

Creating the Colorado Clinical Trials Network

Submitted to: C-Change

Submitted by: University of Colorado Cancer Center

**In Collaboration with:
Colorado Department of Public Health and Environment
Colorado Cancer Coalition
Rocky Mountain Cancer Centers
Colorado Cancer Research Program**

May 9, 2005

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Creating the Colorado Clinical Trials Network

Currently three major oncology organizations offer clinical research trials to adult cancer patients in Colorado: University of Colorado Comprehensive Cancer Center (the NCI-designated Cancer Center for Colorado), the Colorado Cancer Research Program (the NCI-designated Community Clinical Oncology Program for Colorado), and the Rocky Mountain Cancer Centers (the largest private oncology practice in Colorado). These three organizations now offer complementary access to clinical trials in Colorado. Though the three organizations have not been highly competitive for trials or patients, and though the leadership of these organizations has been very collegial (especially through the Colorado Cancer Coalition activities), there has never been a concerted effort to create collaboration or to design synergistic activities.

This application describes the commitment of these three organizations, in partnership with the Colorado Department of Public Health and Environment's Comprehensive Cancer Program, to designing and implementing a program of collaboration intended to increase participation in clinical trials across Colorado. This application will describe how we intend to work together to develop a means of sharing information and improving access to all relevant clinical cancer studies for all adult cancer patients in Colorado. We will create a Colorado-wide network of sites and practices that provide/conduct cancer clinical trials, we will increase cancer clinical trials accrual by all three organizations, and we will create multiple, user-friendly channels for patients and physicians to find information about cancer clinical trials in Colorado.

Section I - Colorado and Comprehensive Cancer History and Planning Process

Cancer is the second leading cause of death in Colorado as it is in the U.S. Colorado is one of the first states to have secured CDC funding to develop and implement a comprehensive cancer plan and program. The state of Colorado has a sincere commitment to improving cancer control for its citizens, which is demonstrated by the Colorado Cancer Coalition and the Colorado Cancer Plan. This section will describe the Colorado Cancer Plan as well as the Colorado Cancer Coalition, the organization that implements the Plan in collaboration with the Comprehensive Cancer Program as a program of work.

Cancer control activities in Colorado are guided by the Colorado Cancer Coalition (CCC)(Attachment), which coordinates the efforts of the many Colorado agencies involved in cancer control; promotes cancer prevention activities; identifies barriers to appropriate screening, diagnosis, treatment, and after-care; and serves as a basis for coordinating funding opportunities for services and programs. This CCC plan lays out goals, objectives and suggested strategies to reduce cancer mortality, increase surveillance activities, increase primary and secondary prevention efforts, and address the availability of appropriate cancer treatments. In order to achieve our goals, the Plan defines strategies to fight cancer in a coordinated approach, forming a partnership between private and public organizations. In order to achieve our goals, Colorado must continue the fight against cancer in a coordinated approach.

The Colorado Cancer Coalition (CCC) implements the Plan as a program of work. Coalition membership (Attachment A) is engaged as a broad representation of public and private health agencies, academia, insurers, professional societies, community groups, policy makers, and consumers in a variety of efforts. The CCC represents over 129 organizations and 336 individuals from the broad areas of research, prevention, screening, diagnosis, treatment, rehabilitation, survivorship, palliative care, and end of life care services that exist in Colorado. The CCC meets to formally review current Colorado Cancer Plan priorities, discuss policy issues, educate one another about existing programs, and create programmatic partnerships where gaps in service exist. (Attachment B). A key feature of the Colorado Cancer Plan which the CCC has not yet fully addressed is the improved access to Phase II and Phase III cancer clinical trials for all afflicted citizens of Colorado. Colorado's Cancer Plan 2005 is congruent with the C-Change

RFA as it includes specific objectives and strategies to increase awareness and accruals in clinical trials as outlined below.

OBJECTIVE 1.4 - To increase knowledge of ongoing clinical trials in chemopreventive measures for persons at high risk of cancer.

Strategies:

- Disseminate information on clinical trials, e.g., via the National Institutes of Health website on clinical trials of cancer chemoprevention;
- Promote how to access clinical trials in Colorado through:
University of Colorado Comprehensive Cancer Center
Colorado Cancer Research Program; and,
- Support training mechanisms, which will increase public and health care providers' knowledge about clinical trials.

Objective 4.5- To facilitate increased participation in clinical trial protocols.

Strategies:

- Ensure ready access to cancer treatment, prevention, and control clinical trials through the NCI-affiliated clinical trials organizations in Colorado, the Colorado Cancer Research Program (CCRP) and the University of Colorado Comprehensive Cancer Center (UCCC);
- Review current health insurance legislation and insurance efforts for provisions that promote coverage of the National Cancer Institute-approved clinical trials and state-of-the-art therapies;
- Promote the advantages of clinical trials participation; and,
- Enhance awareness of the clinical trials through the Colorado Cancer Research Program (CCRP), a National Cancer Institute (NCI)-supported Community Clinical Oncology Program (CCOP), the University of Colorado Comprehensive Cancer Center (UCCC), an NCI-supported comprehensive cancer center, and the NCI Cancer Information Service.

Objective 5.1-To continue efforts of the Colorado Cancer Coalition, a public-private collaboration that focuses on comprehensive cancer prevention and control.

