



Duluth Clinic

An affiliate of SMDC Health System

Division of Education and Research

ANNUAL REPORT – FY 2009

Thomas E. Elliott, MD
Chief, Education and Research
August 2009

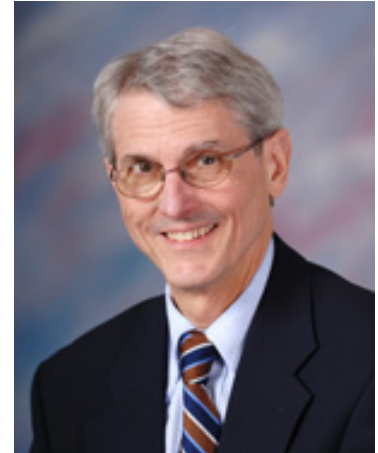
**DIVISION OF EDUCATION AND RESEARCH
ANNUAL REPORT – FISCAL YEAR 2009
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DIVISION OF EDUCATION & RESEARCH INTRODUCTION

DIVISION CHIEF'S MESSAGE

The medical chief, administrative leadership, and staff of Duluth Clinic's Division of Education and Research are pleased to present this annual report for fiscal year 2009. The productivity of the division represents the team effort of physicians, credentialed practitioners, health care professionals, scientists, and support staff of all participating clinical sections, programs, departments and divisions within SMDC Health System. In addition, this outcome is the result of our collaboration with many other organizations engaged in health care delivery, research and education in our region and the nation. The Duluth Clinic Division of Education and Research serves people and sponsors activities across SMDC Health System.



This year marks the 19th anniversary of the Division of Education and Research. The division was formally initiated July 1, 1990. Significant growth in education and research activities has occurred continuously over this time.

The mission of the division is to discover and disseminate scientific knowledge. By conducting research and producing educational activities, we improve the health of our patients. To fulfill this mission, the division supports clinical research on prevention, causes, and management of diseases and injuries, and the promotion of health. Our clinical and translational research focus is cancer, cardiovascular diseases, and neurosciences. In addition, the division supports population-based research and health services research to improve the processes and outcomes of care. The division provides on-going education for area physicians and other providers as well as clinical experiences for physicians, practitioners, pharmacy and health sciences students, and other allied professionals. The results of research and educational activities are disseminated through publications and presentations. This report reflects our excellent strides toward fulfilling this mission and achieving these goals.

Research and education are inextricably linked to the success of SMDC Health System, its affiliated organizations, and the health of the regional population. The division has had impressive growth in education activities and research productivity over the 19 years of the division's history. Our vision is St. Mary's Duluth Clinic research will be among the leading non-university health systems in the Upper Midwest. The division looks forward to another successful year and a bright future that will allow fulfillment of its mission and fulfillment of its vision.

Over the last year members of the division and more than 50 other individuals from SMDC Health System, Innovis Health, Essentia Community Hospitals and Clinics, and Essentia Health have been planning the design, business plan and pro forma of the Essentia Institute of Rural Health (EIRH). This new institute will be implemented January 1, 2010 and SMDC Health System's Division of Education and Research will be the primary component of the EIRH and its personnel will populate the majority of the positions.

DIVISION OF EDUCATION AND RESEARCH

MISSION STATEMENT

The mission of the Duluth Clinic Division of Education and Research is to discover and disseminate scientific knowledge. By conducting research and producing educational activities, we improve the health of our patients.

To fulfill this Mission, the Division will:

- Conduct research focused on the prevention, causes, and management of disease and injuries, and the promotion of health;
- Conduct public health research and health services research to improve the processes and outcomes of health care;
- Provide education for physicians, other providers, and health sciences students;
- To meet our future healthcare workforce needs by providing healthcare preceptorships; and
- Publish and disseminate the results of education and research activities.

The fields of research focus are:

- Cancer
- Cardiovascular Diseases
- Neurosciences
- Health Services Research

Adopted by the Duluth Clinic Board of Directors
June 30, 1993

Most recent review by Duluth Clinic Board of Directors
September 7, 2008

Most recent review by SMDC Health System Board of Directors
September 7, 2008

OBJECTIVES OF THE DIVISION

Fiscal Year 2009

The objectives for the Division for FY-2009 were developed through several meetings of the Research Committee, Medical Education Committee and the staff of the Division. The objectives were based on the following criteria: consistency with the SMDC mission, financial feasibility, value added to the program (productivity, resources and people available or procurable, efficiency, and probability of publications), achievability, and prospect for enhancing the health status of the region.

EDUCATION PROGRAM - CME

- Respond to health professionals needs for electronic information.
- Prepare for CME program reaccreditation survey.
- Integrate CME and SMDC's Quality Improvement programs.

MEDICAL EDUCATION - Medical Teaching/Preceptorships

- Study feasibility of a General Internal Medicine residency program.
- Develop nursing and pharmacy student education infrastructure.
- Refine our relationship with Duluth Family Medicine Residency Program.

RESEARCH PROGRAM

- Ensure safe and responsible conduct of research.
- Create a new system-wide strategy for growing research at SMDC.
- Implement an IRB and research management computerized database (iRIS).
- Increase research staff and facilities to support growth in research.
- Design an electronic Data Warehouse for Essentia Health to conduct health services research.
- Design, write a business plan and pro forma for Essentia Institute of Rural Research.
- Develop translational research model with University of Minnesota.
- Design strategy to grow health services research.

SUMMARY OF EDUCATION AND RESEARCH ACTIVITIES

Fiscal Year 2009

CONTINUING MEDICAL EDUCATION OUTCOMES

• CME outreach programs provided	101
• Visiting professorships	14
• Regional CME conferences sponsored/jointly-sponsored	7
• Intramural conferences sponsored	371
• Individual/Miscellaneous conferences sponsored	4
• Jointly sponsored CME activities	5
• Continuing education credit	10,720

MEDICAL TEACHING OUTCOMES

• Duluth Clinic physicians participating in education of students and/or residents	263
• Residents, med students, and credentialed practitioners preceptorships/experiences....	283
• Paramedical program students/interns.....	941

RESEARCH PROGRAM OUTCOMES

• Publications by SMDC physicians, nurses and scientists	55
• Subjects accrued onto clinical trials or engaged in studies	1,396
• Grant and contract support:	
Government	\$ 863,024
Industry	\$1,027,012
Foundations	\$ 201,501
Research Committee	\$ 23,965
• Grant applications submitted:	
Government	14
Foundations/Associations	7
Research Committee	12
• Grant applications pending:	
Government	5
Foundations/Associations	3
• Grant applications funded:	
Government	4
Foundations/Associations	3
Research Committee	12
• Research projects conducted	355
• SMDC physicians engaged part-time in research	99

CONTINUING MEDICAL EDUCATION MISSION STATEMENT

Purpose: To provide high quality continuing medical education (CME) for physicians in our referral region through sponsorship of CME activities. Whether acting as a sponsor or a joint-sponsor with non-accredited organizations in our region, our CME activities will meet the essentials and standards established by the Minnesota Medical Association Committee on Accreditation and CME and the Accreditation Council for CME.

Target Audience: Through its mission, SMDC Health System is committed to enhancing medical education and research, being a model and innovative regional teaching center, and servicing the educational needs of physicians and credentialed practitioners of the region throughout their careers. Although physicians are our primary target audience for continuing medical education, our activities usually include credentialed practitioners. Therefore, in this document the term “physician” is inclusive of credentialed practitioners.

Types of Activities Provided:

1. Provide CME activities that meet needs of SMDC quality improvement activities, requests from the various clinical sections, departments, and divisions at Duluth Clinic, requests from the local hospital staffs, and requests from appropriate health care organizations.
2. Provide major, daylong conferences for Duluth Clinic physicians and regional physicians.
3. Conduct and support regularly occurring conferences that meet the MMA’s Essential Areas and policies in order to meet the needs of Duluth Clinic physicians and other physicians in the immediate area, which may include weekly Grand Rounds, weekly clinical decision-making conferences, and specialty and subspecialty conferences.
4. Provide for a Visiting Professorship Program that will meet the needs of all physicians but, especially, specialists and subspecialists.
5. Provide an outreach CME program for physicians throughout the referral region.

Content: SMDC utilizes the ACGME/ABMS core competencies as a basis for the content areas of our CME activities, which include clinical care, medical knowledge, professionalism, communication skills, practice-based improvement and systems based practice. With these core competencies as a platform, content is developed based on the needs of our physician audience and frequently includes, but is not limited to, 1) the diagnosis, treatment and prevention of disease, 2) efficient and cost-effective health care delivery, 3) medical ethics, 4) clinical research and 5) professionalism for all clinical specialties.

Expected Results: The desired results of our CME program are maintaining high standards of patient care and professional performance and achieving optimal patient outcomes. We will endeavor to measure learning outcomes at one or more of the following four levels:

1. Learner satisfaction with the CME activity experience [measured for all activities]; or
2. Change in learner knowledge from the CME activity [measured for many activities]; or
3. Change in learner practice performance [measured for some activities]; or
4. Change in patient outcomes [measured for a few, selected activities]. 1

1 Most recent review by the Duluth Clinic Medical Education Committee March 19, 2009

CONTINUING MEDICAL EDUCATION PERFORMANCE MEASURES FISCAL YEAR 2009

Since its inception in 1978, the medical education program at Duluth Clinic has been meeting the educational needs of practicing physicians at SMDC and in the region with the overall goal of improving patient care. SMDC physicians are continually involved in medical student, postgraduate/resident physician, and continuing medical education (CME). The majority of the 441 Duluth Clinic physicians are clinical faculty of the University of Minnesota School of Medicine Duluth.

- CME Outreach Lectures provided to 16 cities in the region 101

- Regional CME Conferences sponsored/jointly-sponsored 7

- Ongoing Intramural Conferences sponsored: 371
 - Friday Morning Conference 37
 - Friday Noon Grand Rounds 37
 - Anesthesiology Grand Rounds 1
 - Cancer Conference 51
 - Cardiology Conference 42
 - Clinical Spine Conference 9
 - Deer River Journal Club 6
 - Dermatopathology Conference 7
 - Dermatopathology Journal Club 8
 - Diabetes and Endocrinology Review 9
 - Gastroenterology Journal Review 1
 - General Surgery Journal Club..... 3
 - Geriatric Case Consulting 9
 - Head & Neck Tumor Board..... 1
 - Hematology/Oncology Journal Club 10
 - Hospitalists' Morbidity & Mortality Journal Club 5
 - Internal Medicine Journal Club 3
 - Multidisciplinary Breast Cancer Conference 45
 - Multidisciplinary Gastroenterology Conference 4
 - Multidisciplinary Ultrasound/Prenatal Diagnosis Conference 7
 - Neurology/Neurosurgery/Radiology Case Review 11
 - Noon Ophthalmology Conference 2
 - OB/GYN Journal Club 7
 - OB/GYN Pathology Conference 2
 - Orthopedics Conference 14
 - Palliative Medicine Rounds 11
 - Pediatric Care Journal Club 1
 - Pediatric Case Conference 9
 - Renal Biopsy Meeting 1
 - Sports Medicine Study Group 6
 - Trauma Conference 9
 - Trauma Outreach Education Series (Session VII) 1
 - Trauma Peer Review..... 2

CME PERFORMANCE MEASURES (CONTINUED)

• Visiting Professorships/Speakers:	14
Friday Morning Conference	4
Friday Noon Grand Rounds	3
Anesthesiology Grand Rounds	2
Annette Boman Symposium	1
Lake Superior Pathology Society Meeting	3
Reclaiming the Heart of Healthcare/Dr. Rachel Remen	1
• Leadership CME Activities:	27
Essentia Health Physician Leadership Academy	2
SMDC Leadership Development	3
SMDC Physician Leadership Forum	2
SMDC Service Excellence for Physicians	18
SMDC University Leadership Development	2
• Ongoing EpicCare Training..... (number of months provided:) 11	
Office Visit Essentials	10
Comprehensive Features	9
Communication/Resources	5
Progress Note Documentation	7
ASAP Emergency Provider Class	5
• Individual/Miscellaneous CME Activities sponsored:	4
4 th Annual Heart Failure Regional Meeting	1
APN/PA 4 th Annual Education Networking Program	1
Chronic Pain Management Workshop	1
Human Participation Protection Education	1
• Enduring Materials	147
• Jointly sponsored CME activities:	5
Lake Superior Pathology Society Meeting	5
• CME hours of instruction offered	892
• Physicians/participating served by SMDC sponsored/jointly-sponsored CME activities	5,643
• NPs/PAs/CNSs/Participants served by SMDC sponsored/jointly-sponsored CME activities	1,457
• Other health care professionals served by SMDC sponsored/jointly-sponsored CME activities	3,039
• Continuing education credit:	
Physicians	8,132

CME PERFORMANCE MEASURES (CONTINUED)

Live activities	7,780.50
Enduring materials (345 physicians)	351.50
NPs/PAs/CNSs	2,588
Live activities	2,394.50
Enduring materials (172 NP/PA/CNS)	193.55
TOTAL	10,720

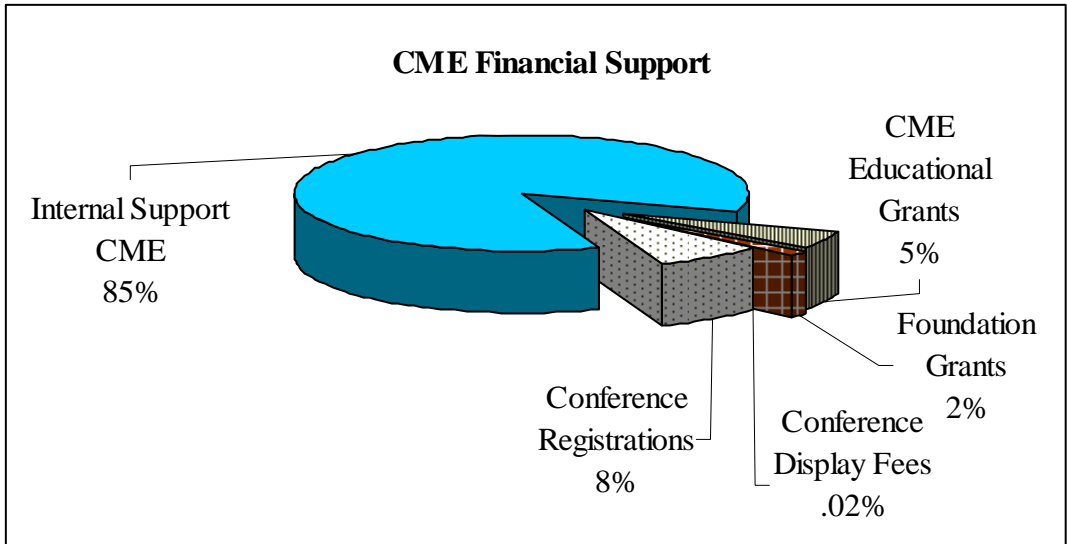
- Activities accredited for athletic trainers:

Number of Activities	9
ATC Continuing Education Units (CEU) Issued	190.50

CONTINUING MEDICAL EDUCATION FINANCIAL SUPPORT DISTRIBUTION

Fiscal Year 2009

Internal Support CME		\$ 547,704
External Support CME		
CME Educational Grants	\$ 30,000	
Foundation Grants	9,692	
Conference Display Fees	100	
Conference Registrations	<u>49,772</u>	
Total External Support		<u>\$ 89,564</u>
Total CME Support		\$ 637,268



DULUTH CLINIC CME COMMITTEE

Fiscal Year 2009

FUNCTIONS AND RESPONSIBILITIES OF COMMITTEE

1. Participate in strategic planning for the medical education program.
2. Advise in budgetary and resource utilization issues.
3. Develop or promote new educational methods and technologies.
4. Annually review the extent to which the CME Mission is being achieved by its educational activities.
5. Ensure that ACCME Essential Areas and policies regarding CME activities are being met.
6. Ratify/confirm the actions of the Director of Medical Education regarding CME activities.

