

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
NOTICE OF PUBLIC HEARING

October 3, 2018
10:00 a.m. Central Time
Nebraska State Office Building – Lower Level B
301 Centennial Mall South, Lincoln, Nebraska

The purpose of this hearing is to receive comments on the adoption of amendments to and repeal of the following regulations:

The following regulation is proposed for AMENDMENT:

Title 183 NAC 2 - *Rules and Regulations Governing Grants and Contracts for Research of Cancer or Smoking Disease or Both.*

The proposed changes will streamline the regulations, eliminate outdated practices and terminology, and combine the current Chapters 2 and 7 into one chapter of regulation.

The following regulation is proposed for REPEAL in its entirety. Portions of the current Chapter 7 are being included in the proposed amendments to Chapter 2.

Title 183 NAC 7 - *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.*

Authority for these regulations is found in Neb. Rev. Stat. § 81-3117(7).

Interested persons may attend the hearing and provide verbal or written comments or mail, fax or email written comments, no later than the day of the hearing to: DHHS Legal Services, PO Box 95026, Lincoln, NE 68509-5026, (402) 742-2382 or dhhs.regulations@nebraska.gov, respectively.

A copy of the proposed changes is available online at <http://www.sos.ne.gov>, or by contacting DHHS at the mailing address or email above, or by phone at (402) 471-8223. The fiscal impact statement for these proposed changes may be obtained at the office of the Secretary of State, Regulations Division, 1201 N Street, Suite 120, Lincoln, NE 68508, or by calling (402) 471-2385.

Auxiliary aids or reasonable accommodations needed to participate in a hearing can be requested by calling (402) 471-8223. Individuals with hearing impairments may call DHHS at (402) 471-9570 (voice and TDD) or the Nebraska Relay System at 711 or (800) 833-7352 TDD at least 2 weeks prior to the hearing.

FISCAL IMPACT STATEMENT

Agency: Department of Health and Human Services	
Title: 183	Prepared by: Monica Pribil
Chapter: 2 & 7	Date prepared: 1/4/18
Subject: Cancer and Smoking Disease Research Program	Telephone: (402) 471-0925

Type of Fiscal Impact:

Please check all that apply

	State Agency	Political Sub.	Regulated Public
No Fiscal Impact	(<input checked="" type="checkbox"/>)	(<input checked="" type="checkbox"/>)	(<input checked="" type="checkbox"/>)
Increased Costs	(<input type="checkbox"/>)	(<input type="checkbox"/>)	(<input type="checkbox"/>)
Decreased Costs	(<input type="checkbox"/>)	(<input type="checkbox"/>)	(<input type="checkbox"/>)
Increased Revenue	(<input type="checkbox"/>)	(<input type="checkbox"/>)	(<input type="checkbox"/>)
Decreased Revenue	(<input type="checkbox"/>)	(<input type="checkbox"/>)	(<input type="checkbox"/>)
Indeterminable	(<input type="checkbox"/>)	(<input type="checkbox"/>)	(<input type="checkbox"/>)

Provide an Estimated Cost & Description of Impact:

State Agency:

Political Subdivision:

Regulated Public:

If indeterminable, explain why:

TITLE 183 FINANCIAL ASSISTANCE

CHAPTER 2 CANCER AND SMOKING DISEASE RESEARCH PROGRAM

TABLE OF CONTENTS

<u>SECTION</u>	<u>PAGE</u>
<u>001. SCOPE</u>	<u>1</u>
<u>002. DEFINITIONS</u>	<u>1</u>
<u>003. ONE-CENT APPLICATION PROCESS</u>	<u>1</u>
<u>004. ONE-CENT USE OF FUNDS</u>	<u>1</u>
<u>005. ONE-CENT RATE OF FUNDING</u>	<u>2</u>
<u>006. ONE-CENT UNREVIEWED APPLICATIONS</u>	<u>2</u>
<u>007. ONE-CENT ADDITIONAL INFORMATION</u>	<u>2</u>
<u>008. ONE-CENT NOTIFICATION OF FUNDING</u>	<u>2</u>
<u>009. TWO-CENT PROPOSAL PROCESS</u>	<u>2</u>
<u>010. TWO-CENT USE OF FUNDS</u>	<u>2</u>
<u>011. TWO-CENT RATE OF FUNDING</u>	<u>3</u>
<u>012. TWO-CENT UNREVIEWED PROPOSALS</u>	<u>3</u>
<u>013. TWO-CENT ADDITIONAL INFORMATION</u>	<u>3</u>
<u>014. TWO-CENT NOTIFICATION OF FUNDING</u>	<u>3</u>