Strategies:

- Seek funding sources to support the Colorado Cancer Coalition (CCC) and to implement priority strategies of the Colorado Cancer Plan;
- Share programs, resources, and best practices among CCC members; and
- Hold an annual Colorado Cancer Conference to share best practices, increase skills, and commence new initiatives throughout the state.

Objective 5.3 -Monitor and coordinate cancer control and quality-of-life activities in Colorado.

Strategies:

- Establish an online information service for cancer control in Colorado;
- Continue to maintain and expand the Colorado Cancer Coalition, enhancing its value, membership, and efficacy; and
- Keep apprised of, and disseminate information on, the activities of organizations engaged in implementing or supporting cancer control and quality-of-life activities in Colorado.

Section II - Current Plan to Increase Statewide Access to Clinical Trials

The University of Colorado is the largest state funded institution of higher education in Colorado. The University is comprised of campuses in Boulder, Denver, and Colorado Springs and includes the main undergraduate and graduate campus in Boulder (UCB); the University of Colorado at Denver and Health Sciences Center (UCDHSC) consolidated into a single entity in 2004 and is now located on three campuses (the original HSC campus in Denver, the new HSC campus in Aurora, and the downtown Denver campus); and the mostly undergraduate campus is located in Colorado Springs (UCCS).

The University of Colorado Comprehensive Cancer Center (UCCCC) was founded in 1998 and received Comprehensive Cancer Center status from NCI in 1997. The UCCCC has served as a catalyst for the growth of multidisciplinary cancer research and education programs based at UCDHSC, where the four professional schools (Schools of Medicine, Pharmacy, Dentistry, and Nursing) and the Graduate School have significant participation, as well as a number of Denver metro area affiliated institutions, e.g., Denver VA Medical Center, National Jewish Center, Denver Health Medical Center, The Children's Hospital, and the AMC Cancer Research Center. Total peer-reviewed UCCC extramural research funding has grown by 39% over the past five years (FY 1999- FY 2004) at UCCC to \$116,746,236 (\$43,260,410 from NCI) focused on cancer research. Total federal research grants and contracts to the School of Medicine for Academic year 2003 was \$223,530,579, which places CU Medical School at number 15 out of 126 U.S. medical schools in research funding.

Cancer clinical trials are an essential component of UCCC research activities, providing opportunities for cancer patients to receive promising new therapies, for those at risk to explore chemoprevention strategies, and to serve as a conduit for translation of UCCC laboratory findings into clinical applications. Information about UCCC cancer clinical trials is accessible from its website (www.ucc.info) as well as by contacting listed coordinators for the various disease sites and other links from the UCCC website. An integral component of UCCC since its beginning in 1987, the Clinical Investigations Core (CIC) has continued to increase dramatically in the number of active protocols, protocol accruals, clinical investigators, participating sites, and dedicated managers and study coordinators. Currently UCCC offers more than 300 clinical cancer trials, with 67 principal investigators supported by more than 50 study coordination and administration staff. Therapeutic and chemoprevention accruals have increased by 440% over the past 15 years, and 251% over the past five years; total accruals have increased 36 fold over the past 15 years, and more than doubled over the most recent five years. With the continued expansion of clinical facilities, ongoing investigator recruitments, expansion of multi-center leadership in clinical trials, enhancement of the Clinical Trials Database with integration of financial aspects of trial management, development of robust quality assurance programs and creation of regulatory and finance teams, we anticipate continued increases in enrollments to UCCC clinical trials over the next five years as well.

UCCCC investigators have been particularly active in clinical trials design and recruitment. Approximately 20% of newly-diagnosed adult cancer patients cared for at the UCCCC are now enrolled into clinical trials. UCCCC investigators have also been active in clinical trials education and innovation. The SELECT, NLST, and PLCO clinical trials centers at the UCCCC have been among the most successful of all the national centers for these landmark NCI trials, especially in area the minority recruitment in the community. Dr. Linda Krebs has carried out community clinical trials education programs under a NCI-funded education grant, as has Dr. Estevan Flores, as part of his Hispanic community cancer network efforts.

The UCCC interacts with outside institutions on local, regional, and national levels. The community outreach program has several affiliation mechanisms. Hospitals may become affiliated with UCCC through the Southwest Oncology Group Cooperative Group Outreach Program (CGOP) or may also be permitted to participate in other UCCC studies as primary affiliates. Participants are shown in the table below. UCCC has already established a formal consortium agreement with the Rocky Mountain Cancer Centers (RMCC) for selected clinical cancer trials. Sites outside the Denver metro area currently include Colorado Springs, Montrose, Glenwood Springs, and Fort Collins. UCCC cancer clinicians travel to Colorado Springs, Montrose, and Glenwood Springs as part of the UCCC effort to extend oncology care and access to clinical trials to other areas of Colorado. These affiliate sites outside the metro area have provided CRC support for the UCCC cooperative group and selected other Phase II and Phase III trials.

Madeleine A. Kane, MD, PhD, Professor of Medical Oncology and Principal Investigator for this proposal, is the medical Director for the UCCC Clinical Trials Program. In this position she can facilitate communication with the other participating oncology organizations, encourage membership of oncology groups without ready access to cancer clinical trials, and support the use of NCI Central IRB as the approving IRB for cooperative group and NCI-sponsored trials as a means to facilitate ready sharing of access to clinical trials among these organizations. She will also work closely with Timothy Byers, MD, MPH, Professor of Preventive Medicine at the University of Colorado School of Medicine, and an executive committee member of the Colorado Cancer Coalition, to champion the Colorado Cancer Clinical Trials Network.

