

Minnesota Attorney General: Administrative Rules Proceedings

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Version 3
August 20, 2018

RULES REVIEW CHECKLIST

DATE RULES RECEIVED 5/25 Temporary Rule _____

Resubmitted and Received _____

DUE DATE 6/14

a. Returned to Agency w/o filing w/Secy of State _____
b. Approved _____ Date Sent Back to Agency _____

- -

1. Rules as Adopted ✓
2. Rules as Proposed ✓
3. Certificate of Board's Authorizing Resolution, where applicable N.A.
4. Order for Hearing ✓
5. Notice of Hearing ✓
   (i) Sufficiency ✓
6. Secretary of State's List ✓
7. Certificate of Acquisition of Secretary of State's List ✓
8. Affidavit of Mailing ✓
   (i) At least 30 days prior to hearing ✓
9. Statement of Need and Evidence ✓
10. Hearing Examiner's Report ✓
11. Agency's Findings of Fact ✓
12. Certificate of Board's Resolution Adopting Rules, where applicable N.A.
13. Order Adopting ✓
14. Report of Chief Hearing Examiner ✓
    (i) Finding of No Substantial Change ✓
    (ii) Permission to Incorporate by Reference, where applicable ✓
15. Certificate of Compliance with Rulemaking Procedures ✓
16. Copy of Notice of Intent to Solicit Outside Opinion, where applicable N.A.
17. Petition by Public, where applicable N.A.

1.305 A

p.1 ① Improper cite – shld G Chp. 453

1.305 ② C,1 " " " " " "

O.K. – as long as "est." as opposed to "governor" ③ 1.305 C (4) – drop 1965 as its been amended.

O.K. – Delegation by rule ④ p.3 1.305 C(10) – Since money is Dep't of Health, can signature of SHCC repres. bind Health?

~~644-4473~~
~~645-6602~~
646-9444

O.K. – governor by SCHH & Rules of order ⑤ How award decision made – maj. vote, etc?

~~⑥ p.5 1.306 (C) – Beware of "expended by" vs. "expended~~

Agency disagree & justified disagreement ⑦ p. 12 of HE Rept: Recommendation no Long. accumulating young researcher priority

~~⑧ No [illegible] where~~

RECEIVED
MAY 22 1978
OFFICE OF HEARING
EXAMINERS

STATE OF MINNESOTA

State Planning Agency

IN THE MATTER OF THE PROPOSED ADOPTION OF RULES OF THE STATE PLANNING AGENCY GOVERNING THE HEALTH RESEARCH PROGRAM

STATEMENT OF COMPLIANCE WITH MANUAL OF RULE MAKING PROCEDURES

I, William E. Dorigan, Special Assistant Attorney General, do hereby declare that I have examined the proposed rules and all related documents and that, based on them and my personal familiarity with the applicable procedures, the Manual of Rule Making Procedures has been followed.

William E. Dorigan

Special Assistant Attorney General

Dated: May 19, 1978

PLAN-78-001-HK

EXHIBIT G
REPORT OF CHIEF HEARING EXAMINER

STATE OF MINNESOTA
OFFICE OF HEARING EXAMINERS

FOR THE MINNESOTA STATE PLANNING AGENCY

IN THE MATTER OF THE RULES PROPOSED) FOR ADOPTION BY THE MINNESOTA STATE) PLANNING AGENCY RELATING TO THE AD-) MINISTRATION OF THE HEALTH RESEARCH) PROGRAM (HRP).)

REPORT OF THE CHIEF HEARING EXAMINER

WHEREAS, a hearing was held on April 7, 1978, before Howard L. Kaibel, Jr., a Hearing Examiner of the State Office of Hearing Examiners, on the above-entitled matter in compliance with Minn. Stat. § 15.0412, Subd. 4; and

WHEREAS, the Report of Hearing Examiner made pursuant to Minn. Stat. § 15.052, Subd. 3, was issued to the State Planning Agency on May 4, 1978; and

WHEREAS, the State Planning Agency has now determined to adopt rules pursuant to Minn. Stat. § 15.0412, Subd. 4; and

WHEREAS, the State Planning Agency has submitted said rules to the Chief Hearing Examiner for review pursuant to Minn. Stat. § 15.052, Subd. 4, and Rule HE 107; and

WHEREAS, the Chief Hearing Examiner finds that the final proposed rules are not substantially different from those proposed at the public hearing and that the State Planning Agency has met all requirements of Minn. Stat. § 15.0412, Subd. 4.

NOW, THEREFORE, upon receipt of this Report, the State Planning Agency has the responsibility of submitting the complete hearing record and the rules as adopted by the Agency to the Attorney General and to publish in the State Register, all pursuant to Minn. Stat. § 15.0412, Subd. 4.

Dated this 12th day of May, 1978.

Duane R. Harves

DUANE R. HARVES
Chief Hearing Examiner

Minnesota State Planning Agency
101 Capitol Square Building
550 Cedar Street
St. Paul, Minnesota 55101
Phone (612) 296-2407

May 24, 1978

Mr. Lee Sheehy
Special Assistant Attorney General
Room G19K
Administration Building
50 Sherburne Avenue
St. Paul, Minnesota 55115

Re: In the Matter of the Rules Adopted by the Minnesota State Planning Agency Relating to the Administration of the Health Research Program

Dear Mr. Sheehy:

As required by Minn. Stat. § 15.0412, Subd. 4 (1977), I am enclosing the following materials relating to the above entitled matter for review by the Attorney General:

Five copies of the Rules as Adopted (Exhibit A)

Three copies of the Rules as Proposed (Exhibit B)

One transcript of the public hearing on the proposed rules (Exhibit C)

Three sets of the following:

Order for Hearing (Exhibit D-1)

Notice of Hearing (Exhibit D-2)

Affidavit of Acquisition of Mailing List (Exhibit D-3)

Secretary of State's Certificate (Exhibit D-4)

Mailing List (one copy only) (Exhibit D-5)

AN EQUAL OPPORTUNITY EMPLOYER

Affidavit of Mailing (Exhibit D-6)

Statement of Need (Exhibit D-7)

SPA Findings of Fact (Exhibit D-8)

Order Adopting Rules (Exhibit D-9)

Statement of Compliance with the Attorney General's Rulemaking Procedures (Exhibit D-10)

Public Hearing Exhibits (Exhibit E, one copy each)

Report of the Hearing Examiner dated May 4, 1978 (Exhibit F, one copy)

Report of the Chief Hearing Examiner dated May 23, 1978 (Exhibit G, one copy)

Sincerely,

John Dilley, Director
State Health Planning and
Development Agency

JD:ka

Enclosures

STATE OF MINNESOTA

COUNTY OF RAMSEY

STATE PLANNING AGENCY

In the Matter of the Proposed Rules of the Minnesota State Planning Agency for Administering the State Health Research Program

AFFIDAVIT OF MAILING

Karen Asper, being first duly sworn, deposes and says:

That on the 27th day of February, 1978, at the City of St. Paul, County of Ramsey, State of Minnesota, she served the attached Notice of Hearing by depositing in the United States mail at said City of St. Paul, a true and correct copy thereof, properly enveloped, with postage prepaid, to all persons and associations at the addresses listed on the attached Certificate of the Secretary of State.

Karen Asper

Subscribed and sworn to before me this 27th day of February, 1978.

Notary Public

[illegible] NOTARY PUBLIC-MINNESOTA [illegible] 18, 1983

STATE OF MINNESOTA

COUNTY OF RAMSEY

In the Matter of the Proposed Rules of the Minnesota State Planning Agency for Administering the State Health Research Program

CERTIFICATE

I hereby certify that the attached 487 Labels - 1 sheet(s) constitute the complete list of persons, associations, and other interested groups who as of 1:30 o'clock P.M., this 24th day of February, 1978, have requested pursuant to M.S. 1976, Section 15.0412, Subd. 4, that their names be placed on file with the Secretary of State for the purpose of receiving notice of public hearing on proposed rules on the subject captioned above.

Secretary of State

Joan Anderson Growe

By Grace L. Mattson

STATE OF MINNESOTA

COUNTY OF RAMSEY

STATE PLANNING AGENCY

In the Matter of the Proposed Rules of the Minnesota State Planning Agency for Administering the State Health Research Program

AFFIDAVIT OF RECEIPT OF THE SECRETARY OF STATE'S LIST

Janet C. Anderson, being duly sworn on oath deposes and says:

1) That she is an employee of the State Planning Agency of the State of Minnesota.

2) That on the 24th day of February, 1978, she went to the Secretary of State's Office for the State of Minnesota and requested a current list of all representatives of associations or other interested groups or persons who had registered their names with the Secretary of State for the purpose of obtaining notices of public hearings relating to the promulgation of rules pursuant to M.S. 15.0412 (1976).

3) That on the 24th day of February, 1978, in response to the above request, the Secretary of State provided her with such a list, a copy of which is attached hereto and incorporated by reference.

Further affiant sayeth not.

Janet C. Anderson

Subscribed and sworn to before me this 24th day of February, 1978.

Notary Public

LEO M. STEINER
RAMSEY COUNTY
NOTARY PUBLIC-MINNESOTA
MY COMMISSION EXPIRES NOV. 30, 1982

PLAN-78-001-HK

STATE OF MINNESOTA

COUNTY OF RAMSEY

RECEIVED
FEB 17 1978
OFFICE OF HEARING EXAMINERS

STATE PLANNING AGENCY

In the Matter of the Proposed Rules of the Minnesota State Planning Agency for Administering the State Health Research Program

NOTICE OF PUBLIC HEARING

Notice is hereby given that a public hearing will be held pursuant to Minnesota Statutes, § 15.0412 (1977 Supp.) and Minnesota Statutes §4.17 (1977 Supp.) in the above-entitled matter commencing in St. Paul in Room 83, the Auditorium, of the State Office Building on Wabasha Street in St. Paul, Minnesota at 9:30 a.m. on April 7, 1978. The hearing will be continued to such time and place as the Hearing Examiner may designate until all representatives of associations or other interested groups or persons have had an opportunity to participate and be heard concerning adoption of the proposed Rules captioned above by submitting either oral or written data, statements or arguments. Statements or briefs may be submitted to the Office of Hearing Examiners, Howard Kaibel, Hearing Examiner, Room 300, 1745 University Avenue, St. Paul, Minnesota 55104, without appearing at the hearing and will be accepted for a period of 5 working days after the public hearing ends, or for a longer period not to exceed 20 days if ordered by the hearing examiner.

The purpose of these Rules is generally as follows: To establish procedures for administering the Health Research Program. The Health Research Program will provide funds to help maintain biomedical research in Minnesota and to strengthen the state's ability to produce health services research, non-medical health research, and health policy research on issues of importance to the state. These rules will provide a mechanism for determining the types of research programs which will be eligible for grant awards. These rules will also describe criteria for applicant eligibility, criteria for selection of grant award recipients and criteria to determine the amount and terms of the grant awards.

Copies of the proposed Rules are now available for review at the following location:

Minnesota State Planning Agency
101 Capitol Square Building
550 Cedar Street
St. Paul, Minnesota 55101

Notice is also given that under Minn. Stat. § 10A.01, subdivision 11 (1976) any individual engaged for pay or other consideration for the purpose of representing persons or associations attempting to influence administrative action, such as the promulgation of these Rules, must register with the State Ethics Commission as a lobbyist within five days of the commencement of such activity by the individual. The State Ethics Commission is located at 410 State Office Building, St. Paul, Minnesota 55155.

Dated this 17th of February, 1978

STATE OF MINNESOTA

STATE PLANNING AGENCY

Peter Vanderpoel

Peter Vanderpoel, Director

RECEIVED
FEB 17 1978
OFFICE OF HEARING EXAMINERS

STATE OF MINNESOTA

COUNTY OF RAMSEY

STATE PLANNING AGENCY

In the Matter of the Proposed Rules of the Minnesota State Planning Agency for Administering the State Health Research Program

ORDER FOR HEARING

To effectively implement the State Health Research Program, the Minnesota State Planning Agency deems it necessary to consider adoption of the proposed Rules captioned above, pursuant to the authority granted in Laws of Minnesota 1977, Chapter 454, Section 27 and Minnesota Department of Administration Reorganization Order No. 83 (1977).

NOW THEREFORE, IT IS ORDERED that a public hearing on the proposed Rules be held commencing in St. Paul in the auditorium, Room 83, of the State Office Building, Wabasha Street, St. Paul, Minnesota at 9:30 a.m. on April 7, 1978 and continuing until all interested persons, representatives and organizations have had an opportunity to be heard by submitting oral or written data, statements, comments or arguments or by presenting witnesses.

IT IS FURTHER ORDERED, that notice of said hearing be given to all persons and associations who have registered their name with the Secretary of State for that purpose and that notice of said hearing shall be published in the State Register.

Dated this 17th day of February, 1978.

STATE OF MINNESOTA

STATE PLANNING AGENCY

By Peter Vanderpoel
Peter Vanderpoel, Director

RECEIVED
MAY 3 2 1978
OFFICE OF HEARING
EXAMINERS

STATE OF MINNESOTA
MINNESOTA STATE PLANNING AGENCY

In the Matter of the Rules Proposed for Adoption by the Minnesota State Planning Agency Relating to the Administration of the Health Research Program (HRP).

STATE PLANNING AGENCY
FINDINGS OF FACT AND
CONCLUSIONS

The above-entitled matter came on for hearing before Hearing Examiner Howard L. Kaibel of the Minnesota Office of Hearing Examiners on April 7, 1978, at 9:30 a.m. in Room 83, the Auditorium, of the State Office Building on Wabasha Street in St. Paul, Minnesota.

William E. Dorigan, Special Assistant Attorney General, appeared as counsel for the State Planning Agency (hereinafter "SPA"). John Dilley, Director of the State Health Planning and Development Agency, a constituent part of the SPA; Steven Mosow, Assistant Director of the State Health Planning and Development Agency; and Jan Anderson, Health Planner, testified on behalf of the SPA. The hearing continued until all interested groups or persons had an opportunity to be heard concerning the adoption of the proposed rules.

The purpose of the hearing was to determine whether proposed Minn. Rules 10 MCAR 1.305-1.310, dealing with the subject matter captioned above, should be adopted.

The matter of the HRP began in January 1977 when Governor Perpich presented his budget message to the Minnesota Legislature. The Governor cited Minnesota's leadership in the areas of biomedical research and reform of the health care delivery system. In order to support and expand the state's role in these areas, he recommended an appropriation for a health research program, to be expended over the next two fiscal years. He suggested that the funds be used to support research in a number of areas: biomedicine, dental care, the health services delivery system, and other health-related issues.

Individual legislators felt that the scope of the proposal warranted further in-depth analysis by outside experts. Legislative leadership and the Governor therefore agreed that a study of the issue would be made by InterStudy, an independent

health policy research organization, and the results reported to the Legislature and Governor. The Dayton-Hudson Foundation agreed to provide financial support for the study. The report, entitled "Alternatives for State Support of Health Research," was published in April 1977. The study concluded that some additional state support for health research would be a wise investment.

Subsequent to these events, an appropriation of $1.5 million was made by the Minnesota Legislature (Minn. Laws 1977, Ch. 454, Sec. 27) for the purpose of funding a state program to further health research in Minnesota. This Health Research Program is intended to provide state funds for merit fellowships and other grants in the areas of non-medical research, health services research, and health policy studies. The $1.5 million appropriation is to be allocated in the following manner: $1,000,000 for merit fellowships, $300,000 for non-medical and health services research grants, and $200,000 for health policy studies. The funds were appropriated for fiscal year 1979.

The appropriation was originally made to the Minnesota Department of Health, However, Minn. Laws 1977, Ch. 454, Sec. 27 directs the Statewide Health Coordinating Council (SHCC) to administer the disbursement of these funds. Due to its direct relationship to the SHCC, the State Planning Agency, which houses the State Health Planning and Development Agency, was viewed as the more appropriate state agency to which the funds should be allocated. Therefore, Minnesota Department of Administration Reorganization Order No. 83 was issued to transfer the appropriation from the Department of Health to the State Planning Agency.

The SHCC has appointed a Committee on the Health Research Program (CHRP) which will have primary responsibility for administering the program and evaluating the proposals for HRP funds which are received. The committee will make its recommendations to the full SHCC, which will have the final review and approval authority.

The State Health Planning and Development Agency (SHPDA), with the assistance and advice of the Attorney General's Office, drafted proposed rules for the HRP. Staff of the SHPDA and the appropriate representative of the Attorney General's Office then met with the Committee on the Health Research Program to review and discuss the draft rules. Suggestions and changes made by the committee were incorporated and the revised version presented to the SHCC for its consideration at its meeting

of February 15, 1978. Following general discussion and suggestions for minor changes, the SHCC approved the draft rules for initiation of the formal rulemaking process required by Minn. Stat. Chapter 15, the Administrative Procedures Act. As part of that rulemaking process, the public hearing was held on April 7, 1978, before the Hearing Examiner.

The purpose of these rules is to establish procedures for administering the Health Research Program. The HRP is intended to help maintain biomedical research in Minnesota and to strengthen the state's ability to produce health services research, non-medical health research, and health policy research on issues of importance to the state. The rules are intended to create a process which will be clear and predictable to all potential applicants for HRP funds, yet efficient and practical for administration by the CHRP and SHCC. In developing these rules, an attempt was made to closely reflect (1) the Governor's concept as proposed in his budget message to the 1977 Legislature; (2) the findings of the InterStudy report prepared for the Governor and Legislature; and (3) legislative intent as established in bills developed during the 1977 legislative session. No final bill enacting the Health Research Program was ever passed by the Legislature. The InterStudy report, which was commissioned to give the Legislature further information on which to base a decision concerning the Governor's proposal, was not published until April 15, 1977. A Senate bill (S.F. 1361) was introduced and first read on April 18, 1977. A companion bill to the Senate version was introduced in the House (S.F. 1497). S.F. 1361 was passed by the Senate on May 19, 1977, and transmitted to the House on the same day. The House bill, however, was never passed, and thus no final enactment was forthcoming from the Legislature. The appropriation for the Health Research Program was made by the Legislature on May 21, 1977, as a rider to the appropriations for the Minnesota Department of Health (Minn. Laws 1977, Ch. 454, Sec. 27). Since there was no HRP bill itself enacted, S.F. 1361 was utilized as a basis for interpreting legislative intent.

The SPA proposes to adopt the rules as amended. It is therefore submitting the complete hearing record, including its Findings and Order, to

the Chief Hearing Examiner no earlier than five days subsequent to its receipt of the Report of the Hearing Examiner. This submission indicates changes made to the rules as originally proposed, in the format that will be submitted to the State Register for publication. The Chief Hearing Examiner shall complete his review and submit his report to the SPA on the issues of substantial changes in the rules and compliance with Minn. Stat. § 15.0412 (1977) within ten calendar days. Thereafter, the SPA shall be responsible for filing the rules with the Attorney General and for notifying persons who have indicated that they wish to be notified of such filing.

