

IRB Project #: _____



IRB FORM 2

REQUEST FOR IRB REVIEW

REQUEST FOR IRB REVIEW	
Principal Investigator or Project Director: Wells Shoemaker MD, Principal Investigator	
Funding agency/organization: Agency for Healthcare Research and Quality	
Project Title: Santa Cruz County, CA Diabetes Mellitus Registry (DMR)	
Date Request Submitted: 03-01-05; revised 04-19-05	
Date Review Required: 04-01-05	
Project Start and End Date: 09-30-2004 – 09-29-2007	
Type of Review: <input checked="" type="checkbox"/> Initial Review <input type="checkbox"/> Continuing Review (Renewal) <input checked="" type="checkbox"/> Request for Expedited Review	Reason for Review: <input checked="" type="checkbox"/> No Previous Review <input type="checkbox"/> Minor Modifications <input type="checkbox"/> Requested Changes Made <input type="checkbox"/> Exempting Conditions <input type="checkbox"/> Other (please specify):
Special Populations Involved: (Check all that apply) <input type="checkbox"/> Fetuses/Embryos <input type="checkbox"/> Pregnant and post partum women <input type="checkbox"/> Children <input type="checkbox"/> Prisoners <input type="checkbox"/> Minors	
<input type="checkbox"/> Mentally Impaired <input type="checkbox"/> Physically Impaired <input type="checkbox"/> Emotionally Impaired <input type="checkbox"/> Other: No Special Populations involved in this research.	

SUBMITTED: 3/1/05; REVISED: 4/19/05

IRB Project #: _____



IRB FORM 3

PROPOSED RESEARCH PROTOCOL

Instructions to Project Director: Please complete this form and attach copies of all supporting documentation. Do not consider your responses to each to appear limited by the space appearing on your screen. Submit a complete copy to the IRB administrator, who will forward it to the IRB chair.

PROPOSED RESEARCH PROTOCOL

Principal Investigator: Wells Shoemaker MD
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Co-investigators:

Project Title: Santa Cruz County, CA Diabetes Mellitus Registry (DMR)

Funding Agency: Agency for Healthcare Research and Quality
Department of Health and Human Services

Special Review Requirements: (e.g., OMB review required, child abuse—mandated reporting, etc.)

No special review requirements.

Appendices to Form 3

- A: Diabetes Registry Definition
- B: Safety Net Clinic Kick-off Pamphlet
- C: Research Consent Form
- D: Pre-training Survey
- E: Post-training Survey
- F: User Survey
- G: Stakeholder Survey

SUBMITTED: 3/1/05; REVISED: 4/19/05

PROPOSED RESEARCH PROTOCOL

Protocol Summary

Please fill out the information requested in the following categories. If the item does not apply to your research, simply indicate that the question is not applicable.

1. Purpose of the study: What are the specific scientific aims or hypotheses of this study?

The Santa Cruz County Diabetes Mellitus Registry Project, now called the Community Chronic Care Network (CCCN), builds on a history of productive collaboration among the County's public, private, and not-for-profit health sectors. The participating organizations are: three community healthcare collaboratives (Health Improvement Partnership, Safety Net Clinic Coalition & Regional Diabetes Collaborative); two physician organizations (Physicians Medical Group & Sutter/Santa Cruz Medical Foundation); the County's Medicaid HMO (Central Coast Alliance for Health); the health department (Health Services Agency); a local community college (Cabrillo College); and a local philanthropy (Pajaro Valley Community Health Trust).

The clinical entities including the Physicians Medical Group (PMG), Sutter/Santa Cruz Medical Foundation (SCMF), the Santa Cruz County Health Services Agency (HSA), the Safety Net Clinic Coalition (SNCC), and the Central Coast Alliance for Health (Alliance) have agreed to share encounter/claim data, laboratory, and pharmacy data to populate a County-wide diabetes registry. The registry software was developed by one of the physician groups, whose Medical Director serves as the project's Principal Investigator. The existing registry is Web-based and interactive, giving physicians and their colleagues many options for improving the standard of diabetes care provided to patients. Prompts can remind physicians and medical assistants about needed tests at the point of care; the registry also can generate lists of patients overdue for exams or tests so that medical office staff can accelerate the appointment process. Because most of the data are captured electronically, the registry is populated with minimal burden within the office itself. Patients who change providers or health care plans can do so without losing their extensive histories of diabetes care; likewise, their providers potentially have immediate access to useful, accurate, and up-to-date information about their patients. The immediate goal of the Santa Cruz DMR Project is to extend the existing registry to as many County providers as possible. This will be accomplished in phases, by customizing training, reaching agreements among the organizations about sharing data, and piloting and launching the registry in increments. This, in turn will make it possible to track the County's diabetes population in the aggregate, to identify trends in key indicators of care and control of this preventable but potentially devastating – and costly – disease.