UCCC Sites in Colorado for Cancer Clinical Trials

	Community Affiliates
Anschutz Cancer Pavilion (Aurora)	Lutheran Medical Center (West Denver)
University of Colorado Hospital - 8 East (Denver)	Rocky Mountain Cancer Center (Central Denver)
General Clinical Research Center (Denver)	
Denver Veterans Administration Medical Center (Denver)	The Oncology Clinic (Colorado Springs)
Denver Health and Hospital Authority (Denver)	Montrose Memorial Hospital (Montrose)
The Children’s Hospital (Denver)	Valley View Hospital (Glenwood Springs)
National Jewish Medical and Research Center (Denver)	Poudre Valley Medical Center (Fort Collins)

The Colorado Cancer Research Program (CCRP) is a NCI -approved “Community Clinical Oncology Program” or CCOP since 1984. As a CCOP, the CCRP delivers its mission to advance cancer research through the conduct of cancer clinical trials. Clinical trials test for better ways to treat, control, and even prevent cancer. CCRP’s presence in the community has meant access to clinical trials research in the form of national cancer clinical trials sponsored by the NCI directly to the physicians and patients in the community - physicians and patients - ensuring local access to national cancer clinical trials sponsored by the NCI. CCRP is affiliated with the following Cooperative Groups that serve as part of the national clinical trials network of research bases that design and develop oncology protocols: Eastern Cooperative Oncology Group (ECOG); National Surgical Adjuvant Breast and Bowel Project (NSABP); University of Rochester Cancer Center (URCC); North Central Cancer Therapy Group (NCCTG); Mayo Clinic Consortium; and the NCI Clinical Trials Support Group (CTSU). CCRP’s network includes 12 community hospitals and 117+ community physicians who participate in clinical trials. This local participation, while providing cancer patients with the most advanced cancer care medicine, helps to accelerate the advancement of the research. CCRP’s network serves (primarily) the Front Range, where approximately 65% of state’s population resides. CCRP affiliated physicians are NCI-approved and must have human subjects training certification. These physicians are private practitioners that include RMCC affiliated and Kaiser Permanente Colorado physicians. CCRP enrolls approximately 350 adults per year

onto treatment, symptom control, and prevention clinical trials. CCRP was 1 of 200 approved sites enrolling Colorado women onto the NSABP's STAR breast cancer prevention trial. For five years, the CCRP remained in the top 5% of enrolling sites to the STAR trial.

Throughout the past four years, CCRP has committed continued efforts to increase clinical trials participation. Participation includes physician participation as well as human subjects' participation. These subjects include individuals diagnosed with cancer or are at increased risk for developing certain cancers. In 2001, CCRP conducted a comprehensive survey among its 100+ CCRP physicians, their clinic staff, and of a variety of primary care physicians. This survey was completed to assess barriers, challenges, and successes in participation of cancer clinical trials. The response rate averaged between 85% among primary care providers to 90% by physicians and clinic staff. In 2004, CCRP developed a comprehensive plan to implement a broad educational & marketing campaign to increase clinical trials awareness. CCRP is seeking funds to conduct that campaign. In January 2005, CCRP participated in the C-Change Survey (Study of Phase II and Phase II Cancer Clinical Trials, their Functional Requirements and Costs) with the intent to help improve understanding of the complex and frustrating elements in conducting clinical trials. From March through April 2005, CCRP has been providing input to a major NCI-driven effort, the Clinical Trials Working Group. This equally impressive group is now submitting final recommendations that will improve the scientific implementation and delivery of NCI-sponsored clinical trials.

Eduardo Pajon, MD, Director, CCRP, has re-energized the efforts of the CCRP in Colorado. He is an active and effective leader with wide-ranging community oncology ties from his years of oncology practice. He currently works at the Denver VAMC as a staff hematologist/oncologist, where he interacts closely with Dr. Kane, Chief, Medical Oncology.

Rocky Mountain Cancer Centers (RMCC) was formed in 1997, and has since become the largest community based oncology research program in Colorado. Because RMCC is committed to providing the best available care to all of our patients, research is and will continue to be the cornerstone of the organization. RMCC currently supports a comprehensive research program to provide new and exciting therapeutics to all patients with all types of cancer, within their own communities. The staff at RMCC currently provides patient care in 24 different out patient settings across Colorado and surrounding rural communities.

The RMCC research program currently consists of Phase I-III clinical trials, actively participating in over 80–100 clinical trials per year. Since 1999, more than 1,600 patients have been involved in some type of clinical research study. Approximately 500 patients each year elect to participate in the research program, the majority of these in Phase II and III clinical trials. Through the unique community-based practice and strong affiliations with other research entities such as pharmaceutical sponsors, US Oncology, Colorado Cancer Research Program (CCR) and academic centers including UCCC, Dana Farber Cancer Institute, and others, RMCC has been able to achieve access to numerous clinical trials with the ability to bring these clinical trials to our patients in many community settings across the state.

Participating in clinical research requires special dedication on the part of RMCC doctors, research staff, nurses, and business staffs. RMCC's research program has 56 participating physicians and currently supports 24 full-time employees, including 17 dedicated research nurses. RMCC's participation in clinical research trials exemplifies the staff's dedication to improving the quality of care and therapeutic options available for patients. These protocols often represent state-of-the-art treatments that, up until recently, had only been available to patients that were willing to travel to large academic centers. RMCC has continually demonstrated a strong and lasting commitment in support of clinical trials and their availability to patients in all communities.

