Executive Summary:

The Academic Health Center (AHC) of the University of Minnesota is dedicated to the improvement of health of Minnesotans and all peoples with the development of new knowledge by innovative research, the transmission of that knowledge in education programs and service through clinical practice and outreach. Basic research in the laboratory develops new understandings of disease mechanisms and treatments. Clinical research (CR) applies those discoveries to patient populations to prevent and treat diseases. The AHC of the University of Minnesota aspires to be a center of excellence and a leading research institution devoted to bringing forward basic laboratory discoveries to benefit the patient through CR.

To accomplish this mission, a substantial and recurring investment in CR development, organization and infrastructure is required. The AHC must also establish and maintain:

1. Dedicated and energetic CR leadership at all levels.
2. An efficient and responsive organizational structure to develop and support junior faculty dedicated to CR careers.
3. Support mechanisms for senior faculty to mentor junior clinical investigators.
4. A CR infrastructure, including biostatistics, bioinformatics, and pharmacy cores, to allow the University to be a top-tier CR institution.
5. Training programs for investigators, students and staff in the conduct of CR.
6. AHC, Fairview and University-wide administrative and budgetary systems that facilitate CR.
7. Appropriate space to support clinical investigations.

This program of excellence in CR will require an estimated investment of $10 million per year.

The benefits of this initiative will be in the improved health of Minnesotans and improved external funding at the University of Minnesota estimated to approximately $50 million per-year by the end of five years.
I. Introduction

A. Charge to the Task Force from Vice President Cerra:

Dr. Frank Cerra, Senior Vice President for Health Sciences, organized a Clinical Research Taskforce (CRTF) to address the question, “What is being done by the AHC to move basic research into the clinic?” Further, he indicated that the focus of the CRTF would be patient-oriented research.

In discussing his charge to the CRTF, Dr. Cerra expressed concern that the University of Minnesota was no longer a leading CR institution due, in part, to a lack of institutional support. In this context, numerous groups, including the National Institutes of Health (NIH), the American Association of Medical Colleges (AAMC), and the Institute of Medicine, have expressed concern over the quality and quantity of CR performed in academic health centers across the country.

Dr. Cerra charged the CRTF to examine the current status of CR at the University of Minnesota, to develop a vision and goals for CR, to explore the training required for clinical investigators and staff, and to determine the ability of the Academic Health Center to leverage external resources for CR.

B. Clinical Research Task Force

The Clinical Research Taskforce was assembled under the leadership of co-chairs Drs. Russell Luepker (School of Public Health) and Dr. Charles Schulz (Medical School). Dr. Mark Paller (AHC) served as an ex officio member. Representatives of each school within the AHC were selected to participate. These members included Drs.:

- Barbara Elliott, School of Medicine, Duluth
- Susan Henly, School of Nursing
- Pam Jacobson, College of Pharmacy
- Bryan Michalowicz, School of Dentistry
- David Polzin, College of Veterinary Medicine
- Betsy Seaquist, GCRC (Medical School)
- Daniel Weisdorf, Medical School
- Dan Gilchrist, Staff

To address the charges to the CRTF, an information-gathering process was devised that included:
1. Regular meetings of the CRTF, beginning on November 26, 2002. The group met 16 times on a biweekly and then weekly basis over the next seven months.

2. Creation of an “environmental scan” through a “strengths-weaknesses, opportunities-threats” (SWOT) analysis for each school.

3. Formation of a vision statement for each school.

4. Invitation of area experts to CRTF’s regular meetings, including junior faculty, established clinical researchers, biostatisticians and Fairview and University administrators.

5. Visits to successful CR programs at four universities--University of Iowa, Duke University, University of North Carolina Chapel Hill, and Columbia University.

6. Interviews of individual faculty and staff by CRTF co-chairs.

II. Background and Rationale

A. Definition of CR

According to participants in a recent American Medical Association (AMA) and American Association of Medical Colleges (AAMC)-sponsored national summit, CR “embraces a continuum of studies involving interaction with patients (both human and animal), diagnostic clinical materials or data, or populations, in any of these categories: disease mechanisms; translational research; clinical knowledge, detection, diagnosis, and natural history of disease; therapeutic interventions including clinical trials; prevention and health promotion; behavioral research; health services research, including outcomes; epidemiology; community-based and managed care-based research (“Breaking the Scientific Bottleneck: Clinical Research: A National Call To Action,” November 1999)."

In essence, CR was defined as investigations that involve direct contact with patients, using scientific methods to answer questions about disease mechanisms, diagnosis, prevention and treatment.

B. Background and Significance

The tools of CR have expanded dramatically in the last two decades. A revolution in molecular biology has allowed basic scientists and clinical investigators to explore the underlying mechanisms of many of the major illnesses worldwide. The concurrent and dramatic advances in bioinformatics, biostatistics, genetics, imaging, pharmacology and computer technology have also changed the nature of CR performed around the world. Coupled with a new appreciation of the importance of human subjects in research and a renewed commitment to ensure that all human investigation is done according to the
highest ethical standards, patient-oriented inquiry has become a high priority for the National Institutes of Health and other major funding agencies. As a result of this new emphasis on the study of human disease using human and animal patients, research-intensive universities have begun to capitalize on the sophistication and interdisciplinary nature of new research tools. However, at the University of Minnesota, the potential remains largely unrealized.

Translating basic science advances to improvements in patient care has historically been slow. The CRTF concluded that interactions between basic science and clinical researchers at the University are infrequent, inconsistent and inadequate. Better communication through multidisciplinary research teams, multidisciplinary research conferences, and feedback among clinical researchers and basic scientists could speed the process of moving advances in the laboratory to clinical testing. Better research training and opportunities for clinically oriented faculty would greatly facilitate this process.

In addition to fostering the translation of discoveries from the laboratory to the bedside, attention needs to focus on the assessment of emerging treatments, devices, medications, or genes. Patients and their physicians need to be informed about the efficacy of new treatments, and quality information can be generated only through the systematic and rigorous testing in humans that is CR.