As discussed below, research in closed health care systems has demonstrated that use of this type of registry system in primary care settings improves clinical outcomes for persons with diabetes. The research purpose of this Project is to test a collaborative methodology for community-wide development and deployment of a diabetes registry and clinical guidelines in order that this proven practice can be replicated outside of a closed healthcare system.

The hypothesis of the CCCN research is that implementation of an inclusive, community-wide, collaboratively developed and deployed electronic registry for adults with diabetes with embedded, evidence-based guidelines and care management prompts will:

1. Improve measurable provider performance for regular testing and intervention for people with diabetes;
2. Reduce disparities in diabetes care within Santa Cruz County; and
3. Decrease the incidence of avoidable complications of diabetes.

PROPOSED RESEARCH PROTOCOL

The subjects of this research are Santa Cruz County healthcare providers including leaders of clinical entities; health information and technology staff; physicians; and other members of the outpatient care team. The clinical value of a diabetes registry and of clinical guidelines has been well demonstrated and is not the purpose of this research.

2. Background: State the background of the study, including a critical evaluation of existing knowledge and the information gaps that this research proposes to fill. Describe previous work that provides a basis for the proposed research and that supports the expectations of obtaining useful information without undue risk to human subjects. Please include relevant citations.

In 1993 the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institute of Health published a 10-year clinical study of 1,441 persons with type 1 diabetes in 29 medical centers in the United States and Canada.¹ The Diabetes Control and Complications Trial (DCCT) demonstrated that keeping blood glucose levels as close to normal as possible slows the onset of complications of diabetes. The results showed that with intensive treatment persons with type 1 diabetes achieved HbA1c levels closer to normal and that they experienced far fewer diabetic complications. Five years later, a UK study of persons with type 2 diabetes showed similar results.² The UK Prospective Diabetes Study was a 20-year trial which recruited 5,102 patients with type 2 diabetes in 23 clinical centers in England, Northern Ireland and Scotland. The large UK study demonstrated the effectiveness of tight glucose control, as well as control of hypertension, weight, and correlations with ethnicity (white, south Asian, Afro-Caribbean).

In the 10-years following the publication of the DCCT results, numerous studies confirmed the conclusion that intensive medical treatment to control blood glucose and hypertension significantly reduces the risk of development of the complications for persons with type 1 and 2 diabetes. In addition, numerous studies have been published providing evidence of improved outcomes from regular foot exams, dental exams, dilated eye exams, depression management, regular testing of microalbuminuria, blood lipids, self-glucose monitoring, medical nutrition therapy, physical activity, aspirin therapy and smoking cessation.

Based on a formal review and approval by the Professional Practice Committees of the American Diabetes Association (ADA) of this wealth of research, Clinical Practice Recommendations were published by ADA in 2003.³ In 2003-2004, the California Diabetes Prevention & Control Program and the Diabetes Coalition of California published Basic Guidelines for Diabetes Care.⁴ These guidelines were developed by local and national experts in a consensus process and are consistent with the ADA Clinical Practice Recommendations.

The Clinical Committee of the Community Chronic Care Network adopted the evidence-based California Basic Guidelines for Diabetes Care for use in the Santa Cruz County diabetes registry in January 2005.

The research advances in diabetes reflect the explosion of knowledge and technology in the treatment of many

¹ The Diabetes Control and Complications Trial Research Group: The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *New England Journal of Medicine* 329: 977-986, 1993.

² United Kingdom Prospective Diabetes Study. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes. (UKPDS 33) *Lancet* 352: 837-853, 1998.

³ American Diabetes Association: Clinical Practice Recommendations 2003, *Diabetes Care* 26 (Supplement 1), 2003.

