Cancer and Smoking Disease Research Program

One-Year (LB 506)

Grant Application

2025

Due: January 16, 2024, 11:59 p.m. CT



Application Checklist

In addition to the requirements noted throughout the application, please confirm the following prior to submitting: ☐ Use this year's application, labeled "2024-25 506 Application" in the footer. ☐ The Face Page is filled out completely and correctly. Confirm mailing address, email address and other contact information. Ensure the appropriate boxes are checked throughout. Ensure that all required signatures are included. ☐ Check the math on the budget worksheet and budget justification. o The same amounts must be requested in the line item budgets on both the worksheet and justification. o Provide sufficient detail related to expenditures in the justification. ☐ Include a letter of support from the department chair or supervisor. • Place all letters of support and collaboration AT THE END of Section 1, after the Equipment Attestation Form. ☐ Name the application correctly – including the comma between the LastName and FirstName. LastName, FirstName of Principal Investigator – LB506 – 2025 Example: Smith, Mary – LB506 – 2025 ☐ If an Appendix is included, provide a table of contents. Ensure the Appendix is named correctly: LastName, FirstName of Principal Investigator – Appendix Example: Smith, Mary – Appendix

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Application Form	<u>Fillable Word Form</u>

Introduction

The Nebraska Cancer and Smoking Disease Research Program was created by the Nebraska Legislature in 1981, when one-cent (1¢) of the tax per pack of cigarettes sold in the state was designated to fund the program.

A portion of the revenue generated from the tax also funds the University of Nebraska Eppley Institute for Research in Cancer and Allied Diseases and the Cancer Registry at the Nebraska Department of Health & Human Services.

The remainder is awarded to all campuses of the University of Nebraska and Creighton University which compete annually for the funds.

Nebraska Department of Health and Human Services Cancer and Smoking Disease Research Program Grant Application: Timeline

Fiscal Year 2025

Public Announcement of Application/ Application is Available	November 9, 2023
Applications Due to DHHS	January 16, 2024, 11:59 p.m. CT
Review Committee Convenes	April 2024
Certifications for Human Subjects, Animals and Recombinant DNA Due to DHHS	April 29, 2024
Award Notification	June 1, 2024
Funding Period Begins	July 1, 2024
First Quarter Fiscal Report Due	October 30, 2024
Second Quarter Fiscal Report Due	January 31, 2025
Third Quarter Fiscal Report Due	April 30, 2025
Funding Period Ends	June 30, 2025
Program Report Due	September 30, 2025
Fourth Quarter Fiscal Report Due	September 30, 2025

Nebraska Department of Health and Human Services Cancer and Smoking Disease Research Program Grant Application: General Instructions

Fiscal Year 2025

Applications will be accepted by the Nebraska Department of Health and Human Services (DHHS) between November 9, 2023, and January 16, 2024. The application is available on the Nebraska Department of Health and Human Services website or by contacting program staff via email at DHHS.CancerAndSmokingResearch@nebraska.gov.

Applications must be received by 11:59 p.m. (CT) on January 16, 2024 – NO EXCEPTIONS.

- Check the accuracy of the application and ensure it is complete prior to submitting.
- Absolutely no revisions will be accepted once submitted.

Applications are initially screened by DHHS staff to ensure compliance with legislative intent and application requirements.

To help determine legislative intent, <u>a clear statement of the project's relevancy to cancer or</u> smoking disease must be included in the abstract.

Applications found to be consistent with legislative intent will be referred to the Nebraska Cancer and Smoking Disease Research Program Review Committee. Applications not meeting the intent of the legislation will be excluded from further consideration and will be returned without review.

The Review Committee is composed of scientists and physicians who are not affiliated with Nebraska universities. Review committee member names and affiliations are available upon request to DHHS after the review is completed.

The review is based upon the following criteria specified in Neb. Rev. Stat. § 81-639:

- 1) The relevancy of the applicant's proposal to the furthering of research of cancer and smoking diseases;
- 2) The feasibility of the applicant's proposal;
- 3) The availability of other sources of funding for the applicant's proposal;
- 4) The facilities, personnel and expertise available to the applicant for use in the proposal; and
- 5) 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.

Other factors also considered in the review are:

- Is the Principal Investigator (PI) level of effort adequate to support the project?
- Is the PI a senior, or first author, on a peer-reviewed publication relevant to the project?

