General and specialized animal colonies;
- 004.01A1(d) Radiation facilities and services;
- 004.01A1(e) Electron microscope facilities and services;
- 004.01A1(f) Histology and pathology services;
- 004.01A1(g) Cell and tissue culture;
- 004.01A1(h) Media preparation;
- 004.01A1(i) Specialized instrument shops;

004.01A1(j) Glassware washing;

004.01A1(k) Tumor procurement services;

004.01A1(l) Immunology or immunoparameters testing facilities, including monoclonal antibody preparation;

004.01A1(m) Nucleic acid sequencing/synthesis laboratories;

004.01A1(n) Chemical and drug synthesis laboratories;

004.01A1(o) Mass spectrometry laboratories;

004.01A1(p) Protein sequencing;

004.01A1(q) Protein and nucleic acid data bases and modeling;

004.01A1(r) Flow cytometry facilities;

004.01A1(s) Cell analysis facilities;

004.01A1(t) Peptide chemistry and synthesis laboratories;

004.01A1(u) Radioimmunoassay and receptor binder laboratories; and

004.01A1(v) Clinical cancer research data services.

004.01A2 Examples of resources and services which are highly specialized to the types of research described in the application include, but are not limited to:

004.01A2(a) Biosafety services;

004.01A2(b) Specialized research library services; and

004.01A2(c) Photography and illustration services.

004.01B Planning and evaluation. This category may include, but is not limited to, special meetings to identify cancer or smoking disease research opportunities, advisory committee meetings, and meetings to evaluate the effectiveness of the applicant's internal planning and evaluation activities, meetings to plan joint projects by eligible applicants, and institutional peer review.

004.01C Developmental. This category may include but is not limited to:

004.01C1 Recruitment of investigators for research;

004.01C2 Developing new shared resources (existing shared resources and those planned to begin in the first year of the project must be included in the shared resources and services project described in section 004.01A above);

004.01C3 Providing temporary interim support to highly productive and qualified investigators who have lost their peer-reviewed funding temporarily; and

004.01C4 Supporting enhancement of meritorious projects and pilot projects of relatively short duration depending on the nature of the research. Such projects may include laboratory, clinical research, population, behavioral, epidemiological, field, statistical basic, applied or other types of investigations, studies, or experiments, or any combinations of these.

004.02 The following are not eligible for funding.

004.02A Clinical trials (any human subject investigation that involves a drug or device and is conducted at multiple institutions); and

004.02B Projects which are funded under Neb. Rev. Stat. Section 81-638(1).

004.03 Project Duration. Projects may be for up to five years in length. Itemized budgets must be submitted for the overall project period and for each year of the project.

005 PROPOSAL PROCESS

005.01 Due Date. The Department shall give no more than sixty days notice to eligible applicants of the date proposals are due. Proposals shall be submitted no later than 5:00 p.m. on that date.

005.02 The Director of Health shall review each proposal and shall make the final decision for funding no later than 120 days after the application deadline.

005.03 Criteria for review. The Director of Health shall consider the following when awarding grants or contracts for cancer and smoking disease research:

005.03A The relevancy of the applicant's proposal to furthering research of cancer and smoking diseases;

005.03B The feasibility of the applicant's proposal;

005.03C The availability of other sources of funding for the applicant's proposal;

005.03D The facilities, personnel, and expertise available to the applicant for use in the proposal; and

005.03E Evidence of the quality of the applicant's prior or existing programs for research of cancer and smoking diseases or the applicant's potential for developing new programs for such research.

005.04 Proposal Review. The Department shall evaluate the quality and completeness of the proposals which includes the following:

005.04A Department review to determine if required programmatic and fiscal components are described adequately. Additional materials may be requested by the Department.

005.04B An external review process that includes an on-site study panel which is composed of Department staff members and consultants selected by the Department.

005.04B1 Consultants are selected for their expertise and experience on peer and/or institutional review panels.

005.04B2 Consultants are selected from a pool of reviewers based on expertise needed for review of the applicant's research focus.

005.04B3 Consultants shall not have any direct affiliation with the applicants receiving funds from the Department. Consultants shall not have Any direct association with the Department, except in the capacity of reviewer for cancer research grants or contracts.

