



I. STATEMENT OF GENERAL PURPOSE OF THE CENTER

In 2006, the National Institutes of Health (NIH) chartered a major initiative to more effectively bridge basic science research with clinical science research (i.e., bench to bedside) and back again—a concept referred to as translational research. In 2008, the University of Colorado Denver (UCD) was awarded a 5-year, \$76 million grant by the National Institutes of Health to fund the Colorado Clinical and Translational Sciences Institute (CCTSI). The CCTSI directly addresses the NIH translational research initiative as it will promote, facilitate, and develop new areas, infrastructure, and opportunities for clinical and translational research at UCD.

In keeping with the goals and mission of the NIH roadmap and the CCTSI, the Center for Translational Pharmacokinetics and Pharmacogenomics is being developed at the UCD to promote the science of pharmaceutical drugs and their clinical use (i.e., clinical pharmacology). The academic mission of the Center for Translational Pharmacokinetics and Pharmacogenomics, hereafter referred to as the Center, is to provide leadership, stimulate learning, and advance multidisciplinary research and education in the areas of pharmacokinetics, pharmacogenomics, and pharmacodynamics.

- *Pharmacokinetics: the study of the time course of absorption, distribution, metabolism, and excretion (i.e., disposition) of drugs in the body.*
- *Pharmacogenomics: the study of how genetic variation influences interindividual variability in drug disposition and response.*
- *Pharmacodynamics: the study of the relationship between drug concentrations and drug response in the body.*

The Center will provide intellectual and technical resources in the research and service areas of clinical and basic pharmacokinetics, pharmacogenomics, and pharmacodynamics to scientific collaborators from a diverse range of disciplines. These disciplines include, but aren't limited to, cardiovascular disease, metabolic disease (e.g., diabetes), infectious disease (e.g., HIV), liver disease (e.g., hepatitis), and oncology. In this way, the Center will build collaborations in the areas of clinical science and basic science pharmacokinetics, pharmacogenomics, and pharmacodynamics. Through these collaborations, the Center will lead the discovery of clinical and genetic factors governing variability in drug disposition and response across a broad range of patient populations including, adults, children, elderly, and pregnant women.

The Center will promote the incorporation of pharmacokinetics, pharmacogenomics, and pharmacodynamic research into clinical and basic science research studies in order to foster future drug development and improve the safe and effective use of medications. In this way, the Center will enhance the national and international visibility of the current efforts in clinical and basic science pharmacokinetics, pharmacogenomics, and pharmacodynamics, and enhance the ability of Center members and collaborators to attract externally funded grants. Another integral part of the Center will be to provide training and education of clinical and basic scientists in translational pharmacokinetics, pharmacogenomics, and pharmacodynamics. By providing training and education to clinical and basic scientists, the Center will foster the incorporation of



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pharmacokinetic, pharmacogenomic, and pharmacodynamics principles into clinical and basic science research at the local, regional, national, and international levels.

II. CONGRUENCE OF MISSIONS

The Center resides within the UCD School of Pharmacy. The mission of the Center is fully compatible and in congruence with both the missions of the School of Pharmacy and UCD. The Center provides leadership, stimulates learning, and advances multidisciplinary research and education in the areas of pharmacokinetics, pharmacogenomics, and pharmacodynamics. These goals are consistent with the mission of the UCD School of Pharmacy, which is to provide a comprehensive institution of higher education committed to excellence in teaching, research, and public/professional service in areas unique to the practice of pharmacy and to the pharmaceutical sciences. The Center also aligns with the mission of the UCD, which aims to serve as a diverse teaching and learning community that creates, discovers, and applies knowledge to improve the health and well-being of Colorado and the world.

III. IMPLEMENTATION CAPABILITY

The faculty members of the Center will be responsible for the physical implementation of the Center. The Center will not occupy its own physical space initially. The Center's physical space will be comprised of the laboratories of the members. A website will be created to manage the Center activities. The Department of Pharmaceutical Sciences within the School of Pharmacy will provide some start-up funds for the development of this website. The School of Pharmacy will also provide meeting room space, as needed, for Center seminars and meetings. The upkeep of the website and any future physical space dedicated to the Center will be implemented with private donations and federal, and non-federal funds from the members or the UCD institution.

