Cancer and Smoking Disease Research Program -

One-Year (LB 506) -

Grant Application -

2020 -

Due: January 7, 2019, 11:59 p.m. CT
Application Checklist

In addition to the requirements noted throughout the application, please confirm the following prior to submitting:

☐ The Face Page is filled out completely and correctly.
  ○ Confirm mailing address and other contact information.
  ○ Ensure all appropriate boxes in 2g. are checked.
  ○ Ensure that all required signatures are included.

☐ Check the math on the budget worksheet and budget justification.
  ○ Correct any errors.
  ○ Provide more detail related to expenditures in the justification.

☐ Include a letter of support from the department chair or supervisor.
  ○ Place all letters of support AT THE END of Section 1, after the Certification of Non-Acceptance of Tobacco Funds.

☐ Name the application correctly.
  ○ LastName, FirstName of Principal Investigator – LB506 – 2020
    Example: Smith, Mary – LB506 – 2020

☐ 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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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 2020 -

Public Announcement of Application ..........................November 5, 2018 -

Application is Available ...........................................November 5, 2018 -

Applications Due to DHHS ...........................................January 7, 2019, 11:59 p.m. CT -

Certifications for Human Subjects, Animals and -
Recombinant DNA Due to DHHS ..................................April 30, 2019 -

Review Panels Convene .........................................March/April 2019 -

Award Notification ....................................................June 1, 2019 -

Contracts with Universities Completed ......................June 30, 2019 -

Funding Period Begins ..............................................July 1, 2019 -

Six-Month Progress and Fiscal Reports Due ...............January 31, 2020 -

Funding Period Ends ..................................................June 30, 2020 -

Final Progress and Fiscal Reports Due .........................September 30, 2020 -
Applications for Fiscal Year 2020 Cancer and Smoking Disease Research Grant funding will be accepted by the Nebraska Department of Health and Human Services (DHHS) between November 5, 2018 and January 7, 2019. 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 Monday, January 7, 2019 – NO EXCEPTIONS.

- Check the accuracy of the application and ensure it is complete prior to submitting.
- Absolutely no substitutions or additions will be accepted after the application due date.

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

To help determine legislative intent, a clear statement of the project’s relevancy to cancer or 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 Technical or Behavioral Review Committees. Applications not meeting the intent of the legislation will be excluded from further consideration and will be returned without review.

The Review Committees are 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.
The Review Committees assess the scientific merit of each proposal and assign an NIH (National Institutes of Health) score to each application considered competitive for funding.

Based on the Review Committees’ scores and the statutory criteria, DHHS staff make recommendations to the Director regarding the research projects to be funded. The Director has the final decision-making authority for determining which projects will be funded. DHHS will notify applicants by June 1, 2019, as to which research projects will be funded in FY 2020. Funding begins on July 1, 2019. All decisions are contingent upon continued funding by the Nebraska Legislature.

Only applications for pilot projects that can be completed within one year will be considered.

Applications proposing one-year projects with a budget of up to $50,000 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, not to exceed one (1) page, summarize any substantial additions, deletions and changes that have been made. Include responses to weaknesses noted on the previous application review form. Highlight the changes within the text of the Research Plan by appropriate bracketing, indenting, or changing typeface. 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.

Changes in Principal Investigators will be reviewed on a case-by-case basis.

A change in the Principal Investigator after an application has been reviewed and approved for funding will not be approved without a thorough review of the qualifications of the new Principal Investigator.

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

Each application requires that the following certifications be provided, as appropriate:

- 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.
Submission
Follow the instructions carefully. To be considered for funding, technical (biomedical) applications and behavioral science (psychology, psychobiology, etc.) applications must:

1. Use the application form provided on the DHHS website.
2. Be titled as follows: “LastName, FirstName of Principal Investigator – LB506 – 2020”
3. Contain required signatures and any required letters.

When complete, email the application as a PDF document to: DHHS.CancerAndSmokingResearch@nebraska.gov, by the 11:59 p.m. (CT) deadline on Monday, January 7, 2019.

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

- All pages must be on 8 ½” x 11” paper, portrait orientation.
- Do not exceed the page limits noted throughout the application.
- Font size, type style and margins: no smaller than 12 point, Times New Roman or Arial/Helvetica, one inch page margins all-around.
- A smaller – LEGIBLE – font size can be used for figures, charts, tables and footnotes.

Applications will be returned without review if page limits are exceeded or the font sizes are too small to be legible.

Review the application for accuracy and completeness before submitting, as no substitutions or additions will be accepted after the application due date. An application will be considered incomplete and returned if it fails to follow the instructions or if the material presented is insufficient to permit 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 character spaces – including spaces and punctuation.
   a. - **NEW** applications must have a different title from any other research project 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 (PI) Name.** Name the person responsible to the applicant organization for the specific and technical direction of 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, such as medical, dental, engineering, graduate, nursing or public health.
   2f. **PI Contact Information.** Include area code and any extensions.
   2g. **Technical Application, Behavioral Application, New Application, Revised Application.** Check the appropriate boxes. If the application replaces a prior unfunded version, insert the number of the prior application. **Note:** an application is either a technical or a behavioral project – it cannot be both.

