

Nebraska Department of Health and Human Services Research Policy

I. PURPOSE

The purpose of the Nebraska Department of Health and Human Services (DHHS) Research Policy is: a) to provide a process for the submission of research proposals to the DHHS; b) to delineate the process and requirements for DHHS review and approval of such requests; c) to outline the requirements for research involving clients and staff of the DHHS; and, d) to specify the requirements that researchers must agree to in order to have access to DHHS clients, staff, and/or data.

II. POLICY STATEMENT

It is the policy of the Nebraska Department of Health and Human Services (DHHS) to support research which: a) leads to improved health and human services; or, b) increases the body of knowledge about health and human services. It is the responsibility of the DHHS to protect the health, dignity, general well-being, and rights to privacy of persons who receive services from the DHHS and employees of the DHHS.

III. PRIORITIES

The mission of the Department of Health and Human Services is to help people live better lives through effective health and human services. While the DHHS fully supports research that contributes to improvements in services, the DHHS's legislatively mandated responsibilities remain its top priority.

IV. RESEARCH REQUESTS VERSUS MAJOR DATA REQUESTS

This policy distinguishes between "research requests" and "major data requests". A "research request" is a request for access to DHHS clients, client records, or staff for research purposes. A "major data request" is a request: a) to access records which are considered to be public records; or b) for DHHS to compile data for the requester that are not regularly collected, analyzed, or presented, but which may exist within the records or databases of the DHHS. Included in this Research Policy are requests from agencies, organizations, or individuals outside the DHHS, or from DHHS staff or contract employees conducting research for purposes other than work assignments. (Major data requests should be submitted directly to the division or program from which the data are requested.)

DHHS maintains several registries, including the Cancer Registry, the Head Injury Registry, and the Birth Defects Registry. Special rules govern the use and release of Registry data. If a researcher is interested in Registry data, s/he should contact the Data Management Section within DHHS Department of Public Health. The Registries are not included under this Research Policy.

V. 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. Failure to receive preliminary approval from DHHS before submitting a research grant application could automatically result in disapproval of the request.

VI. RESEARCH REQUESTS

- A. 1. All research requests shall be submitted in writing, using the format in Appendix A, to the DHHS Financial Services Division (hereafter referred to as “the Division”) (See paragraph A.2. for the policy for DHHS facilities or Service Areas having their own research review process.) The Division administrator, or his/her designee, shall consult with relevant DHHS staff to review the research design or proposal for: completeness; consistency with the goals, objectives, and mission of the DHHS; compliance with the requirements of this Policy; benefit or potential harm to the DHHS, its clients¹ and staff; and protection of the rights to privacy, and informed consent, of participants. Depending upon the nature and subject of the research, persons involved in the review of the proposal shall include the Division administrator or his/her designee(s); a representative from the division(s) required to perform the work; a representative(s) from the facility(s), or program or service delivery area that is the site or subject area for the research and, as appropriate, the following: a representative from the Legal Services Division, a representative of the DHHS medical staff, and a representative from the Human Resources Division. Research designs and proposals may be returned to the researcher for clarification or additional information as required, and/or the researcher may be asked to meet with DHHS staff. Following review of the research design or proposal, the Division shall submit its recommendations for approval or disapproval of the request to the Chief Executive Officer.

Following receipt of the completed research request, researchers should allow DHHS at least 45 days to review the research request.

2. All DHHS 24-hour facilities, Service Areas, and programs are required to follow this research policy. Some DHHS facilities, Service Areas, and programs may have additional research requirements, pertaining to their service population, with which the researcher is also required to comply.

