NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES

GUIDANCE DOCUMENT

"This guidance document is advisory in nature but is binding on an agency until amended by such agency. A guidance document does not include internal procedural documents that only affect the internal operations of the agency and does not impose additional requirements or penalties on regulated parties or include confidential information or rules and regulations made in accordance with the Nebraska Administrative Procedure Act. If you believe that this guidance document imposes additional requirements or penalties on regulated parties, you may request a review of the document."
Pursuant to

Neb. Rev. Stat. § 84-901.03

Nebraska Department of Health and Human Services Research Policy	
Issue Date: January 10 2020	
Effective Date:	January 10 2020
Signature:	Dannette R. Smith Chief Executive Officer Department of Health and Human Services

I. PURPOSE

This policy provides a process for the submission of research proposals to DHHS; delineates the process and requirements for DHHS review and approval of such requests; and outlines the requirements for research involving DHHS staff and persons served by DHHS.

II. POLICY STATEMENT

The Nebraska Department of Health and Human Services (DHHS) supports research which leads to improved health and human services or increases the body of knowledge about health and human services. However, research must be conducted in a manner that safeguards the health, dignity, general well-being, and privacy rights of DHHS employees and the people the agency serves.

III. RESEARCH REQUESTS AND DATA REQUESTS

A research request falls under this policy if it contains a request for access to DHHS staff, wards, persons committed to DHHS, persons served by DHHS, applicants for services, or any records pertaining to any of these persons for the purpose of conducting research. Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

This policy does not apply to public records requests which are covered by laws relating to requests for access to publicly available information or records. This policy also does not apply to registries maintained by DHHS. Special rules govern the use and release of registry data. Researchers interested in registry data should contact the DHHS Division that maintains the registry.

IV. PRE-PROPOSAL CONTACT WITH DHHS

Researchers are strongly encouraged to contact DHHS representatives to explore their ideas before developing research proposals or incorporating DHHS sites as part of research or grant proposals. DHHS employees cannot make representations or promise the agency will participate in research or endorse a grant proposal for research unless a request has been submitted and approved under this policy.

V. RESEARCH REQUESTS

A. 1. All research requests must be submitted in writing to DHHS Communications using the form set forth in this guidance document. Communications will consult with relevant DHHS Directors and staff to review the research design or proposal for: completeness; consistency with the goals, objectives, and mission of DHHS; compliance with the requirements of this policy; benefit or potential harm to DHHS or persons it serves; and protection of the rights to privacy and informed consent of participants. Persons involved in the review of the proposal include: the Division Directors or designees; a representative from any facility involved; Legal Services; the Chief Medical Officer or designee; and Human Resources. Researchers must provide clarification or additional information as required.

2. All DHHS 24-hour facilities, Service Areas, and programs are required to follow this research policy. Some DHHS facilities and programs may have additional research requirements with which the researcher will be required to comply.

3. Research involving human subjects must comply with the additional requirements of Title 45 CFR Part 46. In addition, persons committed to DHHS, or who reside at facilities operated by DHHS, may be entitled to additional safeguards relating to research involving prisoners. This includes, but is not limited to, special consideration relating to the capacity to voluntarily consent and whether participation in the research could affect a person's release from DHHS custody.

4. All proposals for research to be conducted on human subjects shall be reviewed and approved by the educational institution's or the facility's Institutional Review Board (IRB). All research involving DHHS facilities or persons committed to DHHS must be approved by the DHHS CEO and either the Chief Medical Officer or the Executive Medical Officer.

B. All research designs or proposals must specify the purpose, hypothesis, methodology, and data requirements for the research, and the benefit and potential harm of the

research to the DHHS, its employees, and the people the agency serves. The research proposal form must be completed and submitted to DHHS. In addition, the researchers must submit finalized survey instruments when applicable. Authorization to proceed will depend on the nature of the proposal; the potential impact on DHHS and persons served by it; the cost to DHHS; and the amount of DHHS staff time required.