MEMBERSHIP

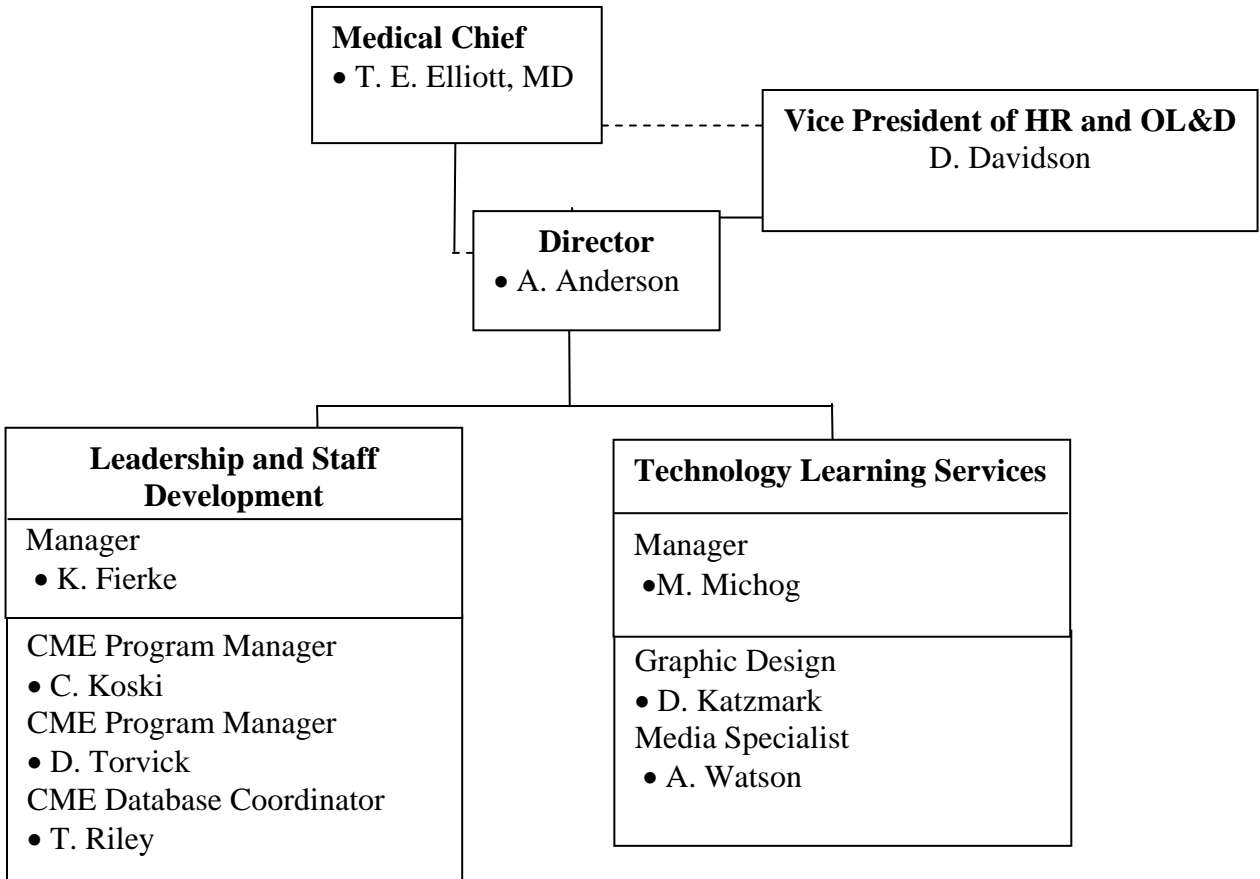
Name

Thomas E. Elliott, MD (Chair)
Jeffrey L. Adams, MD
Rahul Aggarwal, MD
Arlene J. Anderson, MS
Gail E. Baldwin, MD
Robert P. Boman, MD
Stephen R. Carlson, MD
Tamara J. Dolenc, MD
Alan M. Johns, MD
Brian K. Konowalchuk, MD
Robert H. Lund, Jr., MD
Jay L. Parker, DO
Elizabeth L. Sobczak, BA
Mathew J. Sorensen, RN, CNS
Michael L. Whitcomb, MD

Specialty/Discipline

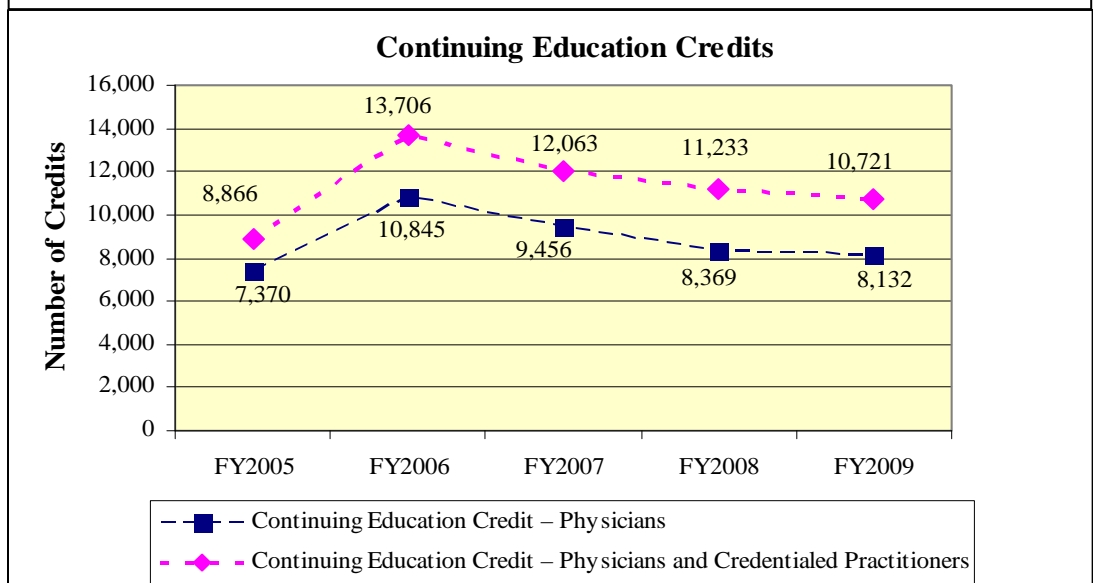
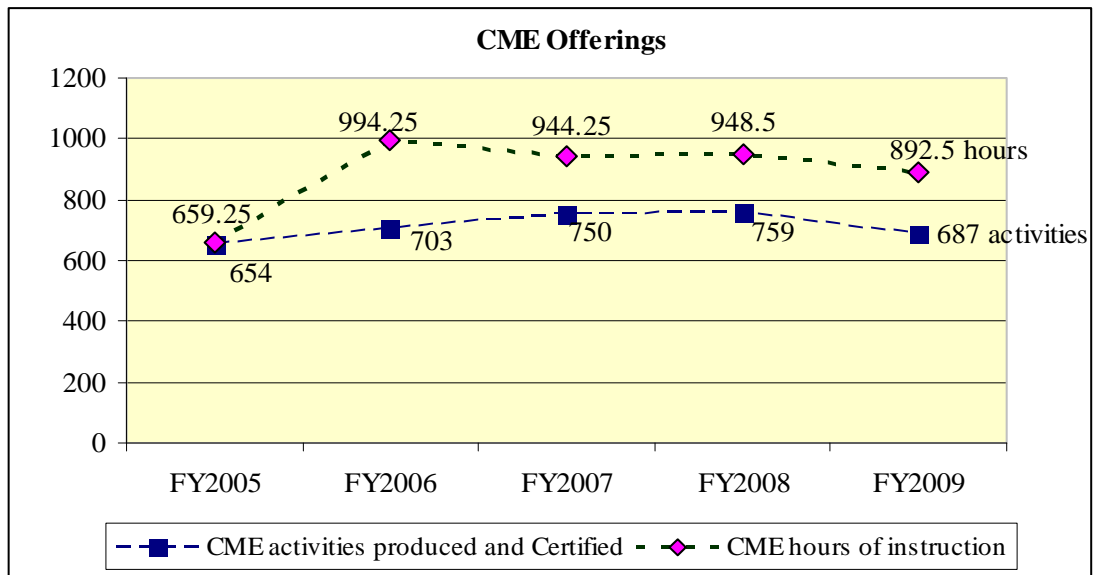
Chief, Division of Education and Research
Emergency Medicine
Pediatric Intensive Care
Director, Organizational Learning & Development
Family Practice
Internal Medicine
Family Practice
Behavioral Health
Internal Medicine
Occupational Medicine
Dermatology
Allergy
Health Sciences Library
Behavioral Health
Internal Medicine

CONTINUING MEDICAL EDUCATION (CME) ORGANIZATION CHART



CONTINUING MEDICAL EDUCATION PROGRAM PRODUCTIVITY

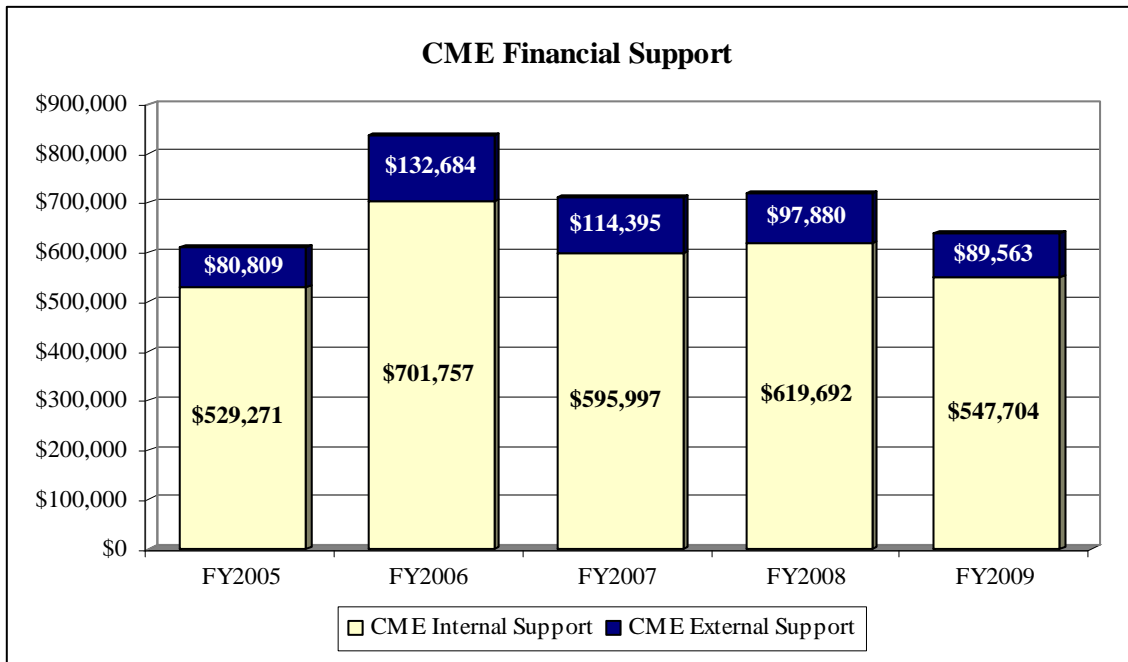
	<u>FY2005</u>	<u>FY2006</u>	<u>FY2007</u>	<u>FY2008</u>	<u>FY2009</u>
Number of CME activities produced and Certified for AMA PRA Category 1 Credit™:	654	703	750	759	687
Number of CME hours of instruction offered	659.25	994.25	944.25	948.5	892.5
Continuing Education Credit – Physicians	7,370	10,845	9,456	8,369	8,132
Continuing Education Credit – Physicians and Credentialed Practitioners	8,866	13,706	12,063	11,233	10,721
Medical education staff (FTE)	6.66	6.92	6.78	5.97	5.51
Internal costs to produce CME activities	\$529,271	\$701,757	\$595,997	\$619,692	\$637,267



CME FINANCIAL SUMMARY

Fiscal Year 2005- 2009

	FY2005	FY2006	FY2007	FY2008	FY2009
CME Internal Support	\$529,271	\$701,757	\$595,997	\$619,692	\$547,704
CME External Support	80,809	132,684	114,395	97,880	89,563
CME Educational Grants	16,489	15,604	5,000	22,000	30,000
Foundation Grants	0	0	7,089	7,468	9,692
Conference Display Fees	12,500	18,000	19,445	800	100
Conference Registrations	<u>51,820</u>	<u>99,080</u>	<u>82,861</u>	<u>67,612</u>	<u>49,771</u>
TOTAL	\$690,889	\$967,125	\$824,787	\$815,452	\$726,830



MEDICAL TEACHING MISSION STATEMENT

VISION

To meet our future healthcare workforce needs.

MISSION

To improve the health of our region by embracing quality, sustainability, and cost-efficiency of care through education

MEDICAL EDUCATION FORUM

A SMDC leadership group which oversees the medical education enterprise for SMDC - provide strategic direction, oversight, coordination, and standardization of all medical education programs and activities. Medical education programs include all education and training provided by SMDC to health science students enrolled in an accredited university or college. Undergraduate Medical Education (UME) and Graduate Medical Education (GME) are included.

MEDICAL TEACHING OUTCOMES

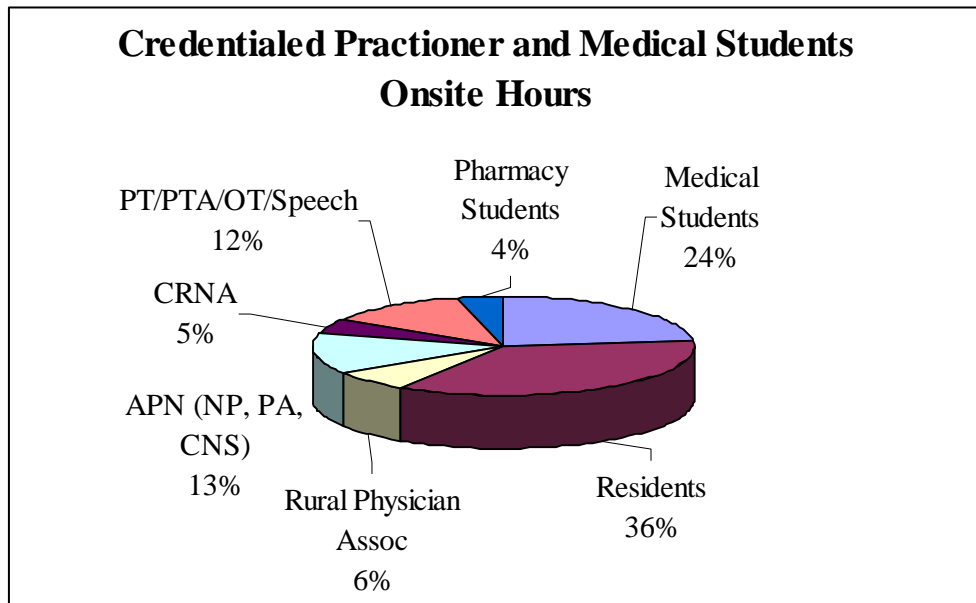
Fiscal Year 2009

- Initiate and develop a task-force to plan the GIM residency program
 - Plan is on hold due to congressional residency cap restrictions
- Define relationship with Duluth Family Medicine Residency Program
 - New Affiliation Agreement February 2009, aligns residency with UMN
- Increase CMS GME and IME Reimbursement
 - SMDC Medical Center added as an approved site for Duluth Family Medicine Residency Program
 - Duluth community affiliation agreement in place between St. Mary's Medical Center, SMDC Medical Center and St. Luke's Hospital to capture unclaimed resident FTE
- Develop a SMDC Financial Plan for FY10
 - System funding plan proposed (May 2009) – matches expenses with revenue received
 - 15% of MERC funds reserved to cover cost of centralized med teaching expenses
 - Duluth community affiliation agreement allows CME reimbursement for residency teaching in SMDC provider based clinics
 - \$1.6 million received from CMS IME/GME and \$1.6 million from MERC
 - Received grant of \$17,600 from SMDC Foundation to partial fund the Summer Internship in Medicine program (student stipends)
 - Capture revenue from OB Procedural Medicine Fellowship (FY10)
- Evaluate and revise APN/PA student plan
 - New Clinical Education Coordinator model
 - Coordination of placements with programs
 - Recruitment/development of new APN/PA Preceptors
 - Developed student and preceptor evaluation forms
 - Developed a Preceptor Manual
 - Improved partnership with CSS faculty leaders to improve capacity for clinical experience
- Evaluate and revise Nursing student plan
 - Obtained grant funding for creation of SMDC simulation lab space; partnership with UMD Med School to share simulation equipment in the future
 - Created goals for interprofessional staff & student education using simulation; partnership with UMD for future delivery of interprofessional courses
 - Created and delivered BA nursing elective (Perioperative Nursing) as a workforce strategy and faculty development
 - Streamlined clinical placement process for undergraduate nursing students
 - Partnered with LSC and FDLTCC to provide additional nursing clinical experience programs
 - Partnered with CSS to provide ongoing mentorship for CNS students & align clinical projects with SMDC initiatives (VAP, diabetes resource nurses)
 - Provision of nursing faculty updates to SMDC nursing programs
- OB/Procedural Fellowship implemented in July 2008
 - Brielle Loe, MD completed fellowship June 30, 2009; began employment at Duluth Clinic – Ely in July 2009
 - Angela GatzkePlamann, MD began fellowship July 2009.
- Build Med Teaching Intranet Site <http://intranet/DCPractice/medteaching.htm>