The Review Committee assesses the scientific merit of each proposal and assigns an NIH (National Institutes of Health) score to applications considered competitive for funding.

Based on the scores; the statutory criteria; and adherence to the criteria noted in this application, DHHS determines the research projects to be funded. DHHS will notify applicants by June 1, 2024, as to their funding status. Funding begins on July 1, 2024. All decisions are contingent upon continued funding by the Nebraska Legislature. Award decisions are final.

Research projects must be completed within one year.

- Projects with a budget of up to \$65,000 will be considered.
- Applications that focus on innovative, new research that could support future applications for external peer-reviewed funding are preferred.
- Research projects are not eligible for renewal.

Revised Applications (Those submitted previously, but not funded.)

In an introduction, <u>not to exceed one (1) page</u>, summarize any substantial changes that have been made. Include responses to weaknesses noted on the previous application review. Highlight the changes within the text of the Research Plan by appropriate bracketing or italicizing. Incorporate in the Preliminary Results section of the Research Plan any work done since the previous application was submitted. **An application can be revised a maximum of two times.** A revised application will not be considered for funding if substantial revisions are not clearly indicated.

Approvals for Use of Human Subjects, Animals and/or Recombinant DNA.

As appropriate, the following certifications must be provided prior to funding:

- ✓ Human Subjects
- ✓ Vertebrate Animals
- ✓ Recombinant DNA

The certifications are noted by checking the appropriate boxes on the application's **Face Page**. They are verified by the signature of the **Official Signing for Applicant Organization**on the **Face Page** of the application.

Nebraska Department of Health & Human Services Cancer and Smoking Disease Research Program Grant Application: Specific Instructions

Fiscal Year 2025

Section 1. General Information

Submission

Follow the instructions carefully. To be considered for funding applications must:

- 1. Use the application form provided on the DHHS website.
- **2.** Be titled as follows:
 - "LastName, FirstName of Principal Investigator LB506 2025"
- **3.** Contain required signatures and any required letters.

When complete, email the application as a PDF document to: DHHS.CancerAndSmokingResearch@nebraska.gov, by 11:59 p.m. (CT) on January 16, 2024.

See Section 3 for instructions on submitting an Appendix – if included.

- All pages must be 8 ½" x 11", portrait orientation.
- Do not exceed the page limits noted throughout the application.
- Font size, type style and margins: Arial/Helvetica, 11 point.
- A smaller LEGIBLE font size can ONLY be used for figures, charts, tables and footnotes.
- One-inch margins all-around.
- Ensure all pages are numbered.

Applications will be returned without review if page limits are exceeded, <u>or</u> the font is not legible, <u>or</u> pages are not numbered.

Review the application for accuracy and completeness before submitting, as no revisions will be accepted once submitted.

An application will be returned without review if it fails to follow the instructions noted in this application or if the material submitted is insufficient for an adequate review.

Only one application per Principal Investigator may be submitted.

Application Face Page

- **1. Title of Project**. Choose a title that is descriptive of the research to be conducted. *Do not exceed 81 characters including spaces and punctuation.*
 - **a. NEW** applications must have a different title from any other research project previously funded by the Nebraska Cancer and Smoking Disease Research Program with the same Principal Investigator.
 - **b. REVISED** applications generally have the same title. However, if the specific aims of the revised application have changed significantly, choose a new title.
- **2. Principal Investigator Name**. Name the person responsible to the applicant organization for the research project.
 - **2a.** Degree(s). Indicate academic and professional degrees.
 - **2b. Position Title**. If the Principal Investigator has more than one title, indicate the one most relevant to the research project.
 - **2c.** Mailing Address. Self-explanatory.
 - **2d. Department, Service, Laboratory or Equivalent**. Indicate the organizational affiliation.
 - **2e. Major Subdivision**. Indicate the school, college or other major subdivision.
 - **2f. PI Contact Information.** Include area code and any extension numbers and the institutional email address.
 - **2g. New Application, Revised Application**. Check the appropriate box. If the application replaces a prior unfunded version, indicate the number of the prior application.
- 3. Human Subjects. If activities involving human subjects are not planned at any time during the project period, check "NO." If activities involving human subjects whether or not exempt from Institutional Review Board (IRB) regulations for the protection of human subjects are planned at any time during the project period, check "YES." Insert the date of approval by the applicant organization's IRB. If the activities are designated to be exempt from the regulations, insert the date the exemption was approved by the applicant organization's IRB.
- **4. Vertebrate Animals.** If activities involving vertebrate animals are not planned at any time during the project period, check "NO." If activities involving vertebrate animals are planned at any time during the project period, check "YES." Insert the date of approval or exemption by the applicant organization's review board for the humane treatment and use of vertebrate animals.