Allen Cohn, MD, Chairman, RMCC Clinical Research, Chairman of national GI Committee for US Oncology Research, and Clinical Associate Professor, UCCC, will facilitate the implementation of the CCTN for RMCC. He was recruited to RMCC from UCCC and has worked closely with faculty at UCCC, including Dr. Kane, on collaboration on cancer clinical trials, and was instrumental in realization of the formal UCCC-RMCC Consortium.

Section III - Use of C-Change Funding to Increase Access and Accrual

As described in Section II above, Colorado has three outstanding systems for clinical trials. Although these three systems are collegial, they are not yet designed to be complementary or collaborative in an overall mission to increase adult cancer clinical trial accruals across Colorado. This proposal defines a plan to increase our collective infrastructure to build the coordination and information sharing needed to increase awareness and accrual in Phase II and III clinical trials in Colorado.

The initial development phase comprises the first nine months of the 18-month grant and the second nine months is focused on implementation of the new statewide network for cancer clinical trials. Colorado will utilize the C-Change funding to establish a new coordinated information and delivery network that builds upon the foundation laid by the Colorado Cancer Coalition, the Colorado Cancer Plan 2005, and the three existing networks in Colorado (the University of Colorado Comprehensive Cancer Center, the Colorado Cancer Research Program, and the Rocky Mountain Cancer Centers). Additional population areas with oncology centers (Durango and Grand Junction) will be recruited into the network. We propose to create a Colorado Cancer Clinical Trials Network as described below.

Phase 1 – Development: Create a Colorado-wide network of sites and practices that conduct cancer clinical trials

The development phase will focus on five key objectives.

1. Build organizational capacity
2. Build a coordinated information and delivery network
3. Enhance the Colorado Cancer Coalition's existing website to serve as the statewide network
4. Design a public awareness campaign aimed at distinct audiences (patients, community oncologists, cancer treatment centers)
5. Establish system to measure impact and outcomes

Objective 1 – Build organizational capacity of the Colorado Cancer Clinical Trials Network

The organizational capacity required to successfully design and implement this statewide network and ensure its ongoing sustainability includes several key roles as described below.

- **Lead Agency (Applicant for the Grant)** – The University of Colorado Cancer Center will lead this collaborative activity. *Madeleine Kane, MD and Tim Byers, MD will lead the effort for the UCCC. Dr Kane will serve as the principal investigator for this grant.*
- **Executive Oversight Committee** – The Executive Oversight Committee will have the following responsibilities.
 - Oversight of multi-site coordination and regulatory compliance
 - Identification of cancer clinical trials to be shared throughout the network
 - Facilitate CIRB application process

- Disseminate information about the CCTN to cancer care providers and citizens of Colorado
- Review accruals throughout the network
- Devise informational and resource need assessment strategies to enhance accruals throughout the network

The committee will meet regularly during the implementation phase to assist in building buy-in to the statewide network and establishing the memorandums of understanding. This committee may elect to utilize sub-committees to accomplish its work in a timely manner, on topics such as the MOUs, website and public awareness campaign. *The committee will be comprised of five to 10 representatives from the Colorado Cancer Coalition (including the existing networks and state health department, community oncology, a physician representative and a patient representative).*

- **Project Manager** – This individual will be responsible for managing the overall project, including submission of reports to the grantor (Lessons Learned Reports and Quarterly Progress Reports), facilitating regular meetings of the Steering Committee and sub-committees as needed, facilitating a process to establish the memorandums of understanding, coordinating with the state health department and existing networks, working with consultants needed to staff the project, and overseeing the project schedule and deliverables. *Karla Raines, Vice President of Corona Research, will serve as Project Manager.*
- **Clinical Trials Expert** – Dr. Madeleine Kane will serve as the project champion, work closely with the Project Manager, and provide subject matter expertise on cancer clinical trials, Internal Review Boards (IRBs), and other health issues.
- **Existing Networks** – The three existing networks (Colorado Cancer Research Program, Rocky Mountain Cancer Centers, and University of Colorado Comprehensive Cancer Center) will play an active role in making the case for a coordinated statewide network to the IRBs and in the design of that network. The more widespread use of the NCI Central IRB will be a focus of these efforts. *Joni Newman, Tomiko Takeda, and Andrea Buchmeier will serve as administrative liaisons to the existing networks.*
- **Liaison to the Colorado Cancer Plan** - Colorado Department of Public Health and Environment (CDPHE) coordinates the work of the Colorado Cancer Coalition and is charged with updating the cancer plan. The designated individual will provide linkage to the current plan and update it to reflect changes resulting from this grant. *Sara Miller, Director of the Comprehensive Cancer Prevention and Control Program at CDPHE, will be the liaison to CDPHE.*
- **Consultants** – Consultants will be used to design and implement the website and create the public relations campaign. Additionally, a research firm will be retained to gather and analyze the pre- and post-implementation data for this grant. *Klein Buendel, developer of the Colorado Cancer Coalition’s new website will design the new website pages. The public relations consultant will be selected upon grant award. Corona Research will serve as the research evaluator for this project.*
- **Fiscal Agent** – The designated fiscal agent will process payments for services to agency staff and contractors and provide regular financial records to the Project Manager. *The University of Colorado Cancer Center will serve as fiscal agent for this project.*

Once the Executive Oversight Committee has been established, and stakeholders identified, then an informational retreat/workshop will be held to orient everyone to the project and its key tasks in order to build support for the successful creation of the network. In addition, the Executive Oversight Committee, Clinical Trials Expert and Project Manager will play active roles in building buy-in through a series of

meetings early in the development phase, with the intent of entering into memorandums of understanding (MOUs) among key players on issues of collaboration, shared trials and use of the NCI CIRB.