TITLE 183 FINANCIAL ASSISTANCE

CHAPTER 2 CANCER AND SMOKING DISEASE RESEARCH PROGRAM

001. SCOPE. These regulations govern grants and contracts for cancer and smoking disease research established by Neb. Rev. Stats. §§ 81-637 through 81-640.

002. DEFINITIONS. For the purposes of these regulations, definitions in Neb. Rev. Stats. §§ 81-637 through 81-640 and the following definitions apply:

002.01 ONE-CENT CONTRACTS AND GRANTS. One-cent contracts and grants means contracts and grants awarded by the Department pursuant to Neb. Rev. Stat. § 81-638(1).

002.02 PRINCIPAL INVESTIGATOR. Principal investigator means the person who directs a research project or program and is responsible for the management of the research.

002.03 TWO-CENT CONTRACTS AND GRANTS. Two-cent contracts and grants means contracts and grants awarded by the Department pursuant to Neb. Rev. Stat. § 81-638(2).

003. ONE-CENT APPLICATION PROCESS. Eligible institutions are notified by the Department of a competitive application period during which applications will be accepted.

003.01 APPLICATION FORM. An applicant must complete and submit a Department approved application with all required information for funding consideration.

004. ONE-CENT USE OF FUNDS. Eligible cancer and smoking disease research projects consist of the following investigations, studies, or experiments:

- (1) Laboratory;
- (2) Clinical;
- (3) Population;
- (4) Behavioral;
- (5) Epidemiological;
- (6) Field;
- (7) Statistical;
- (8) Basic; or
- (9) Applied.

004.01 GENERAL. Any funds awarded must be expended solely for the work outlined in the approved research project and cannot be transferred to a non-cancer or non-smoking disease

research related area at the eligible applicant institution.

005. ONE-CENT RATE OF FUNDING. The awarding of funds is contingent upon the appropriation of funding by the Nebraska Legislature.

006. ONE-CENT UNREVIEWED APPLICATIONS. Applications not meeting the criteria described in these regulations, the statutes, and in the Department approved application will be returned without review.

007. ONE-CENT ADDITIONAL INFORMATION. The Department may request additional information prior to awarding funding. Failure to submit the required additional information in the time specified by the Department may result in the application not being funded.

008. ONE-CENT NOTIFICATION OF FUNDING. Award notification will be sent in writing or electronically to the principal investigator and the eligible applicant institution.

008.01 FINAL DECISION. Award decisions are final.

009. TWO-CENT PROPOSAL PROCESS. Eligible applicant institutions are notified by the Department of the proposal acceptance period. Applicant institutions must submit a proposal with all required information for funding consideration.

010. TWO-CENT USE OF FUNDS. The following types of work are eligible for funding:

- (1) Resources and services.
- (2) Planning and evaluation.
- (3) Development.

010.01 RESOURCES AND SERVICES. Resources and services include core facilities that are centralized and shared, such as:

- (A) Centralized equipment facilities, biostatistical services, specialized instrument shops, and laboratories.
- (B) General and specialized animal colonies.
- (C) Radiation, histology, pathology, and tumor procurement services.
- (D) Electron microscope facilities, protein sequencing, and database modeling.
- (E) Flow cytometry and cell analysis facilities.
- (F) Clinical cancer research data services.
- (G) Biosafety services.

010.02 PLANNING AND EVALUATION. Planning and evaluation includes, but is not limited to:

- (A) Identifying research opportunities;
- (B) Advisory committee meetings;
- (C) Institutional peer review;
- (D) Evaluating the effectiveness of efforts; and
- (E) The coordination of research efforts.