Based upon all the records and proceedings herein, the SPA makes the following:

FINDINGS OF FACT

PROCEDURAL REQUIREMENTS

1. On February 17, 1978, the SPA filed, in proper form and duly executed, the following documents with the Chief Hearing Examiner, pursuant to Minn. Reg. HE 102:

(a) A copy of the proposed rules;
(b) A proposed Order for Hearing;
(c) A proposed Notice of Hearing; and
(d) A statement of the number of persons expected to attend the hearing and the estimated length of the hearing.

2. The Notice of Hearing and the proposed rules were published in the State Register on March 6, 1978.

3. On February 27, 1978, the SPA mailed the Notice of Hearing to all persons and entities who had registered their names with the Secretary of State for the purpose of receiving such notice.

4. On March 13, 1978, the SPA filed with the Office of Hearing Examiners the following documents:

(a) The Order for Hearing;
(b) The Notice of Hearing as mailed;
(c) The Affidavit of Receipt of the Secretary of State's list;
(d) The Affidavit of Mailing;
(e) The Secretary of State's Certificate and list;
(f) The Statement of Need and Evidence (with attachments); and
(g) The names of agency personnel who would represent the SPA at the hearing.

The documents were available for inspection at the Office of Hearing Examiners from the date of filing to the date of the hearing.

5. On March 17, 1978, the SPA made an additional voluntary mailing of the Notice of Hearing and the proposed rules to its own list of parties who had expressed an interest in the Health Research Program.

6. On March 22, 1978, the SPA issued a press release concerning the proposed rules and the scheduled public hearing to 37 newspapers throughout the state. These newspapers were, with the assistance of the seven Health Systems Agencies covering Minnesota, identified as the major regional newspapers which would be most likely to provide the greatest exposure to the public.

7. The SPA made it a practice to provide the Notice of Public Hearing and a copy of the proposed rules to any and all parties who made inquiries concerning the Health Research Program later than the March 17, 1978, mailing outlined in Item 5 above.

8. The record remained open through April 14, 1978, for the receipt of written comments and statements.

9. All comments which addressed the proposed rules, whether oral or written, were reviewed by the Hearing Examiner and were considered in the preparation of his Report, except written comments received after the record closed.

10. All other substantive and procedural requirements of statutes or regulations have been complied with.

10 MCAR § 1.305A. - AUTHORITY

11. The SPA's authority to propose and adopt rules for administering the HRP is contained in Minn. Stat. § 4.17 (1976), Minn. Laws 1977, Ch. 454, § 27, and Minnesota Department of Administration Reorganization Order No. 83. Reference to specific statutory provisions or the absence of such specific statutory authority is noted in this report where such authority or lack thereof is relevant and necessary to complete understanding of the Findings. No one questioned the SPA's general authority or legislative mandate to establish rules to implement the HRP.

Reference to the statute authorizing the rules is reasonable and necessary to allow easy reference for anyone wishing to refer to the specific statutory language and to check those parts of the law which are not contained in the rules.

10 MCAR § 1.305B. - PURPOSE

12. § 1.305B. is reasonable and necessary in order to declare to interested parties the reason for the promulgation of these rules and the purpose of the program to which they apply. The language reflects the purpose of the program as discussed

above in the introduction to these Findings of Fact.

10 MCAR § 1.305C. - DEFINITIONS

13. § 1.305C. reasonably provides definitions which are necessary to understand the precise meaning of terms used in the rules. Unless specified to the contrary, all definitions proposed in 10 MCAR § 1.305C. are considered to be reasonable and necessary for the reasons set forth in the Statement of Need and Evidence (Exhibit 1).

14. In a letter dated April 5, 1978, submitted to the SPA prior to the hearing, John E. Kralewski indicated a concern that § 1.305C. (6) through (9) do not adequately clarify the distinction between biomedical research and the other categories of health services research. However, no clarifying language amendment was suggested. The SPA finds that the definitions as proposed adequately serve the purpose of the rules by making the distinction between the four types of health-related research to be funded by the HRP. The definitions in question were derived directly from the InterStudy report (see Exhibit 1). The terms themselves, and the categories of research which they represent, appeared in S.F. 1361. The SPA concludes that the definitions as proposed are reasonable and necessary for the purposes of administering the HRP. It is therefore recommended that no amendment be made to 10 MCAR § 1.305C.

10 MCAR § 1.306A. - NOTICE OF AVAILABILITY

15. Minn. Laws 1977, Ch. 454, Sec. 27 provided no specific directives to the SHCC concerning the manner in which the HRP is to be administered (with the exception of total sums for each grant category). For this reason, procedures to be utilized by the SHCC must be established by the rulemaking process to make them clearly known and predictable to all relevant parties. A major practical necessity is to inform the public of the existence of the Health Research Program and the opportunity to apply for a grant under this program. Several methods have been proposed as a means of providing the public with information about the HRP. The SPA finds that, unless specified to the contrary, the methods proposed in § 1.306A. are reasonable and necessary for the reasons set forth in the Statement of Need and Evidence (Exhibit 1).

16. The SPA originally proposed to publish the Notice of Availability "two consecutive weeks in a newspaper of general circulation in each county of the state." This method was proposed as one of several ways of informing the public about the

existence of the Health Research Program and the opportunity to apply for a grant from the funds available.

Further study by the SPA, however, has indicated several things relevant to this section of the rule. First, items submitted to newspapers as "news releases" have no guarantee of appearing in print. This uncertainty is not consistent with the goal of ensuring public awareness of the HRP and thus is not considered an acceptable method.

Items submitted as "official notices" are guaranteed publication, but a fee is charged for the publication. Publishing the notice twice, then, would double the cost involved without necessarily ensuring wider public exposure. The SPA finds that the elimination of unnecessary expenditures of public monies is desirable. The SPA therefore recommends that the rule be amended to require only one such publication.

The SPA also concluded that publication in "newspapers of general circulation in each county" may not be the best method of reaching public readership. It was pointed out that many county newspapers are weeklies and have very small and limited circulations, while the newspapers published in the larger nearby cities usually have widespread circulation throughout the entire region. The SPA contacted the seven local Health Systems Agencies (HSA) covering all of Minnesota. Each HSA was asked to identify the major regional newspapers in its area which it routinely uses to publish various required legal notices. The SPA feels that these 37 newspapers provide statewide circulation sufficient to ensure wide public exposure. It did, in fact, utilize this same list to issue a news release concerning the promulgation of rules and the public hearing (see Item 6 above).

The SPA therefore recommends that proposed 10 MCAR § 1.306A. 2. be amended to read: "An announcement shall be published in the form of a legal notice in 37 major newspapers providing circulation through the state." The SPA submitted to the Hearing Examiner a list indicating the specific 37 newspapers which it proposes to utilize. This list was incorporated as part of the hearing record (Exhibit 1).

17. In a letter dated April 4, 1978, and submitted during the five-day period for receiving comments, Ellen Alkon, M.D., suggested that the list of entities specified in § 1.306A. 3. be amended to include "Boards of Health" due to their association with preventive health care techniques designed to improve the public health. The SPA finds that the suggested addition is in keeping with the rule's intent of reaching the health-related research community and therefore recommends that § 1.306A. 3. be amended to include the following additional item: "(m) Local Boards of Health."

10 MCAR § 1.306B. - ANNOUNCEMENT OF GRANT AWARDS

18. Just as it is important to notify the public concerning the availability of state funds, it is also considered important to provide notice of the disposition of such public monies. Several methods have been proposed as a means of providing such public notice. The SPA finds that, except where specified to the contrary, the methods proposed are reasonable and necessary for the reasons set forth in the Statement of Need and Evidence (Exhibit 1).

19. In a letter dated April 4, 1978, and submitted during the five-day period for receiving comments, Ellen Alkon, M.D., suggested that § 1.306B. 3. also be amended to include local Boards of Health for the same reasons indicated in Item 17 above. The SPA finds that the suggested addition is in keeping with the intent of notifying the health-related research community of the types of research to be performed using the HRP grants, and therefore recommends that § 1.306B. 3. be amended to include the following additional item: "(m) Local Boards of Health."

10 MCAR § 1.306C. - COMMENCEMENT OF FUNDING

20. During the hearing of April 7, 1978, John Kralewski, Ph.D., made a comment indicating that any HRP funds should be allocated for a two-year period as are the merit fellowship grants. SPA staff pointed out that § 1.306C. stipulates that all funds awarded under the HRP, not only the merit fellowship grants, may be expended up to June 30, 1980. Therefore, the proposed rule already contains the provision suggested by the commentor and no amendment is necessary.

10 MCAR § 1.307 - APPLICATION PROCEDURES

21. Section 1.307 is reasonable and necessary for the reasons set forth in the Statement of Need and Evidence (Exhibit 1). No comments, oral or written, were offered on this portion of the rules.

10 MCAR § 1.308A. - MERIT FELLOWSHIP GRANTS

22. In a letter dated April 5, 1978, and submitted to the SPA prior to the hearing, John Kralewski, Ph.D., questioned the provision in § 1.308A. 1. that merit fellowship grants are to be used to fund exploratory analysis and pilot research. He offered the opinion that merit fellowship grants should be allowed to fund research projects which are beyond the exploratory/pilot stage.

The InterStudy report recommended that a category of fellowships be established, indicating that it would help to build a core of researchers in the state. The InterStudy report viewed this type of grant as an "investigatorship" which, in addition to providing a stipend to the researcher, would provide a small amount of "seed money" for research expenses. S.F. 1361 retained this concept by stipulating that fellowship grants be used for exploratory analysis and pilot research, as did H.F. 1497. As was explained in the Statement of Need and Evidence (Exhibit 1), Minn. Laws 1977, Ch. 454, Sec. 27 provided very little information to the Statewide Health Coordinating Council (SHCC) for its use in administering the HRP. Therefore, the background documents (i.e., the InterStudy report, S.F. 1361, and H.F. 1497) were utilized as a basis for interpreting legislative intent. The SPA finds that the proposed rule reflects that intent and therefore recommends that no amendment be made.

23. In a letter dated April 5, 1978, and submitted to the Examiner prior to the hearing, D.A. Barnes indicated a concern that the proposed rules seem to favor the established individual as opposed to an individual more junior. Some of this concern appears to be based on § 1.308A. 2., which indicates that, among other things, merit fellowship grant applications shall be evaluated in terms of the applicant's "demonstrated past performance in doing health-related research." The InterStudy report recommended that the fellowships be used to support young researchers, and there is some concern that the evaluation criterion mentioned above might work to the disadvantage of such young researchers who have not yet established a long record of research accomplishments.

SPA staff pointed out that § 1.308A. 2 a. requires the evaluation of "the applicant's professional credentials," which would reflect the training and education possessed by any young researcher, including any research experience obtained during that training or education. It is only practical to consider any relevant experience

of an applicant, but the proposed rule as written does not, the SPA feels, discriminate against young researchers. The remainder of § 1.308A. 2. clearly indicates that each proposal will be judged independently on the merits of the proposal itself, not simply the qualifications of the applicant. The SPA points out that every member of the SHCC, including those serving on the Committee for the Health Research Program, has been provided with a copy of the InterStudy report and is familiar with its recommendations.

Mr. Barnes suggested that merit fellowship grants be divided into two types: a junior merit fellowship and a senior merit fellowship, the only difference being the degree of demonstrated past performance could be established in order to differentiate "junior fellows" from "senior fellows." SPA staff pointed out (Transcript, p. 56) that neither the InterStudy report, S.F. 1361, nor H.F. 1497 contained any language which could be interpreted as suggesting that the merit fellowship grants be split in such a way. Furthermore, both S.F. 1361 and H.F. 1497 contained language indicating that past performance should be one factor considered when evaluating merit fellowship grant applicants.

In his report, the Hearing Examiner recommended (p. 12) that "language should be incorporated instead upon final adoption indicating that the InterStudy concern for funding young researchers will be an explicit consideration in grant allocation." The SPA disagrees with this suggestion for several reasons. First, as was indicated above, all members of the SHCC are already aware of the recommendations of the InterStudy report, and the award of the grants was left to the discretion of the SHCC by Minn. Laws 1977, Ch. 454, Sec. 27. The most serious objection, however, is based on the difficulty of establishing a justifiable and defensible distinction between "young" and "not young" researchers (or "junior" versus "senior" as suggested above). The Hearing Examiner provided no suggestion as to how this distinction might be made explicit in any added language. The SPA feels strongly that the addition of language indicating that special consideration will be given to "young" researchers, without an explicit and defensible explanation of what will be considered "young," could potentially cause more confusion than clarification. The SPA concludes that the proposed rule, as written, reflects legislative intent and recommends, therefore, that no amendment be made.

24. During the hearing of April 7, 1978, David M. Brown, M.D., voiced some concern regarding § 1.308A. 3., which establishes merit fellowship grants as consisting of a maximum of $50,000 per year for two years. Dr. Brown suggested reducing the maximum amount to a lower level in order to increase the number of fellowship grants which could be awarded.

The funding level set forth in this rule is taken directly from both S.F. 1361 and H.F. 1497. It is therefore considered inappropriate and contradictory to legislative intent to reduce the maximum funding level. It must be noted that the $50,000 per year amount is a maximum and that there is no requirement that all merit fellowships be funded at that level. The amount of funds to be awarded to each merit fellow, up to the maximum, is left to the discretion of the Statewide Health Coordinating Council. The SPA finds, therefore, that the type of flexibility suggested by Dr. Brown is already contained in § 1.308A. 3. and that no amendment is necessary.

25. § 1.308A. 4. sets forth a stipulation that at least one half of the merit fellowship grants shall be allocated to health services research, non-medical health research, and health policy study. Concern was expressed by N.L. Gault, M.D., both during the hearing of April 7 and in a letter dated April 7, 1978, and submitted during the five-day period following the hearing; and by John E. Kralewski, Ph.D., in a letter dated April 5, 1978, that the proposed rule as stated does not clearly indicate that the remainder of merit fellowships may be awarded to biomedical research proposals. Both suggested that some clarifying language be added.

In a letter dated April 14, 1978, and submitted during the five-day period allowed for comments, the SPA indicated its agreement that the option of using merit fellowships to fund biomedical research should be more clearly stated by including a specific reference to that category of research. It therefore recommended that 10 MCAR § 1.308A. 4. be amended to read as follows: "Merit fellowship grants shall be allocated to biomedical research, health services research, non-medical health research, and health policy research and analysis. At least one half of these grants shall be allocated to health services research, non-medical health research, and health policy research and analysis." The SPA finds that this amendment does not substantially change the intent of the rule but does clarify its meaning. It is therefore recommended that § 1.308A. 4. be amended as proposed by the SPA.

26. Both of the commentors identified in Item 24 above also questioned the language of § 1.308A. 4. in terms of whether the intent was to earmark at least half the number of grants or half the amount of funds available for award. The InterStudy report's recommendations concerning merit fellowships appear to be based on the supposition that all the fellowship grants would be a flat $100,000 over a two-year period. Thus a recommendation that half the grants be earmarked for non-biomedical research is equivalent to recommending that half the funds be allocated to those types of research. While S.F. 1361 and H.F. 1497 utilized the language "half the grants," it seems clear from the intended emphasis of the HRP (discussed in greater detail in the following item) that the intention was to see that at least half the support available went to the areas of non-medical health research, health services research, and health policy research and analysis. The SPA finds that clarifying language which will avert potential confusion may be substituted without substantially changing the meaning of the rule. It is therefore recommended that § 1.308A. 4. be amended, in keeping with the amendment recommended in Item 25 above, to read as follows: "Merit fellowship grants shall be allocated to biomedical research, health services research, non-medical health research, and health policy research and analysis. At least one half of these funds shall be allocated to health services research, non-medical health research, and health policy research and analysis."

27. The major concern expressed during the hearing of April 7, 1978, related to the issue of HRP funding support for biomedical research. During the hearing Dr. N.L. Gault questioned the rules' failure to provide flexible support specifically for biomedical research to the University of Minnesota and the Mayo Clinic. SPA staff pointed out that Dr. Gault's comments related to a grant category entitled "Research Support for University of Minnesota and Mayo Clinic" which had appeared in S.F. 1361 along with the other three grant categories. That fourth category in S.F. 1361 reflected a recommendation by the InterStudy report that the state provide such flexible support for biomedical research. H.F. 1497, however, did not include a specific category for support of biomedical research. The deciding factor, however, is that the Legislature simply did not fund that category. Merit fellowships, non-medical and health services research, and health policy research were funded; a category exclusive to biomedical research was not. It is therefore deemed inappropriate for the SPA to promulgate rules setting forth certain amounts of

funds to be earmarked for biomedical research when no such authorization was made by the Legislature. The SPA therefore finds that no amendment addressing biomedical research support to the University of Minnesota and Mayo Clinic should be added to the rules.

28. The proposed rules do provide for making awards to biomedical research proposals under the category of merit fellowship grants. 10 MCAR § 1.308A. 4. stipulates that "at least one half of the merit fellowship grants (amended to read "funds" as discussed in Item 26 above) shall be allocated to health services research, non-medical health research, and health policy analysis." During the hearing of April 7, 1978, Dr. David Brown suggested that the rules add a provision stipulating that, of the remaining funds, a certain percentage be earmarked for award to biomedical research proposals.

The SPA indicated that, given the lack of specific directives in Minn. Laws 1977, Ch. 454, Sec. 27, it relied heavily on the draft legislation as a basis for interpreting legislative intent. The language in § 1.308A. 4. is taken verbatim from both S.F. 1361 and H.F. 1497. The SHCC is thus given the authority to award the remaining merit fellowship grant funds as it deems most appropriate. Biomedical research proposals could, therefore, receive up to 50% of the merit fellowship funds. The SPA finds that it would be inappropriate to earmark a certain percentage of those funds for biomedical research proposals since no such intent was ever expressed by the Legislator (i.e., no such stipulation is provided by S.F. 1361, H.F. 1497, or Minn. Laws 1977, Ch. 454, Sec. 27). In a letter dated April 14, 1978, and submitted during the five-day period following the hearing, the SPA argued that such a provision could potentially lead to complaints of inappropriate discretion in the disbursement of funds by applicants with health services, non-medical, or health policy research proposals, who could argue that their applications were denied funding due to an arbitrary "cut-off point" (e.g., 50%) which had no basis in legislative intent.

The SPA finds that the InterStudy report, which was commissioned to give the Legislature further information and analysis on which to base a decision concerning the Governor's proposal for state funding of health research, is quite clear in its conclusions regarding the issue of funding biomedical versus the other types of health research. It found (p. 3) that "Minnesota has a large, excellent, and competitive biomedical research community, well able to attract and even increase its share of

federal and private research support. On the other hand," the report points out, "we have little in the way of health services research, non-medical health research, and health policy research, despite growing federal, state, and private concern in these areas." The report went on to conclude (p. 5) that "with respect to biomedical research, the emphasis should be on maintaining and strengthening the quality and competitiveness of our existing research community, not on increasing its size. The state already has large, first-rate biomedical research institutions. Major expansion in research positions and facilities at this time will place future operational funding demands upon these institutions." It goes on to point out (pp. 5-6) that "unlike biomedical research, where the state already possesses an excellent core of institutions and researchers, the state has few researchers or programs in the non-biomedical health research areas. Yet these areas are as likely to improve health as biomedical research (and probably in more cost-effective ways)...and the benefits accrue more directly within the state itself."