Objective 2 - Build a coordinated information and delivery network

Colorado's coordinated information and delivery network is built upon seven key components, beginning with strengthening and expanding the network of clinical trials providers to creating a shared database and reviewing accrual data from the network. Each of these eight components is described in more detail below.

1. The first step in building the statewide network is to strengthen the collaboration between the three existing networks (UCCC, RMCC and CCRP). This will include determining the logistics involved in collaborating and identifying the barriers to collaborating and possible solutions with the aim of sharing access to relevant studies.
2. Next, the network of providers can be expanded to include rural oncology affiliates and other large groups such as Kaiser Permanente. The network will need to assess the needs of rural oncology affiliates for CRC support of clinical trials and establish affiliations with and cancer clinical trial access for the oncology groups in Durango and Grand Junction. The network will also invite the participation of the Kaiser Permanente oncology group.
3. Once the statewide network of providers has been created, then attention will shift to identifying the cancer clinical trials to be shared throughout the network.
4. Colorado also needs to establish an effective means of obtaining full IRB approval for shared studies. In some cases this may be to collectively use NCI CIRB for appropriate Phase III studies with the current IRBs accepting CIRB as IRB of record. This mechanism is in place and successfully utilized at UCCC via its IRB, Colorado Multiple Institutional Review Board (COMIRB), for cooperative group and other NCI-sponsored peer-reviewed studies through the Clinical Trials Study Unit (CTSU). Where necessary, memorandums of understanding (MOU) will be established between the IRBs and the Colorado Cancer Clinical Trials Network.
5. A shared database will be created for entry of clinical trial data. This will include a mechanism for retrieving summary information on accruals from the database of the organization that is the primary trial sponsor.
6. It is important to identify strategies to enhance accruals throughout the network. These strategies will be identified through an informational and resource needs assessment of network members. The findings from that assessment will be incorporated into the website and public awareness strategies described later in this proposal.
7. After the network has been established, shared trials identified, and a cooperative IRB process established, Colorado will need to ensure ongoing multi-site coordination and regulatory compliance. This will be a focus of the Executive Oversight Committee and Clinical Trials Expert.

Objective 3 - Enhance the Colorado Cancer Coalition's existing website to serve as the statewide network

The Colorado Cancer Coalition is currently developing a website (www.coloradocancercoalition.org) which will be enhanced to serve as a coordinated information and delivery network for clinical trials.

This website will provide linkages between cancer treatment centers, support groups, national websites such as clinicaltrials.gov, community oncologists, and patients in order to increase awareness and accrual of clinical trials. The website will also be a source of information for patients and oncologists, including information such as a listing and description of open trials. The initial design of the enhanced site will be completed during the development phase.

Objective 4 - Design a public awareness campaign aimed at distinct audiences (patients, community oncologists, cancer treatment centers)

An important element of increasing awareness and accrual in cancer treatment trials is enhanced public awareness about trials, especially among the general public and cancer patients. Past surveys and studies, such as the one conducted by Harris Interactive, have indicated that lack of awareness and understanding of clinical trials has impacted the enrollment of new patients. Others have rejected the opportunity to be in clinical trials due to fear. The ongoing success of the Colorado Cancer Clinical Trial Network depends upon increased awareness among the three key constituents in the clinical trials process: patients, community oncologists, and cancer treatment centers. A public awareness campaign will be designed to increase awareness in general and educate key constituents about the new coordinated information and delivery network. It will also disseminate information about the CCTN to cancer care providers and citizens of Colorado. Some new strategies might include appearances on radio or local TV talk shows and CCTN phone information access.

Objective 5 - Establish system to measure impact and outcomes

Colorado is committed to measuring the difference made by this new comprehensive system. Part of this commitment will be realized through the submission of the Lessons Learned reports, which will document process outcomes as of March 2006. Interviews will be conducted with key players to ascertain what worked well, what did not work well, and identify any suggestions for improvement. The project will also gather baseline data to measure increased access and awareness. This data will be obtained by network members (accrual) at the beginning of the project. It will be important to share these various outcomes with key stakeholders to secure ongoing buy-in to the project as well as continued financial support.

Phase 2 – Implementation: Increase cancer clinical trials accrual

The development phase will focus on six key objectives.

1. Maintain organizational capacity
2. Maintain the coordinated information and delivery network
3. Launch and maintain website
4. Launch public awareness campaign
5. Gather and analyze pre- and post-implementation data
6. Secure ongoing funding as needed

Objective 1 - Maintain organizational capacity

The Project Manager, Clinical Trials Expert, and Steering Committee will meet at least every other month during the implementation phase. These meetings will serve to update the committee on implementation activities, such as the launch of the website and public relations campaign, and ask for their advice and guidance on any challenges that have emerged. If a challenge emerges that requires more active engagement of the committee, such as an IRB no longer honoring its MOU, then the committee will be called upon for timely assistance. The Project Manager will continue to engage in regular communication

with the Clinical Trials Expert and Steering committee. In addition, regular status reports will be provided to C-Change, the Steering Committee, and other key players.