⁴ Diabetes Coalition of California and California Diabetes Prevention and Control Program. Basic Guidelines for Diabetes Care, 2003-2004. (www.caldiabetes.org)

PROPOSED RESEARCH PROTOCOL

diseases in the 1990's. By 1999 the number of clinical trials conducted was estimated to be over 10,000 a year. Despite this explosion in medical knowledge (or perhaps because of it), a committee of experts from the Institute of Medicine found that the health care system frequently failed to translate this knowledge into practice. In 2001, the Institute of Medicine (IOM) published a call for action to address what was called the "quality chasm" in health care.⁵ The IOM committee proposed six aims for improvement and stated that: "Health care should be safe, effective, patient-centered, timely, efficient and equitable." The IOM report called for a transformation of the health care system focusing on a set of priority conditions including diabetes.

In January 2004, the IOM convened the 1st Annual Crossing the Quality Chasm Summit. Representatives of 15 innovative communities from across the country, including Santa Cruz County, met with national leaders and organizations to identify strategies for high-quality care for persons with five chronic diseases—asthma, depression, diabetes, heart failure, and pain control. The Summit developed recommendations for key strategies in measurement; information and communications technology; care coordination; patient self-management support; and finance.⁶ Santa Cruz County was selected to attend this prestigious summit based on the collaborative work of the Health Improvement Council and the Regional Diabetes Collaborative to focus on diabetes care including a commitment to communitywide systems of care. Based on research that demonstrates that a registry model of care improves provider performance to achieve standards of care the Santa Cruz County decided to work toward creating a communitywide diabetes registry.

Group Health Cooperative of Puget Sound and Kaiser Permanente have both adopted computerized databases for chronic care management including diabetes. As large health maintenance organizations with a defined population and an integrated delivery system, Group Health and Kaiser have been able to implement diabetes registries and demonstrate their cost effectiveness. In 2001 Group Health Cooperative of Puget Sound published a study that demonstrated that a registry-based diabetes care management model is associated with a decrease in complications and significant cost savings within 1 to 2 years of improvement.⁷

Alan Glaseroff MD has just completed a study of implementing a diabetes registry in an independent practice association (IPA) in rural Humboldt (California) county.⁸ Over a two-year period this study demonstrated a significant improvement in glucose control. The California Healthcare Foundation (CHCF) and a grant-in-kind from the International Diabetes Center (IDC) funded this study.

The CCCN project builds on the work of Dr. Glaseroff extending the concept of a community-wide diabetes registry to a larger community with an IPA (Physician's Medical Group), a large group practice (Santa Cruz Medical Foundation), public and private not-for-profit Safety Net clinics, and countywide MediCal managed care (Alliance). In addition, the CCCN's diabetes registry has several features not included in the Humboldt County registry. The internet-based CCCN registry was developed over a two-year period by the Physician's Medical Group and includes automating data entry from payer, pharmacy and laboratory sources; online provider access and data entry; and the ability for providers to generate patient reports.

⁵ Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academy Press, 2001.

⁶ Institute of Medicine. *The 1st Annual Crossing the Quality Chasm Summit: A Focus on Communities*. Washington, DC: The National Academies Press, Washington, 2004.

⁷ Wagner EH, et al.: Effect of improved glycemic control on health care costs and utilization. *Journal of the American Medical Association* 285(2): 182-189, 2001.

⁸ Glaseroff, A.: Implementing Evidence-based Guidelines in a Rural IPA: A Model for Integration. Project Narrative Report, February, 2005 (unpublished).

⁹ Rogers, EM. *The Diffusion of Innovations, 4th edition*. New York: The Free Press, 1995.

¹⁰ JCAHO. *Cycle for Improving Performance*. OakBrook Terrace, Ill, 1995.

¹¹ National Institute for Health Care Management. *Advancing Health Information Technology*, December, 2004.

PROPOSED RESEARCH PROTOCOL

Research by the CCCN on the implementation of a community-wide electronic diabetes registry also supports President George W. Bush's Executive Order of April 27, 2004, which called for widespread deployment of health information technology within 10 years to help realize substantial improvements in safety and efficiency. The Executive Order created the position of National Health Information Technology Coordinator and articulated a vision of developing a nationwide interoperable health information technology infrastructure that ensures that appropriate information to guide medical decisions is available at the time and place of care. The Executive Order calls for a Plan that addresses privacy and security issues related to interoperable health information technology and recommends methods to ensure appropriate authorization, authentication, and encryption of data for transmission over the Internet. It is within this policy context that AHRQ awarded grants to community collaboratives including the CCCN for the planning and implementation of health information technology systems.