Productivity measures CREDENTIALLED PRACTITIONER AND MEDICAL STUDENTS

Fiscal Year 2009

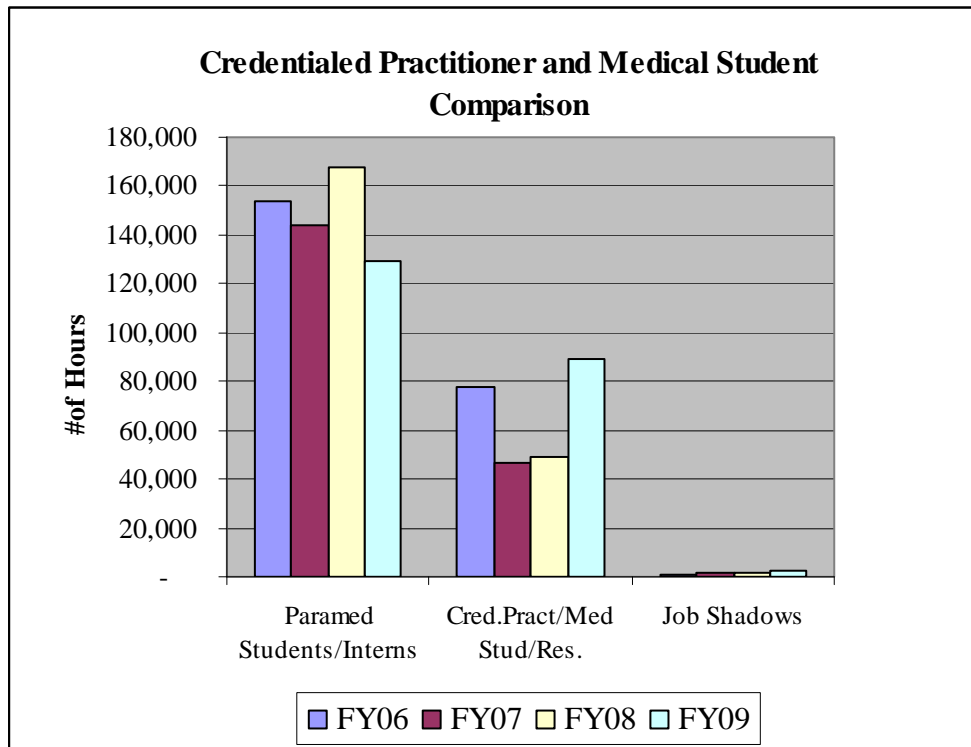
Program	Number Students	# of Onsite hours
Medical Students	111	20,992
Residents	31	31,760
Rural Physician Assoc	4	5,760
APN (NP, PA, CNS)	63	11,717
CRNA	13	4,571
PT/PTA/OT/Speech	39	10,612
Pharmacy Students	22	3,584
Total	283	88,996



**PRODUCTIVITY MEASURES
CREDENTIALLED PRACTITIONER AND
MEDICAL STUDENTS
STUDENT COMPARISON REPORT
Number of Students**

Programs	# of Students				% Chg - FY06-FY08	% Chg - FY07-FY08	% Chg - FY08-FY09
	FY06	FY07*	FY08	FY09			
Paramed Students/Interns	785	913	1086	941	38.34%	18.95%	-13.35%
Cred.Pract/Med Stud/Res.	230	270	338	283	46.96%	25.19%	-16.27%
Job Shadows	140	291	290	272	107.14%	-0.34%	-6.21%

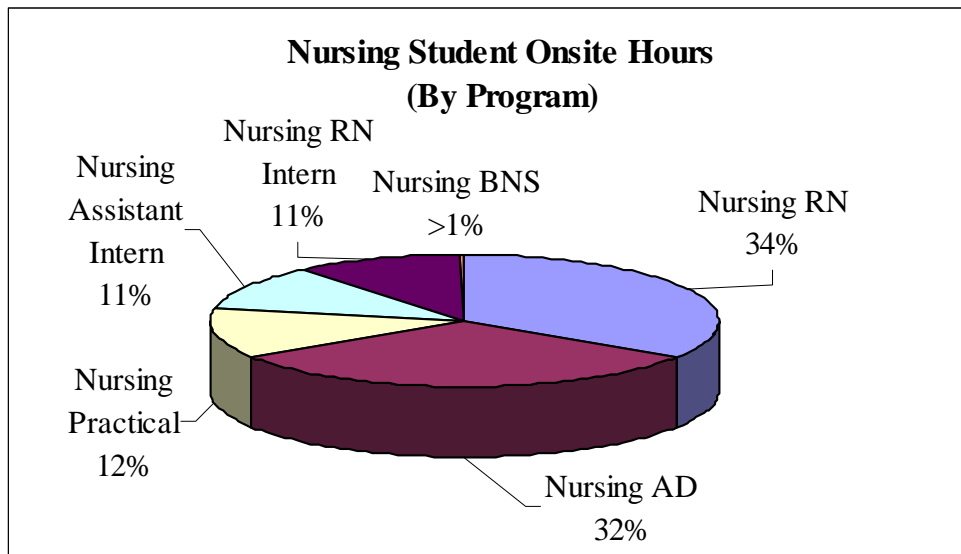
*(thru 07/07)



PRODUCTIVITY MEASURES NURSING STUDENTS

Fiscal Year 2009

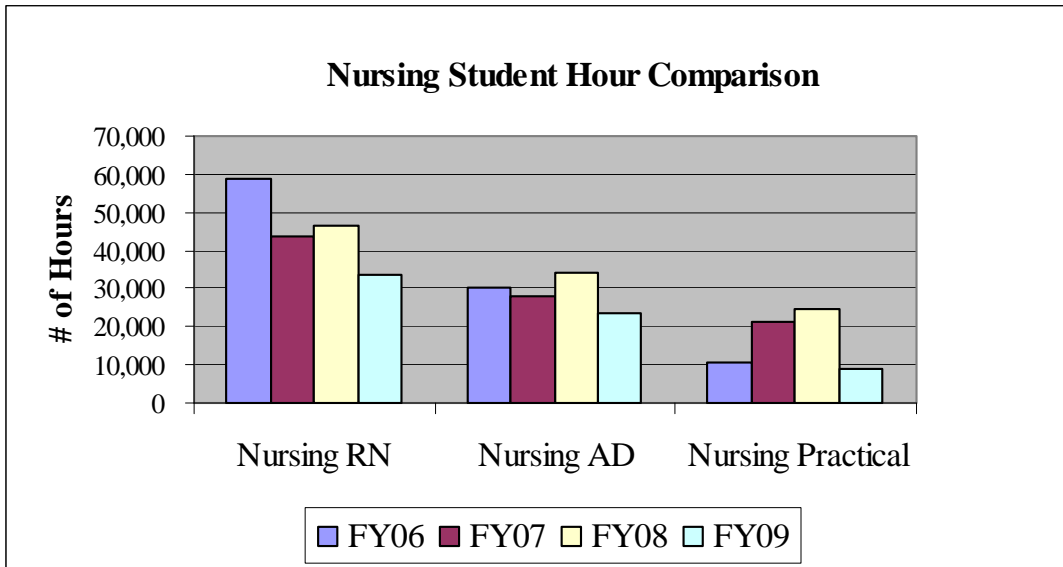
Program	Number Students	# of Onsite hours
Nursing RN	242	25,682
Nursing AD	208	23,728
Nursing Practical	120	9,206
Nursing Assistant Intern	28	8,468
Nursing RN Intern	29	7,973
Nursing BNS	2	120
Total	629	75,177



PRODUCTIVITY MEASURES NURSING STUDENTS STUDENT COMPARISON REPORT

Number of Hours

Programs	# of Hours				% Chg - FY06- FY08	% Chg - FY07-FY08	% Chg - FY08-FY09
	FY06	FY07*	FY08	FY09			
Nursing RN	58,869	43,867	46,590	33,655	-25.48%	6.21%	-27.76%
Nursing AD	30,261	28,004	34,353	23,728	-7.46%	22.67%	-30.93%
Nursing Practical	10,819	21,189	24,598	9,206	95.85%	16.09%	-62.57%
Nursing Mgmt	29	0	0	120			



MEDICAL EDUCATION PHYSICIAN PAYMENT AND SUPPORT DISTRIBUTION

FISCAL YEAR 2009

	Revenue	
CMS, IME, and GME	\$ 1,700,000	
MERC	1,600,000	
Duluth Family Practice Clinic contract	80,498	
University of MN contract	56,595	
Total Revenue		\$3,437,093

	Expenses	
DFPC distribution		
MERC	\$1,093,000	
CMS, IME/GME	1,029,000	
MERC Department distribution:	225,000	
Pharm, APN/PA, CRNA		
DC Physician Comp	480,000	
SMDC Leadership/Support	415,000	
Stipends	20,000	
Total Expenses		\$3,262,000

ST. MARY'S/DULUTH CLINIC HEALTH SYSTEM DIVISION OF EDUCATION AND RESEARCH LIBRARY SERVICES

Fiscal Year 2009

The value of library services in the health care setting is often seen in their ability to positively affect clinical and administrative decision-making. Studies have shown that patient care costs and length of stay are reduced by health care professionals' access to critical information. Savings are also realized when organizational leaders are able to turn to current management resources for information that helps them effectively update service models and business practices. The SMDC Health Sciences Library plays a vital role in these processes by providing both the print and electronic information resources that are needed by its many users.

Traditional Library Services

Supporting clinical, administrative, research, and educational activities, hundreds of literatures searches are done by the SMDC medical librarians each year. With access to an expanded array of information sources, these searches have become more comprehensive than ever before. Library customers also receive interlibrary loan services from a worldwide network of libraries with documents, in the last year, being shared with organizations as far away as Italy, Egypt, India, and Japan. This reciprocal sharing among libraries has resulted in the savings of thousands of dollars that would otherwise be spent by the SMDC Health System to obtain the same articles through publishers' pay-per-view schemes.

Digital Library Services

The SMDC Library Services intranet site offers users a wonderful variety of databases and other online resources. Because technological changes continue to create new methods for accessing information, previously paper-based services are more often being delivered using paperless methods. One recent example of this is the conversion of a good portion of the library's contents service to electronic journal updates that patrons now receive by e-mail. Another improvement during the last year was the installation of wireless Internet access in the library's reading room and resource center. Laptop users find this service very convenient and they are currently a common sight in these two library areas.

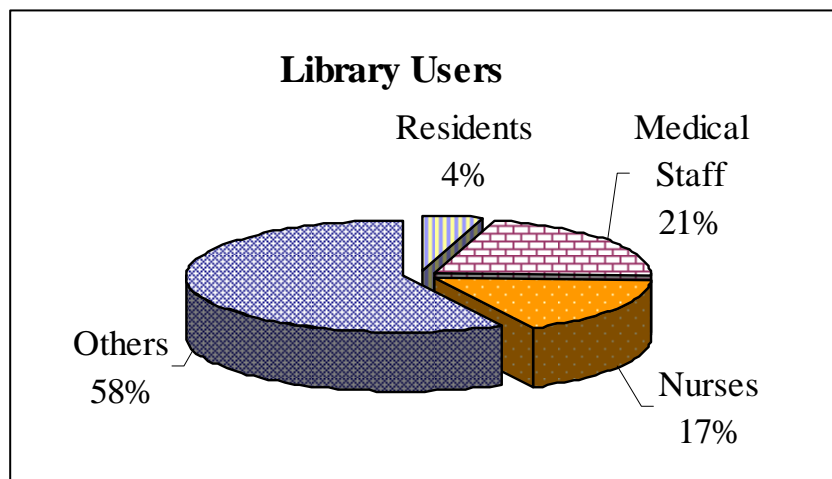
Future Directions

As part of an Essentia Institute of Rural Health initiative, planning is being done to extend the SMDC Library Services user population to include other Essentia Health affiliates. There are presently over seventy facilities in Minnesota, Wisconsin, North Dakota, Idaho, and Montana that could potentially benefit from these shared library resources and services.

HEALTH SCIENCES LIBRARY SUMMARY

Fiscal Year 2009

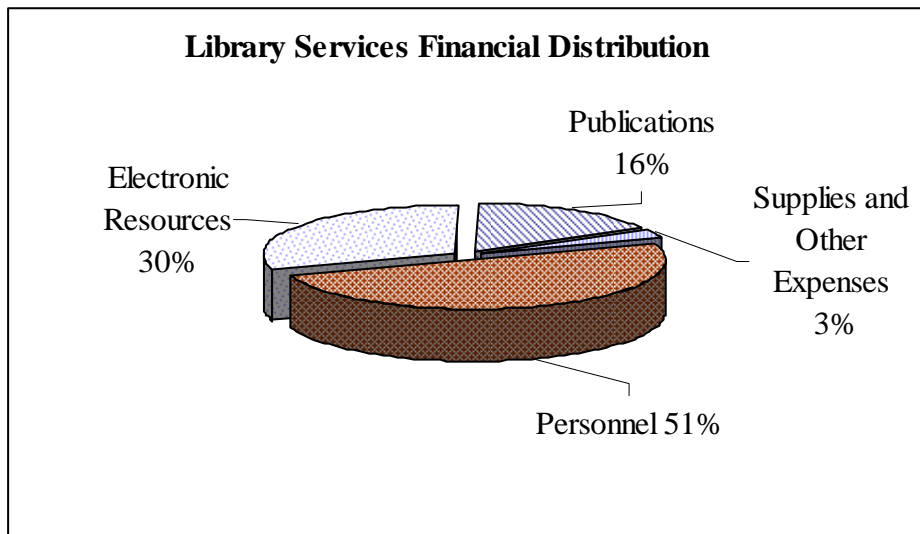
- Library Users:..... 11,274
 - Residents 554
 - Medical Staff 2,697
 - Nurses 2,228
 - Others 7,385
- Library Personnel 3.48 FTE
- Library Intranet Site Total Hits 698,001
- Books And Journals Used (Excluding Electronic) 7,590
- Library Services:
 - Requested Interlibrary Loans 2,513
 - Provided Interlibrary Loans 852
 - Literature Searches 457
 - Resources Photocopied/Printed 10,954
 - CME Enduring Materials Circulated 645



HEALTH SCIENCES LIBRARY FINANCIAL DISTRIBUTION SUMMARY

Fiscal Year 2009

Personnel	\$ 188,234
Electronic Resources	112,446
Publications	60,958
Supplies and Other Expenses	<u>9,942</u>
Total Library Support	\$ 371,580



RESEARCH MISSION STATEMENT

The mission of the Duluth Clinic Division of Education and Research is to discover and disseminate scientific knowledge. By conducting research we improve the health of our patients.