Objective 2 - Maintain the coordinated information and delivery network

The Cancer Clinical Trial Network will need to focus some of its energy on maintaining the network itself. This includes:

- Providing resources to support CRC effort at sites which have need;
- Coordinating oversight of trial conduct; and
- Entering clinical trial and subject specific information into a shared database.

These tasks will be the responsibility of the Medical Coordinator and Project Manager. When necessary, these individuals will ask for assistance from the Executive Oversight Committee and its members.

Objective 3 - Launch and maintain website

The website's new pages will be built during the first two to three months of the implementation phase and then the enhanced site will be launched. Once the site has been launched it will be hosted by a reliable provider and maintained by the design firm.

Objective 4 - Launch public/professional awareness campaign

The public relations campaign designed during Phase 1 of the project will be implemented in Phase 2. This campaign will seek to raise the consciousness of the Colorado citizenry about the importance of cancer clinical research, and will likely consist of public service announcements, earned media (via press release rather than paid media), and education and outreach sessions to physicians. The campaign will also focus on getting the word out about the new website prior to launch.

Objective 5 - Measure impact and outcomes

It will be important to measure the overall impact that this project has made in Colorado and begin to measure outcomes. Possible process outcomes that could be measured for this project include the establishment of the coordinated network via the website (i.e. every website in Colorado links into new website), the launch of the public awareness campaign (i.e. hosted X # educational forums around the state), updating of the Colorado Cancer Plan 2005 to incorporate the new changes, and the establishment of MOUs among IRBs and existing networks. The final Lessons Learned report will again use interviews with key players to ascertain what worked well, what did not work well, and identify overall lessons learned and issues for the future.

Colorado will also gather and analyze data on clinical trial accruals as provided by network members. Possible program outcomes measures include website hits, internal inquiries about clinical trials and clinical trials participation. Both of these outcomes would provide an indication of the general public's response to the public awareness and education campaign, as well as the effectiveness of the coordinated network and enhanced website.

This analysis will compare the baseline data obtained at the beginning of Phase 2 with that collected at the end of Phase 2. The grant applicant recognizes that true outcomes are long-term in nature and that initial data gathered during the nine-month implementation phase will provide a baseline at most. Additionally, this initial data may indicate where additional public awareness is needed across Colorado.

Objective 6 - Secure sustainable funding

One of the reasons that Colorado has chosen to implement an enhanced website through the C-Change grant is that it will require more substantial funding for design and start up, and should be relatively inexpensive to maintain once the online network has been established. Likely funding sources to sustain the network once it has been implemented include the state's recent tax increase in tobacco sales tax as well as other private foundations with a commitment to a healthy Colorado. The Project Manager and Steering Committee will identify new funding sources during Phase 2 with the goal of securing sustainable funding by November 30, 2006.

Section IV - Timeline for Project

Phase 1 – Development (July 1, 2005 – March 31, 2006)

Objective 1 – Create organizational capacity

07/05	Convene Steering Committee
07/05	Hire Project Manager
07/05-03/06	Coordinate with CDPHE and existing networks
07/05-10/05	Oversee selection of consultants
07/05-03/06	Oversee project schedule and deliverables
07/05-03/06	Submit Quarterly Progress Reports to C-Change, Steering Committee
08/05	Update Colorado Cancer Plan
08/05-03/06	Facilitate regular meetings of the Steering Committee
08/05-03/06	Facilitate sub-committee meetings as needed
10/05	Hold an information retreat for committee and stakeholders

Objective 2 - Build a coordinated information and delivery network

07/05-11/05	Facilitate process to establish CIRB
08/05-09/05	Strengthen collaboration between three existing networks
08/05	Hold meeting at the state comprehensive cancer meeting
10/05-11/05	Expand network to include other providers (i.e. rural, Kaiser)
12/05-02/06	Identify possible shared clinical trials
01/06-03/06	Create shared database
01/06-03/06	Identify strategies to enhance accruals via needs assessment
03/06	Ensure ongoing multi-site coordination and regulatory compliance

Objective 3 - Enhance existing website

12/05-03/06	Design new web pages with input from Steering Committee and others
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Objective 4 - Design a public awareness campaign

12/05-03/06	Create public awareness campaign and plan
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Objective 5 - Establish system to measure impact and outcomes

10/05-12/05	Identify current data sources
01/06-03/06	Create data collection and monitoring procedures

Phase 2 – Implementation (April 1, 2006 – December 15, 2006)

Objective 1 - Maintain organizational capacity

04/06-12/06	Facilitate regular meetings of the Steering Committee
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04/06-12/06 Address emerging issues/challenges as needed
04/06-12/06 Facilitate sub-committee meetings as needed
04/06-12/06 Coordinate with CDPHE and existing networks
04/06-12/06 Work with consultants
04/06-12/06 Oversee project schedule and deliverables
04/06-12/06 Submit Quarterly Progress Reports to C-Change, Steering Committee

Objective 2 – Maintain the coordinated information and delivery network

04/06-11/06 Provide resources to support CRC efforts at sites which have need
04/06-11/06 Coordinate oversight of trials
05/06-11/06 Enter clinical trial and subject specific data into database

Objective 3 - Launch and maintain website

04/06-06/06 Build new web pages
07/06 Launch enhanced website
07/06-12/06 Maintain site, including tracking of hits