Finally, the CCCN project is based on research on adoption of change in health care. Don Berwick MD of The Institute for Healthcare Improvement (IHI) is a national resource on information on the issue of dissemination of best practices in health care. IHI suggests dissemination of new systems occurs when several elements are present including strong executive and day-to-day leadership; widely available information for potential users on how to implement the change; a communications campaign with a strong message about the benefits of the new system, data on desired outcomes, and identification and training of key messengers who can explain the new system to others. These elements are drawn from the work of Everett Rogers⁹. Both the Physicians Medical Group and the Santa Cruz Medical Foundations have adopted the IHI approach to adoption of change as participants in the Breakthroughs in Chronic Care Project and the California Diabetes CQI Project.

Another important aspect of these Projects is the use of the PDSA Cycle for project improvement. The Plan-Do-Study-Act cycle developed by Walter Shewart and popularized by W. Edwards Deming was adopted to healthcare in the 1990's and used for quality improvement by many organizations including the Joint Commission on Accreditation of Healthcare Organizations.¹⁰ Use of this rapid response approach supports the adoption of change because it increases belief that the change will work and minimizes resistance to implementation.

The non-profit California Healthcare Foundation has sponsored a nationally acclaimed, highly selective, intensive, 2-year Healthcare Leadership Fellowship for health professionals in positions to stimulate significant change in California. The science and strategy of population-based care improvement is a central focus of the program. Santa Cruz County is fortunate to have 3 physicians who have completed or will soon complete this program, all of whom are directly involved with the diabetes registry project: Larry DeGhetaldi MD, CEO of Sutter/Santa Cruz Medical Foundation and president of steering committee; Wells Shoemaker MD, Medical Director of Physicians Medical Group and Principal investigator; and Barbara Palla MD, Medical Director of the Alliance and co-chair of the Clinical Committee. Dr. Glaseroff, mentioned above is a graduate. In addition, CHCF fellow Neal Adams MD, California Mental Health Director, is exploring collaborative opportunities to better serve Santa Cruz County residents with diabetes and depression.

There is also a body of knowledge about the adoption of healthcare technology. In Summer 2004, the National Institute for Health Care Management (NIHCM) convened a meeting of national experts to develop strategies to accelerate the adoption of HIT and electronic health records.¹¹ Participants at the meeting identified two issues –productivity and workflow--that need to be addressed in successful implementation of health information technology. Successful implementation “means working across boundaries to effect local initiatives with sensibilities to local issues and values.” The CCCN Research Project is designed to help fill the gap in knowledge on how to successfully make this type of local adoption.

PROPOSED RESEARCH PROTOCOL

3a. Study Population: Describe the characteristics of the subject population such as the anticipated number, age range, gender, ethnic background and health status. Provide a candid discussion of potential problems related to the study population. *It is the policy of the NIH that women, members of minority groups and children be included in all NIH supported biomedical and behavioral research involving human subjects, unless a clear and compelling rationale and justification is provided with respect to the health of the subjects of the purpose of the research. If applicable, provide a scientific justification for the exclusion of specific gender, racial/ethnic groups, age range, or females of childbearing age*

As stated above, health care providers with offices in Santa Cruz County are the subjects of this research. The Project includes all primary care settings located in Santa Cruz County:

- Safety Net Clinics (Health Services Agency, Salud Para la Gente, Women's Health Center, and Planned Parenthood)
- Santa Cruz Medical Foundation adult primary care offices
- Physicians Medical Group adult primary care offices
- Unaffiliated primary care offices
- Diabetes self-management education programs (Diabetes Health Center, Santa Cruz Medical Foundation and Dominican Hospital Lifestyle Center)

In these settings, all levels of patient care providers will be involved in the training and implementation of the diabetes registry. Patient care providers include physicians (MDs/DOs), nurse practitioners (RNNP), physician's assistants (PAs), registered nurses (RNs), registered dietitians (RDs), medical assistants (MAs), receptionists and community outreach workers. In addition, the project includes the health information management and information technology staff of these clinical entities. Finally, the executive leaders of the partner organizations of the CCCN are the stakeholders and part of the study population.