In recent years, the potential and need for quality CR has been recognized both locally and nationally. The public and political leadership in Minnesota and across the United States believe that taxpayer dollars should be invested in methods to prevent illness, reduce symptoms of disease, and address or cure diseases that cause pain, suffering and disability. In Minnesota, the public and its leaders look to the Academic Health Center of the University of Minnesota to build on its reputation as a comprehensive, research-intensive institution and its pledge to innovation.

C. Internal Context and Potential at the University of Minnesota

1. A strong and internationally recognized history of CR at the University of Minnesota includes important achievements such as the first open-heart surgery, the first bone marrow transplant, and the first pacemaker implantation. The CRTF was of the opinion that, with adequate institutional support, alignment of resources, and faculty commitment, the University could again attain prominence in CR.

2. The CRTF found many Minnesota investigators performing high quality CR. The University of Minnesota has a cadre of active and well-funded clinical researchers. This group, however, is widely dispersed and generally disjointed. In the CRTF’s opinion, the AHC has been unable to leverage individual successes to benefit the wider education of researchers or the institution’s reputation for CR.
3. Unique opportunities for the University of Minnesota are provided by the multi-school Academic Health Center. Compared with other institutions, the AHC offers opportunities for collaborative research across its seven schools as well as support for large projects, such as NIH multi-center projects and NIH centers.

4. The University’s recent and substantial investment in basic and translational sciences, including outlays in emerging fields such as genomics and proteomics, provides a promising foundation for clinical exploration.

5. The continued success of the University of Minnesota Physicians (UMP) adds to the potential. UMP is considering strategies to include CR in the proposed new ambulatory care facility. This group of active clinicians is an important potential collaborator in the University’s CR activities.

6. The Clinical Research Network (Family Practice) is a valuable resource for CR – both for specific projects and state-wide studies.

III. Review of Individual Schools (Also see appended materials in Appendix 1)

The Colleges and Schools of the Academic Health Center each constituted a committee to conduct a SWOT analysis (Strengths, Weaknesses, Opportunities and Threats) of CR in its unit. While evaluations were unique to each school, a number of common themes emerged, which are summarized below.

A. Strengths

1. A strong history of excellence and external support for CR is present.

2. An active NIH-funded General Clinical Research Center (GCRC) exists.

3. An NIH supported K30 training program in CR exists.

4. Experienced mid-level and senior faculty are available.

5. Collaborations with community resources is on-going.

6. Experience is extensive in the design, management and analysis of large clinical studies.

7. A multidisciplinary AHC has diverse skills and resources.
B. Weaknesses

1. The existing culture that values basic research over CR.
2. Poor communication and collaboration within and between Departments, colleges and schools results in fragmented research efforts.
3. A research administration system that is frequently slow and unresponsive to clinical researchers needs.
4. CR is not an integral component of Fairview/University Hospital’s mission.
5. Start-up packages and protected time for clinicians interested in CR careers are inadequate.
6. Senior mentoring for junior clinicians interested in CR careers is inadequate.
7. The promotion and tenure system does not consistently recognize or reward the efforts of clinical researchers.
8. Relatively few national leaders in CR are on the faculty.
9. An inadequate number of potential research participants in several critical areas.
10. The physical facilities needed to conduct world class CR is lacking.
11. Statistical and coordinating center support is not well-integrated with other AHC researcher activities.
12. Research laboratory support is inadequate.

C. Opportunities

1. Nationwide interest in CR is growing.
2. NIH is increasing its commitment to CR.
3. Opportunity exists to consolidate space in the new UMP facility.
4. Investment and advances in basic research offers opportunities for partnerships and translation into clinical applications.
5. Partnerships are established with University-affiliated and other community clinics and hospitals.
6. The device and biomedical industry in this state is growing.
7. Foundation, industry and corporate giving is strong.

8. The Fairview system has potential for much more research.

9. A Masters program in CR is producing qualified graduates.

D. Threats

1. State budgets are declining seriously.

2. Increasing threats exist to healthcare dollars in the Fairview System, secondary to insurance industry, State and Federal cuts.

3. Industry is moving towards private CROs for research protocols.

4. The current system for indirect cost recovery (ICR) does not promote building an AHC-wide CR infrastructure.

5. Competition exists with other academic institutions and local healthcare systems.

6. Recruiting and retaining skilled CR faculty is difficult.

7. The pool of experienced and trained CR staff is inadequate.

8. Department chairs are not consistently committed to supporting CR.

9. As large CR projects emerge, space for investigators is inadequate.

IV. Recommendations

During its discussions of school reports, and following interviews with guest experts and visits to four strong CR universities, the CRTF identified several factors it thought were critical to ensure the success of any CR initiative. These included leadership, faculty support and development, space, statistics and coordinating center resources, clinical pharmacology resources, teaching and training, and research administration.

A. Leadership: During the visits to the four strong CR universities, leadership emerged as the most critical success factor. The CRTF was repeatedly impressed with the importance of a leader or group of leaders who were passionate in their commitment to CR. The University needs to address the issue of leadership in CR at the AHC, school, and departmental levels.
1. AHC level: Specific recommendations for the AHC are to:

   a. Strengthen and expand AHC-wide support for CR through the creation of an Office of Clinical Research. This should involve substantial reorganization and expansion of the Research Services Organization (RSO) purview beyond grants from industry to all CR activities. This office would:

      i. Foster the development of CR across the AHC.

      ii. Provide proactive consultation on all aspects of CR to researchers and their teams.

      iii. Coordinate the building and space allocation program for CR.

      iv. Devise an accountability system to oversee AHC investments in CR. The CRTF recommends that the AHC create a CR advisory board to provide advice and guidance to colleges and schools on how to foster and sustain CR programs.

      v. Establish an external CR advisory board comprised of representatives from industry, government and academia. This board would provide oversight and consultation on CR-related activities and report directly to the Senior Vice President. It would play an important role in the development of funding.

   b. Expand the scope of the RSO to become proactive in finding resources and connecting faculty with funding from federal, foundation and industry sources.

   c. Assign a central role to the GCRC and encourage improved visibility among all researchers—from junior faculty to department heads across the AHC.

   d. Devise a plan for ongoing funding for cross-AHC CR initiatives and functions.

   e. Develop and implement a website that provides information about CR capabilities and information about subject recruitment.