Objective 4 - Launch public awareness campaign

04/06-12/06 Implement campaign

Objective 5 - Measure impact and outcomes

04/06 Gather pre data
04/06-05/06 Analyze pre data
11/06 Gather post data
11/06-12/06 Analyze post data and compare to pre data
12/06 Report findings to Steering Committee
12/15/06 Report Lessons Learned from implementation phase

Objective 6 - Secure sustainable funding

04/06-06/06 Identify funding prospects
07/06-10/06 Cultivate funding prospects
11/06 Obtain long-term commitment from funders

Section V - Detailed Budget and Justification

Section VI - Maintaining the Network

Once the Colorado Clinical Trials Network is established utilizing C-Change Resources, Colorado partners have a strong commitment to maintain this effort using internal resources from the University of Colorado, the Colorado Cancer Research Program, Rocky Mountain Cancer Centers, and the Colorado Department of Public Health (please see attached commitment letters). These Colorado Cancer Coalition partners have also garnered support from many additional organizations (attached letters of support).

Colorado has recently passed a new tobacco tax, which aims dollars and resources towards the implementation of the Colorado Cancer Plan. If this effort proves successful, the organizations will apply for continued support through this revenue source in Colorado. The Colorado Clinical Trials Network partners will also pursue additional support from local foundations in our state including Caring for Colorado and the Colorado Trust. The successful utilization of C-Change resources will enable the Colorado Cancer Coalition to leverage these new resources.

Section VII - Commitment of Applicant regarding Reporting Requirements

The University of Colorado Cancer Center commits to submit the following series of reports to C-Change; 1) Quarterly Progress Reports, due by the 15th of month, following the end of the each quarter; 2) A report on the experiences and lessons learned during the developmental phase of the project, due by March 30, 2006 and; 3) A report on the experiences and lessons learned, during implementation phase of the project, due by December 15, 2006. The partners on the Colorado Clinical Trials Network all recognize that the latter two reports may be distributed by C-Change, to other state governments and stakeholders interested in developing a state clinical trials network. Colorado is committed to assisting other states learn from our experiences and know that we will be a valuable resource as other cancer coalitions strive to implement a comprehensive clinical trials program.

Section VIII - Biographical Sketches of Proposed Staff/Project Members

Biographical sketches or resumes are included in the attachments for the following individuals:

University of Colorado Cancer Center

Madeleine Kane, MD

Tim Byers, MD, MPH

Colorado Comprehensive Cancer Program

Sara Miller, MPA

Colorado Cancer Research Program

Tomiko Tekada, MA

Ed Pajon, MD

Corona Research

Karla Raines, MA

Rocky Mountain Cancer Centers

Joni Newman, RN

Allen Cohen, MD

Andrea Buchmeier

Section IX - Appendices and Attachments

CCC Member Organization List
Current Colorado Cancer Plan
Biographical Sketches/Resumes of Key Staff
Letters of Support
Work Plan

List of Colorado Cancer
Coalition Members



Bringing together and coordinating cancer prevention, early detection, treatment, support, and research efforts to improve the quality of life for everyone in Colorado.

9Health Fair

- | | |
|--------------------------------------------------------|--------------------------------------------------|
| Advanced Health Directions | Colorado State University, Cooperative Extension |
| AMC Cancer Research Center | Colorado Women's Health Campaign |
| American Association of Retired People, Rocky Mountain | Cooper Institute |
| American Cancer Society, Rocky Mountain | COPIC Insurance |
| American Lung Association | Day of Caring |
| Asian Pacific Development Center | Denver Health Medical Center |
| Aspen Valley Medical Association | Denver Indian Health and Family Services |
| Cancer Information Service, NCI | Dept. of Human Services, Women's Health |
| Caring Hearts Adult Care | Exempla Lutheran Medical Center |
| Cancer League of Colorado | Full Circle Intergenerational Project |
| Centennial Radiation Oncology, PC | Gilda's Club of Denver |
| Centers for Medicare and Medicaid Services | Hands on Health |
| Clinica Tepayac | HealthOne at PSL |
| Colorado Cancer Research Program | Jefferson County Health Department |
| Colorado Clinical Guidelines Collaborative | Jewish Family Center |
| Colorado Chinese News | Juntas Contra el Cancer del Seno |
| Colorado Community Health Network | Kaiser Permanente of Colorado |
| Colorado Department of Public Health and Environment: | Klien Buendal, Inc. |
| Colorado Dermatologic Society | La Clinical Tepayec |
| Colorado Foundation for Medical Care | LARASA |
| Colorado Foundation for Public Health and Environment | Latino Cancer Prevention/Control Network |
| Colorado Health Outcomes Program | Latino/a Research & Policy Center |
| Colorado Hospice Organization | Memorial Cancer Center |
| Colorado Hospital Association | Mercy Medical Cancer Center |
| Colorado Medical Society | Metro Denver Black Church Initiative |
| Colorado Tobacco Education and Prevention Alliance | Myriad Genetics |
| | Native American Cancer Research |
| | Navitas, Inc |