IV. ADMINISTRATIVE STRUCTURE AND REPORTING RELATIONSHIPS

The Center will be based in the UCD School of Pharmacy and will report directly to the Dean of the School of Pharmacy. There will be two co-Directors (Director of Pharmacokinetics and Director of Pharmacogenomics) and one Associate Director of Pharmacokinetics who must be full time faculty within the School of Pharmacy and have the necessary resources and equipment to meet the Center objectives. The Center is led by the Co-Directors with assistance from the Associate Director of Pharmacokinetics. The Co-Directors are responsible for management of Center research and research-related activities, membership, and reporting on Center activities. The Center will have an Advisory Committee that includes, from the School of Pharmacy: the Dean, the Associate Dean of Academic Affairs, the Chairs of the Department of Pharmaceutical Sciences and the Department of Clinical Pharmacy, the co-Directors and the Associate Director of the Center, and one faculty member from outside the School of Pharmacy at a rank above Assistant Professor. The committee will be responsible for resolving conflicts within the Center and for consulting on important decisions. Further details of the duties of each of these entities are found in the By-Laws for the Center.



V. BY-LAWS

ARTICLE I - PURPOSE

Section 1.1 – Purposes and Powers. The purpose of the UCD Center for Translational Pharmacokinetics and Pharmacogenomics is to promote the incorporation of pharmacokinetics, pharmacogenomics, and pharmacodynamic research into clinical and basic science research studies in order to foster future drug development and improve the safe and effective use of medications. The Center shall have the purposes and shall exercise those powers in the furtherance of its purposes as stated in these bylaws and as permitted by the rules of the University of Colorado Denver.

Section 1.2 – Objectives of the Center. The Center for Translational Pharmacokinetics and Pharmacogenomics is a multidisciplinary group whose objectives are to:

- a. Build research collaborations in the areas of clinical and basic pharmacokinetics, and pharmacogenomics.
- b. Lead the discovery of clinical and genetic factors governing variability in drug disposition (pharmacokinetics) and response (pharmacodynamics) in humans;
- c. Promote the incorporation of pharmacokinetic, pharmacogenomic, and pharmacodynamic research into patient-oriented clinical research studies and basic research studies in order to foster future drug development and improve the safe and effective use of medications;
- d. Provide training and education of clinical and basic scientists in translational pharmacokinetics and pharmacogenomics research;
- e. Provide an intellectual and technical resource in the areas of clinical and basic pharmacokinetics, pharmacogenomics, and pharmacodynamics to scientific collaborators from a diverse range of disciplines;
- f. Enhance the national and international visibility of the current efforts in clinical and basic pharmacokinetics, pharmacogenomics, and pharmacodynamics at UCD;
- g. Enhance the ability of Center members and collaborators to attract externally funded grants.

ARTICLE II - OFFICES

Section 2.1 – Offices. Initially, there will not be an office dedicated to the Center. The Center's physical space will be comprised of the offices and laboratories of the members.

ARTICLE III – STATUS WITHIN THE UNIVERSITY

Section 3.1 – Status within UCD. The Center shall be recognized as a multidisciplinary “center” housed within the UCD School of Pharmacy. Regular membership to the Center will be open to all full-time faculty within UCD who request membership, including but not limited to



faculty in the Schools of Medicine and Dental Medicine, the College of Nursing, and the Colorado School of Public Health. Linkages will be developed with other local entities since full-time faculty from other nearby institutions (e.g., National Jewish and Colorado State University), or interested professionals in industry or government may hold an adjunct membership in the Center.

ARTICLE IV – GOVERNANCE

Section 4.1 – Co-Directors.

Section 4.1a – Qualifications. There will be a Director for each of the two focuses of study (a Director of Pharmacokinetics and a Director of Pharmacogenomics). The co-Directors must possess a minimum of three years of active research experience in the respective fields. The co-Directors must be full time faculty within the School of Pharmacy and have the necessary resources and equipment to meet the center objectives.

Section 4.1b – Appointment, Terms, Removal. Co-Directors will be appointed by the Dean of the UCD School of Pharmacy for three year terms. Co-directors may serve successive terms. The Dean of the School of Pharmacy can also remove Co-Directors.

Section 4.1c – Duties.

- a. Co-Directors will be responsible for managing the Center affairs including the image projected to the community such as the Center website and Center-initiated seminars; interactions with prospective collaborators or other interested parties when initiated through the Center; and management of projects initiated through the Center.
- b. Projects initiated through the Center will be assessed by the Co-Directors and Associate Director of Pharmacokinetics on a continual basis, and with mutual agreement, assigned to appropriate Center members based on therapeutic area, available resources, and level of expertise.
- c. The Co-Directors and Associate Director of Pharmacokinetics will meet bimonthly to discuss Center projects (both incoming and ongoing).
- d. The Center will hold two meetings per year that are open to all Center members and adjunct members. The purpose of these meetings is to discuss Center productivity and progress and to identify areas for improvement. The Center Co-Directors will lead these meetings.

Section 4.2 – Associate Director of Pharmacokinetics.

Section 4.2a – Qualifications. There will be one Associate Director of Pharmacokinetics who must be full time faculty within the School of Pharmacy and have the necessary resources and equipment to meet the center objectives.