2. School level

   a. Each school within the AHC should develop a plan to expand its CR activities. The plan should include specific goals, which may compliment other initiatives within each school.
b. Each school should appoint an Associate Dean for Clinical Research to lead the school’s investments in CR. This need not be a full-time administrative position. This Associate Dean should be an established and active clinical researcher.

c. Just as within the AHC, each school should develop a system to track and guide the school’s investments in CR to ensure accountability.

d. Each school should create a mechanism to facilitate interdisciplinary research—across its own departments and across the AHC.

3. Department level

a. Where appropriate, each department chair should develop a plan to expand and sustain its CR activities. The plan should contain specific goals and a timetable for evaluating whether these goals are being met.

b. Each department chair should oversee the department’s investments in CR.

c. Accountability for the CR plan should be built into each department chair’s evaluation.

B. Faculty support and development: A hallmark characteristic of top-tier CR institutions is that they have systems in place to train, mentor, and support junior CR faculty. The CRTF discussed the differences between the development of basic science faculty and CR faculty at the University of Minnesota, noting the substantial clinical burden placed on many faculty who wish to develop CR careers. Furthermore, it was noted that CR mentors were scarce and successful researchers were generally unavailable or too busy to mentor junior faculty. Therefore, the CRTF recommends the following.

1. CR Scholars

The AHC should create 30 junior faculty positions over the next three to four years. Candidates would include individuals who have completed specialty training and have either a CR MS, a current NIH K-type award, or completed a CR fellowship.

a. A faculty development plan should be established for junior faculty interested in careers in clinical investigation. The individualized program should have well-defined goals and objectives. Additional components of this plan should include:
i. Three years of protected and paid time (75% FTE with a FTE cap at the NIH level, $171,000).

ii. $100,000 per year startup funding.

iii. The commitment of a qualified CR mentor.

b. Evaluation of the CR scholar program

i. The principal measures of success will be the scholar’s success in procuring external research funding (NIH or similar) within the first three years.

ii. Promotion within the CR scholar’s department will be another measure of success.

c. Selection

i. CR Scholars will be assigned to departments based on a formal application process. It is imperative that the candidates receive strong departmental support for these activities.

ii. Review of proposals will be by a peer committee similar to an NIH process.

2. Mentorship and Senior Faculty Support

Financial support to a junior investigator is not itself sufficient for a successful CR enterprise. Therefore, a plan for mentorship and senior faculty support needs to be devised. Senior faculty involved in these programs should already be accomplished clinical researchers at the national level. The CRTF recommends:

a. That senior faculty receive up to 5% salary recovery for their efforts in mentoring CR scholars and junior faculty. Each CR scholar should have a mentor for whom a specific amount of time is available for career development, paper writing, and grant applications.

b. Expanded availability of academic leave opportunities through increased funding for these activities, better recognition that expanded clinical research skills and experiences benefit not only the senior researcher, but also the junior faculty they work with and, ultimately, the AHC’s clinical research enterprise.

c. That funding to enable senior faculty to develop CR proposals be expanded.
3. **Space**

Space is a challenge for all research universities, including the University of Minnesota. Several issues arose during the CRTF’s discussion regarding space.

a. The AHC needs to consider and review potential plans for a research site that could be adjacent to or part of the new clinical ambulatory building of UMP. This site should consist of a dedicated core staff with a shared staff model. Funding for such a site could be made through an investment of the AHC and through funds obtained from the National Center for Research Resources through the GCRC. Among the AHC’s fundraising priorities, philanthropic support for facilities and infrastructure should be actively explored and industry-sponsored work should be self-supporting.

b. Even if a dedicated CR facility is built, specialized research could occur in smaller “pods” adjacent to or within specialized clinics. This model is used at other research universities.

c. Some of the space concerns could be alleviated if the AHC improved coordination between CR and inpatient clinical care at FUMC.

d. The GCRC is a crucial asset for CR progress and coordination is needed for space needs with activities in the GCRC.

e. Discussion with UMP leadership has revealed that there is currently space in UMP clinics for CR. Mechanisms for cost accounting would need to be developed.

C. **Statistics and coordinating center support**

In numerous interviews and school reports, resources in biostatistics were considered an important part of the plan for success. The CRTF found there was an insufficient number of both senior statisticians available to plan and write grant applications, and biostatisticians needed to assist with the analysis of data from current projects. The CRTF recommends that the AHC develop a statistics and coordinating support center that is dedicated to supporting CR endeavors and training CR scholars. This center would logically be housed in the Division of Biostatistics in the School of Public Health.

Biostatisticians interested in providing direct service in collaborative research with clinical investigators should be hired either as faculty or research fellows in the Biostatistics Division.
The statistics and coordinating center needs to be capable of collaborating on local, national and international multi-center studies. The funding should be shared between AHC and the School of Public Health. Individual grants should support a portion of this program.

D. Clinical Pharmacology

The CRTF concluded that clinical pharmacology is a crucial factor in the success of CR programs. Therefore, the CRTF recommends the establishment of a Clinical Pharmacology Center:

1. The Center would provide expertise in the design and conduct of phase I-IV clinical trials that require pharmacokinetic, pharmacodynamic and pharmacogenetic analyses, specialized blinding or unique drug formulations, dose-response relationships and concentration controlled trials.

2. The Center should be capable of collaborating on local, national, and international multi-center studies.

3. The clinical pharmacology center could be initiated with shared funding from the AHC and the School of Pharmacy.

E. Teaching and training

The CRTF noted that there is inadequate training in CR for medical and dental students, residents and staff. Therefore, the recommendations for teaching and training are as follows.

1. Students

Clinical electives and CR instruction should be included in AHC schools curricula.