To fulfill this Mission, the Division will:

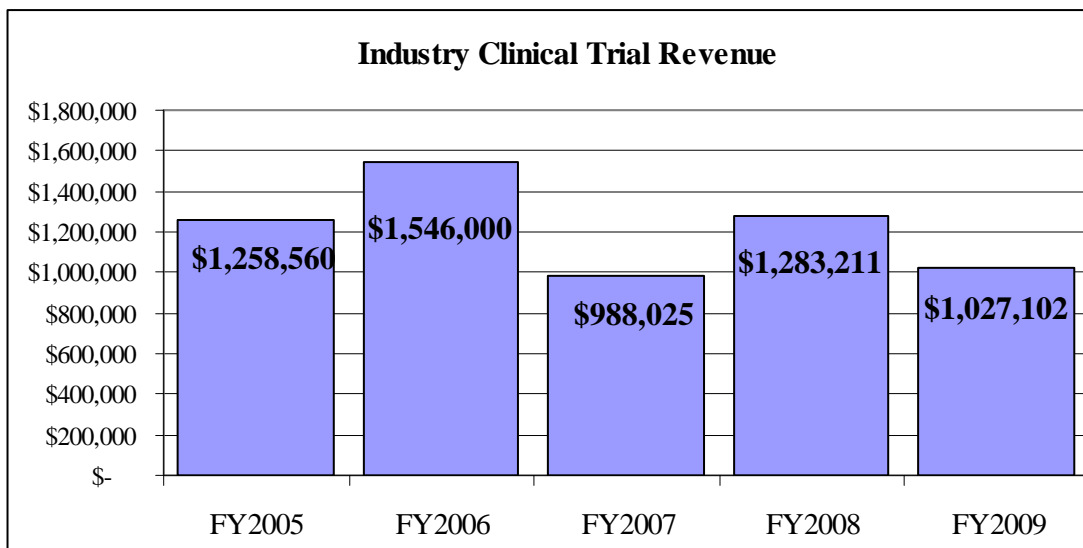
- Ensure safe and responsible conduct of research.
- Create a new system-wide strategy for growing research at SMDC.
- Implement an IRB and research management computerized database (iRIS).
- Increase research staff and facilities to support growth in research.
- Design an electronic Data Warehouse for Essentia Health to conduct health services research.
- Design, write a business plan and pro forma for Essentia Institute of Rural Research.
- Develop translational research model with University of Minnesota.
- Design strategy to grow health services research.

RESEARCH OUTCOMES

Fiscal Year 2009

- The number of new and continuing research grant applications submitted for funding represents the best indicator for measuring investigator-initiated research at Duluth Clinic: 19 out of 32 applications submitted received funding.
- Our research infrastructure includes the Institutional Review Board (IRB), Research Committee, support staff, scientists, accountants, administrators, resources, and policies and procedures to ensure responsible conduct of research. The FDA conducted an on site audit of our IRB and related infrastructure in 2008. The audit found our actions, policies, and procedures to be adequate and compliant with federal regulations.
- Consolidation of clinical trial staff for Cardio-Pulmonary, Neuromusculoskeletal and Other Services under one manager structure has been accomplished. The restructure allows for staffing adjustments and cross training to achieve cost efficiency due to active studies and enrollment variables by focus areas.
- The Essentia Institute of Rural Health (EIRH) has been designed with a business plan and proforma has been completed. During FY2010, EIRH will be reviewed and approved by various governing boards and will be implemented January 1, 2010.
- The division is implementing a software application, iRIS, for the IRB and research management, which will be completed during the next fiscal year. An electronic system will ensure safety and improve efficiency and productivity, while reducing cost.
- Our industry sponsored clinical trial revenue have been varied consistent with the pharmacy and device market conditions.

Industry clinical trial revenue:



RESEARCH ACTIVITIES SUMMARY

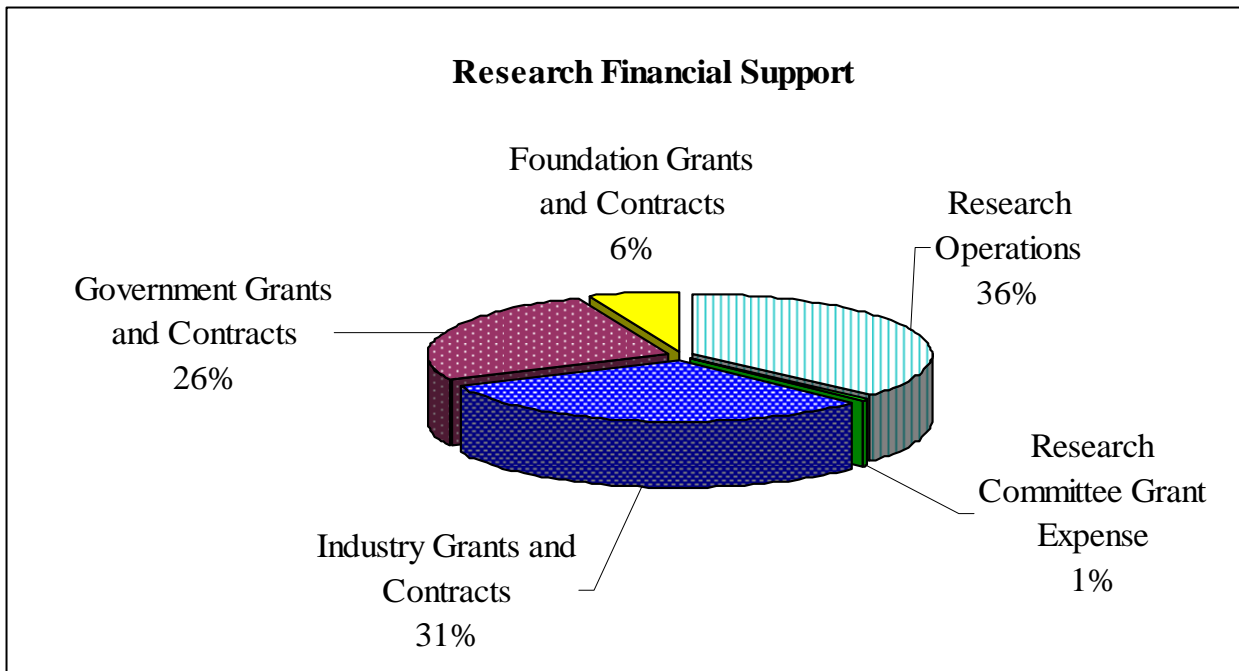
Fiscal Year 2009

• Publications by SMDC physicians, scientists and nurses	55
• Research Personnel (as of June 30, 2007)	
* Physicians engaged part-time in research	99
• Research staff, full-time	37
Internal Support General Research:	13
External Support:	
Industry Contracts	11
NIH Grants	10
Foundation Grants	3
• New research projects approved	73
CCOP.....	35
Industry-Sponsored/Other	38
• Research projects in progress	282
CCOP.....	192
Industry-Sponsored/Other	90
• Subjects participating in research	1,396
Subjects Enrolled on Clinical Trials:	
Industry Sponsored Contracts	231
NIH Grant – CCOP	189
Subjects Followed on Clinical Trials:	
Industry Sponsored Contracts	918
NIH Grant – CCOP	478
• Research Funding:	
Internal Support:	\$1,243,026
External Support:	<u>2,091,627</u>
TOTAL RESEARCH SUPPORT	\$3,334,653

RESEARCH FINANCIAL SUPPORT DISTRIBUTION EXPENSE SUMMARY REPORT

Fiscal Year 2009

Internal Research Support		
Research Operation	\$1,219,061	
Research Committee Grant Expense	<u>23,965</u>	
Subtotal		\$1,243,026
External Research Support		
Industry Grants and Contracts	\$1,027,102	
Government Grants and Contracts	863,024	
Foundation Grants and Contracts	<u>201,501</u>	
Subtotal		<u>2,091,627</u>
Total Support		\$3,334,653



**RESEARCH
GRANT AWARDS
Fiscal Year 2009**

Federal Grant Awards

TITLE	P.I.	SPONSOR	DIRECT	INDIRECT	TOTAL
Duluth Community Clinical Oncology Program (CCOP)	D. Nikcevich, MD	National Institutes of Health/NCI	\$564,316	\$182,838	\$747,154
Extended-Release Mixed Amphetamine Salts for Adults ADHD and Cocaine Dependence	I. Haller, PhD	National Institutes of Health (subcontract through University of Minnesota)	\$8,960	\$3,020	\$11,980
Consequences of Agricultural Injuries (RRIS III)	C. Renier	National Institute for Occupational Safety and Health (subcontract through University of Minnesota)	\$33,455	\$10,839	\$44,294
Subtotal Federal Awards			\$606,731	\$196,697	\$803,428

Foundation Grant awards

TITLE	P.I.	SPONSOR	DIRECT	INDIRECT	TOTAL
Quit Plan	P.Zimmerman, MD	M.P.A.A.T.	\$59,783	\$8,967	\$68,750
Metabolic Approaches to Radiosensitization (MARS)	K. Dornfeld, MD	Duluth Clinic Foundation	\$20,000		\$20,000
Vitamin D Inadequacy: Documentation in Rural Populations and Evaluation of Correction by Food Supplementation (MERC WIPP)	I. Haller, PhD	The Wisconsin Partnership Program (subcontract through University of Wisconsin-Madison)	\$45,059		\$45,059
Pediatric Oncology Research Assistant II (PED ONC II)	J. Wiermaa, MD	St. Mary's Duluth Clinic Foundation	\$10,000		\$10,000
The Effect of Daily Hempseed Consumption on Triglycerides in Mid-to-Older Women (HS-42 - Fdn.)	Jessica Backe, BAN, RN	Duluth Clinic Foundation	\$6,017		\$6,017
Subtotal Foundation Awards			\$140,859	\$8,967	\$149,826

**RESEARCH
GRANT AWARDS (CONTINUED)
Fiscal Year 2009**

SMDC Research Committee Grant Awards

TITLE	P.I.	TOTAL
A Survey of Advanced Practice Nurses and Physician Assistants at SMDC (APN/PA Survey)	M. Sorenson, MSN, RN	\$3,380
System Changes to Enhance Care and Efficiency: Implementation and Control Clinic Comparison (Phoenix)	M. Belknap, MD	\$4,999
Reducing Lost Work Days After Work Related Injuries (ATWC) at SMMC (Inpatient Warfarin)	M. Sorenson, ATC, CSCS, CSHE	\$379
Gap/Readiness Analysis for Magnet Recognition Status of St. Mary's Duluth Clinic Health System (GRA-SMDC)	J. Mundy, CRNA	\$2,693
Implementation of a Cost Containment and Waste Reduction Strategy for Use of Eptifibatide in an Acute Care Setting Utilizing Smart Infusion Pump Technology (SymbiqCost1)	J. Boehne, PharmD	\$1,913
Intracoronary Eptifibatide Bolus Administration via the ClearWay Catheter During Percutaneous Coronary Intervention for Acute Coronary Syndromes (ClearWay Catheter)	A. Deibele, MD	\$4,560
The Effects of the Spine X Exercise Program in Persons with Benign Spinal Pain (Spine X)	T. Silvestrini, MD	\$2,417
The Effect of Daily Hempseed Consumption on Triglycerides in Mid-to-Older Women (HS-42)	Jessica Backe, BAN, RN	\$5,000
Impact of a Medication Reconciliation Service Provided by Student Pharmacists in the Emergency Room (MRS)	M. Swanoski, PharmD	\$1,255
Sedation Vacation Including Spontaneous Breathing Trial Influence on Mechanically Ventilated Intensive Care Unit Patients (SV/SBT)	D. Salo, PharmD	\$2,327
Medication Therapy Management Referral at Discharge: An initiative to Connect Inpatient Medication Reconciliation Practices to Outpatient Medication Therapy Management Services (MTM)	A. Imberg, PharmD	\$2,373
Evaluation of the San Marco Housing Project (San Marco)	C. Gessert, MD	\$307

Subtotal Research Committee Awards **\$31,603**

GRANT AWARDS TOTAL \$984,857

**RESEARCH
CONTRACT AWARDS
Fiscal Year 2009**

Federal Funded Contract

TITLE	P.I.	SPONSOR	TOTAL
Treatment of Early Aggressive Rheumatoid Arthritis (TEAR)	R. Leff, MD	National Institutes of Health (subcontract through University of Alabama)	\$3,705
Natural History Study of the Development of Type I Diabetes (Diabetes Trialnet)	J. Boman, MD	National Institute of Diabetes and Digestive and Kidney Diseases (subcontract through The George Washington University)	\$465
Rheumatoid Arthritis Associated Autoimmunity in High Risk Populations Studies of the Etiology of Rheumatoid Arthritis (SERA)	R. Leff, MD	National Institutes of Health (subcontract through University of Nebraska Medical Center)	\$600
Rheumatoid Arthritis: Comparison of Active Therapies in Patients With Active Disease Despite Methotrexate Therapy (RACAT)	R. Hausch, MD	National Institutes of Health (subcontract through University of Nebraska Medical Center)	\$3,300
Diuretic Optimization Strategies Evaluation in Acute Heart Failure (DOSE-AHF)	K. Boddicker, MD	National Institutes of Health (subcontract through Minneapolis Medical Research Foundation)	\$6,600
Cardiovascular Outcomes in Renal Atherosclerotic Lesions Randomized and Multi-Center Two-Group Clinical Trial to Assess the Best Treatment for Patients with High Blood Pressure and Renal Artery Stenosis: Stenting with Anti-Hypertensive Medical Therapy, Compared to Medical Therapy Alone (CORAL)	C. Bunch, MD	National Institutes of Health (subcontract through the University of Toledo)	\$4,500
Protocol for the Cardiorenal Rescue Study in Acute Decompensated Heart Failure (Caress HF)	K. Boddicker, MD	National Institutes of Health (subcontract through Minneapolis Medical Research Foundation)	\$25,675

**RESEARCH
CONTRACT AWARDS (CONTINUED)
Fiscal Year 2009**

Federal Funded Contract (continued)

TITLE	P.I.	SPONSOR	TOTAL
Evaluation of the Impact of Pharmaceutical Care Delivered Post-Hospitalization on Readmission and Emergency Department Visits (EPCP-Revised U of MN)	M. Swanoski, PharmD	Peter's Institute (subcontract through Minneapolis Medical Research Foundation)	\$3,051
NCCTG Subaward	D. Nikcevich, M.D.	National Institutes of Health (subcontract through Mayo Clinic College of Medicine)	\$11,700
Subtotal Federal Funding			\$59,596