Section 4.2b – Appointment, Terms, Removal. The Associate Director will be appointed by the Dean of the School of Pharmacy for three year terms. The Associate Director may serve successive terms. The Dean of the School of Pharmacy can also remove an Associate Director.



Section 4.2c – Duties.

- a. Projects initiated through the Center will be assessed by the Co-Directors and Associate Director of Pharmacokinetics on a continual basis, and with mutual agreement, assigned to appropriate Center members based on therapeutic area, available resources, and level of expertise.
- b. The Co-Directors and Associate Director of Pharmacokinetics will meet bimonthly to discuss Center projects (both incoming and ongoing).
- c. The Associate Director will maintain a roster of the members of the Center on the Center website. The roster will accompany the annual report to the Dean of the School of Pharmacy.

Section 4.3 – Advisory Committee.

Section 4.3a – Qualifications. The Center will have an Advisory Committee that includes, from the UCD School of Pharmacy: the Dean, the Associate Dean of Academic Affairs, the Chairs of the Department of Pharmaceutical Sciences and the Department of Clinical Pharmacy, and one UCD faculty member from outside the School of Pharmacy at a rank above Assistant Professor, and the co-Directors and the Associate Director of the Center.

Section 4.3b – Appointment, Terms, Removal. The executive administration in the School of Pharmacy will be appointed by virtue of their title. Their terms will not expire while they hold their title. The initial appointment of the UCD faculty member from outside the School of Pharmacy and the co-Directors and Associate Director will be made by the Dean of the School of Pharmacy. Their terms will be three years and are renewable. The Dean will appoint or reappoint the Directors and Associate Director. Any member of the Advisory Committee may be removed by unanimous decision of the other Committee members.

Section 4.3c – Duties. The committee will be responsible for resolving conflicts within the Center and for consulting on important decisions. A Center Advisory Committee meeting will be held once a year.

ARTICLE V – CENTER MEMBERSHIP

Section 5.1 – Center Members.

Section 5.1a – Qualifications. Regular membership will be open to full-time faculty within UCD who request membership. Full-time faculty from other nearby institutions (e.g., National Jewish and Colorado State University), or interested professionals in industry or government may hold an adjunct membership.

Section 5.1b – Appointment, Terms, Removal. Members may be appointed or reappointed by unanimous decision of the co-Directors and Associate Director. Their terms will be three years and are renewable. Removal of members requires a majority decision of the Advisory Committee.

Section 5.1c – Duties. Center members will be expected to attend the two Center meetings held each year and complete Center projects for which they have agreed to participate in a timely and professional manner.



ARTICLE VI – PROVISION FOR CHANGING BY-LAWS

Section 6.1 – Revisions to the By-Laws. Revisions to the by-laws may be voted on during center meetings with a quorum (40%) present, majority vote, and approved by the Advisory Committee.

ARTICLE VII – ADMINISTRATION AND FINANCE

Section 7.1 – Public Policy and Financing Strategies. The short term financing strategies of the Center will include initial funding from seed dollars provided by the UCD School of Pharmacy and the Colorado Clinical/Translational Sciences Institute (CCTSI). The CCTSI will continue to contribute to the Center in subsequent years and support will be sought in subsequent years from the pharmaceutical industry and from grants and contracts. Initial funding will be used to establish a website for the Center, set up seminars to bring in outside speakers to present on topics relevant to Translational Pharmacokinetics and Pharmacogenomics, to pay graduate-level students for Center-related projects, and to pay for software or other tools necessary to conduct pharmacokinetic and pharmacogenomic research through the Center.

Section 7.2 – Fiscal Management and Review. Fiscal management will be conducted in accordance with UCD fiscal and administrative procedures. The UCD oversight and fiscal management reviewer will be the fiscal Administrator for the UCD School of Pharmacy. Pursuant to University policy, all Center deficits will be eliminated by the end of the fiscal year. Pursuant to the University Administrative Policy Statement entitled, “Procedures for the Establishment of Centers, Institutes, Laboratories, and Bureaus” (“the Policy”), the budget officer for UCD has reviewed this proposal.

Section 7.3 – Fiscal Control Provisions. The accounting procedures are followed in accordance with the UCD fiscal policies.

ARTICLE VIII – TERMINATION OF THE CENTER

Section 8.1 - Program Review. The Center shall be reviewed in conjunction with the program review of the School of Pharmacy by the ACPE accrediting body beginning in 2009 and at six (6) year intervals thereafter as required by the University.

Section 8.2 - Termination of the Center. The period of the Center’s existence shall commence with the date of its approval as an academic center in accordance with the policy and shall terminate after regular program review described in 8.1, beginning after the review in 2009, unless formally re-authorized in accordance with policy.

VI. BUSINESS PLAN – attached.