The SPA concludes that, with respect to the issue of HRP funding for biomedical versus non-biomedical research, the rules as proposed reflect the Legislature's intended emphasis on health services research, non-medical health research, and health policy research and analysis. The SPA therefore finds that no substantive change in the rules relevant to the issue of biomedical research is required.

10 MCAR § 1.308B. - NON-MEDICAL AND HEALTH SERVICES RESEARCH GRANTS

29. § 1.308B. reasonably provides directives which, unless specified to the contrary, are necessary and reasonable for the reasons set forth in the Statement of Need and Evidence.

30. In a letter dated March 27, 1978, and submitted to the SPA prior to the hearing, Edith R. Davis suggested that 10 MCAR § 1.308B. 1. be revised to include individuals in addition to the organizational entities specified in that rule.

The InterStudy report recommended that the state funds to be used in funding health research should be used to support individuals and institutions, as is explained in the Statement of Need and Evidence (Exhibit 1). The merit fellowship category achieves the purpose of supporting individuals. An individual who would wish to submit a proposal for doing non-medical or health services research would in no way be restricted by this rule from doing so since, under the category of merit fellowship grants, which are specifically intended to support individual researchers, there is ample opportunity to do so.

The SPA finds that § 1.308B. 1. reflects legislative intent and does not discriminate against individual applicants for the reasons discussed above. No amendment to § 1.308B. 1. is necessary.

10 MCAR § 1.308C. - HEALTH POLICY STUDY GRANTS

31. Section 1.308C. is reasonable and necessary for the reasons set forth in the Statement of Need and Evidence (Exhibit 1). No comments, oral or written, were offered on this portion of the rules.

10 MCAR § 1.309 - PRIORITY CONSIDERATIONS IN THE DISBURSEMENT OF HEALTH RESEARCH PROGRAM FUNDS

32. § 1.309 reasonably sets forth priorities which are necessary to an understanding of the HRP. Unless specified to the contrary, all priorities proposed in § 1.309 are considered to be reasonable and necessary for the reasons set forth in the Statement of Need and Evidence (Exhibit 1).

33. In a letter dated April 5, 1978, and submitted to the Examiner prior to the hearing, D.A. Barnes voiced a concern that the priorities listed in § 1.309 do not specifically mention a priority concern related to biomedical research. He noted that the next-to-last priority relates to biomedical issues, but suggested rewording the criteria to make the relationship more explicit. He recommended amending that priority to read as follows: "Basic biomedical research into the causes of diseases and disability, and the development of methods to reduce their incidence and prevalence in Minnesota."

During the hearing of April 7, 1978, Dr. N.L. Gault expressed the same concern. Then, and in a letter dated April 5, 1978, and submitted during the five-day period following the hearing, he indicated agreement with the language change proposed by Mr. Barnes.

SPA staff indicated that they viewed the proposed amendment as adding worthy clarification to the priority without substantially changing its intent. The SPA therefore recommended (Transcript, pp. 25-26 and 35-36) that the priority be reworded as proposed by Mr. Barnes.

The SPA finds that the proposed amending language adds important clarification to the priority in question but does not substantially change its meaning. It is therefore recommended that the next-to-last priority under § 1.309 be amended by substituting the language indicated above as proposed by D.A. Barnes.

34. In a letter dated April 7, 1978, and submitted during the five-day period following the hearing, Ronald C. Young, M.D., provided some comment concerning the priorities listed in § 1.309. He suggested adding the following criterion: "The provision of residential and community services for the mentally ill, mentally retarded, and chemically dependent."

The priorities listed in § 1.309 are intended to indicate broad priority areas which relate to the entire health services delivery system. The types of services referred to by Dr. Young, while important, represent only one component of the total health care delivery system. To write in a priority specific to that one category of services is equivalent to granting special consideration to applications relating to those services. Dr. Young himself indicates that the clients of these services represent underserved populations, the programs involve a complex of service delivery systems, and the impact of the services is difficult to evaluate. These and other relevant factors would appear to fall under the first, second, fourth, sixth, seventh, ninth, and eleventh priorities listed in § 1.309. For the reasons indicated above, the SPA finds that the priorities proposed in § 1.309 in no way exclude applications relating to the issues identified by Dr. Young, and that it would be inappropriate to add any priorities which could potentially be construed as giving special consideration to a particular type of proposal.

Dr. Young further suggested that the second priority listed in § 1.309 be amended to add "psychiatric/psychological" to the list of services included in that item. The SPA finds that it would be more appropriate to add the more general term "mental health services." It is therefore recommended that the second item listed in § 1.309 be amended to read "...intensive and coronary care, radiation therapy, and mental health services."

10 MCAR § 1.310 - CONFLICT OF INTEREST

35. The SPA finds that the provisions set forth in § 1.310 are reasonable and necessary for the reasons set forth in the Statement of Need and Evidence (Exhibit 1). No comments, oral or written, were offered on this portion of the rules.

Based on the foregoing Findings of Fact, the SPA makes the following

CONCLUSIONS

1. Due, timely, and adequate notice of the hearing was properly served and published by the SPA. All other substantive and procedural requirements of statute and rule have been fulfilled.

2. The SPA has demonstrated its statutory authority to adopt the proposed rules unless specifically indicated to the contrary in the preceding Findings.

3. By an affirmative presentation of facts, the SPA has demonstrated a need for and reasonableness of the proposed rules.

4. The proposed rules should be modified as suggested in the above Findings of Fact.

RECOMMENDATION

The SPA recommends that the proposed rules, as modified herein, be adopted.

Dated this 19 day of May, 1978.

Peter Vanderpoel

PETER VANDERPOEL
Director
Minnesota State Planning Agency

STATE HEALTH RESEARCH PROGRAM RULES

10 MCAR § 1.305 Authority, Purpose, Definitions and General Provisions

A. Authority. The rules contained herein are prescribed by the Statewide Health Coordinating Council and the State Planning Agency pursuant to the authority granted in Minn. Laws 1977, Ch. 453, Sec. 27 and Minnesota Department of Administration Reorganization Order No. 83.

B. Purpose. The purpose of these rules is to establish procedures for administering the Health Research Program. The Health Research Program will provide funds to help maintain biomedical research in Minnesota and to strengthen the state's ability to produce health services research, non-medical health research, and health policy research on issues of importance to the state.

C. Definitions. The following terms as used in these rules have the following meanings:

1. "Health Research Program" (HRP) means the program and corresponding appropriation established by the Minnesota Legislature in Minn. Laws 1977, Ch. 453, Sec. 27 to further health research in Minnesota.

2. "Statewide Health Coordinating Council" (SHCC) means the citizens' council appointed by the Governor of Minnesota pursuant to the National Health Planning and Resources Development Act of 1974, 42 U.S.C. § 300k (1977 Supp.).

3. "Committee on the Health Research Program" (CHRP) means a committee of the SHCC which shall supervise the administration of the Health Research Program. All decisions of the CHRP shall be subject to review and approval by the SHCC.

4. "State Planning Agency" means the agency of state government established by Minn. Laws 1965, Ch. 685 to perform statewide planning functions.

5. "State Health Planning and Development Agency" (SHPDA) means the division of the State Planning Agency designated by the governor to fulfill statewide health planning functions pursuant to the National Health Planning and Resources Development Act of 1974, 42 U.S.C. § 300k (1977 Supp.).

6. "Biomedical research" means research into the basic processes and distribution of health and disease, including clinical interventions that affect these processes.

7. "Health services research" means research on manpower, practice patterns, organization, and economics of health care aimed at improving the efficiency, effectiveness, and distribution of health services as delivered in practice.

8. "Non-medical health research" means research on methods to prevent disease and promote health independently of health services professionals, by minimizing causes of ill health related to lifestyle and environment.

9. "Health policy research and analysis" means the study of health-related problems and the development, testing, and evaluation of various policy options for dealing with such problems. Policy studies may include health services research, non-medical health research and health policy research and analysis.

10. "Grant" means an award of money pursuant to a written agreement signed by the eligible applicant and by the official representative of the SHCC, setting forth the amount of the funds, the time period within which the funds are to be expended, the purposes for which the funds may be used, and other contractual conditions deemed necessary by the SHCC.

10 MCAR § 1.306 Procedures for Informing the Public of the Health Research Program

A. Notice of availability. The SHCC shall inform the public of the availability of Health Research Program funds by the following means:

1. An announcement shall be published in the State Register.

2. ~~An announcement shall be published two consecutive weeks in a newspaper of general circulation in each county of the state.~~ An announcement shall be published in the form of a legal notice in 37 major newspapers providing circulation through the state.

3. An announcement of availability shall be mailed to the following Minnesota organizations and institutions:

a. The University of Minnesota and its affiliated campuses

b. State universities

c. Community colleges

d. Private colleges

e. Vocational-technical institutions

f. All hospitals

g. Associations of health professionals

h. Mayo Foundation for Education and Research

i. Minnesota Department of Health

j. Minnesota Department of Public Welfare

k. Minnesota Legislature

l. The seven Health Systems Agencies located in Minnesota

m. Local Boards of Health

The announcement shall set forth the amount of funds available for award, the period of time during which grant applications will be accepted, priority considerations listed in Section 1.309 of these rules which the CHRP and SHCC will consider in its evaluation of grant applications, the date when grant awards will be announced by the SHCC, and the location where applications should be submitted. The announcement of availability shall also include a detailed description of application procedures and project specifications as defined in Section 1.307 of these rules.

B. Announcement of grant awards. The SHCC shall announce the disposition of available grant funds by the following means:

1. When evaluation and selection have been completed, results will be sent immediately by mail to all applicants.

2. A list of grant recipients, the amount of funds awarded to each recipient, and the nature of the research to be performed by the recipient shall be published in the State Register.

3. A list of grant recipients, the amount of funds awarded to each recipient, and the nature of the research to be performed by the recipient shall be mailed to the following organizations and institutions in order to inform the health-related research community of the types of studies to be performed:

a. The University of Minnesota and its affiliated campuses

b. State universities

c. Community colleges

d. Private colleges

e. Vocational-technical institutions

f. All hospitals

g. Associations of health professionals

h. Mayo Foundation for Education and Research

i. Minnesota Department of Health

j. Minnesota Department of Public Welfare

k. Minnesota Legislature

l. The seven Health Systems Agencies located in Minnesota

m. Local Boards of Health

C. Commencement of funding. All funds awarded under the Health Research Program shall become available to each recipient at the beginning of Fiscal Year 1979 (July 1, 1978) and should be expended by the recipient no later than June 30, 1980.

10 MCAR § 1.307 Application Procedures

A. All applicants for HRP funds will be required to submit a proposal containing the following information:

1. The type of grant being applied for (i.e., whether Merit Fellowship, Non-Medical and Health Services Research, or Health Policy Study).

2. Scope of the project

3. Project goal and objectives

4. Project tasks to be completed

5. A description of the project, including:

a. A restatement of the objectives showing or demonstrating the applicant's view of the nature of the proposed research.

b. Identification and description of the products to be delivered by the applicant.

c. A description of the applicant's background and experience in health-related research.

d. Identification of the personnel who will conduct the research and a detailed description of their training and research experience. No change in professional research personnel assigned to the project will be permitted without the approval of the SHCC.

6. A detailed budget of project costs delineating proposed expenses. No general overhead rate will be allowed in the budget calculation.

7. A project completion date indicating the anticipated termination of the proposed research activity.

8. An indication of any other sources of funding, already possessed or applied for, which would be used to support the proposed research project.

B. All grant applications will be required to be submitted by a time and date specified by the SHCC in the announcement of availability described in Section 1.306A of these rules. Late proposals will not be accepted.

10 MCAR § 1.308 Procedures for Awarding Health Research Program Funds

A. Merit Fellowship Grants

1. Eligibility. An eligible applicant is any individual researcher who resides in or agrees to reside in Minnesota and who proposes to engage in exploratory analysis and pilot

research in a health-related subject or issue which has been established as a priority by the SHCC as defined in Section 1.309 of these rules. As a condition to receipt of a grant, each applicant must provide evidence that he/she has or will have an affiliation with the University of Minnesota, the Mayo Clinic, the Legislature and/or its staff, a state department or agency, a health organization, or post-secondary educational institution. This evidence must include a corroborating statement from the institution or organization with which the researcher affiliates or proposes to affiliate. Further, each applicant, as a condition to receipt of a grant, must agree to and actively seek federal or private support for full-scale research projects based on his or her exploratory analysis and pilot research.

2. Process of award. Grants to merit fellows shall be awarded on a competitive basis with applications being evaluated in terms of:

   a. The applicant's professional credentials.

   b. Demonstrated past performance in doing health-related research.

   c. Proposed subject for study.

   d. Clarity of the project goal and objectives.

   e. The project work plan.

   f. The project budget.

   g. The qualifications of any additional professional research staff who will assist with the research project.

3. Terms of grant. Grants to merit fellows shall be limited to a maximum of $50,000 per year for two years. Each grant may be utilized to provide a stipend to support the researcher and necessary clerical and research assistants and to cover the costs of other professional expenses incurred in the process of performing the research.

4. ~~At least one-half of the merit fellowship grants shall be allocated to health services research, non-medical health research, and health policy analysis.~~ Merit fellowship grants shall be allocated to biomedical research, health services research, non-medical health research, and health policy research and analysis. At least one half of these funds shall be allocated to health services research, non-medical health research, and health policy research and analysis.

B. Non-Medical and Health Services Research Grants

1. Eligibility. An eligible applicant is a Minnesota post-secondary education institution, state department or agency, or other health organization.

2. Purposes. Grants may be used to fund senior research positions, to provide seed money for non-medical and health services research activities, and to provide information, analysis, and technical support to health planners and state agencies on questions of health costs, productivity, health care regulation, and organization of the health care delivery system. The grants may also be used to support investigations and evaluations of preventive health care techniques designed to improve public health.

3. Process of award. Grants for non-medical and health services research shall be awarded on a competitive basis and shall be used only to support activities which are consistent with state health priorities established by the SHCC and listed in Section 1.309 of these rules.

   Applications shall be evaluated in terms of:

   a. Demonstrated past performance of the applicant organization, institution, or agency in doing health-related research.
   b. Proposed subject for study.
   c. Clarity of the project goal and objectives.
   d. The project work plan.
   e. The project budget.
   f. Qualifications of the professional research staff who will carry out the research. The experience of the assigned personnel will be given greater weight than will the demonstrated past performance of the applicant organization, institution, or agency.

4. Determination of grant amount. The amount and nature of the grant shall be determined by the SHCC, which shall take into consideration the amount of funds requested and available; the demonstrated ability of the eligible applicant to perform research in the areas set forth in point B(2) above; and the technical assistance to health planners, state agencies, and the legislature which may be generated by the proposed research.

C. Health Policy Study Grants

1. Eligibility. An eligible applicant is any individual or organization that proposes a study relevant to the formulation of state health policy.

2. Process of award. Grants for health policy studies shall be awarded on a competitive basis and shall be consistent with health policy issues of priority concern as established by the SHCC and listed in Section 1.309 of these rules. Applications shall be evaluated in terms of:

   a. The applicant's professional credentials, where the applicant is an individual, or, where the applicant is an organization, institution, or agency, the demonstrated past performance of the entity in doing health policy research.

   b. Demonstrated past performance in doing health-related research.

   c. Proposed subject for study.

   d. Clarity of the project goal and objectives.

   e. The project work plan.

   f. The project budget.

   g. Qualifications of the professional research staff who will carry out the research. Where the applicant is an organization, institution, or agency, the experience of the assigned personnel will be given greater weight than will the demonstrated past performance of the organization, institution, or agency.

3. Determination of grant amount. The nature and size of the grant shall be determined by the SHCC, which shall take into consideration the amount of funds requested and available, the importance of the proposed subject of study to the state,

and its consistency with the purpose of the HRP as defined in Section 1.305B and the priorities established by the SHCC and listed in Section 1.309 of these rules.

10 MCAR § 1.309 Priority Considerations in the Disbursement of Health Research Program Funds

In evaluating applications for HRP grants, the SHCC will consider the proposed subject of study in terms of the following priorities:

- The provision of primary care services for medically underserved populations located in rural or economically depressed areas.
- The development of multi-institutional systems for coordinating or consolidating institutional health services, including obstetric, pediatric, emergency medical, intensive and coronary care, ~~and~~ radiation therapy, and mental health services.
- The development of multi-institutional arrangements for the sharing of support services necessary to all health service institutions.
- The development of medical group practices (especially those whose services are appropriately coordinated or integrated with institutional health services), health maintenance organizations, and other organized systems for the provision of health care.
- The training and increased utilization of physician extenders, especially nurse clinicians.
- The promotion of activities to achieve needed improvements in the quality of health services.

- The development by health service institutions of the capacity to provide various levels of care (including intensive care, acute general care, and extended care) on a geographically integrated basis.
- The promotion of activities for the prevention of disease, including studies of nutritional and environmental factors affecting health and the provision of preventive health care services.
- The development of effective methods of educating the general public concerning proper personal (including preventive) health care and methods for effective use of available health services.
- ~~Method to reduce the incidence and prevalence of the leading causes of death and disability in Minnesota.~~ Basic biomedical research into the causes of diseases and disability, and the development of methods to reduce their incidence and prevalence in Minnesota.
- The development of improved methodologies for health planning.

10 MCAR § 1.310 Conflict of Interest

When any member of the SHCC or the CHRP has any conflict of interest with respect to a Health Research Program grant application under consideration by the SHCC, that member shall, prior to consideration of the application, voluntarily disclose such interest to the CHRP and SHCC, either verbally or in writing, and shall be disqualified from voting on that particular grant application. A conflict of interest shall be deemed to exist where a SHCC member:

1. has a material financial interest, whether direct or indirect, in the proposed research or study;
2. is a director, trustee, or officer of any organization or institution applying for Health Research Program funds;
3. is an employee of any applicant;
4. is the spouse, child, parent, or sibling of any individual applicant.

Any member of the SHCC may challenge any other member by means of a properly recorded vote which shall determine the status of the challenged member concerning any possible conflict of interest before further voting on the proposed grant application under consideration.

No member of the Minnesota Legislature shall serve on the CHRP. No member of the CHRP, the SHCC, or the Minnesota Legislature shall be eligible to receive a grant under the Health Research Program.

APPROVED AS TO FORM AND LEGALITY

JUN 8 1978 19____

WARREN SPANNAUS, ATTORNEY GENERAL

BY _____

SPECIAL ASSISTANT ATTORNEY GENERAL

STATE OF MINNESOTA
DEPARTMENT OF STATE
FILED
JUN 8 1978
Joan Anderson Growe
Secretary of State
4:00 P.M.

EXHIBIT F
REPORT OF THE HEARING EXAMINER

STATE OF MINNESOTA
OFFICE OF HEARING EXAMINERS

FOR THE MINNESOTA STATE PLANNING AGENCY

In the Matter of the Rules Proposed for Adoption by the Minnesota State Planning Agency Relating to the Administration of the Health Research Program (HRP).