It is estimated that there are approximately 150 physicians and an additional 300 other patient care providers in the study population. This population includes employed men and women of all the racial and ethnic groups represented in the healthcare workforce in Santa Cruz County.

Participation in the CCCN registry is voluntary. Prior to submitting the grant to the Agency for Healthcare Research and Quality, a great deal of work went into obtaining the agreement of all of the partner organizations to participate in the collaborative development and deployment of a community-wide diabetes registry. The primary concern of the partner organizations is that the registry information not be used for competitive gain of any organizations. For this reason, safeguards have been developed in the research design to insure that neither individual providers nor office/clinics can be identified in project reports or other documents. These safeguards will also serve the purpose of protecting providers who voluntarily participate in providing the data and information for the research component of this Project.

Before the diabetes registry is implemented in a clinic/office, the participating clinic/office will sign a Participant Agreement with the CCCN. This Agreement will outline responsibilities of the participating provider organization for compliance with HIPAA and other governmental regulations including the requirements for patient consent and notification.

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3b. Indicate the criteria for exclusion and inclusion into the study and explain the system for equitable selection of

PROPOSED RESEARCH PROTOCOL

subjects. If a control group is necessary, provide justification including, why controls are necessary, and a description of the characteristics of the control group.

The criterion for inclusion in this research study is a medical office or clinic located in Santa Cruz County providing primary care to persons with diabetes. Persons with diabetes are defined using NCQA/HEDIS® criteria without the continuous enrollment requirement. The NCQA*/HEDIS®** criteria include persons age 18 years and older through age 75. For the diabetes registry there is no age cap and persons over 75 years of age will be included. (See Appendix A for other specific NCQA/HEDIS criteria.)

There is no control group in this study. Registry data will be compared with comparable California data including NCQA/HEDIS®. Research analysis will include comparisons of use of the registry by types of practices and clinical outcomes. The analysis will be reported so that no individual provider or office/clinic can be identified.

*NCQA = National Committee for Quality Assurance

**HEDIS® = Health Employer Data and Information Set

3c. Recruitment: Describe the methods that will be used to identify and recruit all potential subjects. Attach a copy of all planned advertisements, flyers and letters, etc. that will be used to recruit potential subjects

The Research Plan specifies a phased implementation plan for the CCCN Registry. In Phase I, the Registry will be implemented for the Safety Net Clinics (Spring, 2005). At the same time Central Coast Alliance (MediCal HMO) payer data will be added to the registry database.

Physicians Medical Group (PMG) HMO data is already in the database and many PMG physicians are currently using the registry. The second new source of payer data planned for the CCCN registry is Medicare. With the addition of the Alliance and Medicare data the second implementation group will be to expand the use of the database by PMG physicians. This Phase is scheduled for Summer/Fall, 2005.

In the second year of the Project the CCCN Registry will be implemented for providers of the Santa Cruz Medical Foundation (SCMF). This implementation will be timed to coordinate with the implementation of an electronic medical record at the SCMF and is estimated for Winter/Spring, 2006. Simultaneously PPO (Preferred Provider Organization) data will be added to the registry database.

The last Phase of the implementation will be to add other sources of payer data and to recruit unaffiliated physicians, new providers and clinics/offices, and clinics/offices that chose not to participate in the first phases of the implementation. The goal is to complete the implementation at provider sites by Fall, 2006 to allow the final year for studying the implementation and clinical outcomes of using the CCCN database.

Recruitment of provider organizations as users of the database is voluntary. The basis of the organizational recruitment is the work done in developing the CCCN collaborative. As noted above, the Project is drawing on the research and experience with provider adoption from the California Diabetes Continuous Quality Improvement Project and the Breakthroughs in Chronic Care Program including use of the PDSA cycle.

The clinic/office recruitment strategy begins with a kick-off meeting by the trainers at the clinic/office site. The objective of the kick-off meeting is to introduce all levels of provider staff to the patient care reasons for implementing the CCCN registry. In addition it is an opportunity for the staff to meet the trainers and for the trainers to identify a physician champion and staff advocate. For the Safety Net Clinic implementation, Dr. George Wolfe, the public health consultant to the Project will also participate in the kick-off meetings. A copy of the brochure for the Safety Net kick-offs is attached as Appendix B.

