Council Approval

Note: This form is intended to track the progress of a proposal (whether from Academic Affairs or Health Sciences) through the Undergraduate and Graduate Councils.

Proposal: Clinical Pharmacology PhD

This proposal needs to go through:

Undergraduate Council	☐
Graduate Council	X
Both Approvals	☐
Grad Approval/Undergrad Notification	☐

This proposal has been approved by:

Chair of Undergraduate Council _____ Date: _____

Chair of Graduate Council _____ Date: 11/1/17

Once the appropriate signature(s) have been obtained, please forward this completed form to the Office of the Senior Vice President for Academic Affairs. *(NOTE: The SVP-AA is the Chief Academic Office for the University of Utah and reports to the Board of Regents in this capacity. When necessary, the CAO will get a signature from the SVP-HSC.)*

Chief Academic Officer _____ Date: 11-13-17

Once the Chief Academic Officer's signature has been obtained, this approval document will be forwarded to the **Office of the Academic Senate**.

Utah System of Higher Education
New Academic Program Proposal
Cover/Signature Page - Full Template

Institution Submitting Request:	University of Utah
Proposed Program Title:	Ph.D. in Clinical Pharmacology
Sponsoring School, College, or Division:	School of Medicine
Sponsoring Academic Department(s) or Unit(s):	Division of Clinical Pharmacology, Department of Pediatrics
Classification of Instructional Program Code[1] :	26.1001
Min/Max Credit Hours Required to Earn Degree:	60 min /
Proposed Beginning Term[2]:	Fall 2018
Institutional Board of Trustees' Approval Date:	

Program Type (check all that apply):

☐ (AAS)	Associate of Applied Science Degree
☐ (AA)	Associate of Arts Degree
☐ (AS)	Associate of Science Degree
☐	Specialized Associate Degree (specify award type[3]:)
☐	Other (specify award type[3]:)
☐ (BA)	Bachelor of Arts Degree
☐ (BS)	Bachelor of Science Degree
☐	Professional Bachelor Degree (specify award type[3]:)
☐	Other (specify award type[3]:)
☐ (MA)	Master of Arts Degree
☐ (MS)	Master of Science Degree
☐	Professional Master Degree (specify award type[3]:)
☐	Other (specify award type[3]:)
☒	Doctoral Degree (specify award type[3]: PhD)
☐	K-12 School Personnel Program
☐	Out of Service Area Delivery Program

Chief Academic Officer (or Designee) Signature:
I, the Chief Academic Officer or Designee, certify that all required institutional approvals have been obtained prior to submitting this request to the Office of the Commissioner.

_____ Date:

☐ I understand that checking this box constitutes my legal signature.

[1] For CIP code classifications, please see http://nces.ed.gov/ipeds/cipcode/Default.aspx?y=55.
[2] "Proposed Beginning Term" refers to first term after Regent approval that students may declare this program.
[3] Please indicate award such as APE, BFA, MBA, MEd, EdD, JD

Utah System of Higher Education
Program Description - Full Template

Section I: The Request

University of Utah requests approval to offer the following Doctoral degree(s): Ph.D. in Clinical Pharmacology effective Fall 2018. This program was approved by the institional Board of Trustees on .

Section II: Program Proposal

Program Description

Present a complete, formal program description.

The Clinical Pharmacology graduate program at the University Of Utah School Of Medicine is an innovative, interdisciplinary program that trains students to conduct research encompassing methodology from clinical pharmacology perspectives. The program was designed specifically for students who are interested in clinical pharmacology and translational research and share our goal of advancing the science of pharmacology and therapeutics to improve the safe and effective use of drugs by patients. In our program, students will study clinical pharmacology of various drugs prescribed to adult patient as well as to pregnant women, neonates, children, adolescent, and elderly patients. Students will focus on new routes of drug administration, pharmacokinetics, and pharmacodynamics of newly discovered drugs, optimization of dosing of drugs requiring therapeutic drug monitoring, pharmacometrics, developmental pharmacology, pharmacogenomics, immunotherapy, and translational research in a **highly individualized** course of study that will be chosen in close consultation with their advisors.

Program of Study

The doctoral program in Clinical Pharmacology requires a minimum of 64 credit hours. These required credit hours must be taken from three different areas:

1. Clinical pharmacology main courses including Research-in-Progress seminars, Clinical Pharmacology Special Seminars, and Clinical Pharmacology Journal Club, minimum 20 credit hours required

2. Dissertation credits: minimum 14 credit hours required

3. Electives tailored to the individual needs of the student: 30 credit hours minimum required

Supervisory Committee

Students after successful completion of two semesters of coursework (minimum of 12 credit hours) will choose members of their Supervisory Committee. The Supervisory Committee must consist of five members: two faculty members of the Division
of Clinical Pharmacology, Pediatrics at the University of Utah, one faculty representing one of the clinical divisions of the Department of Pediatrics and two faculty members from the Department of Pharmacotherapy, College of Pharmacy at the University of Utah or any other departments of SOM. The Graduate Committee of the doctoral program in Clinical Pharmacology, formed from the faculty members (Drs. Diana Brixner, Chris Reilly, Elena Enioutina and Xiaoxi Liu) and the Clinical Pharmacology Division chief will confirm student choice or propose another member of the Supervisory Committee. One of the members will be designated chair of the student's supervisory committee. The Chair of the Supervisory Committee must be tenured or tenure-track faculty from the Department of Pediatrics or College of Pharmacy. The Supervisory Committee will be approving the student's academic program, approving and judging the qualifying examination, approving the dissertation subject and final dissertation, and administering and judging the dissertation defense. The Supervisory Committee will meet at least twice per calendar year or upon request of the student or the Chair of

the Supervisory Committee.