Some DHHS 24-hour facilities and Service Areas have their own research review processes. If a research request involves only one facility or Service Area, and that facility or Service Area has its own research review process, the facility or Service Area research committee will be responsible for reviewing the research proposal and deciding whether it should be approved or disapproved. It is recommended, however, that the research request first be submitted to the Division. The Division will document the request on behalf of DHHS and forward the request to the appropriate facility or Service Area for review. The Chair of the facility/Service Area’s Research Committee shall inform the Division regarding the approval or disapproval of the request and, if disapproved, the reason for disapproval. Researchers processing their proposals through

¹ The word “client” refers to any person receiving services provided by, or financed in whole or in part by or through, the Nebraska Department of Health and Human Services.

the facility/Service Area's research review process are still required to sign the Statement of Agreement (Attachment B). (The review of research proposals involving more than one facility and/or Service Area will be coordinated through the Division; this is true even for those facilities or Service Areas having their own research review processes.) Research involving DHHS facilities, Service Areas, or programs must be reviewed and approved by the facility, Service Area, or program administrator.

Note: Under no circumstances will medical, pharmaceutical, or cosmetic research be conducted in the Youth Rehabilitation and Treatment Centers.

3. Researchers who are not employees of the Nebraska Department of Health and Human Services, or under contract with the DHHS, shall not, without written consent of the agency director, have access to client records or other sensitive documents governed by statutory confidentiality requirements.
- 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 clients, or staff. Attachment A, "Research Proposal", must be completed and submitted to the Division. 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 clients or staff; 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 Chief Executive Officer for DHHS or his/her designee.² Written approval shall include, but not be limited to:
 1. DHHS authorization for access to specified data, clients, or staff; and
 2. Researcher agreement to abide by the DHHS policies and procedures regarding human subjects in research, misconduct in research, informed consent for research participants, protection of confidentiality, data security, special policies pertaining to State wards (if applicable), regulations or protocols pertaining to specific data bases and specific populations, and disclosure and dissemination of research findings.
 - D. All researchers shall agree to abide by this Policy. This agreement shall be documented by signature of the researcher(s) on the "Statement of Agreement" (Attachment B). (The "Statement of Agreement" will be initiated by DHHS.) No research requests will be approved until the "Statement of Agreement" has been signed by the researcher(s), the Chief Executive Officer, his/or designee, or the facility/Service Area administrator and forwarded to the Division. The Chief Executive Officer's, or facility/Service Area administrator's, signature on the Statement of Agreement indicates approval by DHHS.
 - E. Once approval is granted, research needs to commence within 60 days. This deadline can be extended with permission of the Division. If the approval to conduct research is suspended, the researcher must re-apply for permission to conduct research. All research delays or requests for an extension of the 60-day time period are to be coordinated through the Division.

² The administrator of facilities or Service Areas with research review processes may approve research requests, if the research involves only one facility or Service Area.

VII. 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 of each participating State ward's case manager.

1. The exact procedure by which the potential participants' consent will be solicited shall be described in the proposal. The Informed Consent form used by the researcher shall be included with the proposal.
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.

Researchers involving, as research subjects, clients who are impaired or under age shall obtain the consent of a parent or legal guardian. The researcher will provide DHHS with a copy of the signed consent form (or refusal) to be placed in the client's file.

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 subjects' 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 some data is governed by State statute or Federal regulations. Acknowledgement of the existence of these statutes/regulations, and assurance of compliance with the statutes/regulations, shall be included in the proposal.

C. Protection of Human Subjects

All proposals for research to be conducted in the 24-hour facilities of the Department of Health and Human Services shall be reviewed and approved by the educational institution's or the facility's Institutional Review Board (IRB).

All research involving DHHS clients as subjects must be approved by the DHHS Chief Medical Officer or his/her designee.

VIII. 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 Division for review and comment.

IX. 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.”

X. FINAL REPORTS

The researcher must provide the Division 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.

XI. MISCONDUCT IN RESEARCH

Individuals conducting research with U.S. Department of Health and Human Services’ Public Health Service research grants must comply with their affiliate organization’s policy regarding Misconduct in Research. Researchers are to report to the Division any misconduct in research, involving DHHS or its clients, of which they become aware.