REPORT OF HEARING EXAMINER

The above-entitled matter came on for hearing before Hearing Examiner Howard L. Kaibel, Jr. of the Minnesota Office of Hearing Examiners on April 7, 1978, at 9:30 a.m. in Room 83, the Auditorium, of the State Office Building on Wabasha Street in Saint Paul, Minnesota.

William E. Dorigan, Special Assistant Attorney General, appeared as counsel for the State Planning Agency (hereinafter "SPA"). John Dilley, Director of the State Health Planning and Development Agency, a constituent part of the SPA; Steven Mosow, Assistant Director of the State Health Planning and Development Agency; and Jan Anderson, Health Planner, testified on behalf of the SPA. The hearing continued until all interested groups or persons had an opportunity to be heard concerning the adoption of the proposed rules.

The purpose of the hearing was to determine whether proposed Minn. Rules 10 MCAR 1.305-1.310, dealing with the subject matter captioned above, should be adopted.

The matter of the HRP began in January, 1977, when Governor Perpich presented his budget message to the Minnesota Legislature. The Governor cited Minnesota's leadership in the areas of biomedical research and reform of the health care delivery system. In order to support and expand the state's role in these areas, he recommended an appropriation for a health research program, to be expended over the next two fiscal years. He suggested that the funds be used to support research in a number of areas: biomedicine, dental care, the

health services delivery system, and other health-related issues.

Individual legislators felt that the scope of the proposal warranted further in-depth analysis by outside experts. Legislative leadership and the Governor therefore agreed that a study of the issue would be made by InterStudy, an independent health policy research organization, and the results reported to the Legislature and Governor. The Dayton-Hudson Foundation agreed to provide financial support for the study. The report, entitled "Alternatives for State Support of Health Research", was published in April, 1977. The study concluded that some additional state support for health research would be a wise investment.

Subsequent to these events, an appropriation of $1.5 million was made by the Minnesota Legislature (Minn. Laws 1977, Ch. 454, Sec. 27) for the purpose of funding a state program to further health research in Minnesota. This Health Research Program is intended to provide state funds for merit fellowships and other grants in the areas of non-medical research, health services research, and health policy studies. The $1.5 million appropriation is to be allocated in the following manner: $1,000,000 for merit fellowships, $300,000 for non-medical and health services research grants, and $200,000 for health policy studies. The funds were appropriated for fiscal year 1979.

The appropriation was originally made to the Minnesota Department of Health. However, Minn. Laws 1977, Ch. 454, Sec. 27 directs the Statewide Health Coordinating Council (SHCC) to administer the disbursement of these funds. Due to its direct relationship to the SHCC, the State Planning Agency, which houses the State Health Planning and Development Agency, was viewed as the more appropriate state agency to which the funds should be allocated. Therefore, Minnesota Department of Administration Reorganization Order No. 83 was issued to

transfer the appropriation from the Department of Health to the State Planning Agency.

The SHCC has appointed a Committee on the Health Research Program (CHRP) which will have primary responsibility for administering the program and evaluating the proposals for HRP funds which are received. The committee will make its recommendations to the full SHCC, which will have the final review and approval authority.

The State Health Planning and Development Agency (SHPDA), with the assistance and advice of the Attorney General's Office, drafted proposed rules for the HRP. Staff of the SHPDA and the appropriate representative of the Attorney General's Office then met with the Committee on the Health Research Program to review and discuss the draft rules. Suggestions and changes made by the committee were incorporated and the revised version presented to the SHCC for its consideration at its meeting of February 15, 1978. Following general discussion and suggestions for minor changes, the SHCC approved the draft rules for initiation of the formal rulemaking process required by Minn. Stat. Ch. 15, the Administrative Procedures Act. As part of that rulemaking process, the public hearing was held on April 7, 1978, before the Hearing Examiner.

The stated purpose of these rules is to establish procedures for administering the Health Research Program. The HRP is intended to help maintain biomedical research in Minnesota and to strengthen the state's ability to produce health services research, non-medical health research, and health policy research on issues of importance to the state. The rules are intended to create a process which will be clear and predictable to all potential applicants for HRP funds, yet efficient and practical for administration by the CHRP and SHCC. In developing these rules, an attempt was made to closely reflect (1) the Governor's concept as proposed in his budget message to the 1977 Legislature; (2) the findings of

the InterStudy report prepared for the Governor and Legislature; and (3) legislative intent as established in bills developed during the 1977 legislative session. No final bill enacting the Health Research Program was ever passed by the Legislature. The InterStudy report, which was commissioned to give the Legislature further information on which to base a decision concerning the Governor's proposal, was not published until April 15, 1977. A Senate bill (S.F. 1361) was introduced and first read on April 18, 1977. A companion bill to the Senate version was introduced in the House (H.F. 1497). S.F. 1361 was passed by the Senate on May 19, 1977, and transmitted to the House on the same day. The House bill, however, was never passed, and thus no final enactment was forthcoming from the Legislature. The appropriation for the Health Research Program was made by the Legislature on May 21, 1977, as a rider to the appropriations for the Minnesota Department of Health (Minn. Laws 1977, Ch. 454, Sec. 27). Since there was no HRP bill itself enacted, S.F. 1361 was utilized as a basis for interpreting legislative intent.

Pursuant to Minn. Stat. § 15.0412, subd. 4 (1977), this Report shall be available for review to all affected individuals upon request for at least five days.

The SPA shall, if it proposes to adopt the rules as originally proposed or amended, submit the complete hearing record, including its Findings and Order, to the Chief Hearing Examiner no earlier than five days subsequent to the receipt of this Report. This submission shall clearly indicate any changes made to the rules as originally proposed, preferably in the format that will be submitted to the State Register for publication. The Chief Hearing Examiner shall complete his review and submit his report to the SPA on the issues of substantial changes in the rules and compliance with Minn. Stat. § 15.0412 (1977) within ten calendar days. Thereafter, the SPA shall be responsible for filing the rules with the Attorney

6. On March 22, 1978, the SPA issued a press release concerning the proposed rules and the scheduled public hearing to 37 newspapers throughout the state. These newspapers were, with the assistance of the seven Health Systems Agencies covering Minnesota, identified as the major regional newspapers which would be most likely to provide the greatest exposure to the public.

7. The SPA made it a practice to provide the Notice of Public Hearing and a copy of the proposed rules to any and all parties who made inquiries concerning the Health Research Program later than the March 17, 1978, mailing outlined in Item 5 above.

8. The record remained open through April 14, 1978, for the receipt of written comments and statements.

9. All comments which addressed the proposed rules, whether oral or written, have been reviewed by the Examiner and have been considered in the preparation of this Report.

10 MCAR § 1.305A. - Authority

10. The SPA's authority to propose and adopt rules for administering the HRP is contained in Minn. Stat. § 4.17 (1976), Minn. Laws 1977, Ch. 454, § 27, and Minnesota Department of Administration Reorganization Order No. 83. Reference to specific statutory provisions or the absence of such specific statutory authority is noted in this report where such authority or lack thereof is relevant and necessary to complete understanding of these Findings. No one questions the SPA's general authority or legislative mandate to establish rules to implement the HRP.

Reference to the statute authorizing the rules is reasonable and necessary to allow easy reference for anyone wishing to refer to the specific statutory language and to check those parts of the law which are not contained in the rules.

10 MCAR § 1.305B. - Purpose

11. Section 1.305B. is reasonable and necessary in order

General and for notifying persons who have indicated that they wish to be notified of such filing.

Based upon all the records and proceedings herein, the Examiner makes the following:

FINDINGS OF FACT

PROCEDURAL REQUIREMENTS

1. On February 17, 1978, the SPA filed, in proper form and duly executed, the following documents with the Chief Hearing Examiner, pursuant to Minn. Reg. HE 102:

(a) A copy of the proposed rules;
(b) A proposed Order for Hearing;
(c) A proposed Notice of Hearing; and
(d) A statement of the number of persons expected to attend the hearing and the estimated length of the hearing.

2. The Notice of Hearing and the proposed rules were published in the State Register on March 6, 1978.

3. On February 27, 1978, the SPA mailed the Notice of Hearing to all persons and entities who had registered their names with the Secretary of State for the purpose of receiving such notice.

4. On March 13, 1978, the SPA filed with the Office of Hearing Examiners the following documents:

(a) The Order for Hearing;
(b) The Notice of Hearing as mailed;
(c) The Affidavit of Receipt of the Secretary of State's list;
(d) The Affidavit of Mailing;
(e) The Secretary of State's Certificate and list;
(f) The Statement of Need and Evidence (with attachments); and
(g) The names of agency personnel who would represent the SPA at the hearing.

The documents were available for inspection at the Office of Hearing Examiners from the date of filing to the date of the hearing.

5. On March 17, 1978, the SPA made an additional voluntary mailing of the Notice of Hearing and the proposed rules to its own list of parties who had expressed an interest in the Health Research Program.

to declare to interested parties the reason for the promulgation of these rules and the purpose of the program to which they apply. The language reflects the purpose of the program as discussed above in the introduction to these Findings of Fact.

10 MCAR § 1.305C. - Definitions

12. Section 1.305C. reasonably provides definitions which are necessary to understand the precise meaning of terms used in the rules. Unless specified to the contrary, all definitions proposed in 10 MCAR § 1.305C. are considered to be reasonable and necessary for the reasons set forth in the Statement of Need and Evidence (Exhibit 1).

13. In a letter dated April 5, 1978, submitted to the SPA prior to the hearing, John E. Kralewski indicated a concern that § 1.305C. (6) through (9) do not adequately clarify the distinction between biomedical research and the other categories of health services research. However, no clarifying language amendment was suggested. The Examiner finds that the definitions as proposed adequately serve the purpose of the rules by making the distinction between the four types of health-related research to be funded by the HRP. The definitions in question were derived directly from the InterStudy report (see Exhibit 1). The terms themselves, and the categories of research which they represent, appeared in S.F. 1361. The defintiions as proposed are reasonable and necessary for the purposes of administering the HRP.

10 MCAR § 1.306A. - Notice of Availability

14. Minn. Laws 1977, Ch. 454, Sec. 27 provided no specific directives to the SHCC concerning the manner in which the HRP is to be administered (with the exception of total sums for each grant category). For this reason, procedures to be utilized by the SHCC must be established by the rulemaking process to make them clearly known and predictable to all relevant parties. A major practical necessity is to inform the

public of the existence of the Health Research Program and the opportunity to apply for a grant under this program. Several methods have been proposed as a means of providing the public with information about the HRP. It is specifically found that, unless specified to the contrary, the methods proposed in § 1.306A. are reasonable and necessary for the reasons set forth in the Statement of Need and Evidence (Exhibit 1).

15. The SPA originally proposed to publish the Notice of Availability "two consecutive weeks in a newspaper of general circulation in each county of the state". This method was proposed as one of several ways of informing the public about the existence of the Health Research Program and the opportunity to apply for a grant from the funds available.

Further study by the SPA, however, has indicated several things relevant to this section of the rule. First, items submitted to newspapers as "news releases" have no guarantee of appearing in print. This uncertainty is not consistent with the goal of ensuring public awareness of the HRP and thus, is not considered an acceptable method.

Items submitted as "official notices" are guaranteed publication, but a fee is charged for the publication. Publishing the notice twice, then, would double the cost involved without necessarily ensuring wider public exposure. The SPA therefore recommends that the rule be amended to require only one such publication.

The SPA also indicated that publication in "newspapers of general circulation in each county" may not be the best method of reaching public readership. It was pointed out that many county newspapers are weeklies and have very small and limited circulations, while the newspapers published in the larger nearby cities usually have widespread circulation throughout the entire region. The SPA explained that it had contacted the seven local Health Systems Agencies (HSA) covering all of

Minnesota. Each HSA was asked to identify the major regional newspapers in its area which it routinely uses to publish various required legal notices. The SPA feels that these 37 newspapers provide statewide circulation sufficient to ensure wide public exposure. It did, in fact, utilize this same list to issue a news release concerning the promulgation of rules and the public hearing (see Item 6 above).

The SPA therefore recommends that proposed 10 MCAR § 1.306A. 2. be amended to read: "An announcement shall be published in the form of a legal notice in 37 major newspapers providing circulation throughout the state". The SPA submitted a list indicating the specific 37 newspapers which it proposes to utilize. This list was incorporated as part of the hearing record (Exhibit 1).

It is specifically found that the elimination of unnecessary expenditures of appropriated research funds is desirable and that the proposed 37 newspapers do in fact provide for adequate circulation throughout the state. The amendment proposed by the SPA is reasonable and necessary.

16. In a letter dated April 4, 1978, and submitted during the five-day period for receiving comments, Ellen Alkon, M.D., suggested that the list of entities specified in § 1.306A. 3. be amended to include "Boards of Health" due to their association with preventive health care techniques designed to improve the public health. The suggested addition is in keeping with the rule's intent to reaching the health-related research community and § 1.306A. 3. should be amended to include the following additional item: "(m) Local Boards of Health."

10 MCAR § 1.306B. - Announcement of Grant Awards

17. Just as it is important to notify the public concerning the availability of state funds, it is also important to provide notice of the disposition of such public monies. Several methods have been proposed as a means of providing such public notice. Except where specified to the contrary, the

methods proposed are reasonable and necessary for the reasons set forth in the Statement of Need and Evidence (Exhibit 1).

18. In a letter dated April 4, 1978, and submitted during the five-day period for receiving comments, Ellen Alkon, M. D., suggested that § 1.306B. 3. also be amended to include local Boards of Health for the same reasons indicated in Finding 16 above. The suggested addition is in keeping with the intent of notifying the health-related research community of the types of research to be performed using the HRP grants, and § 1.306B. 3. should be amended to include the following additional item" "(m) Local Boards of Health".

10 MCAR § 1.306C. - Commencement of Funding

19. During the hearing of April 7, 1978, John Kralewski, Ph.D., made a comment indicating that an HRP funds should be allocated for a two-year period as are the merit fellowship grants. SPA staff pointed out that § 1.306C. stipulates that all funds awarded under the HRP, not only the merit fellowship grants, may be expended up to June 30, 1980. Therefore, the proposed rule already contains the provision suggested by the commentor and no amendment is necessary.

10 MCAR § 1.307 - Application Procedures

20. Section 1.307 is reasonable and necessary for the reasons set forth in the Statement of Need and Evidence (Exhibit 1). No comments, oral or written, were offered on this portion of the rules.

10 MCAR § 1.308A. - Merit Fellowship Grants

21. In a letter dated April 5, 1978, and submitted to the SPA prior to the hearing, John Kralewski, Ph.D., questioned the provision in § 1.308A. 1. that merit fellowship grants are to be used to fund exploratory analysis and pilot research. He offered the opinion that merit fellowship grants should be

allowed to fund research projects which are beyond the exploratory/pilot stage.

The InterStudy report recommended that this category of fellowships be established, indicating that it would help to build a core of researchers in the state. The InterStudy report found that research funding priority should be given to an "investigatorship" which, in addition to providing a stipend to the researcher, would provide a small amount of "seed money" for research expenses. S. F. 1361 retained this concept by stipulating that fellowship grants be used for exploratory analysis and pilot research, as did H. F. 1497. No contrary evidence was submitted on funding priorities. The proposed rule is reasonable and necessary to ensure that funds are spent where the needs are greatest.

22. In a letter dated April 5, 1978, and submitted to the Examiner prior to the hearing, D. A. Barnes indicated a concern that the proposed rules seem to favor the established individual as opposed to an individual more junior. Some of this concern appears to be based on § 1.308A. 2., which indicates that, among other things, merit fellowship grant applications shall be evaluated in terms of the applicant's "demonstrated past performance in doing health-related research". The InterStudy report recommended that the fellowships be used to support young researchers, and there is some concern that the evaluation criteria mentioned above might work to the disadvantage of such young researchers who have not yet established a long record of research accomplishments.

SPA staff pointed out that § 1.308A. 2. a. requires the evaluation of "the applicant's professional credentials", which would reflect the training and education possessed by any young researcher, including any research experience obtained during that training or education. It is only practical to consider any relevant experience of an applicant, and the proposed rule as written does not discriminate against young researchers.

The remainder of § 1.308A. 2. clearly indicates that each proposal will be judged independently on the merits of the proposal itself, not simply the qualifications of the applicant.

Mr. Barnes suggested that merit fellowship grants be divided into two types: a junior merit fellowship and a senior merit fellowship, the only difference being the degree of demonstrated past performance required of each. Mr. Barnes did not provide any specific suggestions on how a justifiable "dividing point" measuring the degree of demonstrated past performance could be established in order to differentiate "junior fellows" from "senior fellows". SPA staff pointed out (Tr. p. 56) that neither the InterStudy report, S. F. 1361, nor H. F. 1497 contained any language which could be interpreted as suggesting that the merit fellowship grants be split in such a way. Language should be incorporated instead upon final adoption indicating that the InterStudy concern for funding young researchers will be an explicit consideration in grant allocation.

23. During the hearing of April 7, 1978, David M. Brown, M.D., voiced some concern regarding § 1.308A. 3., which establishes merit fellowship grants as consisting of a maximum of $50,000 per year for two years. Dr. Brown suggested reducing the maximum amount to a lower level in order to increase the number of fellowship grants which could be awarded.

The funding level set forth in this rule is taken directly from both S. F. 1361 and H. F. 1497. The $50,000 per year amount is a maximum and there is no requirement that all merit fellowships be funded at that level. The amount of funds to be awarded to each merit fellow, up to the maximum, is left to the discretion of the Statewide Health Coordinating Council. The type of flexibility suggested by Dr. Brown is already contained in § 1.308A. 3. and no amendment is necessary.

24. Section 1.308A. 4. sets forth a stipulation that at least one half of the merit fellowship grants shall be allocated to health services research, non-medical health research,

and health policy. Concern was expressed by N. L. Gault, M.D., both during the hearing of April 7 and in a letter dated April 7, 1978, and submitted during the five-day period following the hearing; and by John E. Kralewski, Ph.D., in a letter dated April 5, 1978, that the proposed rule as stated does not clearly indicate that the remainder of merit fellowships may be awarded to biomedical research proposals. Both suggested that some clarifying language be added.

In a letter dated April 14, 1978, and submitted during the five-day period allowed for comments, the SPA indicated its agreement that the option of using merit fellowships to fund biomedical research should be more clearly stated by including a specific reference to that category of research. It therefore recommended that 10 MCAR § 1.308A. 4. be amended to read as follows: "Merit fellowship grants shall be allocated to biomedical research, health services research, non-medical health research, and health policy research and analysis. At least one half of these grants shall be allocated to health services research, non-medical health research, and health policy research and analysis." The proposed amendment does not substantially change the intent of the rule, but does clarify its meaning. It is needed and reasonable.