C. No research effort shall commence without the review and written approval of the DHHS Chief Executive Officer or the Chief Executive Officer's designee.

D. All researchers must abide by this research policy and submit a signed statement of agreement with the research proposal.

E. If approval is granted, research must be completed within the timeframes contained in the research request unless an extension is granted by the DHHS Chief Executive Officer or the Chief Executive Officer's designee.

VI. CONDUCT OF RESEARCH

A. Obtaining Written Consent of Participants

Researchers shall inform subjects in writing of all features of the research that reasonably may influence their willingness to participate and explain all other aspects of the research about which the subject inquires and shall obtain the written consent of the participant. When the research involves State wards, the researchers must obtain the consent from parents, guardians, or the court as deemed appropriate by DHHS.

1. The exact procedure for obtaining consent must be described in the proposal. The Informed Consent form used by the researcher shall be included with the proposal. The very identity of the research subject is usually confidential. Researchers must include in the proposal a methodology for obtaining initial consent from the subject before personal identifying information is released by DHHS.

2. The researcher shall respect the individual's right to decline participation in research or to discontinue participation at any time. Refusal to participate in research shall at no time affect the care or treatment of the individual involved.

3. To give informed consent, the individual concerned must have adequate reasoning faculties and be in possession of all relevant facts. An individual under legal incapacity or who has impairments to reasoning and judgment that render the individual incapable of giving knowing and informed consent cannot be included in research.

The researcher will provide DHHS with a copy of signed consent forms.

B. Anonymity of the Subjects

Information obtained about research subjects is confidential. Data shall be collected and maintained in such a manner that protects the subject's identity. Where the identity of the subject must be included for the purpose of analysis, an artificial system of identification not meaningful to others shall be created. Such a system shall be described in the research proposal. Plans to return, purge, destroy, or erase data files containing client, patient, or staff information must also be described in the proposal. The use or release of data is governed by

State statute or Federal regulations. Acknowledgement of the existence of applicable laws and assurance of compliance with them must be included in the proposal.

VII. REVIEW REQUIRED PRIOR TO DISSEMINATION OF FINDINGS

At least two weeks prior to dissemination or submission for publication, all draft reports, articles, and press releases based upon the research shall be forwarded to the DHHS for review and comment.

VIII. PUBLICATION DISCLAIMER

Any publication of research findings or data must include the following disclaimer: "These findings and their interpretation are the sole responsibility of the author and do not necessarily reflect the opinions of the Nebraska Department of Health and Human Services."

IX. FINAL REPORTS

The researcher must provide DHHS with two copies of all final reports, published articles, press releases, or other documents that use data from the research study. Proper citation or credit to DHHS shall be provided, unless waived by DHHS.

X. MISCONDUCT IN RESEARCH

Individuals conducting research must comply with all applicable federal and state laws and policies regarding misconduct in research. Researchers are to report to DHHS any misconduct in research of which they become aware.

XI. HOLD HARMLESS CLAUSE

The researcher will hold the state, its agencies, employees, and officers, both past and present, harmless from any damages arising from the conduct of the research project or the use or publication of the resulting data or interpretation of the data by the researcher or sponsoring agency.

XII. COST

Researchers may be required to pay for the costs incurred by DHHS in the conduct of the research, including, but not limited to, the actual cost of data retrieval (i.e., staff time, data processing), duplication costs, etc. Researchers will be notified of the potential costs prior to approval.

XIII. VIOLATION OF DHHS POLICY

Violation of this Policy, or other DHHS policies, may result in denial or termination of a research request and any other legally available remedy or sanction.