5. Recombinant DNA. If activities involving recombinant DNA are not planned at any time during the project period, check "NO." If activities involving recombinant DNA are planned at any time during the project period, check "YES." Insert the date of approval or exemption by the applicant organization's review board for biosafety.

Important:

Certifications are best secured prior to submitting the application. If certifications are unavoidably delayed beyond submission, enter "pending" at Numbers 3, 4 and/or 5. The follow-up certification of approval must be received by DHHS no later than April 29, 2024. The follow-up certification must include: the title of the research project, name of the Principal Investigator and institution and date of the review board approval or exemption.

Any modifications in the Research Plan section of the application required by any review board must be submitted with the follow-up certification.

It is the responsibility of the applicant organization or Principal Investigator to submit the follow-up certification by – or before – the April 29, 2024, due date. If the timing of a review board meeting prevents meeting the deadline, DHHS must be informed beforehand. In all cases, if an application is awarded funding, the required certification(s) for that application must be submitted to DHHS prior to initiating a contract with the applicant organization.

- **6. Total Direct Costs for Entire Proposed Project.** Enter the total direct costs from the budget worksheet, Application Page 4.
- 7. Administrative Official to be Notified if an Award is Made. Self-explanatory.
- **8.** Name of Official Signing for Applicant Organization. Name an individual authorized to act on behalf of the applicant organization and to assume the obligations imposed by the requirements and conditions for any grant.
- **9. Principal Investigator Assurance**. Self-explanatory.
- 10. Applicant Organization Certification and Acceptance. Self-explanatory.

Application: Page 1

Table of Contents. Self-explanatory.

Application: Page 2

Abstract. Self-explanatory.

Application: Page 3

Key Personnel. Individuals who contribute in a substantial way to the scientific development or execution of the research project, whether or not salaries are requested.

Pls must be independent investigators with an appropriate faculty appointment, their own adequately assigned laboratory space and the ability to apply for federal grants as a Pl.

PIs must provide a letter of support from their department chair or supervisor confirming:

- 1. Their faculty level appointment;
- 2. The amount of laboratory space assigned to them; and
- 3. Their eligibility to apply for federal grants.

Include consultants only when their level of involvement meets the description noted above. Individuals providing technical services are not considered key personnel.

For each individual, list: name, organization and role on project. Under role on project, indicate how the individual will function with regard to the proposed project, for example, Principal Investigator, Co-Principal Investigator, etc.

Biographical sketches are required for all individuals listed as key personnel.

Application: Pages 4 & 5

Budget Worksheet. List only the direct costs requested for this application. Direct costs are those that can be identified specifically within a particular line item. Indirect costs or overhead costs are not allowed.

The budget worksheet on Application Page 4 must be completed for each application. The budget justification (Application Page 5) must include sufficient detail on the proposed costs. The maximum budget is **\$65,000**.

Applications without a Budget Worksheet and a Budget Justification will be considered incomplete and will not be reviewed.

Personnel. Personnel costs include salaries and associated fringe benefits paid for services rendered to the research project. Personnel costs are determined by the amount of time and effort to be devoted to the project by each individual involved. **Salary support for the Principal Investigator or other faculty on full-time appointments is not allowed.**

List the names, roles and percent of effort for each person involved with the research project. Begin with the PI, followed by (1) key and (2) support personnel. Salary and fringe benefits information is only needed for those funded by the application.

Type of Appointment. Full-time (2,080 hours annually), appointments are assumed. If an appointment is less than full-time (e.g., $\frac{1}{2}$ or $\frac{3}{4}$ time), enter an asterisk (*) after the number of months and provide an explanation in the Budget Justification.

Percent of Effort on Project. Indicate the percent of effort for each position listed. Ensure that the PI effort is adequate to support the project.

Institutional Base Salary. Institutional base salary is defined as the annual compensation that the applicant organization pays for the individual's appointment. Base salary excludes any income that an individual earns outside of duties to the applicant organization. Base salary **cannot** be increased as a result of replacing institutional salary funds with grant funds.