2. Staff

Specific training for research staff should be required and should include the following:

   a. Required training and certification

   b. Classes for CR staff

   c. Classes for clerical staff

   d. Certification of successful completion and regular recertification
3. Faculty

The qualification for faculty to participate in CR was frequently discussed during the CRTF deliberations. Clearly there are many more specific expectations of CR faculty than in years past, so that clarification of training is a crucial topic. Today, CR faculty may participate in a short-term CORC training program, a CR seminar, or the CR Masters Program. The CRTF recommends the AHC develop a CR training program that is less extensive than the MS program, but which provides more extensive training than the current series of short courses.

F. Research Administration

1. Sponsored Projects Administration (SPA): In all areas of discussion ranging from CRTF committee meetings to school appraisals, and through individual interviews, there were concerns about Sponsored Projects Administration. Generally, the concerns focused on timeliness, service to faculty, and competitiveness. For CR to move forward – especially CR associated with pharmaceutical or device industries – attention will need to be paid to this crucial area. The CRTF members who visited other universities were impressed with the efficiencies of their systems.

a. Timely administrative decisions are a "must" for faculty at the AHC to work with industry. One area that was repeatedly noted for problems was contracting. The CRTF members are aware that there is probably no easy solution to this problem, but they noted that other universities have worked with templates and goals for rapid turnaround.

b. Consultation with faculty on procedures was another area noted for concern. On numerous occasions, members of CRTF heard that faculty members were not kept in the information loop regarding progress or negotiations regarding their grants or contracts.

2. Sponsored financial reporting: Four areas were listed as concerning in this area. They include:

a. Timely reporting of expenditures.

b. Prompt negotiation and payment of subcontracts: This was of particular concern for large NIH grants. This is a crucial matter for moving forward with large projects that can add to the AHC’s reputation for excellence in CR.

c. Mechanisms for teaching and collection of per-payment reimbursement or industry-supported trials.
d. Prompt collection and payment of debts.

e. In addition to SPA’s interactions with individual faculty, the importance of the relationship to Departments was noted. The rules and regulations, processes and policies of administrative oversight must be reviewed and refined to provide timely and consistent support.

3. Institutional Review Board (IRB): Major advances in CR cannot move forward without addressing issues related to the IRB. Concerns were raised regarding timely decisions and the expertise of IRB members to assess clinical trials. Furthermore, if members of the University of Minnesota are going to participate in multicenter clinical trials, IRB members and investigators will need to work with the acknowledgement that protocols are written for the entire multicenter group are required for scientific integrity.

a. The CRTF recommended that the AHC allocate resources that enable the IRB to make timely decisions on submissions.

b. The CRTF supports inclusion of more clinical researchers on IRB panels with departmental or AHC support for their time.

c. The CRTF would like to see both improved efficiency of the IRB processes as well as better feedback and timely communication with researchers.

d. The CRTF members discussed the feasibility of a dedicated clinical trials IRB panel. Such a specialized IRB would focus knowledgeable faculty on specific issues of CR and lead to a more efficient system.

4. For CR to prosper on and beyond this complex campus, Fairview University Medical Center and the Fairview System will need to be substantially involved. Areas of common ground for future planning include patient recruitment, involvement of clinical and adjunct faculty, and overall partnership with the CR effort. The CRTF believes that shared involvement and investment between the University and Fairview in areas of CR will enhance both institutions. Specifically, the CRTF discussed these topics:

a. The CRTF applauds Fairview’s recent hiring of a Vice President for CR and recommends that the new VP establish goals for CR in the Fairview system, engage University clinical researchers and develop mechanisms to facilitate CR.
b. The CRTF believes that the hiring of this new position signals an increasing recognition that CR is a valuable enterprise, and encourages further commitment by Fairview’s leadership.

c. There needs to be a development of user-friendly systems for clinical researchers working within the Fairview system. Limited access to medical records and code access for researchers in Fairview computers are among the barriers now facing University clinical researchers.

d. Test and facility prices for CR need to allow investigators to be competitive with other universities so as not to price the University of Minnesota faculty out of CR opportunities when they use Fairview services.

e. The members of CRTF also recognize the importance for Fairview to promote and value CR throughout the system.

5. A unified application process that addresses the needs of all University regulatory bodies would expedite paperwork processing.

VI. Budget and Funding

A. Members of the CRTF felt that a substantial initial investment of recurring AHC-wide funding was required. This may begin with an annual budget of $10,000,000 per year. Specific items for this investment are listed below:

1. AHC research office enhancement as has been noted above – $1,000,000 per year.

2. AHC school’s Associate Dean for Clinical Research positions – $750,000 per year.

3. Junior faculty CR scholar awards – $6,000,000 per year.

4. Senior faculty awards – $750,000 per year.

5. Biostatistical/coordinating center – $1,000,000 per year.

6. Clinical pharmacology center – $250,000 per year.

7. GCRC support – $250,000 per year.

B. The recommendation of a CR building would require $12,000,000 for a 60,000 square foot building. Pricing may vary depending on final placement of the UMP ambulatory clinic building.
VII. Five-Year Timeline for Implementation of Recommendations: The members of CRTF recognize the importance of a long-term plan for implementation of recommendations. Therefore, a five-year timeline was discussed and the general overview is as follows:

**Timeline for Implementation of Recommendations**

I. Year One

   A. Expand the Academic Health Center CR office to support grant submissions and statistical methodology.

   B. Develop the Request for Applications (RFA) for clinical scholars and award 2-4 grants.

   C. Complete recruitment/assignment of School and Department leaders.

II. Year Two

   A. The regular cycle of applications and awards of clinical scholar grants by an established committee.

   B. Initiation of AHC-wide CR symposia that includes outside speakers.

   C. Space planning begins with examination of School/Departmental space and the need for a centralized CR building.

   D. Planning of semester leaves or other programs for mentors/senior clinical researchers completes implementation plan.

III. Year Three

   A. Full complement of clinical scholars and mentors in place at end of third year.

IV. Year Four

   A. Building program for CR Center to reach conclusion.
Guests who spoke to the CRTF:
Jim Neaton, John Connett, Biostatistics; Linda Chlan, Asst. Prof., Nursing; David Cornfield, Prof., Medicine; Hassan Ibrahim, Asst. Prof, Medicine; Mark Kirstein, Asst. Prof, Pharmacy; Michael Kotlyar, Asst. Prof., Pharmacy; Katie Schmitz, Asst. Prof., Epidemiology; Shalamar Sibley, Asst. Prof., Medicine; Diane Treat-Jacobson, Asst. Prof., Nursing; Tonya White, Asst. Prof., Medical/Psychiatry; FUMC President Dr. Gordon Alexander; and VP for Research David Hamilton.