XIV. FOR FURTHER INFORMATION, CONTACT:

Communications and Legislative services
Nebraska Department of Health & Human Services
301 Centennial Mall South
P.O. Box 95026
Lincoln, NE 68509-5026

Phone: (402) 471-312

Nebraska Department of Health and Human Services

Research Proposal

Researcher Name(s): _____

Affiliation: _____

Address: _____

_____

Daytime Phone: _____

Fax Number: _____

Email Address: _____

Research Title: _____

_____

Research Site(s): _____

The Principal Investigator is:

____ **A full-time faculty member**

____ **A part-time faculty member**
____ **A post-doctoral student**
____ **A graduate student**
____ **An undergraduate student**
____ **Other; specify** _____

Research Credentials of Principal Investigator: **Please attach vita or resume of Principal Investigator**

ALL QUESTIONS MUST BE ANSWERED. PLEASE TYPE OR PRINT LEGIBLY. IF ADDITIONAL SPACE IS NEEDED, ATTACH PAGES.

1. PURPOSE STATEMENT:

The purpose (intent, objective) of this research is to:

2. METHODOLOGY (process of the research, analysis procedures, etc.):

3. DATA/INFORMATION REQUESTED:

4. BENEFIT AND POTENTIAL RISK TO DHHS, DHHS CLIENTS, AND/OR DHHS STAFF:

5a. HOW WILL THE CONFIDENTIALITY OF RESEARCH PARTICIPANTS BE MAINTAINED?

5b. HOW WILL INFORMED CONSENT BE OBTAINED? (Attach a copy of the Informed Consent form to be used, if applicable.)

6. PROJECTED START DATE: _____

(Once approval is granted, research must be initiated within 60 days of the projected start date or approval will be suspended. If there are research delays, the DHHS must be contacted to discuss options or alternatives for completing the research by the projected finish date.)

7. PROJECTED FINISH DATE: _____

(Once the research project is completed, results must be forwarded to DHHS for review and comment before dissemination or publication.)

8. WILL A SURVEY INSTRUMENT(S) BE USED? YES NO

If YES, the final instrument(s) must be attached.

9. WILL INSTITUTIONAL REVIEW BOARD (IRB) APPROVAL BE REQUIRED FOR THIS RESEARCH?

YES* NO

IF YES, WHAT IS THE IRB APPROVAL NUMBER? _____

* If IRB approval is required, but you do not have approval at this time, you will be required to submit documentation of IRB approval before research can begin.

10. WHAT PLANS DO YOU HAVE FOR DISSEMINATION/PUBLICATION OF RESEARCH FINDINGS?

SUBMIT THE COMPLETED RESEARCH PROPOSAL TOGETHER WITH A SIGNED STATEMENT OF AGREEMENT FORM TO DHHS COMMUNICATIONS AND LEGISLATIVE SERVICES AT THE FOLLOWING ADDRESS:

Communications and Legislative services
Nebraska Department of Health & Human Services
301 Centennial Mall South
P.O. Box 95026
Lincoln, NE 68509-5026

Nebraska Department of Health and Human Services
Statement of Agreement

Research Proposal Title:

Everyone involved with this research proposal will comply with the research policy and all other applicable policies, procedures, and regulations of the Nebraska Department of Health and Human Services and applicable laws relating to safeguarding confidential information.

A copy of draft reports will be forwarded to DHHS for comment before dissemination or publication.

Data obtained from the Nebraska Department of Health and Human Services will be used only for the purposes stated in the Research Proposal. Data will be stored in a secure location and confidentiality will be safeguarded by all persons involved in the research.

The state, its agencies, employees, and officers, both past and present, will be held harmless from any damages arising out of the conduct of the research project and the use or publication of the resulting data.

DHHS will be informed of the progress of the research and any problems that arise. Any changes to the research design require prior approval by DHHS.

Publication of research findings or data will include the following disclaimer: "These findings and their interpretation are the sole responsibility of the author and do not necessarily reflect the opinions or policy position of DHHS."

DHHS will be provided with two copies of the final report or article.

I agree to pay DHHS for any costs incurred by DHHS in conjunction with this request.

For the Researcher:

_____
Signed

_____
Date

Additional Conditions required by the Nebraska Department of Health and Human Services:

_____
_____
_____
_____

Approved by the Department of Health and Human Services:

_____

Signed

_____

Date

Additional Conditions Accepted by Researcher:

_____

Signed

_____

Date