Foundation Funded Contract

TITLE	P.I.	SPONSOR	TOTAL
CCOP Supplemental Funds:			
National Surgical Adjuvant Breast & Bowel Project	D. Nikcevich, M.D.	NSABP Foundation	\$7,300
STAR Prevention Trial	D. Nikcevich, M.D.	NSABP Foundation	\$50
North Central Cancer Treatment Group	D. Nikcevich, M.D.	Mayo Foundation	\$24,284
Select	D. Nikcevich, M.D.	University of Texas Health Science Center	\$6,601
Preadvise	D. Nikcevich, M.D.	University of Texas Health Science Center	\$5,540
Prostate Cancer Prevention Trial	D. Nikcevich, M.D.	University of Texas Health Science Center	\$400
Southwestern Oncology Group	D. Nikcevich, M.D.	University of Michigan	\$200
Eastern Cooperative Group	D. Nikcevich, M.D.	Frontier Science & Technology Research Fdn.	\$7,300
Subtotal Foundation Funding			\$51,675

CONTRACT AWARDS TOTAL **\$111,271**

TOTAL AWARDS **\$1,096,128**

SMDC RESEARCH COMMITTEE

Fiscal Year 2009

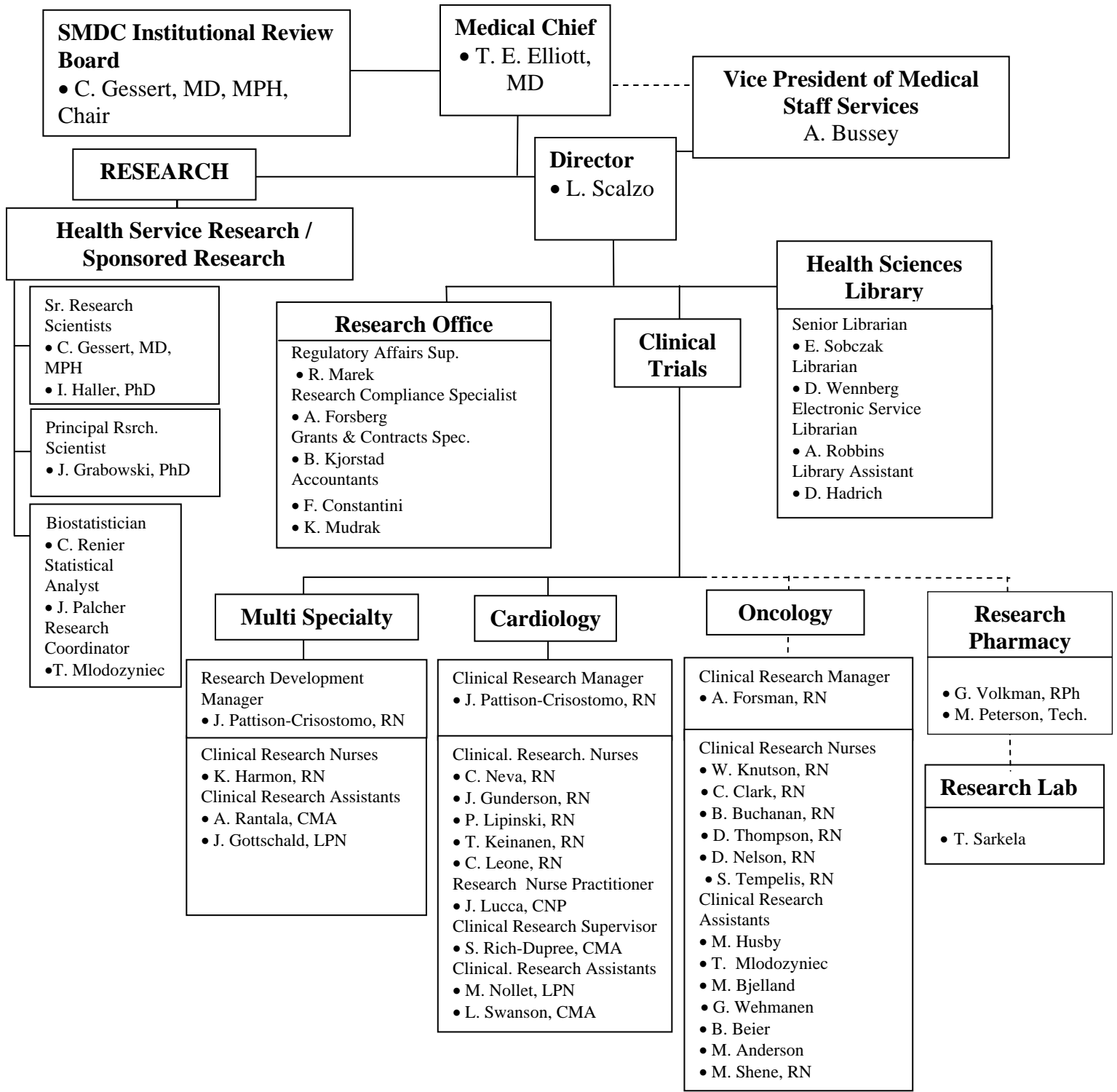
Functions and Responsibilities of Committee

1. Review research proposals for scientific merit, feasibility, and financial and resource availability.
2. Award small grants, up to \$5000, to fund intramural research projects initiated by Duluth Clinic physicians, scientists, and other investigators.
3. Approve, recommend modifications, or reject research proposals according to the approved review criteria.
4. Participate in the annual review of the research program; help establish goals and objectives, and the budget.
5. Advise in the development of research policies, resource utilization, and research support.
6. Assist the Director in promoting and increasing research at SMDC.

Membership

<u>Name</u>	<u>Title, Specialty, Discipline</u>	<u>Organization</u>
Thomas E. Elliott, MD (Chair)	Chief, Education and Research	Duluth Clinic
Ed A. Crisostomo, MD	Neurology	Northland Neurology & Myology
John Deutsch, MD	Gastroenterology	Duluth Clinic
Kenneth Dornfeld, MD, PhD	Radiology Oncology	Duluth Clinic
Barbara A. Elliott, PhD	Professor	UMD Medical School
Bret Friday, MD, PhD	Hematology/Oncology	Duluth Clinic
Charles Gessert, MD, MPH	Senior Research Scientist	Duluth Clinic
John Grabowski, PhD	Principal Research Scientist	Duluth Clinic
Lois J. Heller, PhD	Professor	UMD Medical School
Jane Hovland, PhD	Associate Professor	UMD Medical School
Kathleen Johnson, PharmD	Pharmacy	Duluth Clinic
Daniel A. Nikceovich, MD, PhD	Hematology/Oncology	Duluth Clinic
Ayman M. Noreddin, PhD	Professor	UMD College of Pharmacy
Ann Normand, MD	Surgical Orthopedics	Duluth Clinic
Colleen M. Renier, BS	Biostatistician	Duluth Clinic
Timothy Rich, MD	Pulmonary Medicine	Duluth Clinic
Tracy Udeen, RN, CNS	Care Management	Duluth Clinic
Richard Ziegler, PhD	Professor	UMD Medical School

RESEARCH AND LIBRARY ORGANIZATIONAL CHART



**RESEARCH
PROPOSALS SUBMITTED
Fiscal Year 2009**

PROPOSAL	SMDC PI	SPONSOR	STAT
Lifestyle Interventions For Elementary Schools [LIFE] School-Based Interventions to Prevent Obesity	Renier, Colleen Haller, Irina	NIH/SLH Subaward	Denied
Hospice and Palliative Care Clinical Decision Support System	Elliott, Tom E	NIH/SBIR Talaria, Inc Subaward	Pending
Vitamin D Status, Cardiovascular Health and Diabetes in American Indians; RFA-MD-08-005/NCMHD	Haller, Irina	NIH(NCMHI) U of W subaward	Awarded
A Survey of Advanced Practice Nurses and Physician Assistants at SMDC (APN/PA Survey)	Sorensen, Matt	Research Committee	Awarded
System Changes to Enhance Care and Efficiency: Implementation and Control Clinic Comparison (Phoenix)	Belknap, Mark	Research Committee	Awarded
Development of a Rapid Antigen Capture Assay to Identify Human Anaplasmosis (Rapid Assay)	Froberg, Kent M	DC Foundation	Awarded
Reducing Lost Work Days after Work Related Injuries: The Utilization of Athletic Trainers and a Transitional Work Program (ATWC)	Larson, Matt	Research Committee	Awarded
Consequences of Agricultural Injuries	Renier, Colleen	CDC/NIOSH	Awarded
Gap/Readiness Analysis for Magnet Recognition Status of St. Mary's Duluth Clinic Health System (SMDC) (GRA-SMDC)	Mundy, John	Research Committee	Awarded
Medication therapy management (MTM) referral at discharge: An initiative to connect inpatient medication reconciliation practices to outpatient medication therapy management services (MTM)	Imberg, Audrey	Research Committee	Awarded
Extended-Release Mixed Amphetamine Salts for Adult ADHD and Cocaine Dependence ADHD-SUD (resubmitted)	Haller, Irina	NIH/NIDA UMN Subaward	Awarded
Sedation Vacation Including Spontaneous Breathing Trial Influence on Mechanically Ventilated Intensive Care Unit Patients (SV/SBT)	Salo, David	Research Committee	Awarded
Evaluation of the San Marco Housing Project (San Marco)	Gessert, Charles	Research Committee	Awarded
Implementation of a cost containment and waste reduction strategy for use of eptifibatid in an acute care setting utilizing smart infusion pump technology (SymbiqCost1)	Boehne, Jennifer	Research Committee	Awarded

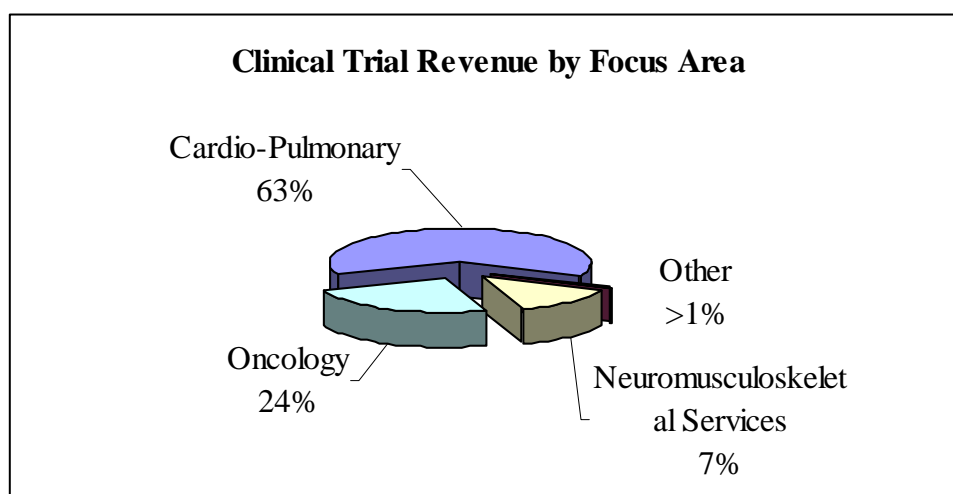
**RESEARCH
PROPOSALS SUBMITTED (CONTINUED)
Fiscal Year 2009**

PROPOSAL	SMDC PI	SPONSOR	STAT
Intracoronary Eptifibatide Bolus Administration via the ClearWay Catheter During Percutaneous Coronary Intervention for Acute Coronary Syndromes (ClearWay Catheter Registry)	Deibele, Albert	Research Committee	Awarded
The Effects of the Spine X Exercise Program in Persons with Benign Spinal Pain	Silvestrini, Tom	Research Committee	Awarded
The Effect of Daily Hempseed Consumption on Triglycerides in Mid-to-Older Women (HS-42)	Backe, Jessica	Research Committee	Awarded
The Effect of Daily Hempseed Consumption on Triglycerides in Mid-to-Older Women (HS-42)	Backe, Jessica	DC Foundation	Awarded
Impact of a Medication Reconciliation Service Provided by Student Pharmacists in the Emergency Room (MRS)	Swansoki, Michael	Research Committee	Awarded
Sex differences in stress, smoking relapse, and varenicline effects	Haller, Irina	NIH UMD Med School subaward	Denied
Duluth Community Clinical Oncology Program	Nikceвич, Dan	NIH/NCI	Awarded
Minnesota Partnership for Action Against Tobacco Smoking Treatment Program (Quit Plan)	Zimmerman, Paul	ClearWay, MN	Awarded
ADHD-SUD competitive submission (extension to methamphetamine addiction) (ADHD-MA)	Haller, Irina	NIH/NIDA UMN subaward	Pending
Pain & SUD Intersect: Reduce Abuse, Improve Treatment, Buprenorphine	Grabowski, John	NIDA	Denied
Essentia Data Warehouse: Improving Rural Health through Information and Technology	Elliott, Thomas	NIH	Denied
CCOP Administrative Supplement Brainerd Nurse Addition	Nikceвич, Daniel	NIH/NCI	Pending
CCOP Administrative Supplement Equipment	Nikceвич, Daniel	NIH/NCI	Pending
Innovative Pharmacotherapy for Women w/Co-Morbid Depression and Cocaine Dependence	Haller, Irina	NIDA UMN subaward	Not Funded
Enhancing OP Therapy: Can we open the anabolic window?	Haller, Irina	UW Madison Dept. Med. subaward	Pending
Medication Development for the Treatment of Amphetamine and Amphetamine-like related disorders	Haller, Irina	NIDA UMN subaward	Pending
Effect of Vitamin D supplementation on muscle mass and function in older adults	Haller, Irina	Merck UW subaward	Not Funded
Pharmacotherapy for methamphetamine: Lisdexamfetamine and Modafinil, combined and separately, vs placebo	Haller, Irina	UMN	Pending

**CLINICAL TRIALS RESEARCH
REVENUE TOTALS BY FOCUS AREAS**

Fiscal Year 2009

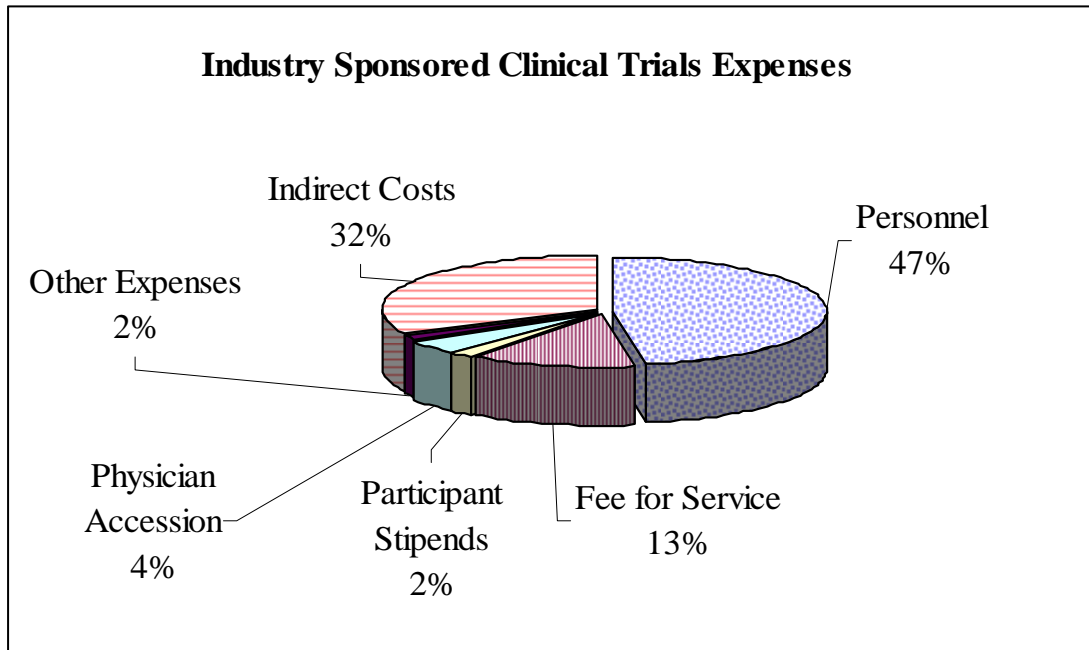
<u>PRIMARY DIVISION</u>	<u>SPECIALTY</u>	<u>REVENUE</u>
• Cardio-Pulmonary	Cardiology	\$ 601,694
	Pulmonary	685
	Vascular Surgery	4,425
	Cardiothoracic	<u>28,680</u>
	Subtotal	\$ 635,484
• Neuromusculoskeletal Services	Neurosurgery	\$ 18,815
	Trauma	51,730
	Neurology	31,476
	Rheumatology	<u>35,194</u>
	Subtotal	\$ 137,215
• Oncology	Hematology/Oncology	<u>\$ 250,897</u>
	Subtotal	\$ 250,897
• Other	Endocrinology	\$ 1,800
	Nephrology	<u>1,706</u>
	Subtotal	\$ 3,506
TOTAL		\$ 1,027,102



INDUSTRY SPONSORED CLINICAL TRIALS EXPENSE DISTRIBUTION

Fiscal Year 2009

Personnel	\$ 502,633	
Fee for Service	132,120	
Participant Stipend	19,438	
Physician Accession	43,607	
Other Expenses	18,795	
	Subtotal	\$716,593
Indirect Costs		339,402
	Total Expenses	\$1,055,995



RESEARCH
SMDC INSTITUTIONAL REVIEW BOARD ACTIVITIES
Fiscal Year 2009

MISSION AND RESPONSIBILITIES OF THE SMDC IRB

The SMDC Institutional Review Board (IRB) reviews, approves, and monitors all research involving human subjects conducted, sponsored, or supported by the SMDC Health System and affiliated/cooperative local institutions. The SMDC IRB operates according to its Bylaws, which are approved annually by the SMDC Board of Directors. The Bylaws are formed upon the principles in The Belmont Report; OPRR Reports for Protection of Human Subjects: Federal Register, 56 (117), June 18, 1991.