25. Both of the commentors identified in the preceding Finding also questioned the language of § 1.308A. 4. in terms of whether the intent was to earmark at least half the number of grants or half the amount of funds available for award. The InterStudy report's recommendations concerning merit fellowships appear to be based on the supposition that all the fellowship grants would be a flat $100,000 over a two-year period. Thus, a recommendation that half the grants be earmarked for non-biomedical research is equivalent to recommending that half the funds be allocated to those types of research. While S. F. 1361 and H. F. 1497 utilized the language "half the grants", it seems clear from the intended emphasis of the HRP (discussed in greater detail in the following Finding) that the intention was to see

that at least half the support available went to the areas of non-medical health research, health services research, and health policy research and analysis. Clarifying language which will avert potential confusion may be substituted without substantially changing the meaning of the rule. The amendment recommended in the preceding Finding will accomplish these purposes.

26. The major concern expressed during the hearing of April 7, 1978, related to the issue of HRP funding support for biomedical research. During the hearing, Dr. N. L. Gault questioned the rules' failure to provide flexible support specifically for biomedical research to the University of Minnesota and the Mayo Clinic. SPA staff pointed out that Dr. Gault's comments related to a grant category entitled, "Research Support for University of Minnesota and Mayo Clinic" which had appeared in S. F. 1361 along with the other three grant categories. That fourth category in S. F. 1361 reflected a recommendation by the InterStudy report that the state provide such flexible support for biomedical research. H. F. 1497, however, did not include a specific category for support of biomedical research. The deciding factor, however, is that the appropriation bill simply did not fund that category. Merit fellowships, non-medical and health services research, and health policy research were funded; a category exclusive to biomedical research was not. It is therefore inappropriate for the SPA to promulgate rules setting forth certain amounts of funds to be earmarked for biomedical research. It is specifically found that no amendment addressing biomedical research support to the University of Minnesota and Mayo Clinic should be added to the rules.

The proposed rules do provide for making awards to biomedical research proposals under the category of merit fellowship grants. 10 MCAR § 1.308A. 4. stipulates that "at least one half of the merit fellowship grants (amended to read "funds"

as discussed in Item 25 above) shall be allocated to health services research, non-medical health research, and health policy analysis". During the hearing of April 7, 1978, Dr. David Brown suggested that the rules add a provision stipulating that, of the remaining funds, a certain percentage be earmarked for award to biomedical research proposals.

The SPA indicated that, given the lack of specific directives in Minn. Laws 1977, Ch. 454, Sec. 27, it relied heavily on the draft legislation as a basis for interpreting legislative intent. The language in § 1.308A. 4. is taken verbatim from both S. F. 1361 and H. F. 1497. The SHCC is thus given the authority to award the remaining merit fellowship grant funds as it deems most appropriate. Biomedical research proposals could, therefore, receive up to 50% of the merit fellowship funds. In a letter dated April 14, 1978, and received during the five-day period following the hearing, the SPA argued that such a provision could potentially lead to complaints of inappropriate discretion in the disbursement of funds by applicants with health services, non-medical, or health policy research proposals, who could argue that their applications were denied funding due to an arbitrary "cut-off point" (e.g., 50%) which had no basis in legislative intent.

The InterStudy report, which was commissioned to give the Legislature further information and analysis on which to base a decision concerning the Governor's proposal for state funding of health research, is quite clear in its conclusions regarding the issue of funding biomedical versus the other types of health research. It found (p. 3) that "Minnesota has a large, excellent, and competitive biomedical research community, well able to attract and even increase its share of federal and private research support. On the other hand," the report points out, "we have little in the way of health services research, non-medical health research, and health policy research, despite growing federal, state, and private concern in these

areas." The report went on to conclude (p. 5) that "with respect to biomedical research, the emphasis should be on maintaining and strengthening the quality and competitiveness of our existing research community, not on increasing its size. The state already has large, first-rate biomedical research institutions. Major expansion in research positions and facilities at this time will place future operational funding demands upon these institutions." It goes on to point out (pp. 5-6) that "unlike biomedical research, where the state already possesses an excellent core of institutions and researchers, the state has few researchers or programs in the non-biomedical health research areas. Yet these areas are as likely to improve health as biomedical research (and probably in more cost-effective ways). . .and the benefits accrue more directly within the state itself."

It is specifically found that, with respect to the issue of HRP funding for biomedical versus non-biomedical research, the rules as proposed are in accord with the uncontroverted evidence relating to placing evidence on health services research, non-medical health research, and health policy research and analysis. No substantive change in the rules relevant to the issue of biomedical research is required.

10 MCAR § 1.308B. - Non-Medical and Health Services Research Grants

27. Section 1.308B. reasonably provides directives which, unless specified to the contrary, are necessary and reasonable for the reasons set forth in the Statement of Need and Evidence.

28. In a letter dated March 27, 1978, and submitted to the SPA prior to the hearing, Edith R. Davis suggested that 10 MCAR § 1.308B. 1. be revised to include individuals in addition to the organizational entities specified in that rule.

The InterStudy report recommended that the state funds to be used in funding health research should be used to support

individuals and institutions, as is explained in the Statement of Need and Evidence (Exhibit 1). The merit fellowship category achieves the purpose of supporting institutions. An individual who would wish to submit a proposal for doing non-medical or health services research would in no way be restricted by this rule from doing so since, under the category of merit fellowship grants, which are specifically intended to support individual researchers, there is ample opportunity to do so.

Section 1.308B. 1. does not discriminate against individual applicants for the reasons discussed above. No amendment to § 1.308B. 1. is necessary.

10 MCAR § 1.308C. - Health Policy Study Grants

29. Section 1.308C. is reasonable and necessary for the reasons set forth in the Statement of Need and Evidence (Exhibit 1). No comments, oral or written, were offered on this portion of the rules.

10 MCAR § 1.309 - Priority Considerations in the Disbursement of Health Research Program Funds

30. Section 1.309 reasonably sets forth priorities which are necessary to an understanding of the HRP. Unless specified to the contrary, all priorities proposed in § 1.309 are considered to be reasonable and necessary for the reasons set forth in the Statement of Need and Evidence (Exhibit 1).

31. In a letter dated April 5, 1978, and submitted to the Examiner prior to the hearing, D. A. Barnes voiced a concern that the priorities listed in § 1.309 do not specifically mention a priority concern related to biomedical research. He noted that the next-to-last priority relates to biomedical issues, but suggested rewording the criteria to make the relationship more explicit. He recommended amending that priority to read as follows: "Basic biomedical research into the causes of diseases and disability, and the development of methods to reduce their incidence and prevalence in Minnesota."

During the hearing of April 7, 1978, Dr. N. L. Gault expressed the same concern. In a letter dated April 5, 1978, and submitted during the five-day period following the hearing, he indicated agreement with the language change proposed by Mr. Barnes.

SPA staff indicated that they viewed the proposed amendment as adding worthy clarification to the priority without substantially changing its intent. The SPA therefore recommended (Tr. pp. 25-26 and 35-36) that the priority be reworded as proposed by Mr. Barnes.

It is specifically found that the proposed amending language adds important clarification to the priority in question but does not substantially change its meaning. It is therefore recommended that the next-to-last priority under § 1.309 be amended by substituting the language indicated above as proposed by D. A. Barnes.

32. In a letter dated April 7, 1978, and submitted during the five-day period following the hearing, Ronald C. Young, M.D., provided some comment concerning the priorities listed in § 1.309. He suggested adding the following criterion: "The provision of residential and community services for the mentally ill, mentally retarded, and chemically dependent."

The priorities listed in § 1.309 are intended to indicate broad priority areas which relate to the entire health services delivery system. The types of services referred to by Dr. Young, while important, represent only one component of the total health care delivery system. To write in a priority specific to that one category of services might be misinterpreted as granting special consideration to applications relating to those services. Dr. Young himself indicates that the clients of these services represent underserved populations, the programs involve a complex of service delivery systems, and the impact of the services is difficult to evaluate. These and other relevant factors would appear to fall under the first, second, fourth, sixth,

seventh, ninth, and eleventh priorities listed in § 1.309. For the reasons indicated above, the priorities proposed in § 1.309 in no way exclude applications relating to the issues identified by Dr. Young, and it would be inappropriate to add any priorities which could potentially be construed as giving special consideration to a particular type of proposal.

Dr. Young further suggested that the second priority listed in § 1.309 be amended to add "psychiatric/psychological" to the list of services included in that item. This can be accomplished by adding the more general term "mental health services". It is therefore recommended that the second item listed in § 1.309 be amended to read ". . .intensive and coronary care, radiation therapy, and mental health services."

10 MCAR § 1.310 - Conflict of Interest

33. The provisions set forth in § 1.310 are reasonable and necessary for the reasons set forth in the Statement of Need and Evidence (Exhibit 1). No comments, oral or written, were offered on this portion of the rules.

Based on the foregoing Findings of Fact, the Examiner makes the following:

CONCLUSIONS

1. Due, timely, and adequate notice of the hearing was properly served and published by the SPA. All other substantive and procedural requirements of statute and rule have been fulfilled.

2. The SPA has demonstrated its statutory authority to adopt the proposed rules unless specifically indicated to the contrary in the preceding Findings.

3. By an affirmative presentation of facts, the SPA has demonstrated a need for and reasonableness of the proposed rules, unless specified to the contrary in the preceding Findings.

Based on the foregoing, the Examiner makes the following:

RECOMMENDATION

IT IS HEREBY RECOMMENDED: That the proposed rules, after

attention to the modifications suggested herein, be adopted.

Dated: May 24, 1978.

HOWARD L. KAIBEL, JR.
Hearing Examiner

MINNESOTA STATE PLANNING AGENCY

In the Matter of the Proposed Rules
of the Minnesota State Planning
Agency for Administering the State
Health Research Program

STATEMENT OF NEED AND EVIDENCE

INTRODUCTION

On January 25, 1977, Governor Perpich presented his budget message to the Minnesota Legislature. The Governor cited Minnesota's leadership in the areas of biomedical research and reform of the health care delivery system. In order to support and expand the state's role in these areas, he recommended an appropriation for a health research program, to be expended over the next two fiscal years. He suggested that the funds be used to support research in a number of areas: biomedicine, dental care, the health services delivery system, and other health-related issues.

Individual legislators felt that the scope of the proposal warranted further in-depth analysis by outside experts. Legislative leadership and the Governor therefore agreed that a study of the issue would be made by InterStudy, an independent health policy research organization, and the results reported to the Legislature and Governor. The Dayton-Hudson Foundation agreed to provide financial support for the study. The report, entitled "Alternatives for State Support of Health Research," was published in April 1977 (this report is attached as Exhibit A and incorporated by reference). The study concluded that some additional state support for health research would be a wise investment.

Subsequent to these events, an appropriation of $1.5 million was made by the Minnesota Legislature (Minn. Laws 1977, Ch. 454, Sec. 27) for the purpose of funding a state program to further health research in Minnesota. This Health Research Program (HRP) is intended to provide state funds for merit fellowships and other grants in the areas of non-medical research, health services research, and health policy studies. The $1.5 million appropriation is to be allocated in the following manner: $1,000,000 for merit fellowships, $300,000 for non-medical and health services research grants, and $200,000 for health policy studies. The funds were appropriated for fiscal year 1979.

The appropriation was originally made to the Minnesota Department of Health. However, Minn. Laws 1977, Ch. 454, Sec. 27 directs the Statewide Health Coordinating Council (SHCC) to administer the disbursement of these funds. Due to its direct relationship to the SHCC, the State Planning Agency, which houses the State Health Planning and Development Agency, was viewed as the more appropriate state agency to which the funds should be allocated. Therefore, Minnesota Department of Administration Reorganization Order No. 83 was issued to transfer the appropriation from the Department of Health to the State Planning Agency.

The SHCC has appointed a Committee on the Health Research Program (CHRP) which will have primary responsibility for administering the program and evaluating the proposals for HRP funds which are received. The committee will make its recommendations to the full SHCC, which will have the final review and approval authority.

The State Health Planning and Development Agency (SHPDA), with the assistance and advice of the Attorney General's Office, drafted proposed rules for the HRP. Staff of the SHPDA and the appropriate representative of the Attorney General's Office then met with the Committee on the Health Research Program to review and discuss the draft rules. Suggestions and changes made by the committee were incorporated and the revised version presented to the SHCC for its consideration at its meeting of February 15, 1978. Following general discussion and suggestions for minor changes, the SHCC approved the draft rules for initiation of the formal rulemaking process required by Minn. Stat. Chapter 15, the Administrative Procedures Act.

The purpose of these rules is to establish procedures for administering the Health Research Program. The HRP is intended to help maintain biomedical research in Minnesota and to strengthen the state's ability to produce health services research, non-medical health research, and health policy research on issues of importance to the state. The rules are intended to create a process which will be clear and predictable to all potential applicants for HRP funds, yet efficient and practical for administration by the CHRP and SHCC. In developing these rules, an attempt has been made to closely reflect (1) the Governor's concept as proposed in his budget message to the 1977 Legislature; (2) the findings of the InterStudy report prepared for the Governor and Legislature; and (3) legislative intent as established in bills developed during the 1977 legislative session. No final bill enacting the Health Research Program was ever passed by the Legislature. The InterStudy report, which was commissioned to give the Legislature further information on which to base a decision concerning the Governor's proposal, was not published until April 15, 1977. A Senate bill (S.F. 1361) was introduced and first read on April 18, 1977. A companion bill to the Senate version was introduced in the House (H.F. 1497). S.F. 1361 was passed by the Senate on May 19, 1977, and transmitted to the House on the same day. The House bill, however, was never passed, and thus no final enactment was forthcoming from the Legislature. The appropriation for the Health Research Program was made by the Legislature on May 21, 1977, as a rider to the appropriations for the Minnesota Department of Health (Minn. Laws 1977, Ch. 454, Sec. 27). Since there was no HRP bill itself enacted, S.F. 1361 has been utilized as a basis for interpreting legislative intent. This bill is attached as Exhibit B and incorporated by reference.

RULE JUSTIFICATION

The format used in preparing this Statement of Need and Evidence is as follows: each rule is stated first, followed by an explanation of the intent of the rule, the need for the proposed rule, and the reasonableness of the rule.

10 MCAR § 1.305 AUTHORITY, PURPOSE, DEFINITIONS, AND GENERAL PROVISIONS

(A) Authority. The rules contained herein are prescribed by the Statewide Health Coordinating Council and the State Planning Agency pursuant to the authority granted in Minn. Laws 1977, Ch. 454, Sec. 27 and Minnesota Department of Administration Reorganization Order No. 83.

This section is necessary to indicate the statutory authority allowing these rules to be promulgated.

(B) Purpose. The purpose of these rules is to establish procedures for administering the Health Research Program. The Health Research Program will provide funds to help maintain biomedical research in Minnesota and to strengthen the state's ability to provide health services research, non-medical health research, and health policy research on issues of importance to the state.

This section is necessary to indicate to interested parties the reason for the promulgation of these rules and the purpose of the program to which they apply. The language reflects the purpose of the program as discussed above in the Introduction to this Statement of Need and Evidence.

(C) Definitions. The following terms as used in these rules have the following meanings:

(1) "Health Research Program" (HRP) means the program and corresponding appropriation established by the Minnesota Legislature in Minn. Laws 1977, Ch. 454, Sec. 27 to further health research.

No official title was ever provided for this state appropriation for funding health research. Therefore, "Health Research Program" was selected as being a clear and direct title whose meaning could be easily understood by all.

(2) "Statewide Health Coordinating Council" (SHCC) means the citizens' council appointed by the Governor of Minnesota pursuant to the National Health Planning and Resources Development Act of 1974, 42 U.S.C. § 300K (1977 Supp.).

Public Law 93-641, the National Health Planning and Resources Development Act of 1974, required that a Statewide Health Coordinating Council be established in each state. The law gave the authority to appoint this council to the Governor of each state. On August 19, 1976, Governor Anderson issued Executive Order 60A, providing for the establishment of Minnesota's Statewide Health Coordinating Council, and on November 8, 1976, he announced his appointments to the council. This council is composed of both providers and consumers of health services and provides geographic representation of all areas of the state. The authority to administer the Health Research Program is given to the SHCC by Minn. Laws 1977, Ch. 454, Sec. 27.

(3) "Committee on the Health Research Program" (CHRP) means a committee of the SHCC which shall supervise the administration of the Health Research Program. All decisions of the CHRP shall be subject to review and approval by the SHCC.

This definition reflects legislative intent: S.F. 1361 (1977) indicated that the SHCC was to appoint a committee to "supervise a program of state grants for health-related research." It further stipulated that all decisions of this committee would be subject to review and approval by the SHCC.

(4) "State Planning Agency" means the agency of state government established by Minn. Laws 1965, Ch. 685 to perform statewide planning functions.

This definition is necessary in order to identify the state agency which will be involved in the administration of the Health Research Program. This agency's role is discussed above in the Introduction.

(5) "State Health Planning and Development Agency" (SHPDA) means the division of the State Planning Agency designated by the Governor to fulfill statewide health planning functions pursuant to the National Health Planning and Resources Development Act of 1974, 42 U.S.C. § 300k (1977 Supp.).

Public Law 93-641, the National Health Planning and Resources Development Act of 1974, required the establishment of a State Health Planning and Development Agency (SHPDA) in each state. Governors were given the authority to designate the entity which would serve as the SHPDA. On August 19, 1976, Governor Anderson issued Executive Order No. 60A, delegating the health planning and development authority mandated by P.L. 93-641 to the Minnesota State Planning Agency. As established by P.L. 93-641, the SHPDA is to provide staff support to the SHCC. S.F. 1361 also stipulated that the State Planning Agency, in its capacity as the SHPDA, would provide necessary staff services and other assistance to the Committee on the Health Research Program.

(6) "Biomedical research" means research into the basic processes and distribution of health and disease, including clinical interventions that affect these processes.

The Governor's budget message to the Legislature made some general distinctions between biomedical research and health services research. The subsequent InterStudy report further refined the distinctions between various kinds of health-related research and provided definitions of four major categories. These categories were further utilized in the legislation developed, including S.F. 1361. Biomedical research is generally viewed as relating to the biological aspects of disease and its medical diagnosis and treatment. The InterStudy definition conveys this meaning clearly and adequately.

(7) "Health services research" means research on manpower, practice patterns, organization, and economics of health care aimed at improving the efficiency, effectiveness, and distribution of health services as delivered in practice.

The Governor's budget message to the Legislature specifically mentioned health services research, including such issues as costs, productivity, regulation, and organization. The InterStudy definition adopted in the proposed rules reflects this meaning and also adds objectives to be attained through such research. S.F. 1361 retains this terminology, which is also used in Minn. Laws 1977, Ch. 454, Sec. 27.

(8) "Non-medical health research" means research on methods to prevent disease and promote health independently of health services professionals, by minimizing causes of ill health related to lifestyle and environment.

The Governor's budget message to the Legislature mentions the investigation and evaluation of preventive techniques to improve health. The InterStudy definition, utilized above, expands on this concept and, more importantly from the standpoint of potential applicants, clarifies the distinction between this type of research and biomedical research, which is more generally associated with disease-oriented curative health services rather than preventive health services. S.F. 1361 retains this terminology. Moreover, Minn. Laws 1977, Ch. 454, Sec. 27, allocates a specific sum of money to grants for non-medical and health services research. It is therefore necessary for the administration of the HRP to retain these two terms and the categories of research which they reflect.