Following the kick-off meeting, the trainers will return to the clinic/office to obtain specific data on the

PROPOSED RESEARCH PROTOCOL

computer hardware and software at each site, patient care workflow and to plan the training in conjunction with the physician champion and staff advocate. This information will be used by the trainers to customize the training to match the technical environment of the clinic/office, to integrate the registry into the clinic/office workflow, and to use the PDSA improvement cycle.

To this point in the implementation process the focus has been on recruiting the clinic/office to adopt the Registry including leadership and staff. Starting with the onsite training, the Project will be recruiting providers to actively use the registry and to participate in the Project research on provider adoption. At training sessions, the trainers will explain the purpose of the adoption research and invite participants to volunteer to participate. Providers who agree to participate in the research component of the Project will be asked to sign Research Consents (Appendix C). The research component includes pre and post training surveys (Appendix D & E) and online user survey (Appendix F).

The Project Manager will recruit the CCCN Steering Committee members and leadership of the Clinical Committee to participate in annual Stakeholder Survey starting in October 2005. The Research Consent will be reviewed and signed with Stakeholders before the survey interview. (Appendix G)

PROPOSED RESEARCH PROTOCOL

Research Methods and Procedures

PROPOSED RESEARCH PROTOCOL

this group of HIT projects is to establish guidelines for collaboratives such as the CCCN to create portable registries and electronic medical records and to ensure full compliance with federal and state regulations regarding privacy and security of personal health information. AHRQ is also committed to assisting grantees to gain public trust for the confidentiality of the emerging technology of the electronic medical record.

To achieve these goals AHRQ has established a National Resource Center to provide templates for grantees to use in structuring the data acquisition and use in full compliance with regulatory standards. The procedures to be used by the CCCN for the acquisition, storage, and use of patient registry data include:

- The Diabetes Registry data will be kept on a separate server. Access to the server data will be restricted to only the Principal Investigator, Project Manager and the IT Lead for authorized use including research reports.
- Patients will be identified on the database with an identifying code number specific to the CCCN registry. Access to the list of code numbers will be restricted to the CCCN IT staff.
- Individual providers, offices/clinics will only have access to data for their assigned patients.
- The database will be accessed by providers, offices/clinics on the secure CCCN website and will require an access pass code specific for that provider.
- The use of the database will be closely monitored by the CCCN IT staff to ensure appropriate use
- Business agreements specifying the use of the data will be signed before any data is obtained from a health plan or other source of data including laboratory data, referral data and data from provider's electronic medical records.
- Provider sites will be required to have patients sign consents that include information about electronic records including the CCCN registry as part of the implementation process.

4b. If your study uses surveys, questionnaires, or psychological tests, please describe the provisions for administering these measures, the mode of administration, the setting and if special training or qualifications are necessary.

The Training Team, IT Lead and Project Manager will administer all surveys and user groups for this Project. These staff members are qualified and experienced in administering surveys, and conducting interviews and user groups. This experience includes administering online surveys, the methodology that will be used for the annual user survey.

Before administering the survey, interview or user group Project staff will review the reasons for the survey or group, the safeguards for individual confidentiality and will obtain a signed copy of the Research Consent. The survey tools do not have any place for names or other identifying numbers.

5. Please complete the following questions regarding data storage:

a. How will the data be collected and recorded? How will the data be coded to protect personal privacy?

Survey research data will be collected on paper and online survey forms and interview/user group notes. No names or identifying numbers will be used on the survey forms or the notes. Because identifying information such as position and clinic are on the survey forms and interview notes, hard copies of the survey forms and notes will be kept in a locked file cabinet. Electronic spreadsheets and databases with research data will be password protected. Sign-in sheets for the training and user groups will be kept by the trainers and separated from the research data

PROPOSED RESEARCH PROTOCOL

b. How will the data be stored during the study?

As noted above, paper records will be stored in a locked file cabinet and kept in the office of the Project Manager. All survey research data entered into an electronic spreadsheet or database will be stored on the hard disk of the CCCN computer and backed up on the project server. The CCCN computer is password protected. In addition the survey databases and spreadsheets will have a separate password.

c. Who will have access to the data and the data codes? If data with subject identifiers will be released, specify the person(s) and agencies to whom this information will be released.