The SMDC IRB assures that research involving human subjects is based on the ethical principles of respect for persons, beneficence, and justice.

The SMDC IRB is mandated to review research for the following purposes:

1. Assess risks to human subjects involved in research. Risk assessment involves identification, balancing against benefits, and minimization through proper procedures.
2. Assess and reduce risks to human subjects, investigators, and the institutions that may be physical, psychological, social, legal, or economic risks.
3. Review and assure proper informed consent forms, procedures, and applications.
4. Assure appropriate and just selection of research subjects.
5. Assure sound research designs and eliminate unnecessary procedures or add procedures to protect human subjects.
6. Monitor ongoing research projects at least annually, and more often if necessary.
7. Address the special considerations of vulnerable populations: Children, minorities, pregnant women, disabled, and other disadvantaged persons.

SMDC IRB EDUCATION

A. SMDC Institutional Review Board members receive a copy of the *IRB Ethics & Human Research*, a bimonthly newsletter published by The Hastings Center.

B. IRB members are required to complete training in an approved course in Human subject protections every five years.

C. An educational presentation is held annually for the SMDC Institutional Review Board members. The 2009 IRB Presentation made May 12, 2009 by Thomas E. Elliot, MD, Chief, Education and Research at SMDC presented "The New Vision for an Essentia Health IRB".

RESEARCH
SMDC INSTITUTIONAL REVIEW BOARD ACTIVITIES
Fiscal Year 2009

PRIMARY MEMBERS

<u>Name</u>	<u>Title, Specialty, Discipline</u>	<u>Organization</u>
Tamara Dolenc, MD, MS	Psychiatry	Duluth Clinic
Charles E. Gessert, MD, MPH	IRB Chair, Senior Research Scientist	Duluth Clinic
Wilson Ginete, MD	Cardiology	Duluth Clinic
Sue Henke, MBA	Community/lay member	Duluth Clinic
Kathleen Johnson, PharmD	Pharmacy	Duluth Clinic
Elizabeth W. Kelley, MD	Pediatric Intensive Care	Duluth Clinic
Anne Lewis, JD	General Counsel	Duluth Clinic
Mary Patricia O'Day, MD	Obstetrics/Gynecology	Duluth Clinic
Nancy Peterson, RN, BA, MS Ed	Registered Nurse (retired)	
Sister Beverly Raway, OSB	Assistant Professor/Clergy	College of St. Scholastica
D. Scott Salveson	Community/lay member	Salveson Consulting
Mary Tanner, PhD	Assistant Professor	College of St. Scholastica
Richard G. Hoffman, PhD	Assoc Dean & Assoc Professor	UMD
Stephen Hedman, PhD	Assoc Vice Chancellor	UMD

Alternate Members

Raymond Hausch, MD	Rheumatology	Duluth Clinic
Alan M. Johns, MD	Internal Medicine	Duluth Clinic
Michael Messer, MD	Psychiatry	Duluth Clinic
Gerard David Spoelhof, MD	Urgent Care	St. Lukes

**RESEARCH
SMDC INSTITUTIONAL REVIEW BOARD**

Fiscal Year 2009

- New research projects approved.....73
 - CCOP 35
 - Industry Sponsored & Other 38

- Research projects approved at annual review (open and closed to accrual).....282
 - CCOP 192
 - Industry Sponsored & Other 90

- Research Amendments approved.....214
 - Full Board review.....40
 - Expedited review.....174

- Research projects completed, permanently closed..... 60
 - CCOP..... 26
 - Industry Sponsored & Other 34

**RESEARCH
RESEARCH STUDIES APPROVED - CCOP
Fiscal Year 2009**

CCOP cancer treatment/cancer prevention research studies approved 35

Eastern Cooperative Oncology Group (ECOG)	4
North Central Cancer Treatment Group (NCCTG)	11
Clinical Trials Support Unit (CTSU)	14
Southwest Oncology Group (SWOG)	1
Children's Oncology Group (COG)	4
National Surgical Breast and Bowel Project (NSABP)	1

IRB Number/CCOP	CCOP Study Title	Principal Investigator
#07-08-21 - ECOG E1A06	An Intergroup Phase III Randomized Controlled Trial Comparing Melphalan, Prednisone and Thalidomide (MPT) VS Melphalan, Prednisone and Lenalidomide (Revlimid) (MPR) in Newly Diagnosed Multiple Myeloma Patients Who Are Not Candidates for High-Dose Therapy	Daniel A. Nikcevich, MD, PhD.
#07-08-22 - CTSU/CALGB 10603	A Phase III Randomized, Double-Blind Study of Induction (Daunorubicin/Cytarabine) and Consolidation (High-Dose Cytarabine) Chemotherapy _ Midostaurin (PKC412) (IND#101261) or Placebo in Newly diagnosed Patients, 60 Years of Age with FLT3 Mutated Acute myeloid Leukemia (AML)	Daniel A. Nikcevich, MD, PhD.
#07-08-23- COG ANBL0532	Phase III Randomized Trial of Single vs. Tandem Myeloablative Consolidation Therapy for High-Risk Neuroblastoma	Jacquelyn Wiermaa, MD.
#08-08-21 - CTSU/CALGB 40503	Endocrine Therapy In Combination with Anti-VEGF Therapy A Randomized, Double-Blind, Placebo-Controlled Phase III Trial of Endocrine Therapy Alone or Endocrine Therapy Plus Bevacizumab (NSC 704865; IND 7921) for Women with Hormone Receptor-Positive Advanced Breast Cancer	Daniel A. Nikcevich, MD, PhD.
#08-08-22 - CTSU/SWOG S0502	A Phase III Randomized Study of Imatinib, with or without Bevacizumab (NSC-704865) in Patients with Metastatic or Unresectable Gastrointestinal Stromal Tumors	Daniel A. Nikcevich, MD, PhD.
#08-08-23- ECOG E3A05	Ancillary Laboratory Protocol for Collecting Diagnostic Material on Patients Considered for Studies of Plasma Cell Disorders	Daniel A. Nikcevich, MD, PhD.
#08-08-24 - CTSU/RTOG 0534	A Phase III Trial of short Term Androgen Deprivation with Pelvic Lymph Node or Prostate Bed Only radiotherapy (SPPORT) in Prostate Cancer patients with a Rising PSA After Radical Prostatectomy	Daniel A. Nikcevich, MD, PhD
#08-08-25 - COG AEWS07B1	A Children's Oncology Group Study for Collecting and Banking Ewing Sarcoma Specimens	Jacquelyn Wiermaa, MD
#09-08-21 - NCCTG N0775	A Randomized Phase II Trial of Temozolomide (TMZ) and Avastin® or ABI-007/Carboplatin (CBDCA) and Avastin® in Patients with Unresectable Stage IV Malignant Melanoma	Daniel A. Nikcevich, MD, PhD.
#09-08-21 - NCCTG N0779	Phase II Study of Vorinostat (SAHA) in Combination with Bortezomib (PS-341) in Patients with Recurrent Glioblastoma Multiforme	Daniel A. Nikcevich, MD, PhD

RESEARCH
RESEARCH STUDIES APPROVED - CCOP (CONTINUED)
Fiscal Year 2009

IRB Number/CCOP	CCOP Study Title	Principal Investigator
#09-08-23 - NCCTG N0779	Phase II Study of Vorinostat (SAHA) in Combination with Bortezomib (PS-341) in Patients with Recurrent Glioblastoma Multiforme	Daniel A. Nikcevich, MD, PhD
#09-08-24 - CTSU/RTOG 0415	A Phase III Randomized Study of Hypofractionated 3D-CRT/IMRT Versus Conventionally Fractionated 3D-CRT/IMRT in Patients with Favorable-Risk Prostate Cancer	Daniel A. Nikcevich, MD, PhD.
#09-08-25 - CTSU/WFU 07-02-03	A Phase III Randomized, Double-Blind, Placebo-Controlled Trial of North American Ginseng Extract (CVT-E002; COLD-fx®) to prevent Respiratory Infection and Reduce Antibiotic Use in Patients with Chronic Lymphocytic Leukemia <i>Expedited Minimal Risk 9/30/08</i>	Daniel A. Nikcevich, MD, PhD
#10-08-21 - ECOG E1305	A Phase III Randomized Trial of Chemotherapy with or without Bevacizumab in Patient with Recurrent or Metastatic Head and Neck Cancer	Daniel A. Nikcevich, MD, PhD.
#10-08-22- CTSU/CALGB 30607	Randomized, Phase III, Double-blind Placebo-Controlled Trial of Sunitinib (NSC #736511, IND #74019) as Maintenance Therapy in Non-Progressing Patients Following an Initial Four Cycles of Platinum-Based Combination Chemotherapy in Advanced, Stage IIIB/IV Non-Small Cell Lung Cancer	Daniel A. Nikcevich, MD, PhD.
#10-08-23 - COG AOST06B1	A Children's Oncology Group Protocol for Collecting and Banking Osteosarcoma Specimens	Jacquelyn Wiermaa, MD.
#11-08-21 - NCCTG N07C2	The Use of Wisconsin Ginseng (panax quinquefolius) to Improve Cancer-Related Fatigue A Randomized, Double-Blind, Placebo-Controlled Phase III Study	Daniel A. Nikcevich, MD, PhD.
#11-08-22 - NCCTG N0776	Phase II Trial of Avastin® in Combination with Sorafenib in Recurrent Glioblastoma Multiforme	Daniel A. Nikcevich, MD, PhD.
#12-08-21 - CTSU/NCCTG N0723	MARVEL <u>M</u> arker <u>V</u> alidation of <u>E</u> rlotinib in <u>L</u> ung Cancer; A Phase III Biomarker Validation Study of Second-Line Therapy in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC) Randomized to Pemetrexed Versus Erlotinib	Daniel A. Nikcevich, MD, PhD.
#12-08-22 - CTSU/SWOG S0777	A Randomized Phase III Trial of CC-5013 (Lenalidomide, NSC-703813) and Low Dose Dexamethasone (LLD) versus Bortezomib (PS-341, NSC-681239), Lenalidomide and Low Dose Dexamethasone (BLLD) for Induction, In Patients with Previously Untreated Multiple Myeloma without an Intent for Immediate Autologous Stem Cell Transplant	Daniel A. Nikcevich, MD, PhD.
#12-08-23 - NSABP B-43	A Phase III Clinical Trial Comparing Trastuzumab Given Concurrently with Radiation Therapy and Radiation Therapy Alone for Women with HER2-Positive Ductal Carcinoma In Situ Resected by Lumpectomy	Daniel A. Nikcevich, MD, PhD.
#01-09-21 - NCCTG N0735	Phase II Trial of Albumin-Bound Paclitaxel in Combination With Gemcitabine and Bevacizumab in Patients With Metastatic Breast Cancer	Daniel A. Nikcevich, MD, PhD.

RESEARCH
RESEARCH STUDIES APPROVED - CCOP (CONTINUED)
Fiscal Year 2009

IRB Number/CCOP	CCOP Study Title	Principal Investigator
#01-09-22 - NCCTG N0821	A Phase II First-Line study of a Combination of Pemetrexed, Carboplatin and Bevacizumab in Advanced Nonsquamous NSCLC Evaluating Efficacy and Tolerability in Elderly Patients (age \geq 70 yrs.) with Good Performance Status (PS < 2)	Daniel A. Nikceovich, MD, PhD.
#01-09-23 - ECOG E4206	A Phase II Clinical and Biologic Study of AMG 706 and Octreotide in Patients with Low-Grade Neuroendocrine Tumors	Daniel A. Nikceovich, MD, PhD.
#01-09-24 - CTSU/ACOSOG Z1041	A Randomized Phase III Trial Comparing a Neoadjuvant Regimen of FEC-75 followed by Paclitaxel plus Trastuzumab with a Neoadjuvant Regimen of Paclitaxel plus Trastuzumab followed by FEC-75 plus Trastuzumab in Patients with HER-2 Positive Operable Breast Cancer	Daniel A. Nikceovich, MD, PhD.
#03-09-21 - CTSU/RTOG 0436	A Phase III Trial Evaluating the Addition of Cetuximab to Paclitaxel, Cisplatin, and Radiation for Patients with Esophageal Cancer who are Treated without Surgery	Daniel A. Nikceovich, MD, PhD.
#03-09-22 - COG AREN0533	Treatment of Newly Diagnosed Higher Risk Favorable Histology Wilms Tumors Local	Jacquelyn Wiermaa, MD
#03-09-23 - NCCTG N08C1	Paclitaxel-Associated Acute Pain Syndrome Natural History Study <i>Expedited Minimal risk</i> – 3/10/09	
#04-09-21 - NCCTG N083E	Phase II Safety Study of Docetaxel and Carboplatin in Combination with Trastuzumab and Lapatinib in Early Breast Cancer	Daniel A. Nikceovich, MD, PhD
#04-09-22 - CTSU/SWOG S0702	A Prospective Observational Multicenter Cohort Study to Assess the Incidence of Osteonecrosis of the Jaw (ONJ) in Cancer Patients with Bone Metastases Starting Zoledronic Acid Treatment	Daniel A. Nikceovich, MD, PhD
#05-09-21 – NCCTG N078D	Phase I/II Trial of Rituximab, Cladribine, and Temozolomide (RCT) Therapy in Newly Diagnosed Mantle Cell Lymphoma	Daniel A. Nikceovich, MD, PhD
#05-09-22 - CTSU/SWOG S0535	A Phase II Study of ATRA, Arsenic Trioxide, and Gemtuzumab Ozogamicin in Patients with Previously Untreated High-Risk Acute Promyelocytic Leukemia	Daniel A. Nikceovich, MD, PhD
#06-09-21 - NCCTG N054C	Phase II Study of Sorafenib/Bevacizumab as Salvage Therapy in Patients with Metastatic Colorectal Cancer	Daniel A. Nikceovich, MD, PhD
#06-09-22 - NCCTG N08C3	Phase III Double-Blind, Placebo-Controlled Study of Gabapentin for the Prevention of Delayed CINV (Chemotherapy Induced Nausea and Vomiting) in Patients Receiving Highly Emetogenic Chemotherapy	Daniel A. Nikceovich, MD, PhD
#06-09-23 - CTSU/CALGB 70604	A Randomized, Phase III Study of Standard Dosing Versus Longer Dosing Interval of Zoledronic Acid in Metastatic Cancer	Daniel A. Nikceovich, MD, PhD

**RESEARCH
RESEARCH STUDIES APPROVED -
INDUSTRY SPONSORED/OTHER
Fiscal Year 2009**

Industry sponsored and research other research studies approved for FY 2009 was 38.