010.03 DEVELOPMENT. Development includes, but is not limited to:

- (A) Recruitment of cancer and smoking disease research investigators;

- (B) Providing support to cancer and smoking disease investigators who have temporarily lost their peer-reviewed funding from other sources; and
- (C) Supporting cancer and smoking disease research projects of no more than six years in duration.

010.03(A) RESEARCH PROJECTS. Research projects consist of the following investigations, studies, or experiments:

- (i) Laboratory;
- (ii) Clinical;
- (iii) Population;
- (iv) Behavioral;
- (v) Epidemiological;
- (vi) Field;
- (vii) Statistical;
- (viii) Basic; or
- (ix) Applied.

010.04 GENERAL. Any funds awarded must be expended solely for the work outlined in the award and cannot be transferred to a non-cancer or non-smoking disease research related area at the eligible institution.

011. TWO-CENT RATE OF FUNDING. The awarding of funds is contingent upon the appropriation of adequate funding by the Nebraska Legislature.

012. TWO-CENT UNREVIEWED PROPOSALS. Proposals not meeting the criteria described in these regulations and the statutes will be returned. Such return does not preclude resubmission of a proposal.

013. TWO-CENT ADDITIONAL INFORMATION. The Department may request additional information or materials to complete the review. Failure to submit the required additional information in the time specified by the Department may result in the proposal not being funded.

014. TWO-CENT NOTIFICATION OF FUNDING. Award notification will be sent in writing or electronically to the eligible applicant institution.

014.01 FINAL DECISION. Award decisions are final.

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

CHAPTER 2 — RULES AND REGULATIONS GOVERNING, GRANTS AND CONTRACTS FOR RESEARCH OF CANCER OR SMOKING DISEASE OR BOTH

TABLE OF CONTENTS

<u>SUBJECT</u>	<u>STATUTORY AUTHORITY</u>	<u>CODE SECTION</u>
Application Process For Contract	81-639, 81-640	009
Application Process For Grant	81-639, 81-640	003
Contract Awards	81-640	011
Definitions - Contracts For Research	81-637, 81-640	007
Definitions - Grants For Research	81-637, 81-640	001
Eligible Projects For Contract For Research	81-640	008
Eligible Projects For Grant For Research	81-640	002
Evaluation And Disposition Of Applications For Grant	81-638, 81-639, 81-640	004
Evaluation And Disposition Of Contract Proposals Or Applications	81-638, 81-639, 81-640	010
Research Project Grant Awards	81-640	005
Use Of Contract Funds	81-640	012
Use Of Grant Funds	81-640	006

TITLE 183 — NEBRASKA DEPARTMENT OF HEALTH

CHAPTER 2 — RULES AND REGULATIONS GOVERNING GRANTS AND CONTRACTS
FOR RESEARCH OF CANCER OR SMOKING DISEASE OR BOTH

————— GRANTS FOR RESEARCH

001 DEFINITIONS - GRANTS FOR RESEARCH

001.01 Definitions. As used in these Regulations the following terms shall have the following meanings:

001.01A Cancer shall mean all malignant neoplasms regardless of the tissue of origin, including malignant lymphoma and leukemia.

001.01B Smoking disease shall mean diseases whose causes are linked to smoking including, but not limited to, cardiovascular, pulmonary, and gastrointestinal diseases.

001.01C Director shall mean the Director of Health.

001.01D Department shall mean the Department of Health.

001.01E Act shall mean sections 81-637 to 81-640, Reissue Revised Statutes of Nebraska, 1943.

001.01F Grant shall mean a money payment awarded by the Department of Health to a researcher of cancer or smoking disease, or both, for the purpose of carrying out a project.

001.01G Grantee shall mean the University of Nebraska.

001.01H Principal investigator shall mean a single individual, designated by the grantee in the grant application and approved by the Director, who is responsible for the scientific and technical direction of the project or program.

001.01I Project or program shall mean the particular activity as described in the application approved by the Director or as modified through amendments approved by the Director within the area of research

of cancer or smoking disease which is supported by a grant award issued under these regulations.