Dr. Schulz interviewed Drs. Kane and Swiontkowski at CORC regarding potential for CR training.
APPENDIX 1

SWOT Analyses
UNIVERSITY OF MINNESOTA  
College of Veterinary Medicine Clinical Research SWOT Analysis

**Strengths**

1. Large clinical caseload
2. Good laboratory resources and equipment
3. Several core focus areas (e.g., oncology, renal/urinary tract disorders, genetics, musculoskeletal disorders, infectious diseases)

**Weaknesses**

1. Philosophical differences between the veterinary teaching hospital and clinical researchers (includes record issues, technical support, etc.)
2. Lack of adequate grantsmanship mentoring
3. Inadequate appreciation of clinical research by the college and departments (including clinician time issues and incentive for research endeavors)

**Opportunities**

1. Increased recognition and development of animal models of human disease
2. Increased linking to federal/corporate/foundation funding

**Threats**

1. Competition from other institutions
2. Funding agency issues (e.g., demands for control of data and researchers, inadequate ICR on clinical research grants)
3. Private practice research center.
UNIVERSITY OF MINNESOTA
School of Nursing (SoN) Clinical Research SWOT Analysis

**Strengths**

1. *A research portfolio that continues a long-standing tradition of clinical research.*
The U of M SoN is 14th among U.S. schools of nursing in NIH-sponsored awards in 2001, the most recent year for which information is available. Most of this funding supports clinical research.

2. *A strong understanding of the focus and goals of clinical research.*
SoN investigators ask important clinical questions that reflect the holistic perspective of nursing as a scientific discipline. A practice perspective that reflects physiological, biobehavioral, psychosocial, and contextual dimensions informs faculty programs of research focused on the health-illness experiences of individuals, families, groups, communities, and populations.

3. *Effective collaboration with community partners across the research process.*
Nurse scientist collaboration with community partners extends the practice presence of professional nurses in hospitals, clinics, schools, government health departments, worksites, and the myriad settings for public health nursing to the research enterprise. Scientist-practitioner links ensure that critical research questions are addressed, that projects are feasible, and that venues for dissemination and utilization of results (especially by those who took part in research projects) are readily available. Community partnerships jointly support the research and service missions of the SoN.

4. *Preparation of investigators for clinical research.*
SoN faculty who serve as principal investigators for clinical research projects all have earned doctoral degrees (most are PhDs; some are DNSc/DSN) in nursing or related fields (e.g., psychology, physiology, family social science). An increasing number of new assistant professors have completed postdoctoral fellowships as well. Uniform preparation of the faculty with the highest research degrees facilitates the conduct of clinical research. Experience with project design was rated as a particular strength, and likely reflects faculty preparation with doctoral degrees.

5. *Infrastructure for preparation of research proposals.*
The SoN Research Resource Center (RRC) effectively facilitates preparation and processing of research grant proposals on a timely basis. The RRC staff is well-qualified and procedures are clearly developed. The SoN has experienced and positive relationships with the IRB. The SoN Research Centers of Excellence (Center for Nursing Research on Elders, Center for Child and Family Health Promotion Research, and Center for American Indian Research and Education) provide mechanisms for internal review of developing work and publicize areas of research focus to facilitate connections with national and international colleagues. The SoN Research Committee has authority and responsibility for reviewing investigator concerns in the conduct of research, which ensures a mechanism for continuous improvement in the research-related processes.
Weaknesses

1. **Statistical assistance**
   Evaluation of statistical assistance was mixed, with faculty providing very high and very low evaluations. Because consultation is available within the SoN, the AHC, and the University, it was thought that some faculty members might not be aware of how to access help that is available.

2. **Student research**
   The SoN graduate program (with about 300 MS and 70 PhD students) is the largest program in the U of M Graduate School. Approximately 14 junior and senior undergraduate students take part in the SoN Honors Program each year. Student participation in research for degree completion is an asset and a liability in the conduct of faculty research programs. Ensuring that students have quality research experiences that also contribute to faculty efforts is a continuing challenge.

Threats

1. **Need for more support of PIs for responsible fiscal management of sponsored projects.**
   This concern is especially true for clinical projects that involve subcontracts with community entities and other academic institutions.

2. **Inadequate funding for sponsored projects.**
   The modal research grant in the SoN is a clinical project funded internally or by a foundation with direct costs ranging from $5000-$25000 with no F&A costs allowed. Increased numbers of proposals (and awards) with more complete coverage of actual costs, including PI salary recovery and F&A costs, would help. These are goals included in Research Committee recommendations for the SoN Strategic Plan for 2004-2007.

3. **Interpretation of criteria for tenure/promotion at AHC second level review.**
   There is general agreement that the criteria for tenure/promotion are written in a way that is consistent with clinical research careers, and that SoN internal review is realistic in the interpretation of the criteria. There is on-going concern about whether interpretation of the criteria at the AHC level for candidates with clinical research careers will be realistic.

Opportunities

1. **Renewed focus on clinical research at national, university, and AHC levels.**
   SoN faculty conduct more clinical research than any other type of research, and think that clinical research is what they do best. Alignment of the priorities of other entities with the interests and priorities of SoN investigators is viewed as an advantage.