IRB Number/Principal Investigator	Industry Sponsored/Other Study Title
No IRB # No IRB # - Thomas E. Elliott, MD	Extubation of Ventilator Dependent Patients in Hospice (Extubation). <i>Review determination: non IRB jurisdiction (deceased patients) – 7/23/08</i>
#08-08-01 - Walter Medlin, MD.	Bariatric Outcomes Longitudinal Database (BOLD) <i>Expedited Minimal Risk – 8/11/08</i>
#08-08-02 - Matthew Sorenson, MSN, RN, CNS.	A Survey of Advanced Practice Nurses and Physician Assistants at SMDC <i>Screened for Exempt Status – Category #2 – 8/11/08</i>
#08-08-03 - Kerry Fierke	Intergenerational Organizations and Leadership Style (Leadership) <i>Expedited Minimal Risk – 8/14/08</i>
#09-08-01 - Albert Deibele, III, MD.	Intracoronary Eptifibatide Bolus Administration via the ClearWay Catheter during Percutaneous Coronary Intervention for Acute Coronary Syndromes (Clearway Catheter Registry) <i>Screened for Exempt Status – Category #4 – 9/8/08</i>
#09-08-02 - Steven Kuross, MD.	An Observational Study of Treatment Patterns and Safety Outcomes for Metastatic or Locally Recurrent Breast Cancer (Virgo)
#09-08-03 - Kenneth Dornfeld, MD, PhD.	International Randomized Study to Compare CyberKnife® Stereotactic Radiotherapy with Surgical Resection in Stage I Non-Small Cell Lung Cancer; Lung Cancer STARS (Stereotactic Radiotherapy vs. Surgery) Trial
#09-08-04 - Kent Froberg, MD, DVM.	Development of a Rapid Antigen Capture Assay to Identify Human Anaplasmosis (Rapid Assay) <i>Screened for Exempt Status – Category #4 – 9/10/08</i>
#10-08-01 - John Deutsch, MD	Outcomes of Endoscopic Ultrasound (EUS) <i>Screened for Exempt Status – Category #4 – 10/13/08</i>
#10-08-02 - Mark Belknap, MD.	System Changes to Enhance Care and Efficiency: Implementation and Control Clinic Comparison (Phoenix) <i>Expedited Minimal Risk – 10/29/08</i>
#11-08-01 - Steven Kuross, MD.	A Study of Pazopanib versus Sunitinib in the Treatment of Subjects with Locally Advanced and/or Metastatic Renal Cell Carcinoma (Comparz)
#11-08-02 - Mark Neustel, MD.	A Clinical Evaluation of the Medtronic Endeavor® Resolute Zotarolimus-Eluting Coronary Stent System in the Treatment of DeNovo Lesions in Native Coronary Arteries with a Reference Vessel Diameter of 2.25 mm to 4.2 mm (Resolute)
#12-08-01 -Jennifer J. Boehne, PharmD	Implementation of a Cost Containment and Waste Reduction Strategy for the use of Eptifibatide in an Acute Care Setting Utilizing Smart Infusion Pump Technology (SymbiqCost1) <i>Expedited Minimal Risk – 12/5/08</i>
#12-08-02 - Albert Deibele III, MD.	Clearway Rx Registry <i>Expedited Minimal Risk – 12/5/08</i>
#12-08-03 - Irina Haller, PhD, MS	Extended-release Mixed Amphetamine Salts for Adult ADHD and Cocaine Dependence (ADHD-SUD) <i>Expedited Minimal Risk responsibilities at SMDC – 12/16/08</i>

**RESEARCH
RESEARCH STUDIES APPROVED -
INDUSTRY SPONSORED/OTHER (CONTINUED)
Fiscal Year 2009**

IRB Number/Principal Investigator	Industry Sponsored/Other Study Title
#12-08-04 - John Mundy, CRNA.	Gap/Readiness Analysis for Magnet Recognition Status of St. Mary's Duluth Clinic Health System (SMDC) (GRA-SMDC) <i>Screened for Exempt Status – Category #2 – 12/18/08 APPROVED 12/22/08</i>
#01-09-01 - Albert Deibele, III, MD.	PLATINUM: A Prospective, Randomized, Multicenter Trial to Assess an Everolimus-eluting coronary Stent System (PROMUS Element™) for the Treatment of up to two De Novo Coronary Artery Lesions (Platinum)
#01-09-02 - Dan Metcalf, MD.	Efficacy of Bioabsorbable Staple Line Reinforcement in Colorectal and Coloanal Anastomoses: A Prospective Randomized Study (CBSG)
#01-09-03 - Mihailo Lalich, MD.	An International, Multicenter, Randomized, Double-Blind Study of Vorinostat (MK-0683) or Placebo in Combination with Bortezomib in patients with Multiple Myeloma (Vantage)
#01-09-04 - Matthew Larson, ATC, CSCS, CSHE	Reducing Lost Work Days after Work Related Injuries: The Utilization of Athletic Trainers and a Transitional Work Program (ATWC) <i>Screened for Exempt Status – Category #4 - 1/21/09</i>
#03-09-01 - Mihailo Lalich, MD.	Randomized, Open-Label, Phase 3 Study of Pemetrexed plus Carboplatin and Bevacizumab Followed by Maintenance Pemetrexed and Bevacizumab versus Paclitaxel plus Carboplatin and Bevacizumab Followed by Maintenance Bevacizumab in Patients with Stage IIIB or IV Nonsquamous Non-Small Cell Lung Cancer (Pointbreak)
#03-09-02 - Daniel A. Nikceovich, MD, PhD.	Randomized Phase II Trial of Pentostatin, Cyclophosphamide, and Rituximab With or Without Concurrent Avastin® for Previously Untreated B-Chronic Lymphocytic Leukemia (CLL) (RC0783)
#03-09-03 - Jessica Backe, BAN, RN.	The Effect of Daily Hempseed Consumption on Triglycerides in Middle-Aged Women (HS-42)
#04-09-01 - Audrey J. Imberg, PharmD.	Medication Therapy Management (MTM) referral at discharge: An Initiative to Connect Inpatient Medication Reconciliation Practices to Outpatient Medication Therapy Management Services (MTM) <i>Expedited approval – Minimal Risk 4/7/09</i>
#04-09-02 - Mudassar Ahmed, MB, BS.	A 104 week, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy of Aliskiren on the Progression of Atherosclerosis in Patients with Coronary Artery Disease when added to Optimal Background Therapy (Aliskiren/SPP100A)
#04-09-03 - Mihailo Lalich, MD.	An Open-Label, Randomized, Parallel-Group Study of Bendamustine Hydrochloride and Rituximab (BR) Compared with Rituximab, Cyclophosphamide, Vincristine, and Prednisone (R-CVP) or Rituximab, Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (R-CHOP) in the First- Line Treatment of Patients with Advanced Indolent Non-Hodgkin's Lymphoma (NHL) or Mantle Cell (Cephalon 3064)
#04-09-04 - Michael Mollerus, MD.	Real Time Spectral Analysis of Ventricular Fibrillation Detected in ICDs (Real Time)

**RESEARCH
RESEARCH STUDIES APPROVED -
INDUSTRY SPONSORED/OTHER (CONTINUED)
Fiscal Year 2009**

IRB Number/Principal Investigator	Industry Sponsored/Other Study Title
No IRB # - Todd Heggestad, MS	MMPI-2-RF Population Norm Project: Bariatric Patients <i>Review determination: non IRB jurisdiction (de-identified data being given out – no involvement in conduct of research)</i>
#04-09-05 -	Impact of a Medication Reconciliation Service Provided by Student Pharmacists in the Emergency Room (MRS) Expedited approval – Minimal Risk 4/28/09
#05-09-01 - Bret Friday, MD	A Randomized Phase III Study of Weekly ABi-007 plus Gemcitabine versus Gemcitabine Alone in Patients with Metastatic Adenocarcinoma of the Pancreas (Abraxis Pancreatic)
#05-09-02 - Daniel A. Nikceovich, MD, PhD	Randomized, Open Label, Multicentric Phase III Trial Evaluating the Benefit of a Sequential Regimen Associating FEC100 and Ixabepilone in Adjuvant Treatment of Non-Metastatic, Poor Prognosis Breast Cancer Defined as Triple-Negative Tumor (HER2 negative-ER negative-PR negative) or HER2 Negative and PR Negative Tumor; in Node Positive or Node Negative Patients (MCCRC PACS 08-0610)
#05-09-03 - Bret Friday, MD	A Phase III, Randomized, Double-Blind Study of Galiximab in Combination with Rituximab Compared with Rituximab in Combination with Placebo for the Treatment of Subjects with Relapsed or Refractory, Follicular Non-Hodgkin's Lymphoma (Target NHL)
#05-09-04 - Subbareddy Konda, MD	The Effect of Acadesine On Clinically Significant Adverse Cardiovascular and Cerebrovascular Events In High-Risk Subjects Undergoing Coronary Artery Bypass Graft (CABG) Surgery using Cardiopulmonary Bypass (Protocol No. P05633): RED-CABG Trial (Reduction in Cardiovascular Events by AcaDesine in Subjects Undergoing CABG) (RED-CABG)
#05-09-05 - Vincent Ohaju, DO	An Open-Label, Randomized, Multicenter Phase IIIb Study to Assess the Efficacy, Safety and Tolerance of BERIPLEX® P/N Compared with Plasma for Rapid Reversal of Coagulopathy Induced by Coumarin Derivatives in Subjects with Acute Major Bleeding (Beriplex BE1116 3002)
#05-09-06 - Vincent Ohaju, DO	An Open-Label, Randomized, Multicenter Phase IIIb Study to Assess the Efficacy, Safety and Tolerance of BERIPLEX® P/N Compared with Plasma for Rapid Reversal of Coagulopathy Induced by Coumarin Derivatives in Subjects Requiring Emergency Surgery or Invasive Intervention (Beriplex BE116 3003)
#06-09-01 - Sarah Westberg, PharmD.	Improving Medication Reconciliation in a Primary Care Clinic through Pharmacist-led Staff Educational Programs Screened for Exempt Status – Category #4 – 6/4/09 External Principal Investigator
#06-09-02 - Nizar Saleh, MD	A Double-Blind, Placebo-Controlled, Randomized, Multi-Center, Dose-Finding Study of SLV320, a Selective A1 Adenosine Receptor Antagonist, to Evaluate the Effect of Renal Function and Safety in Subjects Hospitalized with Acute Decompensated Heart Failure and Renal Dysfunction (Reno-Defend 1)
#06-09-03 - David Gordon, MD	Vertical Expandable Prosthetic Titanium Rib (VEPTR)

RESEARCH PUBLICATIONS REPORT

Fiscal Year 2009

PUBLICATIONS BY TYPE

• Papers (peer-reviewed journals)	32
• Abstracts	16
• Online Publications	7
TOTAL PUBLICATIONS	55

PUBLICATIONS BY DEPARTMENT/SECTIONS

• Division of Education & Research	18
• Administrative	2
• Cardiology	4
• Dermatology	2
• Gastroenterology	9
• Hematology/Oncology	13
• Pathology	2
• Psychology	3
• Surgery	2

<u>TOTAL AUTHORS INVOLVED</u>	21
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**RESEARCH
LIST OF PUBLICATIONS
Fiscal Year 2009**

Journal Articles Published

Authors	Title	Citation
Carlson KF, Gerberich SG, Alexander BH, Masten AS, Church TR, Shutske JM, Ryan AD, Renier CM	Children's behavioral traits and risk of injury: analyses from a case-control study of agricultural households	J Safety Res. 2009;40(2):97-103
Dodd ML, Dolenc TJ, Karpyak VM, Rasmussen KG.	QTc dispersion in patients referred for electroconvulsive therapy	J ECT. 2008 Jun;24(2):131-3.
Dy GK, Hobday TJ, Nelson G, Windschitl HE, O'Connell MJ, Alberts SR, Goldberg RM, Nikcevich DA, Sargent DJ	Long-term survivors of metastatic colorectal cancer treated with systemic chemotherapy alone: a north central cancer treatment group review of 3811 patients, N0144.	Clin Colorectal Cancer. 2009 Apr;8(2):88-93
Elliott BA, Gessert CE, Peden-McAlpine C	Family decision-making in advanced dementia :narrative and ethics	Scand J Caring Sci. 2009;23:251-258
Erkal S, Gerberich SG, Ryan AD, Renier CM, Alexander BH	Animal-related injuries: a population-based study of a five-state region in the upper Midwest: Regional Rural Injury Study II	J Safety Res. 2008;39(4):351-63
Froberg MK, Dannen D, Bernier N, Shieh WJ, Guarner J, Zaki S.	Case Report: spontaneous splenic rupture during acute parasitemia of Babesia microti.	Ann Clin Lab Sci. 2008 Autumn;38(4):390-2.
Gessert CE, Haller IV	Medicare hospital charges in the last year of life: distribution by quarter for rural and urban nursing home decedents with cognitive impairment	J Rural Health. 2008 Spring;24(2):154-60
Harris JM Jr, Elliott TE, Davis BE, Chabal C, Fulginiti JV, Fine PG.	Educating generalist physicians about chronic pain: live experts and online education can provide durable benefits.	Pain Med. 2008 Jul-Aug;9(5):555-63.
Harris JM Jr, Fulginiti JV, Gordon PR, Elliott TE, Davis BE, Chabal C, Kutob RM.	KnowPain-50: a tool for assessing physician pain management education.	Pain Med. 2008 Jul-Aug;9(5):542-54.
Hendershot KM, Bollins JP, Armen SB, Thomas YM, Steinberg SM, Cook CH.	Missed surgical intensive care billing: potential financial impact of 24/7 faculty presence	J Trauma. 2009 Jul;67(1):196-9;discussion 199-201
Holliday-Welsh DM, Gessert CE, Renier CM	Massage in the management of agitation in nursing home residents with cognitive impairment	Geriatr Nurs. 2009 Mar-Apr;30(2):108-17
Khan R, Gessert C, Bockhold S	Pericardial effusion presenting with anuric acute renal failure and hepatocellular damage	J Hosp Med. 2009 Jan;4(1):68-70
Hines SL, Mincey B, Dentchev T, Sloan JA, Perez EA, Johnson DB, Schaifer PL, Alverts S, Liu H, Kahanic S, Mazurczak MA, Nikcevich DA, Loprinzi CL	Immediate versus delayed zoledronic acid for prevention of bone loss in postmenopausal women with breast cancer starting letrozole after tamoxifen-N03CC	Breast Cancer Res Treat. 2009 Feb 12

RESEARCH
LIST OF PUBLICATIONS (CONTINUED)
Fiscal Year 2009

Journal Articles Published

Authors	Title	Citation
Larson-Bright M, Gerberich SG, Masten AS, Alexander BH, Gurney JG, Church TR, Ryan AD, Renier CM.	Parent's safety beliefs and childhood agricultural injury.	Am J Ind Med. 2009 Jul 7;52(9):724-33
Loprinzi CL, Barton DL, Sloan JA, Novotny PJ, Dakhil SR, Verdirame JD, Knutson WH, Kelaghan J, Christensen B.	May Clinic and North Central Cancer Treatment Group hot flash studies: a 20-year experience.	Menopause. 2008 Jul-Aug;15(4 pt 1):655-60.
Loprinzi CL, Dueck AC, Kjoyratty BS, Barton DL, Jafar S, Rowland KN Jr, Atherton PF, Marsa GW, Knutson WH, Bearden JD III, Kottschade L, Fitch TR.	A phase III randomized, double-blind, placebo-controlled trial of gabapentin in the management of hot flashes in men (N00CB).	Ann Oncol. 2009 Mar;20(3):542-9.
Maki J, Robinson K, Reguly B, Alexander J, Wittock R, Aguirre A, Diamandis EP, Escott N, Skehan A, Prowse O, Thayer RE, Froberg MK, Wilson MJ, Maragh S, Jakupciak JP, Wagner PD, Srivastava S, Dakubo GD, Parr RL.	Mitochondrial genome deletion aids in the identification of false- and true-negative prostate needle core biopsy specimens.	Am J Clin Pathol. 2008 Jan;129(1):57-66.
Messer M, Haller IV, Larson P, Pattison-Crisostomo J, Gessert CE	The use of a series of ketamine infusions in two patients with treatment-resistant depression	J Neuropsychiatry Clin Neurosci. (accepted, 5/13/09)
Moeller FG, Schmitz JL, Green CM, Reist C, Lai LY, Swann AC, Grabowski J.	Citalopram combined with behavioral therapy reduces cocaine use: a double-blind, placebo-controlled trial.	Am J Drug Alcohol Abuse. 2007;33(3):367-78.
Mollerus M, Albin F, Lipinski M, Lucca J.	Ectopy in patients with permanent pacemakers and implantable cardioverter-defibrillators undergoing an MRI scan.	Pacing Clin Electrophysiol. 2009 Jun;32(6):772-8.
Moukaddam N, Herin DV, Schmitz J, Grabowski J	LAAM Maintenance for Treatment of Heroin Dependence	Addictive Behaviors and Their Treatment, November 2008
Mollerus M, Lipinski M, Munger T.	A randomized comparison of defibrillation thresholds in the right ventricular outflow tract versus right ventricular apex.	J Interv Card Electrophysiol. 2008 Sep;22(3):221-5.
Mollerus M, Albin F, Lipinski M, Lucca J.	Cardiac biomarkers in patients with permanent pacemakers and implantable cardioverter-defibrillators undergoing an MRI scan	Pacing Clin Electrophysiol. 2008 Oct;31(10):1241-5.