Salary. Enter the annual salary for each position for which funds are requested. The salary requested is calculated by multiplying the individual's base salary, defined above, by the percent of effort on the project.

Fringe Benefits. Fringe benefits may be requested in accordance with the existing rate established by the applicant organization. Note the existing rate in the Budget Justification.

Totals. Calculate the totals for each position and enter the **subtotals** in each column where indicated.

Consultant Costs. Whether or not costs are involved, indicate in the Budget Justification the names and organizational affiliations for any consultants who have agreed to serve in that capacity. Consultant costs are not allowed for full-time faculty or researchers at the same institution as the Principal Investigator. Describe in the Budget Justification the services to be performed; including the number of consultation days, the expected rate of compensation, travel, per diem and any other related costs.

Equipment. Although equipment costs are generally unallowable, there may be exceptions for scientific equipment if sufficient detail is provided in the Budget Justification. Each tangible equipment item must be identified and have a cost assigned. **The purchase of office equipment – including, but not limited to, computers and printers – is not allowed**.

Supplies. Laboratory and office supplies that are needed to conduct the project are allowed. Detail expenditures in the Budget Justification. If animals are involved in the research project, state the species and explain in the Budget Justification why this type of animal is necessary.

Travel. Only travel expenses incurred for collecting, receiving or delivering samples are allowed. Indicate in the Budget Justification, the purpose of any travel, including the number of trips involved, the destinations and the number of individuals for whom funds are requested. When applicable, note the institutional mileage reimbursement rate in the Budget Justification. **Travel expenses to attend national, international, professional research or educational conferences are not allowed.**

Patient Costs. Costs specifically required to conduct the research – which will **not** continue after the research project ends – are allowed. Patient costs **cannot** include travel, lodging or subsistence. **Usual and customary treatment costs are not allowed.** Patient costs must be thoroughly explained in the Budget Justification.

Contractual or Third-Party. Contractual or third-party costs include personnel, supplies and any other allowable expense, for the independent conduct of a portion of the work described in the Research Plan. Contractual or third-party costs must be thoroughly explained in the Budget Justification. **Subcontracting for all necessary services with a single entity to implement the research project is not allowed. Indirect costs are not allowed.**

Other Expenses. Other expenses include postage, data processing and other operating expenses not previously captured. Costs are only allowable if they are incurred for the direct benefit of the research project. The cost of publishing the research findings in a scientific journal are allowable up to \$1,000. Other expenses must be thoroughly explained in the Budget Justification. If core services are utilized, note the number of hours and cost per hour for each core service in the Budget Justification. Telephone and cell phone costs are not allowed. Indirect or overhead costs, such as rent and utilities, are not allowed.

Budget Justification. Follow the instructions for each budget category described above. List budget categories in the same order as on the Budget Worksheet (Application Page 4) and do not change the category names. Describe the specific functions of personnel, collaborators and consultants. Explain and justify all equipment, supplies, travel, patient costs, contractual/third-party and other expenses as indicated.

Application: Page 6

Biographical Sketch. Provide biographical sketches for all **key personnel** listed on Application Page 3. **Do not exceed two pages (Application Page 6 and one additional page) for each biographical sketch**. Place the PI biographical sketch first, followed by the sketches for the remaining key personnel.

Application: Page 7

Other Support. Other support is defined as all financial resources (federal, non-federal, commercial or institutional) available in direct support of the Principal Investigator's research activities, including – but not limited to – research grants, cooperative agreements, contracts and/or institutional awards. Active and pending other support must be indicated.

Other Support information is required for the Principal Investigator only.

If the Principal Investigator has no active or pending support, indicate "None." The application under consideration is not considered other support.

If the support is provided under a consortium/subcontract arrangement or is part of a multiproject award, indicate the project number, Principal Investigator and source for the overall project.

Project Number: If applicable, include a code or identifier for the project.

Source: Name the entity that is providing the support.

Abstract: Include a link to the abstract for each active and pending project, subproject or subcontract.

Dates of Approved/Proposed Project. Indicate the inclusive dates of the project as approved/proposed. For example, in the case of NIH support, provide the dates of the approved/proposed competitive segment.

Annual Direct Costs. In the case of an active project, provide the current year's direct cost budget. For a pending project, provide the proposed direct cost budget for the initial budget period.