2. **Need for leadership in the development of (1) clinical research programs that integrate clinical research activities with education and service missions of the AHC and (2) faculty tenure/promotion review procedures congruent with clinical research careers.**
3. *Possibility of developing AHC procedures for shared recruitment of research participants.*
   Uniform procedures, ability to obtain consent to be contacted from potential subjects, and
   the chance for greater collaboration with UM-Physicians as they develop a clinical
   research emphasis were viewed as opportunities, as was the possibility of utilizing
   services of the GCRC.

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UNIVERSITY OF MINNESOTA  
College of Pharmacy Clinical Research SWOT Analysis

**Strengths**

1. Faculty have expertise in clinical pharmacology and translational research methods including study design, pharmacokinetics, pharmacodynamic, pharmacogenetics, pharmacometrics, clinical trials, drug interactions, statistics, analytical techniques.

2. University of MN College of Pharmacy is a top ranked college, consistently ranking in the top five schools nationally. The faculty are nationally recognized.

3. The College of Pharmacy has a department focused on clinical pharmacology (Experimental and Clinical Pharmacology). Very few colleges have such a department with faculty with this expertise. In addition, several faculty in the other three College of Pharmacy departments (Pharmaceutics, Medicinal Chemistry and Pharmaceutical Care) conduct some clinical pharmacology research. Combined these circumstances make the College unique among schools of pharmacy.

4. Faculty are multidisciplinary and conduct research in areas of infectious disease, neurology, cancer, cardiology, psychiatry and geriatrics. The faculty is also comprised of members with varied training backgrounds (i.e. PharmDs and PhDs; biostats, pharmacology, pharmacokinetics) and areas of expertise that enriches their abilities to conduct multiple types of studies.

5. The College of Pharmacy has access and relationships with several healthcare systems (FUMC, HealthPartners, etc.) through their research programs and the professional education program.

6. A strength of this AHC is that Medicine, Nursing, Dentistry, Public Health and Pharmacy are all located on one campus.

7. The Twin Cities area is the most populous area in the state and hence an excellent population from which to draw study subjects.

8. No internal competition within the AHC for clinical pharmacology research. The Dept. of Pharmacology in Medicine is strong in molecular biology with relatively little interest in clinical research. The Mayo Clinics are involved only to a minor degree in clinical pharmacology research.

9. The Dept. of Experimental and Clinical Pharmacology has a graduate program for training in clinical pharmacology.
**Weaknesses**

1. Access to FUMC subjects for study enrollment is limited.
   
a. There is no overall AHC coordinated approach to enrolling patients into studies (e.g. subjects for enrollment in a pneumonia study may receive care in one of many clinics and unless each clinic/clinician is contacted regarding the study, there is a limited chance that patients will be enrolled).

b. There is no incentive for enrolling patients where the care provider is not the PI or Co-I. As a consequence, many patients are not enrolled in protocols.

c. FUMC has strong programs in specific therapeutic areas, hence the type of patients encountered is limited to these diseases.

2. Amount of bureaucracy associated with administrative and regulatory offices (IRB's, GCRC, CPRC, DSMC, anticipated HIPAA regulations, SPA) is extremely burdensome, limits patient accrual due to time delays and, in general, is discouraging. Reviews from the approving committees can be conflicting and there is no system for timely resolution of conflict established between the committees. Faculty who at one time conducted primarily clinical research are now primarily conducting basic research for these reasons. Basic science is becoming more attractive to faculty and trainees.

3. The UM does not work with an IRB consortium in the Twin Cities nor do we have the mechanisms or infrastructure to effectively collaborate with local health centers in research.

4. Resources within the College are distributed based on the misunderstanding that clinical research requires fewer resources. Support for a clinical research data management center or core analytical facilities is not valued as highly as basic science instrumentation. In addition, industry sponsored clinical research is reimbursed at a lower indirect cost rate than federal grants; hence, from a financial perspective even PI initiated industry research studies are discouraged.

5. AHC wide research facilities, services and supportive personnel are limited. The GCRC has limited nursing resources for appointments, blood draws and data collection, etc. In addition, the GCRC space is in need of remodeling. The present GCRC facility is unappealing for potential research subjects, and is unacceptable for pediatric subjects. Parking for subjects entering the GCRC is difficult.

6. Lack of substantial intramural funding for startup projects. Virtually all extramural funding organizations expect preliminary data; yet funds needed to conduct even small clinical studies is insufficient.
7. The pharmacy faculty expertise is underutilized within the AHC. Expertise extends far beyond the traditional compounding and tableting methods, and drug delivery issues, yet few other AHC faculty are either aware of this resource or take advantage of it. Given that a substantial share of AHC annual research activity is related to drugs and drug therapy, substantial value could be added to proposals through increased collaboration.

8. Relatively limited help for faculty in identifying funding sources or providing "senior mentorship" on potential funding sources. Mentoring of junior and "new to the institution" faculty is limited.

9. Very limited room for growth and new faculty laboratory and office space on campus and within a reasonable distance to the clinics, hospital and GCRC.

10. Contract and grant management is weak within the College of Pharmacy.

11. Although clinical pharmacology is important in all of the AHC schools, there is remarkably little inter-school collaboration in either research training or research collaboration.

Opportunities

1. Every clinical protocol should be viewed as potential opportunity to ask a pharmacology question.

2. Yet untapped potential to enroll more FUMC patients into clinical protocols.

3. Capitalize on pharmacogenetics. Molecular biology research has, and will continue, to exponentially expand the opportunities to develop new therapies for human disease. Increasing the understanding of the factors influencing how and why drugs work lends itself to a quantum improvement in predicting response and avoiding serious adverse effects. Harnessing the collective expertise of AHC, giving the University an exceptional opportunity to leap frog ahead of other academic groups in field of translational and clinical pharmacology.

4. Create a research consortium among health care organizations within the Twin Cities to permit the conduct of clinical research, particularly in disorders, which would otherwise not be possible at a single institution. Such a partnership would allow all participating organizations to leverage close geographic proximity and large population to successfully compete with other areas of the country for research funding.

5. Clinical pharmacology cuts across all the AHC schools. It is an excellent vehicle to foster interdisciplinary research training and collaboration.