002 ELIGIBLE PROJECTS FOR GRANT FOR RESEARCH

002.01 Permissible Activities Within Projects. A project found by the Director to be a research project meeting the criteria for a grant established by these Rules and Regulations in the area of research of cancer or smoking disease, or both, shall be eligible for a grant award. Eligible projects shall consist of laboratory, clinical, population, behavioral, epidemiological, field, statistical, basic, applied or other types of investigations, studies or experiments or combinations thereof and may either be limited to one, or a particular aspect of a problem or subject, or may consist of two or more related problems or subjects for concurrent or consecutive investigation and involving multiple discipline, facilities and resources, providing the project as a whole meets the other standards established by these Regulations.

003 APPLICATION PROCESS FOR GRANT

003.01 Submittal Deadline Notification. The University of Nebraska shall be notified by the Director of a sixty-day period for the acceptance of proposals.

003.02 Notification shall be made by the Director to individuals who have submitted proposals during the two previous years, to the Systems Office of the University, appropriate colleges or departments of the University of Nebraska, and other individuals who indicate their interest.

003.03 Submitting Proposals. To be considered for funding, a grant proposal must be presented to the Director during a period which the Director has designated for accepting grant proposals on 8½ x 11 inch white paper.

003.04 Content of Application. A grant proposal must include the following information at a minimum:

003.04A Must identify the prospective principal researcher and indicate said individual's affiliation with the University of Nebraska.

~~003.04B~~ Must provide a summary of the proposal worded in non-technical language, except where technical terms cannot be avoided to convey intent;

~~003.04C~~ Must provide an itemized list of all proposed expenditures to be made with the grant;

~~003.04D~~ Must demonstrate the relevancy of the proposal to the furthering of cancer and smoking diseases research;

~~003.04E~~ Must demonstrate the feasibility of the applicant's proposal;

~~003.04F~~ Must demonstrate that the facilities, personnel, and expertise necessary to conduct the proposed work are available to the applicant.

~~003.04G~~ Must provide 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; and

~~003.04H~~ Must provide a statement of hypothesis to be tested and an indepth discussion of the methodology to be employed in testing it.

~~003.05 Conduct of Review.~~ The review of proposals shall be completed by the Director and notification concerning awards shall be made within one hundred eighty days of the application deadline.

~~004 EVALUATION AND DISPOSITION OF APPLICATIONS FOR GRANT~~

~~004.01 Evaluation.~~ The Director when making grants to the grantee pursuant to this Act shall consider the following criteria for programs or projects in order to receive funding:

~~004.01A~~ The relevancy of the applicant's proposal to the furthering of research of cancer and smoking diseases;

~~004.01B~~ The feasibility of the applicant's proposal;

~~004.01C~~ The availability of other sources of funding for the applicant's proposal;

~~004.01D~~ The facilities, personnel, and expertise available to the applicant for use in the proposal;

~~004.01E~~ 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; and

~~004.01F That the applicant is the University of Nebraska.~~

005 RESEARCH PROJECT GRANT AWARDS

~~005.01 General.~~ Any funds granted shall be expended solely for the purposes for which the funds were granted in accordance with the approved application and budget, these regulations, and the terms and conditions of the grant award. The awarding of a grant is dependent upon the appropriation of adequate funds by the Legislature.

~~005.02 Notice of Grant Award.~~ The notice of a grant award specifies the length of the project period. The grant will initially be for no more than one year and continuation grant awards will also be for no more than one year at a time. Funding of continuation grants shall be subject to the availability of funds and submission of a continuation grant application, provided that, the proposal meets the applicable criteria.

006 USE OF GRANT FUNDS

~~006.01 General.~~ Grant funds may be utilized for payment of the salaries of personnel participating in the project, but not for the payment of overhead. A progress report, including time and effort as well as other indicator shall be submitted a grantee after the grant has been in effect for a period of six months. If a progress report is not submitted, is submitted late, is incomplete, or indicates a lack of measurable progress, the transmittal of further grant funds may be suspended by the Director until corrective measures have been taken eliminating the deficiencies. Grant funds shall be subject to audit by the Department after the grant has been in effect for a period of six months and for each six months thereafter.