Only the CCCN staff will have access to the research data and information. The Project staff, which includes the Principal Investigator, Project Manager, IT and Training Team, will have access to the survey and interview/user group data for purposes of project improvement and analysis. There are no data codes or subject identifiers on the survey forms or user group notes.

d. What will happen to the data when the study is completed?

All paper data will be destroyed at the end of the Project. The password protected electronic databases and spreadsheets will be the property of the Principal Investigator.

Risk / Benefit Assessment

6. Potential Risks and Discomforts: Describe any potential risks or likely adverse effects of the drugs, biologics, devices or procedures subjects may encounter in the study. State the potential risks – physical, psychological, social, legal or other – connected with the proposed procedures and assess their likelihood and seriousness.

There is no human subjects treatment with drugs, biologics, devices or procedures as a result of this Project. The patient care portion of this project involves the use of evidence-based diabetes care standards adopted by national (American Diabetes Association; Centers for Disease Control) and California organizations (California Diabetes Prevention & Control Program; Diabetes Coalition of California) with consultation to

PROPOSED RESEARCH PROTOCOL

appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subject. Where appropriate describe the provisions for monitoring the data collected to ensure the safety of the subjects.

The research protocols preclude the identification of any individual provider or clinic/office. These measures will eliminate any potential risks to the study population.

9. Has a Data Safety Monitoring Board been established to review data/adverse events related to this study? Yes No

Although there is no specific Data Safety Monitoring Board for this Project, The CCCN Steering Committee serves in this role. The CCCN Steering Committee charter includes oversight of the registry to ensure complete compliance with privacy and security regulations.

In addition, because of the Steering Committee's concern that the data and information from this Project not be used by any partner organization for competitive advantage, the Steering Committee's job is to establish project protocols and report guidelines that will not allow identification of a specific provider, clinic or office.

a. If yes, identify the DSMB involved in this study and describe plans for monitoring adverse events.

Not applicable

b. For multi-site studies, describe the mechanism in place for distributing DSMB reports to all participating investigators for submission to their local IRBs. (PIs must submit a written summary of the DSMB periodic review to their IRB.

Not applicable.

10. Risk/Benefit Ratio

a. Describe the potential benefits the subjects may receive as a result of their participation in the research and what benefits to society may be expected.

The primary benefit for providers of participating in the research component of this Project is the development of a diabetes registry "with sensibilities to local issues and values." (National Institute for Health Care Management. Advancing Health Information Technology, December, 2004.) The potential benefits for providers of the successful implementation of a community-wide diabetes registry include:

- Clinical information system with accurate information for patients with diabetes
- Development of a prepared, proactive practice team for diabetes care management
- Consistent standard of practice throughout the community
- Transition to an interoperable electronic health record
- High performance practice which can respond to payer performance incentives

For the person with diabetes, the successful implementation of a community-wide registry will improve the providers' ability to assist the patient with glucose control and the resulting reduction in the complications of diabetes. A community-wide diabetes registry will also benefit the patient by creating a method to create a portable medical record while assuring privacy of personal health information.

PROPOSED RESEARCH PROTOCOL

b. Next, consider and describe whether those benefits outweigh the risks, compared with available alternatives?

The potential benefits of the research must justify the risks to human subjects. The risk/benefit ratio of the research must be at least as favorable for the subjects as that presented by standard treatments for their condition. When comparing the risk/benefit ratio of research with that of available alternatives, the alternative of doing nothing should be included in the analysis.

As described above the risks of the CCCN research project to the providers are minimal. On the other hand, the potential benefits to the providers and to persons with diabetes are substantial. In this research, the benefits clearly outweigh the minimal risks. There is no patient experimentation and there are no risks to the patient population.

Informed Consent

11. Process of Consent: Please discuss how the consent process will be conducted, describing the following elements:

a. Who will administer the consent process;

The Training Team, Project Manager, and IT Lead will administer the Research Consent.

b. The environment and location where the informed consent will be solicited;

The research consent will be administered at the provider site at the start of a training session, interview, or user group.

c. Opportunities for the potential subjects/parents to discuss their participation with family or others before signing the consent form;

Not applicable.

d. Adequate provisions are made for soliciting the assent of child research subjects, when they are capable of providing assent; and

Not applicable.

e. Translations of consent forms to other languages.