XII. HOLD HARMLESS CLAUSE

The researcher(s) will hold the state, its agencies, employees, and officers, both past and present, harmless from any damages awarded against any or all of them based upon the conduct of the research project and/or the use or publication of the resulting data or interpretation of the data by the researcher(s) or sponsoring agency.

XIII. DHHS STAFF RESPONSIBILITY

DHHS staff must report, to the Division, misconduct or actions of researchers believed to violate DHHS policy.

XIV. COST

Researchers may be required to agree to pay for the costs incurred by DHHS in the conduct of the research, including 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.

XV. VIOLATION OF DHHS POLICY

Violation of this Policy, or other DHHS policies, may result in immediate denial of research/information access to DHHS and/or denial of future requests.

XVI. APPEAL PROCESS FOR DISAPPROVED RESEARCH REQUESTS

Researchers have the right to appeal the disapproval of research requests. The researcher has 30 days from the date of the disapproval letter to submit a written appeal to the Chief Executive Officer or facility/Service Area administrator. The written appeal should explain, in detail, the rationale for reconsidering the proposal. The Chief Executive Officer or facility/Service Area administrator will decide if the proposal should be reconsidered. If the Chief Executive Officer or facility/Service Area administrator agree that the proposal should be reconsidered, the Division will reinitiate the review process. If the Chief Executive Officer or facility/Service Area administrator decide to uphold the decision to disapprove the request, their decision will be final.

XVII. FOR FURTHER INFORMATION, CONTACT:

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Lincoln, NE 68509-5026

Phone: (402) 471-0553

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E-mail: Bryan.Rettig@nebraska.gov

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 or approval will be suspended. Re-application for permission/approval will be required. If there are research delays, the Division should be contacted to discuss options or alternatives for re-application.)

7. PROJECTED FINISH DATE: _____

(Once the research project is completed, results must be forwarded to the Financial Services Division 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 the IRB approval number before research can begin.

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

Nebraska Department of Health and Human Services
Sample Research Statement of Agreement*

I (we) _____,
(Name of Individual(s))

whose position/job title is _____,

am(are) affiliated with _____.
(Organization) (City/State)

My (our) research project proposal concerns/is entitled:

DHHS Research Proposal Number: _____

I (we) understand that some of the information to which I (we) have been given access may be privileged and confidential and I (we) agree to comply with the policies, procedures, and regulations of the Nebraska Department of Health and Human Services and the

(Name of Facility/Program)

I (we) have received a copy of and have read the Nebraska Department of Health and Human Services "Research Policy", and agree to comply with same. I (we) understand that a copy of draft reports shall be forwarded to the Financial Services Division for comment before dissemination or publication.

I (we) stipulate that any data obtained from the Nebraska Department of Health and Human Services will be used only for the purposes stated in the Research Proposal. I (we) further stipulate that data will be stored in a secure location and that client and staff confidentiality will be maintained by all persons involved in the research.

I (we) agree to hold the state, its agencies, employees, and officers, both past and present, harmless from any damages awarded against any or all of them based upon the conduct of the research project and/or the use or publication of the resulting data, or interpretation of the data by the researcher(s) or sponsoring agency.

I (we) agree to keep the DHHS Financial Services Division informed of the progress of the research, any problems that arise, and any changes to the research design/information request.

I (we) understand that violation of DHHS policies is grounds for immediate denial of research access or access to information, and/or denial of future requests.

I (we) agree that any 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."

I (we) agree to provide the Division with two copies of the final report or article.

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

Additional, research-specific requirements, if any:

DHHS agrees to provide consultation to the researchers, to review the research findings prior to publication or dissemination, and to assist the researchers in the appropriate interpretation of DHHS data.

Specific DHHS requirements, if any:

For the Researcher(s):

For the Department of Health and Human Services:

Signed

Signed

Signed

Signed

Date

Date

* This is a SAMPLE agreement. DHHS will initiate a separate agreement for each research project. Please do not sign this sample agreement.