(9) "Health policy research and analysis" means the study of health-related problems and the development, testing, and evaluation of various policy options for dealing with such problems. Policy studies may include health services research, non-medical health research, and biomedical research.

The InterStudy report differentiates between health policy research and analysis and the other categories mentioned above. As the report states, health policy research may address any issues or problems identified in the other health-related research areas. The inclusion of a policy research and analysis category is important, for it clearly indicates that the investment of $1.5 million in public funds should produce results which are useful to public policymakers in addition to the scientific research community. The language in S.F. 1361

reflects this perspective since it retained a category for health policy research and granted the CHRP and SHCC considerable flexibility in awarding grants which would support health policy studies of interest to the state. The Governor's proposal to the Legislature also indicated that one outcome of research funded by the state should be to provide information, analysis, and technical support to health planners and state agencies. Finally, Minn. Laws 1977, Ch. 454, Sec. 27 allocates funds to a specific category for health policy studies. Therefore, it is necessary to retain this terminology and category of research in order to administer the allocation of funds appropriated by the Legislature.

(10) "Grant" means an award of money pursuant to a written agreement signed by the eligible applicant and by the official representative of the SHCC, setting forth the amount of the funds, the time period within which the funds are to be expended, the purposes for which the funds may be used, and other contractual conditions deemed necessary by the SHCC.

S.F. 1361 provided the SHCC with considerable flexibility in awarding HRP grants. Minn. Laws 1977, Ch. 454, Sec. 27 provides the SHCC with no specific directives to follow in awarding HRP funds other than the total amount of funds to be allocated to each grant category. In many cases, therefore, the specific terms of an individual grant (including the amount to be awarded) will be left to the discretion of the CHRP and SHCC. It is felt that these provisions need to be clearly stated in writing and agreed to so that the grantee and the SHCC share a mutual understanding of the conditions and expectations related to the grant. The use of written agreements of a contractual nature will also provide a clear public record of how HRP funds were allocated, to whom, and for what purposes.

10 MCAR § 1.306 PROCEDURES FOR INFORMING THE PUBLIC OF THE HEALTH RESEARCH PROGRAM

(A) Notice of availability. The SHCC shall inform the public of the availability of Health Research Program funds by the following means:

As noted previously, Minn. Laws 1977, Ch. 454, Sec. 27 provided no specific directives to the SHCC concerning the manner in which the HRP is to be administered (with the exception of total sums for each grant category). For this reason, procedures to be utilized by the SHCC need to be established by the rulemaking process to make them clearly known and predictable to all relevant parties. The first practical necessity is to inform the public of the existence of the Health Research Program and the opportunity to apply for a grant under this program. The following methods have been proposed as a means of providing the public with information about the HRP:

(1) An announcement shall be published in the State Register.

The State Register is the official publication of the State of Minnesota and it is therefore deemed appropriate that an official notice be printed in that publication.

(2) An announcement shall be published two consecutive weeks in a newspaper of general circulation in each county of the state.

While the State Register is the official publication of the state, the general population's exposure or access to it can

be assumed to be limited. Therefore, an effort to ensure public exposure to information about the HRP can be enhanced by publishing such information in newspapers of general circulation. An attempt will be made to use the newspaper of largest circulation in each county in order to ensure statewide notice. The notice will be published twice in order to increase public exposure to it.

(3) An announcement of availability shall be mailed to the following Minnesota organizations and institutions:

(a) The University of Minnesota and its affiliated campuses

(b) State universities

(c) Community colleges

(d) Private colleges

(e) Vocational-technical institutions

(f) All hospitals

(g) Associations of health professionals

(h) Mayo Foundation for Education and Research

(i) Minnesota Department of Health

(j) Minnesota Department of Public Welfare

(k) Minnesota Legislature

(l) The seven Health Systems Agencies located in Minnesota

The above list represents an attempt to go beyond the general public notice and more directly reach the health-related research community. The above list includes all major educational institutions, state agencies, associations of health professionals, and health planning agencies which might be eligible for and interested in applying for a HRP grant. It is also recognized that through notices to such organizations, many individuals who might be interested in applying for an HRP grant will be made aware of the opportunity to do so. It was found to be virtually impossible to identify all potentially interested private research organizations, clinics, individual health services providers, etc., and not financially feasible to attempt personal notices to all those which could be identified. It is felt that attempted notice to all potentially interested parties not covered in items (a) through (l) above is otherwise provided for by public notice via the State Register and publication in general newspapers throughout the state.

The announcement shall set forth the amount of funds available for award, the period of time during which grant applications will be accepted, priority considerations listed in § 1.309 of these rules which the CHRP and SHCC will consider in their evaluation of grant applications, the date when grant awards will be announced by the SHCC, and the location where applications should be submitted. The announcement of availability shall also include a detailed description of application procedures and project specifications as defined in § 1.307 of these rules.

All potential applicants will need to know the details of the required application procedures. Therefore, the details specified above will be set forth in the announcement of availability for review by potential applicants.

(B) Announcement of grant awards. The SHCC shall announce the disposition of available grant funds by the following means:

Just as it is deemed important to notify the public concerning the availability of state funds, it is also considered important to provide notice of the disposition of such public monies.

(1) When evaluation and selection have been completed, results will be sent immediately by mail to all applicants.

All applicants are entitled to prompt notification concerning the disposition of their application.

(2) A list of grant recipients, the amount of funds awarded to each recipient, and the nature of the research to be performed by the recipient shall be published in the State Register.

The State Register is the official publication of the State of Minnesota. It is therefore deemed appropriate that the public be notified of the disposition of these state funds via this publication.

(3) A list of grant recipients, the amount of funds awarded to each recipient, and the nature of the research to be performed by the recipient shall be mailed to the following organizations and institutions in order to inform the health-related research community of the types of studies to be performed:

It is considered important to notify, to the extent feasible, the health-related research community of the types of research which will be performed using the HRP grants. This should help to reduce redundant research activities and to strengthen health-related research in Minnesota by keeping the research community well informed.

(a) The University of Minnesota and its affiliated campuses

(b) State universities

(c) Community colleges

(d) Private colleges

(e) Vocational-technical institutions

(f) All hospitals

(g) Associations of health professionals

(h) Mayo Foundation for Education and Research

(i) Minnesota Department of Health

(j) Minnesota Department of Public Welfare

(k) Minnesota Legislature

(1) The seven Health Systems Agencies located in Minnesota

The justification for this particular list of entities is the same as that provided under § 1.306(A)(3) for items (a) through (l).

(C) Commencement of funding. All funds awarded under the Health Research Program shall become available to each recipient at the beginning of Fiscal Year 1979 (July 1, 1978) and should be expended by the recipient no later than June 30, 1980.

Minn. Laws 1977, Ch. 454, Sec. 27 allocates the HRP funds for fiscal year 1979. The funds thus become available on July 1, 1978, for allocation thereafter. Fiscal year 1979 ends on June 30, 1979. However, the InterStudy report recommended that merit fellowship grants be made available for a two-year period of time. The Senate retained this provision (S.F. 1361). It was felt that a two-year time period would allow all potential HRP applicants to develop a research proposal of greater depth or detail than would be feasible for a one-year period. Therefore, it was determined that while the Legislative appropriation would be expended during fiscal year 1979, HRP grantees could utilize the funds awarded to support research extending beyond one year but not longer than two years.

10 MCAR § 1.307 APPLICATION PROCEDURES

(A) All applicants for HRP funds will be required to submit a proposal containing the following information:

(1) The type of grant being applied for (i.e., whether Merit Fellowship, Non-Medical and Health Services Research, or Health Policy Study).

(2) Scope of the project.

(3) Project goal and objectives.

(4) Project tasks to be completed.

(5) A description of the project, including:

(a) A restatement of the objectives showing or demonstrating the applicant's view of the nature of the proposed research.

(b) Identification and description of the products to be delivered by the applicant.

(c) A description of the applicant's background and experience in health-related research.

(d) Identification of the personnel who will conduct the research and a detailed description of their training and research experience. No change in professional research personnel assigned to the project will be permitted without the approval of the SHCC.

(6) A detailed budget of project costs delineating proposed expenses. No general overhead rate will be allowed in the budget calculation.

(7) A project completion date indicating the anticipated termination of the proposed research activity.

(8) An indication of any other sources of funding, already possessed or applied for, which would be used to support the proposed research project.

It is necessary to clarify for potential applicants exactly what will be expected of them in their research proposal. This section sets forth the specific items which must be included. Item (1) is necessary to help the CHRP categorize the applications received and to provide an indication of the general type of research being proposed in an application (e.g., health policy study). Items (2) and (3) are needed to outline the depth and detail of the proposed research and the specific accomplishments to be achieved. Item (4) will set forth the applicant's work plan for accomplishing the project's objectives. Item (5) is needed to provide the applicant's theoretical perspective on the proposed subject of study and the professional experience which makes the applicant qualified to perform such research. No change in the professional research personnel identified by the application to complete the proposed research will be permitted without the approval of the SHCC. This clause is necessary to prevent any subsequent change to less qualified research staff. Item (6) is needed to indicate the amount of funds being applied for and the uses to which they would be put. No general overhead rate has been allowed in the proposed budget due to the relatively small sums available. Item (7) will establish the project duration and indicate when the results of the research would become available. Item (8) is needed to inform the applicant that the SHCC will require the disclosure of all other sources of funding for a proposed research project in order to avoid duplicate funding of any one proposal.

(B) All grant applications will be required to be submitted by a time and date specified by the SHCC in the announcement of availability described in § 1.306(A) of these rules. Late proposals will not be accepted.

The deadline for submission of HRP grant applications will be specified in the notice of availability made to the public as described in § 1.306(A). In order to afford all applicants equal consideration, and to avoid potential cases of special exceptions made for some, all applicants must adhere to the same deadline.

10 MCAR § 1.308 PROCEDURES FOR AWARDING HEALTH RESEARCH PROGRAM FUNDS

(A) Merit Fellowship Grants

(1) Eligibility. An eligible applicant is any individual researcher who resides in or agrees to reside in Minnesota and who proposes to engage in exploratory analysis and pilot research in a health-related subject or issue which has been established as a priority by the SHCC as defined in § 1.309 of these rules. As a condition to receipt of a grant, each applicant must provide evidence that he/she has or will have an affiliation with the University of Minnesota, the Mayo Clinic, the Legislature and/or its staff, a state department or agency, a health organization, or post-secondary educational institution. This evidence must include a corroborating statement from the institution or organization with which the researcher affiliates or proposes to affiliate. Further, each applicant, as a condition to receipt of a grant, must agree to and actively seek federal or private support for full-scale research projects based on his or her exploratory analysis and pilot research.

Fellowships are intended for individual persons rather than for organizations, agencies, or other types of groups. The InterStudy report recommended that such a program of fellowships be established, indicating that it would help to strengthen a core of researchers in the state. This type of program is also consistent with the report's recommendation that state funds generally be used to support research staff and institutions rather than specific projects. The Senate bill accepted these recommendations by establishing a category of "Merit Fellowship Grants."

The InterStudy report viewed this type of grant as an "investigatorship" which, in addition to providing a stipend to the researcher, would provide a small amount of "seed money" for research expenses. S.F. 1361 retained this concept by stipulating that fellowship grants be used for exploratory analysis and pilot research. This provision seeks to ensure that the exploratory research supported by state funds will have meaningful long-range potential and notifies the potential applicant that the state has such expectations.

The Senate bill added the stipulation that the researcher must agree to reside in Minnesota. This is consistent with the goal of building a strong core of researchers in the state. It is also an attempt to ensure that Minnesota, rather than another part of the country, will benefit from the investment of state funds.

The InterStudy report suggested that the researcher should be associated with some consenting organization appropriate to his or her area of research. S.F. 1361 retained this concept by stipulating that a grantee must have an affiliation with a responsible organization or institution of the types named in the rule. This ensures that merit fellows will be integrated with the existing health research community. The required corroborating statement will verify that such an affiliation has indeed been established.

Minn. Laws 1977, Ch. 454, Sec. 27 makes a specific allocation for merit fellowship grants. This category must therefore be retained and procedures established for awarding these grants.

(2) Process of award. Grants to merit fellows shall be awarded on a competitive basis with applications being evaluated in terms of:

(a) The applicant's professional credentials

(b) Demonstrated past performance in doing health-related research

(c) Proposed subject for study

(d) Clarity of the project goal and objectives

(e) The project work plan

(f) The project budget

(g) The qualifications of any additional professional research staff who will assist with the research project.

The InterStudy report recommended that merit fellowship grants be competitive. S.F. 1361 incorporated this recommendation. The items indicated above are consistent with the Senate bill and are intended to provide the information which will be needed by the CHRP and SHCC when they evaluate applications for merit fellowship grants. They are also consistent with the requirements for application contents specified in § 1.307(A) and the reasons for them are, therefore, the same as those set forth in that section.

(3) Terms of grant. Grants to merit fellows shall be limited to a maximum of $50,000 per year for two years. Each grant may be utilized to provide a stipend to support the researcher and necessary clerical and research assistants and to cover the costs of other professional expenses incurred in the process of performing the research.

The InterStudy report recommended that merit fellowships be two-year awards. The Senate bill retained this provision and established the maximum funding level. The stated purposes for which the grant may be used are consistent with both the InterStudy report and S.F. 1361.

(4) At least one-half of the merit fellowship grants shall be allocated to health services research, non-medical health research, and health policy analysis.

The InterStudy analysis found (1) that Minnesota already has a large, excellent, and competitive biomedical research community, and (2) that the state has little in the way of organized health services research, non-medical health research, and health policy research. The report therefore concluded that, with respect to biomedical research, the emphasis should be on maintaining and strengthening Minnesota's existing research community rather than on increasing its size. For these reasons, and to assure responsiveness to the state's concerns, it recommended that at least half of the merit fellowships should go to health research other than biomedical. S.F. 1361 incorporated this recommendation by stipulating that at least half of these grants be awarded to research proposals in the areas specified above.

(B) Non-Medical and Health Services Research Grants

(1) Eligibility. An eligible applicant is a Minnesota post-secondary education institution, state department or agency, or other health organization.

As indicated previously, the InterStudy report recommended that state funds be used to support individuals and institutions. Merit fellowship grants will achieve the objective of supporting individuals. This category of grants will provide research support to institutions. The list of eligible applicants specified above is consistent with the recommendations of the InterStudy report and the intent of S.F. 1361, and is felt to be general enough to cover any qualified organizational applicant.

Minn. Laws 1977, Ch. 454, Sec. 27 makes a specific allocation for non-medical and health services research grants. Therefore, this category must be retained and procedures established for awarding these grant funds.

(2) Purposes. Grants may be used to fund senior research positions, to provide seed money for non-medical and health services research activities, and to provide information, analysis, and technical support to health planners and state agencies on questions of health costs, productivity, health care regulation, and organization of the health care delivery system. The grants may also be used to support investigations and evaluations of preventive health care techniques designed to improve public health.

The InterStudy report recommended that this category of grants be used to fund senior research positions and provide flexible "seed money," indicating that this use of funds would encourage institutions to establish organized programs of research in these areas. The Senate bill incorporated this recommendation. The remainder of the language was added by S.F. 1361 to provide potential applicants with examples of the kinds of research to be funded under this category. It also indicates the expected benefits to the state from such research. The added language directly reflects that in the Governor's proposal to the Legislature.

(3) Process of award. Grants for non-medical and health services research shall be awarded on a competitive basis and shall be used only to support activities which are consistent with state health priorities established by the SHCC and listed in § 1.309 of these rules. Applications shall be evaluated in terms of:

(a) Demonstrated past performance of the applicant organization, institution, or agency in doing health-related research

(b) Proposed subject for study

(c) Clarity of the project goal and objectives

(d) The project work plan

(e) The project budget

(f) Qualifications of the professional research staff who will carry out the research. The experience of the assigned personnel will be given greater weight than will the demonstrated past performance of the applicant organization, institution, or agency.

The items listed above are intended to provide the information which will be needed by the CHRP and SHCC when they evaluate applications for non-medical and health services research grants. Item (f) is intended to avoid situations in which a highly reputed applicant organization, institution, or agency might be awarded a grant and then assign inexperienced research staff to complete the project. The list of items above is also consistent with the requirements for application contents specified in § 1.307(A), and the reasons for them are, therefore, the same as those set forth in that section.

(4) Determination of grant amount. The amount and nature of the grant shall be determined by the SHCC, which shall take into consideration the amount of funds requested and available; the demonstrated ability of the eligible applicant to perform research in the areas set forth in point B(2) above; and the technical assistance to health planners, state agencies, and the legislature which may be generated by the proposed research.

No directive concerning the maximum amount for each grant of this type has been provided to the SHCC. This rule therefore indicates to potential applicants that the amount of each grant will be left to the discretion of the SHCC (keeping in mind that the total appropriation for this grant category is $300,000) and indicates considerations to be applied by the SHCC in determining the amount to be awarded to any particular applicant. Given the limit on total funds available for this category, the SHCC must evaluate the number and size of grants which can be awarded (e.g., a few large grants or several smaller ones). The concern for the applicant's research ability and the potential benefits to the state reflects language in the Governor's proposal and S.F. 1361 and is necessary to indicate to the applicant the state's desire to maximize the usefulness of the research being funded.

(C) Health Policy Study Grants

(1) Eligibility. An eligible applicant is any individual or organization that proposes a study relevant to the formulation of state health policy.

The InterStudy report recommended that the state strengthen its capability to purchase or perform health policy studies. S.F. 1361 incorporated this suggestion by establishing a category for health policy study grants. The Senate bill provided the CHRP and SHCC with great flexibility in awarding these grants, provided that they are used to obtain health policy studies of interest to the state. Minn. Laws 1977, Ch. 454, Sec. 27 makes a specific appropriation for health policy studies, so this grant category must be retained and procedures established for disbursing the funds appropriated.

(2) Process of award. Grants for health policy studies shall be awarded on a competitive basis and shall be consistent with health policy issues of priority concern as established by the SHCC and listed in § 1.309 of these rules. Applications shall be evaluated in terms of:

(a) The applicant's professional credentials, where the applicant is an individual; or, where the applicant is an organization, institution, or agency, the demonstrated past performance of the entity in doing health policy research

(b) Demonstrated past performance in doing health-related research

(c) Proposed subject for study

(d) Clarity of the project goal and objectives

(e) The project work plan

(f) The project budget

(g) Qualifications of the professional research staff who will carry out the research. Where the applicant is an organization, institution, or agency, the experience of the assigned personnel will be given greater weight than will the demonstrated past performance of the organization, institution, or agency.

The items listed above are intended to provide the information which will be needed by the CHRP and SHCC when they evaluate applications for health policy study grants. Item (g) is necessary to avoid situations in which a highly reputed organization, institution, or agency might be awarded a grant and then assign inexperienced research staff to complete the project. The list of items above is also consistent with the requirements for application contents specified in § 1.307(A) and the reasons for them are, therefore, the same as those set forth in that section.