Northeast County Health Department
Oncology Nurses Society
Ortho Biotech Oncology
PacifiCare of Colorado
Park County Nursing Services
Penrose Cancer Center
Pfizer Oncology
Pikes Peak Hospice
Planned Parenthood of Rocky Mountains
Presbyterian/St Lukes Medical Center
Prowers County Health Department
Qualife Wellness Center
Regional Institute for Health and
Environmental Leadership
ROCHE Oncology
Rocky Mountain Cancer Centers
Rocky Mountain Cancer Information Service-
NCI
Rocky Mountain Cancer Rehabilitation
Institute
Sense of Security
South Denver Gastroenterology, PC
Spa for the Spirit
St. Mary Corwin Medical Center, Cancer
Program
Summit County Public Health
Summit Cancer Solutions
Susan G. Komen Foundation
Teller County Public Health
The Center
The Cooper Institute
Tri-County Health Department
University of Colorado Cancer Center
University of Colorado at Denver

University of Colorado Health Sciences
Center, Department of Family Medicine,
Department of Preventive Medicine
University of Northern Colorado: Food
Science & Human Nutrition
U.S. Public Health Service, Region VIII
Veterans Administration Hospital
Visiting Nurse Association
Women's Imaging Center
Wyeth Pharmaceuticals
Y-Me Breast Cancer Organization
Zion Baptist Church Health Ministry/Black
Churches Health Initiative

Work Plan for State Clinical Trials Network

Goal 1 – Develop a coordinated information and delivery network in Colorado (July 1, 2005 - March 31, 2006)

Objectives	Activities	Responsible Party	Timeframe
1. Create organizational capacity	- Convene Steering Committee	CDPHE Liaison	07/05
	- Hire Project Manager	Oversight Comm	07/05
	- Facilitate regular meetings of the Steering Committee		
	- Facilitate sub-committee meetings as needed	Proj Mgr	08/05-03/06
	-Coordinate with the state health department and existing networks	Proj Mgr	08/05-03/06
	- Oversee selection of consultants	Proj Mgr	07/05-03/06
	- Oversee project schedule and deliverables	Oversight Comm	07/05-10/05
2. Build a coordinated information and delivery network	- Submit Quarterly Progress Reports to C-Change, Steering Committee	Proj Mgr	07/05-03/06
	- Update Colorado Cancer Plan	Proj Mgr	07/05-03/06
	- Hold information retreat for committee and stakeholders	CDPHE Liaison	08/05
		Proj Mgr	10/05
	- Facilitate process to establish CIRB	Proj Mgr	07/05 – 11/05
	- Strengthen collaboration between existing networks	Proj Mgr	08/05-09/05
	- Hold meeting at the state comprehensive cancer meeting	Oversight Comm	08/05
3. Enhance the Colorado Cancer Coalition’s existing website to serve as the statewide network	- Expand network to include other providers	Oversight Comm	10/05-11/05
	- Identify possible shared clinical trials	Medical Coord	12/05-02/06
	- Create shared database	TBD	01/06-03/06
	- Identify strategies to enhance accruals	Oversight Comm	01/06-03/06
	- Ensure ongoing coordination and compliance	Medical Coord	03/06
	- Design new web pages with input from Steering Committee and other key players	Consultant	12/05-03/06

Objectives	Activities	Responsible Party	Timeframe
4. Design a public awareness campaign aimed at distinct audiences (patients, community oncologists, cancer treatment centers)	- Create public awareness campaign and plan	Consultant	12/05-03/06
5. Establish system to measure impact and outcomes	- Identify current data sources - Create data collection and monitoring procedures	Corona Research Corona Research	10/05-12/05 01/06-03/06

Goal 2 – Implement a coordinated information and delivery network in Colorado (April 1, 2006 – December 15, 2006)

Objectives	Activities	Responsible Party	Timeframe
1. Maintain organizational capacity	- Facilitate regular meetings of the Steering Committee	Proj Mgr	04/06-12/06
	- Address emerging issues/challenges as needed	Proj Mgr, Oversight Committee, Medical Coord	04/06-12/06
	- Facilitate sub-committee meetings as needed	Proj Mgr	04/06-12/06
	- Coordinate with CDPHE and existing networks	Proj Mgr	04/06-12/06
	- Work with consultants	Proj Mgr	04/06-12/06
	- Oversee project schedule and deliverables	Proj Mgr	04/06-12/06
2. Maintain coordinated network	- Submit Quarterly Progress Reports to C-Change, Steering Committee	Proj Mgr	04/06-12/06
	- Provide resources to support sites which have need	Oversight Comm	04/06-11/06
	- Coordinate oversight of trials	Medical Coord	04/06-11/06
3. Launch and maintain website	- Enter clinical trial and subject specific data into database	TBD	05/06-11/06
	- Build new web pages	Klein Buendel	04/06-06/06
	- Launch enhanced website	Klein Buendel	07/06
4. Launch public awareness campaign	- Maintain site, including tracking of hits	Klein Buendel	07/06-12/06
	- Implement campaign	Consultant	04/06-12/06
5. Measure impact and outcomes	- Gather pre data	Corona Research	04/06
	- Analyze pre data	Corona Research	04/06-05/06
	- Gather post data	Corona Research	11/06
	- Analyze post data and compare to pre data	Corona Research	11/06-12/06
	- Report findings to Steering Committee	Corona Research	12/06
	- Report Lessons Learned from implementation phase	Proj Mgr	12/15/06
6. Secure sustainable funding	- Identify funding prospects	Oversight Comm	04/06-06/06
	- Cultivate funding prospects	Oversight Comm	07/06-10/06
	- Obtain long-term commitment from funders	Oversight Comm	11/06