6. The emerging biomedical industry in Minnesota offers an outstanding opportunity to collaborate.
**Threats**

1. Fewer local and national dollars available for research funding.

2. Scarcity of funds for clinical research makes it difficult, if not impossible, for junior faculty in clinical pharmacology to succeed. There may be no next generation of academic clinical pharmacologists due to the perceived lack of rewards in academics and clinical pharmacology.

3. Healthcare systems outside the University do not have research as a priority and, in some cases, discourage participation. Few healthcare systems have the facilities or staff to participate in collaborative clinical research.

4. College of Pharmacy expansion to Duluth. This expansion is funded by tobacco endowment dollars and should this endowment be taken back by the state the Colleges resources are inadequate to run both programs. We are at risk of losing resources that are currently dedicated to the Twin Cities program to run the rural program.

5. Pharmaceutical industry research is moving rapidly to industry sponsored contract studies. Opportunities for investigator-initiated research is declining.

6. Difficult to find adequately trained candidates in clinical pharmacology and recruit them to Minnesota.
UNIVERSITY OF MINNESOTA
UMD Clinical Research Task Force SWOT Analysis

Strengths

• Minority research
• Network of minority MD graduates
• CAIMH
• Collaborative opportunities – including Whiteside agreement
• Research on-going with rural sites – mental health, etc.
• Community collaborators
• STAR
• CRMHS
• Reactivity (small setting)
• Relationship to state Commissioner of Health
• Tim’s network/SISU network/Preceptor network

Threats

• Realigned research priorities (Bioterrorism)
• Budget crisis
• Billing pressures on MDs
• Joint accreditation
• Clinical research poorly understood
• Few tenured/tenure track positions with this focus

Opportunities

• More money available for clinical research
• Realigned research priorities?
• Moose Lake connection
• Grant preparation skills
• New faculty positions
• UMD collaborators – upcoming pharmacy school
• Open market (no competition)
• SMDC/SLH cancer centers
• Clinicians with interest in research
• Distance health care
• Dynamic mental health care setting
• Student health service
• Renewed emphasis on finding resources for SOMD
Weaknesses

- Anti-clinical research culture
- DLH/MSP relationship
- Critical mass absent
- Minimal support staff
- Experienced MD collaborators
- Time to complete research
- Statistical expertise
- No affiliated clinic physically located on campus for practice base
- Not much money to invest
UNIVERSITY OF MINNESOTA
School of Dentistry Clinical Research SWOT Analysis

Strengths

1. The diversity and expertise of our faculty. The School has graduate and post-doctoral training programs in prosthodontics, periodontics, pediatric dentistry, oral surgery, orthodontics, facial pain/temporomandibular disorders, geriatric dentistry, oral medicine, dental materials, hospital dentistry, endodontology, and oral biology.

2. Our standing as a research institution. The SOD currently ranks first among 49 U.S. dental schools in funding received from the NIDCR ($11+M in FY2002).

3. The School's large, diverse, and growing clinic population. The School registers between 8,000-9,000 new patients every year, which enables clinical researchers to recruit subjects with a wide variety of clinical conditions and treatment needs.

4. The proximity of the School to other colleges, hospitals and centers within the AHC. Our location within the AHC is thought to encourage professional collaborations and help establish multi-disciplinary clinical research programs.

5. The Oral Health Clinical Research Center. This fully-equipped, 10 operatory clinic serves as the administrative center of the OPT Trial and houses the NIDCR Temporomandibular Joint Implant Registry and Repository (TIRR).

6. The Clinical Research Training Workshop. Over 200 investigators from 50 dental schools around the nation have participated in this workshop since 1991. This four-day course includes lecture and seminar training in the following areas: hypothesis testing, literature searches, study design, analysis and interpretation of results, budgeting and administration of research projects, IRB issues, and subject recruitment strategies.

Weaknesses

1. The lack of an active and diverse cadre of senior clinical research mentors willing to train the next generation of researchers.

2. The lack of available startup funds or space for junior clinical researchers.

3. The design of the clinical records system. While detailed information about billing, insurance coding and student productivity can be expertly gleaned from the School's record system, researchers are unable to obtain confidential but quality information about the availability of potential research subjects, or to glean information about health outcomes and/or specific oral pathoses or patient risk factors. A fully-integrated electronic record system would greatly enhance our clinical research programs.

4. Clinical faculty have little time to pursue clinical research given their teaching and administrative responsibilities.
5. The culture of the School. The current culture does not widely value clinical research or
embrace the need to incorporate evidence-based dentistry into the curriculum. The need
for consistent, strong and unwavering departmental support was viewed as an essential
component to building and sustaining a thriving clinical research program.

6. The lack of core support services available to clinical dental researchers. There are no
core services available, for example, in dental microbiology, immunology, imaging or
genomics. One exception is the biostatistical support service available through the
OHCRC.

Opportunities

1. The SOD is the only dental (DDS) training and research institution in the state and is a
teaching and research resource for the Upper Midwest.

2. The budget of the National Institute of Dental and Craniofacial Research has increased
over 60% in the past five years to $370M; its current director has emphasized the need
for more and larger clinical studies in the institute's portfolio. The NIDCR has recently
developed a new clinical trials program to streamline and facilitate the development and
submission of investigator-initiated proposals.

3. The University is widely recognized for its rigorous research standards and ability to
generate high-quality clinical data. With the growth of independent CRO's, it was felt that
the AHC, and the SOD in particular, must continue to develop a model for conducting
clinical studies that is both responsive and flexible to the demands of both private and
public funding groups.

4. The state's and region's thriving biomedical industry was thought to provide an excellent
environment in which the SOD can thrive. Companies such as Lifecore Biomedical and
3M have longstanding commitments to clinical dental research. While the School has
developed and maintains productive relationships with many corporate sponsors, it
should be more aggressive in establishing research collaborations within the private
sector.