Percent of Effort. For an active project, provide the percent of effort (even if unsalaried) as approved for the current budget period. For a pending project, indicate the percent of effort as proposed for the initial budget period.

Overlap. After listing all support, summarize any potential overlap with the active or pending projects and this application in terms of science, budget or commitment. Any necessary resolution of overlap will occur in conjunction with the applicant institution and DHHS prior to funding. If unable to be resolved, the research project will not be funded.

Overlap is defined as:

Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salary) are requested but are already funded or provided for by another source.

Commitment overlap occurs when the Principal Investigator has time commitments exceeding 100 percent. This is the case whether or not a grant includes salary support.

Scientific overlap occurs when:

 substantially the same research is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration; or 2. a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more applications or awards, regardless of the funding source.

Application: Page 8

Certificate of Non-Acceptance of Tobacco Funds. Ensure the certificate is signed by the PI and all fields are correctly populated.

Application: Page 9

Equipment Attestation Form. Ensure the form is signed by the PI and all fields are correctly populated.

Application: Page 10 and more as applicable

Letters of Support and Collaboration.

- 1. Letter of support from the PI's chair or supervisor as described on page 8.
 - a. A PI cannot sign their own letter of support.
- 2. If proposed work relies on collaboration with other researchers at other institutions or companies, and the individuals are not listed as key personnel on application page 3, include letters of collaboration as appropriate.

Letters of support and collaboration must be legible, but do not need to meet the margin and font requirements noted on page 5.

Section 2. Research Plan

Include sufficient information in Section 2 to facilitate an effective review without reference to any previous application. Be specific and avoid redundancies.

- A. Introduction (Revised Applications ONLY)
- **B.** Specific Aims
- **C.** Significance
- **D.** Preliminary Results
- E. Experimental Approach (Research Design and Methods)
- F. Literature Citations

An introduction is required for revised applications only.

- Do not exceed one page for the introduction.
- The one-page introduction does not count towards the five-page limit for the Research Plan.
- Summarize any substantial changes that have been made.
- The introduction must include responses to weaknesses noted on the previous application review.
- Highlight the changes within the text of the Research Plan by bracketing or italicizing.
- Incorporate in the Preliminary Results section any work done since the previous application was submitted.

A revised application will be returned without review if it does not address weaknesses noted on the previous application review and/or an introduction is not included and/or substantial revisions are not clearly indicated.

Do not exceed the five-page limit for Sections B – E. All tables, graphs and photographs must be included within the five-page limit. Full-sized versions of photographs, tables and/or graphs can be included in the Appendix for clarity. **The five-page limit will be strictly enforced. Applications that exceed the page limit or the font size restrictions, will be returned without review.**

Organize the Research Plan as follows:

- **B. Specific Aims**. State the broad, long-term objectives and describe concisely and realistically what the research project intends to accomplish. Include any hypothesis to be tested.
- **C. Significance**. Provide a brief sketch of the project's background, critically evaluate existing knowledge and identify the gaps which the research is intended to fill. State the importance of the research project by relating the specific aims to the broad, long-term objectives.

The titles and complete references to appropriate publications and manuscripts **accepted** for publication can be included in the Appendix.

- **D. Preliminary Results** not required, but if included, describe briefly.
- E. Experimental Approach (Research Design and Methods):
 - Outline the research design and how the specific aims of the project will be accomplished.
 - Describe how the data will be collected, analyzed and interpreted.
 - Note any new methodology and its advantage over existing methodologies.
 - Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims.
 - Provide a tentative sequence of events for the project. Point out any
 procedures, situations or materials that might be hazardous to personnel and
 the precautions to be exercised.
- **F.** Literature Citations. List relevant and current literature citations at the end of the Research Plan. Each literature citation must include the title of the article, the names of all authors, the name of the book or journal, volume number, page numbers and year of publication. **Do not exceed four (4) pages.**

Section 3. Appendix

Combine all Appendix material into one (1) PDF document – separate from the application – attached to the email submitting the application.

Title the PDF document using the following format: "LastName, FirstName of Principal Investigator – Appendix".

At the beginning, provide an Appendix table of contents, listing in order the items included.

The Appendix:

- Is limited to five (5) items.
- Cannot be used to circumvent the five-page limit of the Research Plan.
- Can include publications or other printed materials documenting preliminary studies.
- Does not require page numbering.