005.04B4 Applicants may submit names of suggested reviewers for the Department's external review consultants in advance of submission of proposals in order to permit the Department to expedite arrangements. Suggested reviewers should have expertise in medical and scientific research and should meet the criteria described in Subsections 005.04B1 to 005.04B3 above.

006 CONTENT OF PROPOSALS. Applicants shall submit proposals which provide sufficient information to the Department for scientific peer review of the proposals. The proposals must be for categories of projects which are described in Section 004 of these regulations. Proposals must include the following minimum information (Additional materials which the applicant determines will assist in review may be submitted.):

006.01 A proposal signed by an individual authorized by the governing body of the applicant to enter into legally binding obligations on its behalf, and signed by an individual authorized by the applicant to be the principal investigator.

006.02 An abstract. The abstract is intended to summarize only what is requested in the application. It should be no longer than two pages in length. It is not intended to highlight activities related to past accomplishments or activities in cancer or smoking disease related research.

006.03 Detailed table of contents.

006.04 A description of the applicant's cancer and smoking disease research activities, including:

006.04A A brief description of the applicant's facility and of the origin of the applicant's cancer and smoking disease research program, leadership, scientific research capability;

006.04B A description of the established research program which includes the following:

006.04B1 A description of the main scientific thrust of the program and a statement of its overall goals; and

006.04B2 A brief description of major research accomplishments and achievements of the program.

006.05 A description of the overall plan for the entire project period (for up to five years) and the goals the applicant desires to achieve, including a composite budget for the entire project period and summary budgets by program category.

006.06 A description of the organizational structure and management of the cancer and smoking disease research programs within the institution, i.e., lines of authority and accountability for the programs within the institution.

006.07 A description of the internal planning and evaluation process for the cancer research program which includes the following:

006.07A The responsibilities of the internal advisory, decision making and evaluative groups for purposes of planning, evaluation, and operational management of the program (e.g., executive committee, scientific review committee, etc.); and

006.07B Decision-making mechanisms for the cancer research program;

006.07C The process for review, if any, of the proposal by the applicant's external review consultants, including the names and institutional affiliation of the reviewers, method of selection of reviewers; and

006.07D Reports of the applicant's external consultants, if any.

006.08 For each project category as described in Section 004, the applicant must submit the following information:

006.08A A description of the organizational structure and management within the cancer and smoking disease research program, i.e., lines of authority and accountability for the activities within the project category;

006.08B Annual and overall project period budgets which describe itemized amounts for allowable budget items as described in Section 008;

006.08C A description of institutional commitment, including but not limited to, specific resources currently provided by the parent institution, such as facilities, financial support, personnel, equipment, and other forms of support which demonstrate the institution's commitment to the functional stability, continuing development and success of the cancer and smoking disease research program;

006.08D For the core facility category, submit a policy which ensures that the resources and services are used primarily by peer reviewed research projects and that such projects have priority in access to the resources and services; and

006.08E A detailed description of renovations and alterations to facilities which are directly related to the research, including a justification as to the need for the proposed renovations and alterations, and an itemized budget. Indicate the square footage involved giving the basis for the costs, such as an architect's or contractor's detailed estimate.

006.09 Identification of the principal investigator and senior leadership for each project category, together with attached curriculum vitae.

006.10 A list of research projects within the program, including the name and phone number of each project's principal investigator and total annual direct costs of each project.

006.11 The following policies must be adopted and in effect at the institution. The proposal must include an assurance of compliance with these policies.

006.11A Policy and procedures for the protection of human subjects;

006.11B Policy on patents and other intellectual property rights as they pertain to inventions or works resulting from funded research;

006.11C Policy and procedures to ensure the humane care and use of live vertebrate animals in research;

006.11D Policy on scientific misconduct by researchers;

006.11E Policy on biosafety of research facilities;

006.11F Policy on research using DNA and human genomes.

007 PROGRESS REVIEW AND EVALUATION OF RESEARCH GRANTS AND CONTRACTS.

007.01 The Department of Health shall evaluate the quality and progress of research performed after the award of a contract or grant through the following processes:

007.01A A review of the fiscal and progress reports submitted by applicants to the Department as required by subsections 008.05 through 008.07; and

007.01B On-site visits by Department staff members and consultants selected by the Department. On-site visits will be conducted every three to five years, or more frequently if conditions warrant. The Department will select consultants as described in subsection 005.04B.