Not applicable.

12. Information Withheld from Subjects: Will any information about the research purpose and design be withheld from subjects? If so, please explain the non-disclosure and describe plans for post-study de-briefing.

Not applicable.

Investigator's Assurance

Investigator's Assurance

I certify that the information provided in this application is complete and correct. I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human subjects, conduct of the study, and the ethical performance of the project. I agree to comply with all ASR policies and procedures, as well as with federal, state, and local laws regarding the protection of human subjects in research, including but not limited to the following:

- The research will be performed by qualified personnel
- No changes will be made in the protocol or consent form until approved by the IRB
- Informed consent will be obtained from human subjects unless otherwise waived in this protocol
- Any adverse events or effects relating to the research will be reported to the IRB in a timely manner.

I further certify the proposed research is not currently ongoing and will not begin until IRB approval for this exemption has been obtained.

Principal Investigator

Date

IRB Chair or Designee

Date

Statement of Financial Interest

By their signatures below, each investigator is certifying that either no financial interest exists or that a complete listing of all financial interests related to the proposed project is provided. All individuals named below further acknowledge their responsibility to disclose any new reportable financial interest obtained during the term of the project. The Principal Investigator's signature also certifies that all individuals required to make disclosures have been listed below:

Do you, your spouse, or dependent children, have a financial interest in the work to be conducted under the proposed project?

1. _____ NO YES, Attach Financial Disclosure Form (Attachment 1)
Signature of Principal Investigator Date
2. _____ NO YES, Attach Financial Disclosure Form
Signature of Co-Investigator #1 Date
3. _____ NO YES, Attach Financial Disclosure Form
Signature of Co- Investigator #2 Date



IRB FORM 4

REQUEST FOR EXPEDITED REVIEW

<i>REQUEST FOR EXPEDITED REVIEW</i>	
Principal Investigator:	Wells Shoemaker MD 2880 Soquel Ave, Suite 1 Santa Cruz, CA 95062 wshoemaker@pmgsc.com
Co-investigators:	
Project Title:	Santa Cruz County, CA Diabetes Mellitus Registry (DMR)
<p>Requesting Expedited Review: Federal regulations provide that certain types of research may be considered for review through an expedited process. A primary criterion is that the research be of minimal risk only.</p> <p>Expedited review refers to a review method, not an abbreviated or simplified protocol submission. Accordingly, the first step in requesting expedited review is to complete the protocol package in full. In addition, the investigator must complete and submit this form. In the event that the IRB Chair, or his or her designee, determines that the project is not eligible for expedited review, the protocol will be reviewed by the full IRB.</p> <p>Expedited review categories – Please check all that apply. In order to determine whether a research project qualifies for expedited review, the details of the protocol must indicate that the research activities fulfill requirements A, B, and C. In order for the IRB to consider a protocol for expedited review, please check all that apply.</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> The research activity poses no greater than minimal risk to subjects. <input checked="" type="checkbox"/> The identification of the subjects and / or their responses would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject’s financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that the risks related to invasion of privacy and breach of confidentiality are no greater than minimal. <input checked="" type="checkbox"/> Research is measuring individual or group characteristics or behavior (including, but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research is conducted using surveys, interviews, oral histories, focus groups, or quality assurance methodologies. (Note: Some research in this category may be exempt from IRB review. This application pertains only to research that is not exempt.) 	

Expedited Category Rationale:

The Santa Cruz County, CA Diabetes Mellitus Registry Project meets the criteria for an Expedited Review.

1. The research is measuring group adoption of an evidence-based clinical improvement tool and is limited to measures of healthcare provider satisfaction, attitudes and barriers to adoption. The research is conducted using surveys and user groups and is based on PDSA quality improvement methodology.
2. Names of healthcare providers participating in the research will not be identified on the research tools and notes. Safeguards are in place to prevent unauthorized access to the raw survey and interview data. Reports to the local community, to funding agencies and publications included on the Internet will not identify individual providers, clinics or offices.
3. The research activity poses only minimal risk to the provider participants. The risk of identification of individuals and/or specific clinics/offices has been addressed by the confidentiality protection built into the research study. Although all efforts will be made to scrupulously avoid a breach of provider confidentiality, if such a breach occurred, individual providers would not be significantly harmed.