~~006.02 Delegation of Fiscal Responsibility.~~ The grantee may not in whole or in part delegate or transfer to another responsibility for the use or expenditure of grant funds but this does not prohibit or restrict a grantee from subcontracting for specific services. A grantee shall not subcontract for all necessary services with a single entity to implement the project. The grantee may not make any subgrant to or enter into any subcontract with any school or institution of learning not owned or exclusively controlled by the State of Nebraska or a political subdivision thereof.

~~006.03 Changes in Project or Program.~~ The permissible changes by the principal investigator in the approved project or program shall be limited to changes in methodology, approach or other aspects of the project or program to expedite achievement of the project's research objectives, including changes that grow out of the approved project and serve the best scientific strategy, provided that, as thus changed, the project still furthers the research of cancer and smoking diseases. Any other changes constitute a breach of the grant conditions. Any change in objectives of the approved application shall constitute a breach of the grant conditions unless first approved by the Director.

~~CONTRACTS FOR RESEARCH~~

~~007 DEFINITIONS - CONTRACTS FOR RESEARCH~~

~~007.01 Definitions.~~ As used in these Regulations the following terms shall have the following meanings:

~~007.01A Cancer shall mean all malignant neoplasms regardless of the tissue of origin, including malignant lymphoma and leukemia.~~

~~007.01B Smoking disease shall mean diseases whose causes are linked to smoking including, but not be limited to, cardiovascular, pulmonary, and gastrointestinal diseases.~~

~~007.01C Director shall mean the Director of Health.~~

~~007.01D Act shall mean Nebraska Revised Statutes sections 81-637 to 81-640.~~

~~007.01E Contract shall mean an agreement between the Department and the contractor in which in return for consideration of funding, the contractor shall carry out in a specified manner a specified project or program to further the research of cancer and smoking diseases.~~

~~007.01F Request for Proposals shall mean a Departmental solicitation to prospective offerors or contractors, under procedures for negotiated contract, to submit a contract proposal for research of cancer or smoking disease, or both.~~

~~007.01G Contractor shall mean the University of Nebraska or any other postsecondary institution having a college of medicine located in the State of Nebraska.~~

~~007.01H Contract application or proposal shall mean a written offer to enter into a contract for research of cancer or smoking disease, or both submitted to the Director by a contractor and including as a~~

~~minimum a description of the nature, purpose, duration, benefits and cost of the contract project and the methods, personnel and facilities to be utilized in carrying it out, and meeting the other standards specified by these Regulations.~~

~~007.01J Principal investigator shall mean a single individual designated by the contractor in the contract proposal and approved by the Director, who is responsible for the scientific and technical direction of the contract project or program.~~

~~007.01J Contract project or program shall mean the particular activity, as described in the application approved by the Director or as modified through amendments approved by the Director, within the area of research of cancer or smoking disease which is supported by a contract award issued under these Regulations.~~

~~008 ELIGIBLE PROJECTS FOR CONTRACT FOR RESEARCH~~

~~008.01 Permissible Activities Within Projects Eligible projects shall consist of laboratory, clinical, population, behavioral, epidemiological, field, statistical, basic, applied or other types of investigations, studies or experiments or combinations thereof, and may either be limited to one, or a particular aspect of a problem or subject, or may consist of two or more related problems or subjects for concurrent or consecutive investigation and involving multiple disciplines, facilities and resources, providing the project as a whole meets the other standards established by these Regulations.~~

~~009 APPLICATION PROCESS FOR CONTRACT~~

~~009.01 Submittal Deadline Notification. The University of Nebraska or any other postsecondary institution having a college of medicine located in the State of Nebraska shall be notified by the Director of a sixty-day period for the acceptance of proposals.~~

~~009.02 Notification shall be made by the Director to individuals who have submitted proposals during the two previous years, to the Systems Office of the University of Nebraska, appropriate colleges or departments of the University of Nebraska, all other postsecondary institutions having a college of medicine located in the State of Nebraska and appropriate colleges or departments of the same, and other individuals who indicate their interest.~~

~~009.03 Submitting Proposals. To be considered for funding, a contract proposal must be presented to the Director during a period which the Director has designated for accepting contract proposals on 8 1/2 x 11 inch white paper.~~