(3) Determination of grant amount. The nature and size of the grant shall be determined by the SHCC, which shall take into consideration the amount of funds requested and available, the importance of the proposed subject of study to the state, and its consistency with the purpose of the HRP as defined in § 1.305(B) and the priorities established by the SHCC and listed in § 1.309 of these rules.

No directive concerning the maximum amount for each grant of this type has been provided to the SHCC. This rule is therefore needed to inform potential applicants that the amount of each grant will be left to the discretion of the SHCC (keeping in mind that the total appropriation for this grant category is $200,000) and to indicate considerations to be applied by the SHCC in determining the amount to be awarded to any particular applicant. Given the limit on total funds available for this category, the SHCC must evaluate the number and size of grants which can be awarded (e.g., a few large grants or several smaller ones). The InterStudy report recommended that the state support specific research projects (as contrasted with individuals or institutions) only when those projects could provide specific answers to specific questions of direct interest to the state. The importance of the proposed subject of study is obvious in the case of health policy studies due to the direct usefulness of such research to state decision-makers. The priorities listed in § 1.309 of these rules reflect major concerns related to the state's health services system and thus have direct policy implications.

10 MCAR § 1.309 PRIORITY CONSIDERATIONS IN THE DISBURSEMENT OF HEALTH RESEARCH PROGRAM FUNDS

In evaluating applications for HRP grants, the SHCC will consider the proposed subject of study in terms of the following priorities:

- The provision of primary care services for medically underserved populations located in rural or economically depressed areas.
- The development of multi-institutional systems for coordinating or consolidating institutional health services, including obstetric, pediatric, emergency medical, intensive and coronary care, and radiation therapy.
- The development of multi-institutional arrangements for the sharing of support services necessary to all health service institutions.

- The development of medical group practices (especially those whose services are appropriately coordinated or integrated with institutional health services), health maintenance organizations, and other organized systems for the provision of health care.

- The training and increased utilization of physician extenders, especially nurse clinicians.

- The promotion of activities to achieve needed improvements in the quality of health services.

- The development by health service institutions of the capacity to provide various levels of care (including intensive care, acute general care, and extended care) on a geographically integrated basis.

- The promotion of activities for the prevention of disease, including studies of nutritional and environmental factors affecting health and the provision of preventive health care services. The development of effective methods of educating the general public concerning proper personal (including preventive) health care and methods for effective use of available health services.

  It was felt that, for the benefit of potential applicants, the rules needed to set forth general priorities which the SHCC will consider as it evaluates applications for HRP grants. The considerations listed above are derived from national health priorities set forth in the National Health Planning and Resources Development Act of 1974, 42 U.S.C. § 300k (1977 Supp.). This is the same legislation which created the SHCC and upon which its authority and activities rest.

- Methods to reduce the incidence and prevalence of the leading causes of death and disability in Minnesota.

  This general priority is needed to provide guidelines for evaluating applications proposing biomedical research studies. Information on the leading causes of death and disability in Minnesota and their prevalence is readily available. In April 1977 the Minnesota Center for Health Statistics, Minnesota Department of Health, published a study entitled "Leading Causes of Death in Health Service Areas of Minnesota, 1975." Copies of that study may be obtained from the State Center for Health Statistics.

- The development of improved methodologies for health planning.

  This consideration reflects concerns expressed in the Governor's proposal and in S.F. 1361 that health-related research funded by the HRP should produce results which will be useful for state health planning efforts.

10 MCAR § 1.310 CONFLICT OF INTEREST

When any member of the SHCC or the CHRP has any conflict of interest with respect to a Health Research Program grant application under consideration by the SHCC, that member shall, prior to consideration of the application, voluntarily disclose such interest to the CHRP, and SHCC, either verbally or in writing, and shall be disqualified from voting on that particular grant application. A conflict of interest shall be deemed to exist where a SHCC member:

(1) has a material financial interest, whether direct or indirect, in the proposed research or study;

(2) is a director, trustee, or officer of any organization or institution applying for Health Research Program funds;

(3) is an employee of any applicant;

(4) is the spouse, child, parent, or sibling of any individual applicant.

Any member of the SHCC may challenge any other member by means of a properly recorded vote which shall determine the status of the challenged member concerning any possible conflict of interest before further voting on the proposed grant application under consideration.

A rule providing for conflict of interest situations is necessary in order to avoid any future charges by applicants for HRP funds that any member of the CHRP or SHCC abused his or her discretionary powers in awarding HRP funds.

No member of the Minnesota Legislature shall serve on the CHRP. No member of the CHRP, the SHCC, or the Minnesota Legislature shall be eligible to receive a grant under the Health Research Program.

S.F. 1361 stipulated that no member of the Minnesota Legislature should serve on the CHRP. This rule is necessary because some SHCC members may be Minnesota Legislators. Legislators and members of the SHCC, including its Committee on the Health Research Program, are prohibited from receiving HRP grants due to the obvious potential for conflict of interest charges.

DEPARTMENT Attorney General

Office Memorandum

TO : William E. Dorigan,
Special Assistant
Attorney General
303 Capitol Square Building

DATE: June 9,1978

FROM : Lee E. Sheehy
Special Assistant
Attorney General

PHONE: 296-1288

SUBJECT: Rules as Approved/ Adopted Rules of the State Planning Agency Governing The Health Research Program.

Enclosed herewith are the rules you have submitted for approval. These rules have been approved by this office and filed with the Secretary of State. Note that they have NOT been filed with the State Register; this must be done promptly by your agency.

Upon receipt and before transmittal to your agency, however, it is important that you recheck these rules as to:

1. Affixation of the stamps of the Attorney General and Secretary of State to the last page of the rules;

2. Coverage by these stamps of all rules submitted; and

3. Inclusion of all pages of the rules in the approved set.

Directly following the approved rules is a complete set of required documents and transcript which must be retained with the rules by you or your agency.

If you have any questions in this regard, please contact me.

LES/dw
Enclosure

As proposed

State Planning Agency

Proposed Rules for Administering the State Health Research Program

Notice of Public Hearing

Notice is hereby given that a public hearing will be held pursuant to Minn. Stat., § 15.0412 (1977 Supp.) and Minn. Stat. § 4.17 (1977 Supp.) in the above-entitled matter commencing in St. Paul in Room 83, the Auditorium, of the State Office Building on Wabasha Street in St. Paul, Minnesota at 9:30 a.m. on April 7, 1978. The hearing will be continued to such time and place as the Hearing Examiner may designate until all representatives of associations or other interested groups or persons have had an opportunity to participate and be heard concerning adoption of the proposed Rules captioned above by submitting either oral or written data, statements or arguments. Statements or briefs may be submitted to the Office of Hearing Examiners, Howard Kaibel, Hearing Examiner, Room 300, 1745 University Avenue, St. Paul, Minnesota 55104, without appearing at the hearing and will be accepted for a period of 5 working days after the public hearing ends, or for a longer period not to exceed 20 days if ordered by the hearing examiner.

The purpose of these rules is generally as follows: To establish procedures for administering the Health Research Program. The Health Research Program will provide funds to help maintain biomedical research in Minnesota and to strengthen the state's ability to produce health services research, non-medical health research, and health policy research on issues of importance to the state. These rules will provide a mechanism for determining the types of research programs which will be eligible for grant awards. These rules will also describe criteria for applicant eligibility, criteria for selection of grant award recipients and criteria to determine the amount and terms of the grant awards.

Copies of the proposed Rules are now available for review at the following location:

Minnesota State Planning Agency
101 Capitol Square Building
550 Cedar Street
St. Paul, Minnesota 55101

Notice is also given that under Minn. Stat. § 10A.01, subd. 11 (1976) any individual engaged for pay or other consideration for the purpose of representing persons or associations attempting to influence administrative action, such as the promulgation of these rules, must register with the State Ethics Commission as a lobbyist within five days of the commencement of such activity by the individual. The State Ethics Commission is located at 410 State Office Building, St. Paul, Minnesota 55155.

Dated this 17th day of February, 1978.

Peter Vanderpool, Director

Order for Hearing

To effectively implement the State Health Research Program, the State Planning Agency deems it necessary to consider adoption of the proposed rules captioned above, pursuant to the authority granted in Laws of Minnesota 1977, ch. 454 § 27 and Minnesota Department of Administration Reorganization Order No. 83 (1977).

Now therefore, it is ordered that a public hearing on the proposed rules be held commencing in St. Paul in the auditorium, Room 83, of the State Office Building, Wabasha Street, St. Paul, Minnesota at 9:30 a.m. on April 7, 1978 and continuing until all interested persons, representatives and organizations have had an opportunity to be heard by submitting oral or written data, statements, comments or arguments or by presenting witnesses.

It is further ordered, that notice of said hearing be given to all persons and associations who have registered their name with the Secretary of State for that purpose and that

KEY: PROPOSED RULES SECTION: Underlining indicates additions to pre-existing rule language. ~~Strike outs~~ indicate deletions from pre-existing rule language. If all proposed rules in a set are totally new (i.e. non-amendatory) the entire set is printed in standard type face. RULES SECTION: Underlining indicates additions to proposed rule language. ~~Strike outs~~ indicate deletions from proposed rule language.

notice of said hearing shall be published in the *State Register*.

Dated this 17th day of February, 1978.

Peter Vanderpoel, Director

Rules as Proposed

10 MCAR § 1.305 Authority, purpose, definitions and general provisions.

A. Authority. The rules contained herein are prescribed by the Statewide Health Coordinating Council and the State Planning Agency pursuant to the authority granted in Minn. Laws 1977, ch. 454, § 27 and Minnesota Department of Administration Reorganization Order No. 83.

B. Purpose. The purpose of these rules is to establish procedures for administering the Health Research Program. The Health Research Program will provide funds to help maintain biomedical research in Minnesota and to strengthen the state's ability to produce health services research, non-medical health research, and health policy research on issues of importance to the state.

C. Definitions. The following terms as used in these rules have the following meanings:

1. "Health Research Program" (HRP) means the program and corresponding appropriation established by the Minnesota Legislature in Minn. Laws 1977, ch. 454, § 27 to further health research in Minnesota.

2. "Statewide Health Coordinating Council" (SHCC) means the citizens' council appointed by the Governor of Minnesota pursuant to the National Health Planning and Resources Development Act of 1974, 42 U.S.C. § 300k (1977 Supp.).

3. "Committee on the Health Research Program" (CHRP) means a committee of the SHCC which shall supervise the administration of the Health Research Program. All decisions of the CHRP shall be subject to review and approval by the SHCC.

4. "State Planning Agency" means the agency of state government established by Minn. Laws 1965, ch. 685 to perform statewide planning functions.

5. "State Health Planning and Development Agency" (SHPDA) means the division of the State Planning Agency designated by the governor to fulfill statewide health planning functions pursuant to the National Health Planning and Resources Development Act of 1974, 42 U.S.C. § 300k (1977 Supp.).

6. "Biomedical research" means research into the basic processes and distribution of health and disease, including clinical interventions that affect these processes.

7. "Health services research" means research on manpower, practice patterns, organization, and economics of health care aimed at improving the efficiency, effectiveness, and distribution of health services as delivered in practice.

8. "Non-medical health research" means research on methods to prevent disease and promote health independently of health services professionals, by minimizing causes of ill health related to lifestyle and environment.

9. "Health policy research and analysis" means the study of health-related problems and the development, testing, and evaluation of various policy options for dealing with such problems. Policy studies may include health services research, non-medical health research and health policy research and analysis.

10. "Grant" means an award of money pursuant to a written agreement signed by the eligible applicant and by the official representative of the SHCC, setting forth the amount of the funds, the time period within which the funds are to be expended, the purposes for which the funds may be used, and other contractual conditions deemed necessary by the SHCC.

§ 1.306 Procedures for informing the public of the health research program.

A. Notice of availability. The SHCC shall inform the public of the availability of Health Research Program funds by the following means:

1. An announcement shall be published in the *State Register*.

2. An announcement shall be published two con-

secutive weeks in a newspaper of general circulation in each county of the state.

3. An announcement of availability shall be mailed to the following Minnesota organizations and institutions:

   a. The University of Minnesota and its affiliated campuses

   b. State universities

   c. Community colleges

   d. Private colleges

   e. Vocational-technical institutions

   f. All hospitals

   g. Associations of health professionals

   h. Mayo Foundation for Education and Research

   i. Minnesota Department of Health

   j. Minnesota Department of Public Welfare

   k. Minnesota Legislature

   l. The seven Health Systems Agencies located in Minnesota

The announcement shall set forth the amount of funds available for award, the period of time during which grant applications will be accepted, priority considerations listed in § 1.309 of these rules which the CHRP and SHCC will consider in its evaluation of grant applications, the date when grant awards will be announced by the SHCC, and the location where applications should be submitted. The announcement of availability shall also include a detailed description of application procedures and project specifications as defined in § 1.307 of these rules.

B. Announcement of grant awards. The SHCC shall announce the disposition of available grant funds by the following means:

   1. When evaluation and selection have been completed, results will be sent immediately by mail to all applicants.

   2. A list of grant recipients, the amount of funds awarded to each recipient, and the nature of the research to be performed by the recipient shall be published in the *State Register*.

   3. A list of grant recipients, the amount of funds awarded to each recipient, and the nature of the research to be performed by the recipient shall be mailed to the following organizations and institutions in order to inform the health-related research community of the types of studies to be performed:

      a. The University of Minnesota and its affiliated campuses

      b. State universities

      c. Community colleges

      d. Private colleges

      e. Vocational-technical institutions

      f. All hospitals

      g. Associations of health professionals

      h. Mayo Foundation for Education and Research

      i. Minnesota Department of Health

      j. Minnesota Department of Public Welfare

      k. Minnesota Legislature

      l. The seven Health Systems Agencies located in Minnesota

C. Commencement of funding. All funds awarded under the Health Research Program shall become available to each recipient at the beginning of Fiscal Year 1979 (July 1, 1978) and should be expended by the recipient no later than June 30, 1980.

§ 1.307 Application procedures.

A. All applicants for HRP funds will be required to submit a proposal containing the following information:

   1. The type of grant being applied for (i.e., whether

KEY: PROPOSED RULES SECTION: Underlining indicates additions to pre-existing rule language. ~~Strike outs~~ indicate deletions from pre-existing rule language. If all proposed rules in a set are totally new (i.e. non-amendatory) the entire set is printed in standard type face. RULES SECTION: Underlining indicates additions to proposed rule language. ~~Strike outs~~ indicate deletions from proposed rule language.

Merit Fellowship, Non-Medical and Health Services Research, or Health Policy Study).

2. Scope of the project

3. Project goal and objectives

4. Project tasks to be completed

5. A description of the project, including:

   a. A restatement of the objectives showing or demonstrating the applicant's view of the nature of the proposed research.

   b. Identification and description of the products to be delivered by the applicant.

   c. A description of the applicant's background and experience in health-related research.

   d. Identification of the personnel who will conduct the research and a detailed description of their training and research experience. No change in professional research personnel assigned to the project will be permitted without the approval of the SHCC.

6. A detailed budget of project costs delineating proposed expenses. No general overhead rate will be allowed in the budget calculation.

7. A project completion date indicating the anticipated termination of the proposed research activity.

8. An indication of any other sources of funding, already possessed or applied for, which would be used to support the proposed research project.

B. All grant applications will be required to be submitted by a time and date specified by the SHCC in the announcement of availability described in § 1.306A of these rules. Late proposals will not be accepted.

§ 1.308 Procedures for awarding health research program funds.

A. Merit fellowship grants.

1. Eligibility. An eligible applicant is any individual researcher who resides in or agrees to reside in Minnesota and who proposes to engage in exploratory analysis and pilot research in a health-related subject or issue which has been established as a priority by the SHCC as defined in § 1.309 of these rules. As a condition to receipt of a grant, each applicant must provide evidence that he/she has or will have an affiliation with the University of Minnesota, the Mayo Clinic, the Legislature and/or its staff, a state department or agency, a health organization, or post-secondary educational institution. This evidence must include a corroborating statement from the institution or organization with which the researcher affiliates or proposes to affiliate. Further, each applicant, as a condition to receipt of a grant, must agree to and actively seek federal or private support for full-scale research projects based on his or her exploratory analysis and pilot research.

2. Process of award. Grants to merit fellows shall be awarded on a competitive basis with applications being evaluated in terms of:

   a. The applicant's professional credentials.

   b. Demonstrated past performance in doing health-related research.

   c. Proposed subject for study.

   d. Clarity of the project goal and objectives.

   e. The project work plan.

   f. The project budget.

   g. The qualifications of any additional professional research staff who will assist with the research project.

3. Terms of grant. Grants to merit fellows shall be limited to a maximum of $50,000 per year for two years. Each grant may be utilized to provide a stipend to support the researcher and necessary clerical and research assistants and to cover the costs of other professional expenses incurred in the process of performing the research.

4. At least one-half of the merit fellowship grants shall be allocated to health services research, non-medical health research, and health policy analysis.

B. Non-Medical and health services research grants.

1. Eligibility. An eligible applicant is a Minnesota post-secondary education institution, state department or agency, or other health organization.

2. Purposes. Grants may be used to fund senior re-

search positions, to provide seed money for non-medical and health services research activities, and to provide information, analysis, and technical support to health planners and state agencies on questions of health costs, productivity, health care regulation, and organization of the health care delivery system. The grants may also be used to support investigations and evaluations of preventive health care techniques designed to improve public health.

3. Process of award. Grants for non-medical and health services research shall be awarded on a competitive basis and shall be used only to support activities which are consistent with state health priorities established by the SHCC and listed in § 1.309 of these rules. Applications shall be evaluated in terms of:

   a. Demonstrated past performance of the applicant organization, institution, or agency in doing health-related research.

   b. Proposed subject for study.

   c. Clarity of the project goal and objectives.

   d. The project work plan.

   e. The project budget.

   f. Qualifications of the professional research staff who will carry out the research. The experience of the assigned personnel will be given greater weight than will the demonstrated past performance of the applicant organization, institution, or agency.

4. Determination of grant amount. The amount and nature of the grant shall be determined by the SHCC, which shall take into consideration the amount of funds requested and available; the demonstrated ability of the eligible applicant to perform research in the areas set forth in point B(2) above; and the technical assistance to health planners, state agencies, and the legislature which may be generated by the proposed research.

C. Health policy study grants.

1. Eligibility. An eligible applicant is any individual or organization that proposes a study relevant to the formulation of state health policy.

2. Process of award. Grants for health policy studies shall be awarded on a competitive basis and shall be consistent with health policy issues of priority concern as established by the SHCC and listed in § 1.309 of these rules. Applications shall be evaluated in terms of:

   a. The applicant's professional credentials, where the applicant is an individual, or, where the applicant is an organization, institution, or agency, the demonstrated past performance of the entity in doing health policy research.

   b. Demonstrated past performance in doing health-related research.

   c. Proposed subject for study.

   d. Clarity of the project goal and objectives.

   e. The project work plan.

   f. The project budget.

   g. Qualifications of the professional research staff who will carry out the research. Where the applicant is an organization, institution, or agency, the experience of the assigned personnel will be given greater weight than will the demonstrated past performance of the organization, institution, or agency.