Threats

1. Long-term budget shortfalls. In response to current budget shortfalls and likely future
cuts in state funding, the SOD has proposed to increase its undergraduate class size as a
way to increase tuition revenue and clinic income. Given the paucity of academic dentists
and full and part-time clinical faculty, it was felt that the inevitable increase in workload
would further limit the ability of the faculty to conduct clinical research.

2. The current dental marketplace. The marketplace has hampered the SOD's ability to
recruit and retain faculty who have the interest and expertise in clinical research.
Nationwide, over 300 faculty positions in dental schools remain unfilled and the average
salary of private practitioners remains far above that of a tenure-track faculty.
3. Short-term SOD, AHC and University-wide budget constraints. At present, the administration has restricted hiring of new faculty. It is feared that current and new faculty hires will be provided with less time for scholarly development (e.g., clinical research) as the SOD becomes increasingly reliant on clinic income to cover its operating expenses.

4. Competition from CROs and other dental schools and academic health centers. As more oral health CRO's are established, the quest for private and public research support will likely become more competitive.
UNIVERSITY OF MINNESOTA
School of Public Health Clinical Research SWOT Analysis

**Strengths**

1. Substantial experience in study design, recruitment and retention, data collection, management and analysis and leadership in multi-center clinical research.

2. Experience with international studies including regulatory approval.

3. Dedicated large combined clinical out-patient facility with a critical mass of participants (greater than 1,000 visits per month) and some high-tech facility support.

4. History of cooperative studies and collegiality between units within the School.

5. Availability of large population databases.

6. A K30 Clinical Research MS Program Training Grant.

7. A successful faculty with substantial NIH funding for clinical research.

8. An increasing student body with a specific interest in post-doctoral clinical research training.

**Weaknesses**

1. Some difficulty in communication between divisions and other schools.

2. A lack of physician investigators or other health professionals interested in clinical research careers.

3. An inability to rapidly respond to initiatives for research proposals.

4. The great expertise in management of large clinical trials is inadequate in available time to address the many local needs.

5. Paperwork and red tape can be overwhelming to the investigator.

6. The IRB, at times, seems capricious, arbitrary and dysfunctional. It seems particularly prejudiced against population-based research on healthy individuals.

7. There is a lack of a comprehensive clinical research training program for staff.

8. The Fairview system does not seem to understand clinical research and has higher costs than other university centers.
9. The tenure system does not work well when long-term projects are considered. This is one difference of clinical research from basic laboratory science.

10. There is a lack of ethnic diversity within the University system.

**Opportunities**

1. There is considerable potential to grow and expand in scope. The expertise and international reputation is already available as is a solid track record with the NIH.

2. The NIH has plans to expand clinical research, particularly large collaborative programs.

3. There is the potential to increase the training program and develop more faculty as MS students advance toward that opportunity.

4. There is the potential to consolidate clinical research space with access to high-tech facilities.

5. Clinical research has considerable potential in confronting bioterrorism and in the international health arena.

**Threats**

1. Competition between departments and schools.

2. Inertia and poor service at the level of the AHC, SPA and IRB.

3. Increasing barriers put in place by the IRB with HIPAA and other regulations.

4. Inadequate numbers of trained staff in the Twin Cities.

5. Frustration and discouragement on the part of junior faculty probably due to the lack of appreciation of the time needed to accomplish successful clinical research careers. A lack of mentorship for junior faculty attempting to start a clinical research career.

6. Clinical chairs without clinical research experience and the resulting lack of leadership.

7. A state budget crisis leading to raids on high quality clinical research faculty by other institutions.

8. Concerns regarding the future funding of the NIH following the doubling of the budget.
UNIVERSITY OF MINNESOTA
Medical School Clinical Research SWOT Analysis

**Strengths**

1. The University of Minnesota Medical School has a broad tradition in clinical research. We have recognized expertise in transplantation, cardiovascular diseases, epidemiology, diabetes, and other areas.

2. The General Clinical Research Center (GCRC) is available and growing.

3. The Master’s program in clinical research offers unique and specialized training to develop clinical investigators.

4. There are numerous expert investigators in basic research. Better linkage with translation of clinical opportunities could enhance clinical research success and training opportunities.

5. The AHC-based research institutes (Lillehei Heart Institute, Stem Cell Institute, Biomedical Engineering Institute, Institute of Human Genetics, the Center for Magnetic Resonance Research, and the Bioethics Center) all represent strengths of the institution that could be leveraged to enhance the breadth and scope of clinical research and multidisciplinary collaboration.

**Weaknesses**

1. There is a limited scope of patients and, for many situations, an inadequate number of patients available for enrollment in clinical research. There are barriers to targeted recruitment of patient populations needed for enrollment in clinical research. There is no interface between Medical School-based clinical research and the UMP clinic that could be used for recruitment and invitation for subjects to participate.

2. Institutional fundraising skills and public relations efforts, particularly for clinical research, are limited.

3. The local view is parochial and not outward looking for collaborations in clinical research. Town-grown relationships do not foster the opportunity to bring university clinical research into the community.

4. In the Medical School, younger clinical research faculty are often not offered startup packages or protected time. There are no available funding sources for startup research administration, research nurse, or statistical support. Mentoring and training opportunities for young faculty are limited.
5. Availability of biostatistical expertise is limited. The experts who are known in AHC are quite successful, but generally too busy to give consultation and advice to less experienced clinical investigators. There are only a few national leaders in clinical research, no critical mass of investigators and, thus, few role models of success in clinical research.

6. The promotion and tenure system does not have criteria suitable for clinical research faculty.

**Opportunities**

1. The University of Minnesota offers the sole academic site for clinical research in the region.

2. The city and region are divided into several health systems and a number of large multispecialty groups that are local competition both for clinical patient care and for clinical research recruitment.

3. Fragmented efforts in clinical research (many investigators working alone) offer the possibility for poor compliance with regulatory rules and, thus, risks for compliance violations that could adversely affect all clinical research in the Medical School.

4. The Medical School has no major hospital partner educated about and committed to ongoing clinical research.

5. The increasing regulatory complexity at local, regional, and national levels adds additional burdens to the clinical researcher and to the problems of performing clinical research.