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 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 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. Do not enter dates into the future or the date the application is submitted. **The follow-up certification of approval must be received by DHHS on April 30, 2019.** 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 the April 30, 2019 due date.** If the timing of review board meetings prevent 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 3.

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 for the applicant organization and to assume the obligations imposed by the requirements and conditions for any grant.

9. **Principal Investigator Assurance.** Self-explanatory.


**Application: Page 1 -**

**Table of Contents.** Self-explanatory. -
Application: Page 2

Abstract. Self-explanatory.

Key Personnel. Defined as – and limited to – individuals who contribute in a substantial way to the scientific development or execution of the research project, whether or not salaries are requested.

The PI must be an independent investigator with an appropriate faculty appointment, adequately assigned laboratory space and the ability to apply for federal grants as a PI.

PIs must provide a statement or letter from their Chairperson confirming their faculty level appointment, the amount of research space available to them and their eligibility to apply for federal grants.

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

For each individual, list: name, organization and role on the project. Under role on the project, indicate how the individual will function with regard to the proposed project, for example, Principal Investigator, graduate research assistance, etc. Use additional pages as necessary.

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

Application: Page 3

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 3 must be completed for each application. The budget justification (Application Page 4) must provide greater detail than the budget worksheet to ascertain how costs will be allocated. The maximum budget is $50,000.

Applications which fail to include a budget worksheet and 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.
**Column 1: Type of Appointment.** Full-time (2,080 hours annually) appointments are assumed. If an appointment is less than full-time (e.g., ½ or ¾ time), enter an asterisk (*) after the number of months and provide a full explanation in the Budget Justification.

**Column 2: Percent of Effort on Project.** Indicate the percent of each appointment at the applicant organization to be devoted to this research project.

**Column 3: 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 dollar amounts for each position for which funds are requested. The maximum salary to be 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.

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

**Consultant Costs.** Whether or not costs are involved, provide 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. Briefly 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 thorough detail is provided in the Budget Justification. Each 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 carry-out 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. **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 conclusion of the research project – 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. **It is not allowable to subcontract for all necessary services with a single entity to implement the research project. 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 an approved 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. Telephone and cellphone costs are not allowed. **Indirect or overhead costs, such as rent and utilities, are not allowed.**

**Application: Page 4**

**Budget Justification.** Follow the instructions for each budget category described above. List budget categories in the same order as on the budget worksheet 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. Provide more detail for all expenses than what is listed on the budget worksheet (Application Page 3).

**Application: Page 5**

**Biographical Sketch.** This section contains the biographical sketches of all **key personnel** listed on Application Page 2. **Do not exceed two pages (Application Page 5 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 6**

**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 endeavors,** 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 to be other support.
If the support is provided under a consortium/subcontract arrangement or is part of a multi-project award, indicate the project number, Principal Investigator and source for the overall project and provide all other information for the subproject only.

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

**Source:** Name the agency, institute, foundation or other organization that is providing the support.

**Major Goals:** Provide a brief statement of the overall objectives of the 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 Effort.** For an active project, provide the level of effort (even if unsalaried) as approved for the current budget period. For a pending project, indicate the level 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 the science, budget or an individual’s committed effort. Any necessary resolution of overlap due to this application being funded will occur in conjunction with the applicant institution and DHHS at the time of award.

Overlap is defined as:

- **Budgetary overlap** occurs when duplicate or equivalent budgetary items (e.g., equipment, salary) are requested in an application 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 the grant includes salary support for the effort.

- **Scientific overlap** occurs when: (1) substantially the same research is proposed in more than one application or is submitted to two or more different 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.
Section 2. Research Plan

Include sufficient information in Section 2 to facilitate an effective review without reference to any previous application. Be specific, informative 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 additions, deletions and changes that have been made. The introduction must include responses to weaknesses noted on the previous application review form. Highlight the changes within the text of the Research Plan by bracketing, indenting or changing typeface. Do not underline or shade changes. 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 form 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 and graphs must be included within the five-page limit. Full-sized photographs can be included in the Appendix, however, a copy of any such photograph must also be included within the Research Plan and within the page limitations. 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 specifically identify the gaps which the research is intended to fill. Concisely 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 listed and 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 investigation. Point out any procedures, situations or materials that might be hazardous to personnel and the precautions to be exercised.

Gender and Minority Inclusion: Applications for research projects that involve human subjects are required to include minorities and both genders in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study. Special emphasis should be placed on the need for inclusion of minorities and women in the study of diseases, disorders and conditions which disproportionately affect them.

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 on the Research Plan.
• Can include publications or other printed materials documenting preliminary studies.
• Does not require page numbering.