RESEARCH
LIST OF PUBLICATIONS (CONTINUED)
Fiscal Year 2009

Journal Articles Published

Authors	Title	Citation
Mooney ME, Herin DV, Schmitz JM, Moukaddam N, Green CE, Grabowski J	Effects of oral methamphetamine on cocaine use: a randomized, double-blind, placebocontrolled trial	Drug and Alcohol Dependence. 2009 Apr 1;101(1-2):34-41
Ormiston JA, Mahmud E, Turco MA, Popma JJ, Weissman N, Cannon LA, Mann T, Lucca MJ, Lim ST, Hall JJ, McClean D, Dobies D, Mandinov L, Baim DS.	Direct stenting with the TAXUS Liberte drug-eluting stent: results from the Taxus Atlas Direct Stent Study.	JACC Cardiovasc Interv. 2008 Apr;1(2):150-60.
Perkins JG, Andrew CP, Spinella PC, Blackbourne LH, Grathwohl KW, Repine TB, Ketchum L, Waterman P, Lee RE, Beekley AC, Sebesta JA, Shorr Af, Wade CE, Holcomb JB	An evaluation of the impact of aphaeresis platelets used in the seeting of massively transfused trauma patients	J Trauma. 2009 Apr;66(4 Suppl):S77-84;discussion S84-5
Stotts AL, Mooney ME, Sayre SL, Novy M, Schmitz JM, Grabowski J.	Illusory predictors: Generalizibility of finding in cocaine treatment retention research.	Addict Behav. 2007 Dec;32(12):2819-36.
Tan WW, Hillman DW, Salim M, Northfelt DW, Anderson DM, Stella PJ, Niedringhaus R, Bernath AM, Gamini SS, Palmieri F, Perez EA.	N0332 phase 2 trial of weekly irinotecan hydrochloride and docetaxel in refractory metastatic breast cancer: a North Central Cancer Treatment Group (NCCTG) Trial.	Ann Oncol. 2009 Jul 22.
Santisteban M, Buckner JC, Reid JM, Wu W, Scheithauer BW, Ames MM, Felten SJ, Nikcevich DA, Wiesenfeld M, Jaeckle KA, Galanis E, NCCTGroup	Phase II trial of two different irinotecan schedules with pharmacokinetic analysis in patients with recurrent glioma: North Central Cancer Treatment Group results	J Neurooncol 2009 Apr;92(2):165-75
Zisner DK, McCullough J, Person PE, Renier C, Knutson D	Integrated health care economics--part 1: are specialty physician services revenues reliable predictors of community health system financial performance?	Physician Exec. 2009 May-Jun;35(3):26-31
Zisner DK, Person PE.	The future of management education and training for physician leaders	Physician Exec. 2008 Nov-Dec;34(6):44-6, 48.
Qi Y, Schild SE, Mandrekar SJ, Tan AD, Krook JE, Rowland KN, Garces YI, Soori GS, Adjei AA, Sloan JA	Pretreatment Quality of Life is an Independent Prognostic Factor for Overall Survival in Patients with Advanced Stage Non-small Cell Lung Cancer	J Thorac Oncol. 2009 Jun 19

RESEARCH
LIST OF PUBLICATIONS (CONTINUED)
Fiscal Year 2009

Abstracts

Authors	Title	Event
Schmalenberger S, Giebenhain J, Starr L, Gessert CE	The Medical and Occupational Well-Being of Musicians After Breast Cancer	J Am Geriatrics Soc. 2009 Apr;57(4):S62
Messer MM, Haller IV, Pattison-Crisostomo J, Larson P	Treatment resistant depression: Experience in the use of a series of Ketamine infusions	ANPA Annual Meeting Abstract, San Antonio, TX Feb 19-22, 2009
Bamford JTM, Gessert CE, Haller IV, Kruger K	Rosacea unresponsive to oral zinc sulfate, a randomized controlled clinical trial	Society of Investigational Dermatology Annual Meeting Abstract
Haller IV, Krueger D, Valentine S, Engelke J, Binkley N	Correction of vitamin D inadequacy by food supplementation: A randomized controlled trial	ASBMR annual meeting, Denver, Sep 11-15, 2009, CO
Jett JR, Bernath AM, Foster NR, Molina JR, Nikcevich DA, Steen PD, Flynn PJ, Rowland KM, Fitch TR, Adjei AA	Phase II trial of pemetrexed (P) and carboplatin (C) in previously untreated extensive stage disease small cell lung cancer (ED-SCLC): A NCCTG Study	2008 ASCO Annual Meeting
Micallef IN, Maurer MJ, Nikcevich DA, Cannon M, Moore DF, Kurtin P, Witzig TE	A phase II study of epratuzumab and rituximab in combination with cyclophosphamide, doxorubicin, vincristine and prednisone chemotherapy (ER-CHOP) in patients with previously untreated diffuse large B-cell lymphoma	2008 ASCO Annual Meeting
Nikcevich DA, Grothey A, Sloan JA, Kugler JW, Silberstein PT, Dentchey T, Wender DB, Novotny PJ, Windschitl HE, Loprinzi CL	Effect of intravenous calcium and magnesium (IV CaMg) on oxaliplatin- induced sensory neurotoxicity (sNT) in adjuvant colon cancer: Results of the phase III placebo-controlled, double- blind NCCTG trial N04C7	2008 ASCO Annual Meeting
Hobday RJ, Rowland K, Dueck A, Northfelt D, Lingle W, Morton R, Fitch T, Nikcevich D, Perez EA	N0537: A North Central Cancer Treatment Group (NCCTG) phase II trial of VEGF Trap in patients with metastatic breast cancer (MBC) previously treated with an anthracycline and/or a taxane	ASCO 2008 Breast Cancer Symposium

**RESEARCH
LIST OF PUBLICATIONS
Fiscal Year 2009**

Abstracts

Authors	Title	Event
Jett JR, Bernath AM, Foster NR, Molina JR, Nikceovich DA, Steen PD, Flynn PJ, Rowland KM, Fitch TR, Adjei AA	Phase II trial of pemetrexed (P) and carboplatin (C) in previously untreated extensive stage disease small cell lung cancer (ED-SCLC): A NCCTG Study	2008 ASCO Annual Meeting;
Rizzieri DA, Storms R, Nikceovich D, Peterson B, Misra D, Apple C, Baker M, Gasparetto C, Horwitz M, Chute J, Morris A, Chao NJ	Safety Trial of NK Cell Enhanced Donor Lymphocyte Infusions from a 3-5/6 HLA Matched Family Member Following Nonmyeloablative Allogeneic Stem Cell Transplantation	Blood 2008; 112:
Herin DV, Green C, Moukaddam N, Schmitz J, Grabowski J.	Sequential Medication for Treatment of Cocaine Dependence: Bayesian Analysis	College on Problems of Drug Dependence; June 14-19, 2009
Hendershot KM, Bollins JP, Armen SB, Thomas YM, Steinberg SM, Cook CH.	Missed surgical intensive care billing: potential financial impact of 24/7 faculty presence	J Trauma. 2009 Jul;67(1):196-9;discussion 199-201
Elliott TE, Renier CM, Palcher JA, Heggstad T	Outcomes of a community-based pain management program.	12th Annual World Congress on Pain. IASP Press, Seattle 2008:2378.
Elliott TE	Outcomes of a community-based pain program: Is there a dose-effect?	Pain Med 2009;10:279.
Kottschade IA, Suman VJ, Amatruda T, McWilliams RR, Dakhil SR, Nikceovich DA, Morton RF, Fitch TR, Jaslowski AJ, Markovic SN	A phase II trial of carboplatin and ABI-007 in patients with unresectable stage IV melanoma, N057E	2008 ASCO Annual Meeting;

**RESEARCH
LIST OF PUBLICATIONS
Fiscal Year 2009**

Online Publications

Authors	Title	Publication
Deutsch J.	Continued Expansion of VHJOE	http://www.vhjoe.org/Volume5Issue2/5-2-3.htm
Deutsch J, Davis B.	Dysplastic Fundic Gland Polyps in a Patient with Familial Adenomatous Polyposis	http://www.vhjoe.org/Volume7Issue2/7-2-3.htm
Deutsch J.	Featured Movie: The Visible Human Mediastinum	http://www.vhjoe.org/Volume7Issue2/7-2-11.htm
Belcastro, LW.	Genetic Testing for Hereditary Colorectal Cancer Syndromes	http://www.vhjoe.org/Volume7Issue3/7-3-2.htm
Deutsch J.	Featured Movie: Linear Array EUS of the Common Bile Duct	http://www.vhjoe.org/Volume7Issue3/7-3-9.htm
Deutsch J.	Editorial VHJOE	http://www.vhjoe.org/Volume7Issue3/7-3-9.htm
Deutsch J.	Editorial: Non Steroidal Anti Inflammatory Agents in Gastroenterology	http://www.vhjoe.org/Volume8Issue2/8-2-1.htm
Harden RM, Deutsch J, Parker JL.	Angioedema Presenting as Abdominal Pain with Vomiting	http://www.vhjoe.org/Volume8Issue2/8-2-3.htm
Deutsch J.	Featured Movie: Splenic Vein Gas: EUS Anatomy and the Visible Human	http://www.vhjoe.org/Volume8Issue2/8-2-9.htm

RESEARCH PRODUCTIVITY

Research productivity continues to increase as measured by several indicators as shown in this table:

	<u>FY2005</u>	<u>FY2006</u>	<u>FY2007</u>	<u>FY2008</u>	<u>FY2009</u>
Research Publications	52	53	47	54	55
Research Projects	209	237	272	393	282
Research Staff (FTE)	36	37	37	37	37
Subjects Accrued	2,147	1,858	1,753	1,834	1,396
Submitted	17	13	18	21	32
Funded	13	9	15	18	19
Government	\$ 834	\$ 841	\$ 785	\$ 830	\$ 863
Industry	\$1,259	\$1,546	\$ 988	\$1,283	\$1,027
Foundations	\$ 548	\$ 493	\$ 386	\$ 260	\$ 202
Research Committee	\$ 22	\$ 12	\$ 38	\$ 43	\$ 31
Internal Support ¹	\$1,045	\$1,207	\$1,237	\$1,463	\$1,243
External Support*	\$2,641	\$2,880	\$2,159	\$2,374	\$2,091
Total Support*	\$3,686	\$4,086	\$3,396	\$3,836	\$3,334
External Support, %	72%	70%	64%	62%	62%
Cardiology	\$752	\$1,063	\$ 566	\$ 519	\$ 602
Oncology	\$122	\$ 107	\$ 219	\$ 453	\$ 251
Cardiothoracic	\$101	\$ 119	\$ 49	\$ 51	\$ 29
Neurology	\$ 41	\$ 98	\$ 48	\$ 66	\$ 31
Rheumatology	\$ 82	\$ 42	\$ 18	\$ 43	\$ 35
Others	\$161	\$ 116	\$ 88	\$ 71	\$ 79

^oInvestigator-Initiated

*Shown In Thousands

¹Includes Research Committee Awards

RESEARCH PRODUCTIVITY

- Disseminating Duluth Clinic research results in scientific publications increased to 55 from last year's publication total of 54. Average scientific publications over last 5 years was 49.5.
- Grants from foundations decreased over the last year by \$58,000 (-22%).
- Revenue from industry research contracts decreased by \$256,000 over the last year (-19%).
- The proportion of research expenses covered by external grants and contracts was 62%. Therefore, the majority of Duluth Clinic research was paid by funds from external grants and contracts. Research cost covered by the Duluth Clinic was only 38%.
- No increase in research staff or other resources from the Duluth Clinic have occurred over the last five years.
 1. Research staff FTEs: No increase over last five years.
 2. Duluth Clinic costs: decreased by 15% over last year.

<u>FY2005</u>	<u>FY2006</u>	<u>FY2007</u>	<u>FY2008</u>	<u>FY2009</u>
\$1,045,380	\$1,206,561	\$1,237,113	\$1,462,798	\$1,243,026

**INDUSTRY SPONSORED CLINICAL TRIALS REVENUE
TOTAL BY DEPARTMENT
FY 2005-2009**

Department	FY2005	FY2006	FY2007	FY2008	FY2009
Cardiology	\$751,512	\$1,063,104	\$565,987	\$518,484	\$601,694
Cardiothoracic	101,525	119,130	48,993	51,270	28,680
Endocrinology	12,125	1,955	925	750	1,800
Emergency Medicine	0	0	0	0	0
Family Practice	0	0	0	0	0
Gastroenterology	2,272	5,500	17,758	6,838	0
Hematology/Oncology	121,570	106,989	218,525	452,711	250,897
Internal Medicine	22,024	9,645	14,700	0	0
Nephrology	67,640	70,350	12,245	210	1,706
Neurology	41,181	98,191	47,855	66,319	31,476
Neurosurgery	5,395	4,800	8,000	21,995	18,815
OB/GYN	7,983	0	0	0	0
Orthopedics	0	0	0	3,000	0
Pediatrics	1,100	0	0	0	0
Pulmonary	26,812	4,313	7,000	1,667	685
Radiology	0	0	0	1,500	0
Rheumatology	82,171	42,261	18,198	43,464	35,194
Trauma	6,500	0	2,500	29,636	51,730
Vascular Surgery	7,250	7,250	11,500	4,500	4,425
Miscellaneous	1,500	12,174	13,841	664	0
TOTALS	\$ 1,258,560	\$ 1,545,662	\$988,025	\$ 1,203,008	\$1,027,102