3. Determination of grant amount. The nature and size of the grant shall be determined by the SHCC, which shall take into consideration the amount of funds requested and available, the importance of the proposed subject of study to the state, and its consistency with the purpose of the HRP as defined in § 1.305B and the priorities established by the SHCC and listed in Section 1.309 of these rules.

§ 1.309 Priority considerations in the disbursement of health research program funds. In evaluating applications for HRP grants, the SHCC will consider the proposed subject of study in terms of the following priorities:

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- The provision of primary care services for medically underserved populations located in rural or economically depressed areas.

- The development of multi-institutional systems for coordinating or consolidating institutional health services, including obstetric, pediatric, emergency medical, intensive and coronary care, and radiation therapy.

- The development of multi-institutional arrangements for the sharing of support services necessary to all health service institutions.

- The development of medical group practices (especially those whose services are appropriately coordinated or integrated with institutional health services), health maintenance organizations, and other organized systems for the provision of health care.

- The training and increased utilization of physician extenders, especially nurse clinicians.

- The promotion of activities to achieve needed improvements in the quality of health services.

- The development by health service institutions of the capacity to provide various levels of care (including intensive care, acute general care, and extended care) on a geographically integrated basis.
- The promotion of activities for the prevention of disease, including studies of nutritional and environmental factors affecting health and the provision of preventive health care services.

- The development of effective methods of educating the general public concerning proper personal (including preventive) health care and methods for effective use of available health services.

- Methods to reduce the incidence and prevalence of the leading causes of death and disability in Minnesota.

- The development of improved methodologies for health planning.

§ 1.310 Conflict of interest. When any member of the SHCC or the CHRP has any conflict of interest with respect to a Health Research Program grant application under consideration by the SHCC, that member shall, prior to consideration of the application, voluntarily disclose such interest to the CHRP and SHCC, either verbally or in writing, and shall be disqualified from voting on that particular grant application. A conflict of interest shall be deemed to exist where a SHCC member:

1. has a material financial interest, whether direct or indirect, in the proposed research or study;

2. is a director, trustee, or officer of any organization or institution applying for Health Research Program funds;

3. is an employee of any applicant;

4. is the spouse, child, parent, or sibling of any individual applicant.

Any member of the SHCC may challenge any other member by means of a properly recorded vote which shall determine the status of the challenged member concerning any possible conflict of interest before further voting on the proposed grant application under consideration.

No member of the Minnesota Legislature shall serve on the CHRP. No member of the CHRP, the SHCC, or the Minnesota Legislature shall be eligible to receive a grant under the Health Research Program.

Minnesota State Planning Agency
101 Capitol Square Building
550 Cedar Street
St. Paul, Minnesota 55101
Phone (612) 296-2407

June 8, 1978

Mr. Lee Sheehy
Special Assistant Attorney General
Room G19K
Administration Building
50 Sherburne Avenue
St. Paul, Minnesota 55115

Re: In the Matter of the Rules Adopted by the Minnesota State Planning Agency Relating to the Administration of the Health Research Program

Dear Mr. Sheehy:

Pursuant to your telephone conversation of today with William Dorigan we have gone through the original copy of our rules as adopted, changing the statutory citation throughout to read Chapter 453 rather than Chapter 454. As you have requested we are today bringing you the revised rules with this change for your approval.

Sincerely,

Steve Mosow

Steve Mosow, Assistant Director
State Health Planning and
Development Agency

SM/ks

Enclosure

AN EQUAL OPPORTUNITY EMPLOYER

Order Adopting Rules

RECEIVED
MAY 22 1978
OFFICE OF HEARING EXAMINERS

STATE OF MINNESOTA

State Planning Agency

IN THE MATTER OF THE PROPOSED ADOPTION OF RULES OF THE STATE PLANNING AGENCY GOVERNING THE HEALTH RESEARCH PROGRAM.

ORDER ADOPTING RULES

The above-entitled matter came on for hearing before Howard L. Kaibel, Jr., Hearing Examiner of the Office of Hearing Examiners' of the State of Minnesota on the 7th day of April, 1978, at 9:30 A.M. in the State Office Building Auditorium, St. Paul, Minnesota, after proper notice required by Section 15.0412, M.S. Supp. 1977, was served upon all persons, associations and other interested groups registered with the Secretary of State for that purpose.

After affording interested persons an opportunity to present written and oral data, statements and arguments, having reviewed all of the testimony, having considered all of the evidence adduced, and having considered the Report of the Hearing Examiner and having made my Findings of Fact, and upon the records, files and proceedings herein, and applicable statutory standards or criteria, having withheld action on the proposed rules for the required period of time after receipt of the Hearing Examiner's findings, and having confirmed the need for the above captioned rules and the reasonableness thereof.

NOW, THEREFORE, IT IS ORDERED that these rules identified as 10 MCAR § 1.305-1.310 attached hereto as Exhibit A are adopted this 19 day of May, 1978, pursuant to authority vested in me by Laws of Minnesota 1977, ch. 454 § 27 and Minnesota Department of Administration Reorganization Order No. 83 (1977).

STATE OF MINNESOTA

Peter L Vandepoel

STATE PLANNING DIRECTOR

As Adopted

STATE HEALTH RESEARCH PROGRAM RULES

10 MCAR § 1.305 Authority, Purpose, Definitions and General Provisions

A. Authority. The rules contained herein are prescribed by the Statewide Health Coordinating Council and the State Planning Agency pursuant to the authority granted in Minn. Laws 1977, Ch. 454, Sec. 27 and Minnesota Department of Administration Reorganization Order No. 83.

B. Purpose. The purpose of these rules is to establish procedures for administering the Health Research Program. The Health Research Program will provide funds to help maintain biomedical research in Minnesota and to strengthen the state's ability to produce health services research, non-medical health research, and health policy research on issues of importance to the state.

C. Definitions. The following terms as used in these rules have the following meanings:

1. "Health Research Program" (HRP) means the program and corresponding appropriation established by the Minnesota Legislature in Minn. Laws 1977, Ch. 454, Sec. 27 to further health research in Minnesota.

2. "Statewide Health Coordinating Council" (SHCC) means the citizens' council appointed by the Governor of Minnesota pursuant to the National Health Planning and Resources Development Act of 1974, 42 U.S.C. § 300k (1977 Supp.).

3. "Committee on the Health Research Program" (CHRP) means a committee of the SHCC which shall supervise the administration of the Health Research Program. All decisions of the CHRP shall be subject to review and approval by the SHCC.

4. "State Planning Agency" means the agency of state government established by Minn. Laws 1965, Ch. 685 to perform statewide planning functions.
5. "State Health Planning and Development Agency" (SHPDA) means the division of the State Planning Agency designated by the governor to fulfill statewide health planning functions pursuant to the National Health Planning and Resources Development Act of 1974, 42 U.S.C. § 300k (1977 Supp.).
6. "Biomedical research" means research into the basic processes and distribution of health and disease, including clinical interventions that affect these processes.
7. "Health services research" means research on manpower, practice patterns, organization, and economics of health care aimed at improving the efficiency, effectiveness, and distribution of health services as delivered in practice.
8. "Non-medical health research" means research on methods to prevent disease and promote health independently of health services professionals, by minimizing causes of ill health related to lifestyle and environment.
9. "Health policy research and analysis" means the study of health-related problems and the development, testing, and evaluation of various policy options for dealing with such problems. Policy studies may include health services research, non-medical health research and health policy research and analysis.

10. "Grant" means an award of money pursuant to a written agreement signed by the eligible applicant and by the official representative of the SHCC, setting forth the amount of the funds, the time period within which the funds are to be expended, the purposes for which the funds may be used, and other contractual conditions deemed necessary by the SHCC.

10 MCAR § 1.306 Procedures for Informing the Public of the Health Research Program

A. Notice of availability. The SHCC shall inform the public of the availability of Health Research Program funds by the following means:

1. An announcement shall be published in the State Register.

2. ~~An announcement shall be published two consecutive weeks in a newspaper of general circulation in each county of the state.~~ An announcement shall be published in the form of a legal notice in 37 major newspapers providing circulation through the state.

3. An announcement of availability shall be mailed to the following Minnesota organizations and institutions:

a. The University of Minnesota and its affiliated campuses

b. State universities

c. Community colleges

d. Private colleges

e. Vocational-technical institutions

f. All hospitals

g. Associations of health professionals

h. Mayo Foundation for Education and Research

i. Minnesota Department of Health

j. Minnesota Department of Public Welfare

k. Minnesota Legislature

l. The seven Health Systems Agencies located in Minnesota

m. Local Boards of Health

The announcement shall set forth the amount of funds available for award, the period of time during which grant applications will be accepted, priority considerations listed in Section 1.309 of these rules which the CHRP and SHCC will consider in its evaluation of grant applications, the date when grant awards will be announced by the SHCC, and the location where applications should be submitted. The announcement of availability shall also include a detailed description of application procedures and project specifications as defined in Section 1.307 of these rules.

B. Announcement of grant awards. The SHCC shall announce the disposition of available grant funds by the following means:

1. When evaluation and selection have been completed, results will be sent immediately by mail to all applicants.

2. A list of grant recipients, the amount of funds awarded to each recipient, and the nature of the research to be performed by the recipient shall be published in the State Register.

3. A list of grant recipients, the amount of funds awarded to each recipient, and the nature of the research to be performed by the recipient shall be mailed to the following organizations and institutions in order to inform the health-related research community of the types of studies to be performed:

a. The University of Minnesota and its affiliated campuses

b. State universities

c. Community colleges

d. Private colleges

e. Vocational-technical institutions

f. All hospitals

g. Associations of health professionals

h. Mayo Foundation for Education and Research

i. Minnesota Department of Health

j. Minnesota Department of Public Welfare

k. Minnesota Legislature

l. The seven Health Systems Agencies located in Minnesota

m. Local Boards of Health

C. Commencement of funding. All funds awarded under the Health Research Program shall become available to each recipient at the beginning of Fiscal Year 1979 (July 1, 1978) and should be expended by the recipient no later than June 30, 1980.

10 MCAR § 1.307 Application Procedures

A. All applicants for HRP funds will be required to submit a proposal containing the following information:

1. The type of grant being applied for (i.e., whether Merit Fellowship, Non-Medical and Health Services Research, or Health Policy Study).

2. Scope of the project

3. Project goal and objectives

4. Project tasks to be completed

5. A description of the project, including:

a. A restatement of the objectives showing or demonstrating the applicant's view of the nature of the proposed research.

b. Identification and description of the products to be delivered by the applicant.

c. A description of the applicant's background and experience in health-related research.

d. Identification of the personnel who will conduct the research and a detailed description of their training and research experience. No change in professional research personnel assigned to the project will be permitted without the approval of the SHCC.

6. A detailed budget of project costs delineating proposed expenses. No general overhead rate will be allowed in the budget calculation.

7. A project completion date indicating the anticipated termination of the proposed research activity.

8. An indication of any other sources of funding, already possessed or applied for, which would be used to support the proposed research project.

B. All grant applications will be required to be submitted by a time and date specified by the SHCC in the announcement of availability described in Section 1.306A of these rules. Late proposals will not be accepted.

10 MCAR § 1.308 Procedures for Awarding Health Research Program Funds

A. Merit Fellowship Grants

1. Eligibility. An eligible applicant is any individual researcher who resides in or agrees to reside in Minnesota and who proposes to engage in exploratory analysis and pilot

research in a health-related subject or issue which has been established as a priority by the SHCC as defined in Section 1.309 of these rules. As a condition to receipt of a grant, each applicant must provide evidence that he/she has or will have an affiliation with the University of Minnesota, the Mayo Clinic, the Legislature and/or its staff, a state department or agency, a health organization, or post-secondary educational institution. This evidence must include a corroborating statement from the institution or organization with which the researcher affiliates or proposes to affiliate. Further, each applicant, as a condition to receipt of a grant, must agree to and actively seek federal or private support for full-scale research projects based on his or her exploratory analysis and pilot research.

2. Process of award. Grants to merit fellows shall be awarded on a competitive basis with applications being evaluated in terms of:
   a. The applicant's professional credentials.
   b. Demonstrated past performance in doing health-related research.
   c. Proposed subject for study.
   d. Clarity of the project goal and objectives.
   e. The project work plan.
   f. The project budget.
   g. The qualifications of any additional professional research staff who will assist with the research project.

3. Terms of grant. Grants to merit fellows shall be limited to a maximum of $50,000 per year for two years. Each grant may be utilized to provide a stipend to support the researcher and necessary clerical and research assistants and to cover the costs of other professional expenses incurred in the process of performing the research.

4. ~~At least one-half of the merit fellowship grants shall be allocated to health services research, non-medical health research, and health policy analysis.~~ Merit fellowship grants shall be allocated to biomedical research, health services research, non-medical health research, and health policy research and analysis. At least one half of these funds shall be allocated to health services research, non-medical health research, and health policy research and analysis.

B. Non-Medical and Health Services Research Grants

1. Eligibility. An eligible applicant is a Minnesota post-secondary education institution, state department or agency, or other health organization.

2. Purposes. Grants may be used to fund senior research positions, to provide seed money for non-medical and health services research activities, and to provide information, analysis, and technical support to health planners and state agencies on questions of health costs, productivity, health care regulation, and organization of the health care delivery system. The grants may also be used to support investigations and evaluations of preventive health care techniques designed to improve public health.

3. Process of award. Grants for non-medical and health services research shall be awarded on a competitive basis and shall be used only to support activities which are consistent with state health priorities established by the SHCC and listed in Section 1.309 of these rules.

   Applications shall be evaluated in terms of:

   a. Demonstrated past performance of the applicant organization, institution, or agency in doing health-related research.
   b. Proposed subject for study.
   c. Clarity of the project goal and objectives.
   d. The project work plan.
   e. The project budget.
   f. Qualifications of the professional research staff who will carry out the research. The experience of the assigned personnel will be given greater weight than will the demonstrated past performance of the applicant organization, institution, or agency.

4. Determination of grant amount. The amount and nature of the grant shall be determined by the SHCC, which shall take into consideration the amount of funds requested and available; the demonstrated ability of the eligible applicant to perform research in the areas set forth in point B(2) above; and the technical assistance to health planners, state agencies, and the legislature which may be generated by the proposed research.

C. Health Policy Study Grants

1. Eligibility. An eligible applicant is any individual or organization that proposes a study relevant to the formulation of state health policy.

2. Process of award. Grants for health policy studies shall be awarded on a competitive basis and shall be consistent with health policy issues of priority concern as established by the SHCC and listed in Section 1.309 of these rules. Applications shall be evaluated in terms of:

   a. The applicant's professional credentials, where the applicant is an individual, or, where the applicant is an organization, institution, or agency, the demonstrated past performance of the entity in doing health policy research.

   b. Demonstrated past performance in doing health-related research.

   c. Proposed subject for study.

   d. Clarity of the project goal and objectives.

   e. The project work plan.

   f. The project budget.

   g. Qualifications of the professional research staff who will carry out the research. Where the applicant is an organization, institution, or agency, the experience of the assigned personnel will be given greater weight than will the demonstrated past performance of the organization, institution, or agency.

3. Determination of grant amount. The nature and size of the grant shall be determined by the SHCC, which shall take into consideration the amount of funds requested and available, the importance of the proposed subject of study to the state,

and its consistency with the purpose of the HRP as defined in Section 1.305B and the priorities established by the SHCC and listed in Section 1.309 of these rules.

10 MCAR § 1.309 Priority Considerations in the Disbursement of Health Research Program Funds

In evaluating applications for HRP grants, the SHCC will consider the proposed subject of study in terms of the following priorities:

- The provision of primary care services for medically underserved populations located in rural or economically depressed areas.
- The development of multi-institutional systems for coordinating or consolidating institutional health services, including obstetric, pediatric, emergency medical, intensive and coronary care, ~~and~~ radiation therapy, and mental health services.
- The development of multi-institutional arrangements for the sharing of support services necessary to all health service institutions.
- The development of medical group practices (especially those whose services are appropriately coordinated or integrated with institutional health services), health maintenance organizations, and other organized systems for the provision of health care.
- The training and increased utilization of physician extenders, especially nurse clinicians.
- The promotion of activities to achieve needed improvements in the quality of health services.

- The development by health service institutions of the capacity to provide various levels of care (including intensive care, acute general care, and extended care) on a geographically integrated basis.
- The promotion of activities for the prevention of disease, including studies of nutritional and environmental factors affecting health and the provision of preventive health care services.
- The development of effective methods of educating the general public concerning proper personal (including preventive) health care and methods for effective use of available health services.
- ~~Method to reduce the incidence and prevalence of the leading causes of death and disability in Minnesota.~~ Basic biomedical research into the causes of diseases and disability, and the development of methods to reduce their incidence and prevalence in Minnesota.
- The development of improved methodologies for health planning.

10 MCAR § 1.310 Conflict of Interest

When any member of the SHCC or the CHRP has any conflict of interest with respect to a Health Research Program grant application under consideration by the SHCC, that member shall, prior to consideration of the application, voluntarily disclose such interest to the CHRP and SHCC, either verbally or in writing, and shall be disqualified from voting on that particular grant application. A conflict of interest shall be deemed to exist where a SHCC member:

1. has a material financial interest, whether direct or indirect, in the proposed research or study;
2. is a director, trustee, or officer of any organization or institution applying for Health Research Program funds;
3. is an employee of any applicant;
4. is the spouse, child, parent, or sibling of any individual applicant.

Any member of the SHCC may challenge any other member by means of a properly recorded vote which shall determine the status of the challenged member concerning any possible conflict of interest before further voting on the proposed grant application under consideration.

No member of the Minnesota Legislature shall serve on the CHRP. No member of the CHRP, the SHCC, or the Minnesota Legislature shall be eligible to receive a grant under the Health Research Program.

STATE OF MINNESOTA
DEPARTMENT OF ADMINISTRATION
REORGANIZATION ORDER NO. 83

Pursuant to Minnesota Statutes, 1976, Section 16.125 and 16.135, the following administrative reorganization is made.

The fiscal year 1979 appropriations set forth in Laws of 1977, Chapter 453, Section 27, are transferred from the Department of Health to the State Planning Agency, as follows:

(a) For merit fellowship grants: $1,000,000 to be transferred from the Department of Health (40400:01-10) to the State Planning Agency (12002:21-10)

(b) For nonmedical and health services research grants: $300,000 to be transferred from the Department of Health (40400:02-10) to the State Planning Agency (12002:22-10)

(c) For health policy studies: $200,000 to be transferred from the Department of Health (40400:03-10) to the State Planning Agency (12002:23-10)

The Commissioner of Finance is authorized to complete this transfer.

This transfer is effective July 1, 1978.

10/3/77
Date

Richard L. Brubacher
Commissioner of Administration

10/5/77
Date

Rudy Perpich, Governor

RECEIVED
JUN 7 1978
ATTORNEY GENERAL
ADMINISTRATIVE AGENCIES