~~009.04 Content of Application.~~ A contract proposal must include the following information at a minimum:

~~009.04A~~ Must identify the prospective principal researcher and indicate said individual's affiliation with the University of Nebraska or other postsecondary institution having a college of medicine located in the State of Nebraska;

~~009.04B~~ Must provide a summary of the proposal worded in non-technical language, except where technical terms cannot be avoided to convey intent;

~~009.04C~~ Must provide an itemized list of all proposed expenditures to be made with the grant;

~~009.04D~~ Must demonstrate the relevancy of the proposal to the furthering of cancer and smoking diseases research;

~~009.04E~~ Must demonstrate the feasibility of the applicant's proposal;

~~009.04F~~ Must demonstrate that the facilities, personnel, and expertise necessary to conduct the proposed work are available to the applicant;

~~009.04G~~ Must provide 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; and

~~009.04H~~ Must provide a statement of hypothesis to be tested and an indepth discussion of the methodology to be employed in testing it.

~~009.05 Conduct of Review.~~ The review of proposals shall be completed by the Director and notification concerning awards shall be made within one hundred eighty days of the application deadline.

010 EVALUATION AND DISPOSITION OF CONTRACT PROPOSALS OR APPLICATIONS

~~010.01 Evaluation.~~ The Director when awarding contracts to the contractor pursuant to this Act shall consider the following criteria for contract projects or programs in order to receive funding:

~~010.01A~~ The relevancy of the contract proposal to the furthering of research of cancer and smoking diseases;

~~010.01B~~ The feasibility of the contract proposal;

~~010.01C~~ The availability of other sources of funding for the contract proposal;

~~010.01D~~ The facilities, personnel, and expertise available to applicant for use in the contract proposal;

~~010.01E~~ 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; and

~~010.01F~~ That the applicant is the University of Nebraska or any other postsecondary institution having a college of medicine located in the State of Nebraska.

011 CONTRACT AWARDS

~~011.01 General.~~ Any contract funds awarded shall be expended solely for the purposes which the funds were awarded in accordance with the approved contract proposal or application and budget, these Regulations, and the terms and conditions of the contract award. The awarding of a contract is dependent upon the appropriation of adequate funds by the Legislature.

~~011.02 Notice of Contract Award.~~ The notice of contract award specifies the length of the contract project period. The contract award will initially be for no more than one year and continuation contract awards will also be for no more than one year at a time. Funding of continuation contract awards shall be subject to the availability of funds and submission of a continuation contract proposal, provided that, the proposal meets the applicable criteria.

012 USE OF CONTRACT FUNDS

~~012.01 General.~~ Contract funds may be utilized for the payment of the salaries of personnel participating in the contract project, but not for the payment of overhead. A progress report, including time and effort as well as other indicators, shall be submitted by a contractor after the contract has been in effect for a period of six months. If a progress report is not submitted, is submitted late, is incomplete, or indicates a lack of measurable progress, the transmittal of further contract funds may be suspended by the Director until corrective measures have been taken eliminating the deficiencies. Contract funds shall be subject to audit by the Department after the contract has been in effect for a period of six months and for each six months thereafter.

~~012.02 Delegation of Fiscal Responsibility.~~ The contractor may not in whole or in part delegate or transfer to another responsibility for the use or expenditure of contract funds, but this does not prohibit or restrict a contractor from subcontracting for specific services. A contractor shall not subcontract for all necessary services with a single entity to implement

~~the contract project. The contractor may not enter into any subcontract with any school or institution of learning not owned or exclusively controlled by the State of Nebraska or a political subdivision thereof.~~

~~012.03 Changes in Contract Project or Program. The permissible changes by the principal investigator in the approved contract project or program shall be limited to changes in methodology approach or other aspects of the contract project or program to expedite achievement of the contract project's research objectives, including changes that grow out of the approved contract project and serve the best scientific strategy, provided that, as thus changed, the project still furthers the research of cancer and smoking diseases. Any other changes constitute a breach of the contract. Any change in objectives of the approved application shall constitute a breach of the contract unless first approved by the Director.~~

SOURCE: — Nebraska Revised Statutes
Sections 81-637 to 81-640