008 TERMS AND CONDITIONS OF GRANTS OR CONTRACTS. Grants and contracts with eligible applicants are subject to the following terms and conditions. The applicant's proposal, any revisions to it approved by the Department, and the Department's notice of award constitute the grant or contract documents.

008.01 The award of grants and contracts is subject to appropriation by the Legislature and the availability of monies derived from two cents of the cigarette tax imposed by Neb. Rev. Stat. Section 77-2602 sufficient to fund the project. Unexpended balances are subject to the provisions of Neb. Rev. Stat. Section 81-138.01.

008.02 Any money appropriated for such grant or contract shall only be used for cancer and smoking disease research and shall not be used to support any other program in the institution.

008.03 Full and detailed reporting of the expenditure of all funds under the grant or contract is required. The report shall include, but not be limited to, separate accounting for personal services, equipment purchases or leases, and supplies. Such reports shall be made available to the Legislature; and

008.04 No money appropriated for such grant or contract shall be spent for travel, building construction, or any other purpose not directly related to the research that is the subject of the contract.

008.05 The grantee or contractor shall establish a separate account for the fiscal management of funds received and expended.

008.06 The grantee or contractor shall submit quarterly and annual financial reports to the Department of Health.

008.07 The grantee or contractor shall submit an annual progress report to the Department.

008.08 The grantee or contractor shall submit annual reports within ninety days from the end of the budget period and quarterly reports within thirty days of the end of the quarter.

008.09 The grantee or contractor is permitted to rebudget within and between budget categories of the approved annual budget for each project so long as a change in the budget does not change the project as described in the application;

008.10 Grant or contract funds are for the purpose of advancing research in cancer and smoking diseases. The following are allowable and unallowable costs:

008.10A Allowable Costs:

008.10A1 Salaries and fringe benefits of staff investigators, senior project leaders, or other staff directly involved in the research.

008.10A2 Salary for the principal investigator not to exceed 25% of the institutional annual base salary.

008.10A3 Equipment directly linked to the research.

008.10A4 Supplies, such as laboratory supplies and office supplies.

008.10A5 Services, such as dishwashing services, directly related to the research.

008.10A6 Consultants or subcontracts, except that the institution shall not subcontract for all necessary services with a single entity to implement the project.

008.10A7 Patient costs. If justified, charges for blood samples, X-rays, physical examinations, or comparable procedures are allowed for human subjects involved in the research.

008.10A8 Publication costs up to \$15,000 as described below:

008.10A8(a) The paper reports work supported by the grant or contract;

008.10A8(b) The charges are levied impartially on all papers published by the journal whether or not by government sponsored authors.

008.10A8(c) Other publication costs are allowable if the publication reports work supported by the grant or contract and if the costs of publication for the type of publication are routinely borne by the research institution.

008.10A9 Other operating expenses, such as postage, data processing, long distance phone calls required by the nature of the research, photocopying, correspondence, reports, obtaining samples.

008.10A10 Renovations and alterations directly related to the research.

008.10B Unallowable Costs:

008.10B1 Travel expenses.

008.10B2 Indirect costs or overhead expenses, such as rent, general administrative costs.

008.10B3 Building construction.

008.10B4 Direct patient treatment costs or costs of clinical trials.

008.10B5 Any other expenses not directly related to the research.

008.11 The (Contractor) (Grantee) and any of its subcontractors shall not discriminate against any employee or applicant for employment to be employed in the performance of the (contract) (grant) with respect to hire tenure, terms, conditions, or privileges of employment because of the race, color, religion, sex, age, disability or national origin of the employee or applicant.

The (Contractor) (Grantee) assures that it will comply as applicable with the Americans with Disabilities Act of 1990 and its implementing regulations.

008.12 The (Contractor) (Grantee) shall comply with Neb. Rev. Stat. Sections 81-638 to 81-640.01 and these regulations.

008.13 The (Contractor) (Grantee) shall have and maintain a Drug-Free Workplace Policy governing the conduct of its employees.

008.14 All publications supported by funds awarded under Neb. Rev. Stat. Sections 81-638(2)(3) and 81-639 to 640.01 and these regulations must bear an acknowledgment and disclaimer as appropriate, such as:

This publication (journal article, etc.) was supported by revenue from Nebraska cigarette taxes awarded to (name of Grantee or Contractor) by the Nebraska Department of Health. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the State of Nebraska or the Nebraska Department of Health.