Qualifying Examination

Ph.D. Candidates for Clinical Pharmacology will be required to take the qualifying examination at the completion of a minimum of three semesters of coursework (minimum 20 credit hours). The proposal topic for the qualifying examination must be approved by the student's supervisory committee. The Qualifying Exam will consist of two parts: a written proposal covering the student's approved area of emphasis (minimum double space 5 pages proposal) and an oral examination involving a defense of the student's written proposal. The Supervisory Committee will be responsible for evaluation and grading the written proposal and judging the accuracy of the oral defense. Students must pass the qualifying examination to advance to candidacy.

Dissertation

Students will be required to submit a dissertation with the results of the student's research. The dissertation will be judged and approved by the Supervisory Committee. The student will be required to perform an oral dissertation defense. At least three weeks before the dissertation defense, the student will submit a written draft of the dissertation to the members of the Supervisory Committee.

Institutional Readiness

The Division of Clinical Pharmacology, Pediatrics at the University of Utah is actively developing division with a high level of productivity. The division was offering clinical pharmacology fellowship program for more than six years. Ten fellows successfully graduated from this program. In the past year, the division chief and faculty members have advanced fellowship program to the standards of accredited with American Board of Clinical Pharmacology training programs. The program was ranked very high by the American Board of Clinical Pharmacology following an onsite visit this year. In 2017, Utah Clinical Pharmacology Fellowship program became accredited as Clinical Pharmacology training program.

A number of program faculty members are receiving inquiries on whether a doctoral program is available in Clinical Pharmacology. The division faculty, therefore, considered the creation of a Ph.D. program one of the main objectives for the next two years.

The size of the division faculty body was one consideration in determining division readiness to offer a doctoral degree. The division of Clinical Pharmacology currently has 1 tenured, 5 research track, 2 adjunct (both tenure-track) and 2 emeritus faculty. Four division faculty members are adjunct faculty of other departments. The faculty members have established collaborative relationships with faculty members and research programs in other departments, providing a diversity of opportunities for mentoring and access to research facilities. The division faculty members actively collaborate with faculty members of the Pediatrics Department, Internal Medicine, the Department of Family and Preventative Medicine, the Department of OBGYN and most important faculty members of the College of Pharmacy, Department of Pharmacotherapy. Many of these collaborating faculty members participate in the fellow training within Clinical Pharmacology fellowship program and have expressed interest in contributing to the training and mentorship of our Ph.D. students.

The Pediatrics Department will limit initial enrollment in the doctoral program to no more than 2 new students per year (1 student will be jointly funded by the Division of Clinical Pharmacology, Pediatrics and the Department of Pharmacotherapy, or Pharmacology & Toxicology, College of Pharmacy).

To increase interaction of Clinical Pharmacology program Ph.D. students with their peers at the College of Pharmacy, all students will be advised to take one or more College of Pharmacy courses aimed to facilitate interaction between students (e.g., Journal clubs, Research seminars, and Clinical seminars). Additionally, program students will be attending national clinical pharmacology meetings as well as locally organized

workshops where students will be able to present their work and interact with other Ph.D. students and national and international experts in clinical pharmacology.

Faculty

The division faculty members have strong records of scholarship that has been steadily increasing over the past several years. The faculty's research has been extensively published in the peer-reviewed journals including: *The European Journal of Clinical Pharmacology, American Journal of Perinatology, Journal of Pharmacy and Pharmacology, Antimicrobial Agents and Chemotherapy (AAC), Archives of Disease in Childhood (Fetal and Neonatal edition, BMC Pharmacology and Toxicology, Basic & Clinical Pharmacology & Toxicology, Biopharmaceutics & Drug Disposition, British Journal of Clinical Pharmacology, Clinical Pharmacokinetics, European Journal of Clinical Pharmacology, Expert Review of Clinical Pharmacology, International Journal of Adolescent Medicine and Health, The Journal of Clinical Pharmacology, Journal of Pharmacokinetics and Pharmacodynamics, Pediatric Anesthesia, Pediatric Pulmonology, Therapeutic Drug Monitoring, Vaccine journal, Journal of Immunolog*y. Several members have received institutional, regional, national and international awards for their research efforts. Our faculty represent senior leadership in numerous national and international professional societies including The American Society for Clinical Pharmacology and Therapeutics (ASCPT), the American College of Clinical Pharmacology (ACCP), Academic Pediatric Association, International Association of TDM and Clinical Toxicology, American Society for Clinical Pharmacology and Therapeutics, International Society of Pharmacometrics, American Association of Pharmaceutical Scientists, ESDPPP - European Society for Developmental Perinatal and Pediatric Pharmacology, and Society for Pediatric Research. The demonstrated excellence in scholarship of the division ensures that potential Ph.D. students will be immersed in a productive scholarly environment.

Staff

No additional professional staff would be needed to support the doctoral program in the division. Because of the limited number of students to be admitted to the program initially, the existing staff in the Division of Clinical Pharmacology will be able to provide support to the program.

Library and Information Resources

The Library has verified it has sufficient resources available to provide for any faculty or student needs.

Admission Requirements

The graduate school must admit applicants for the admission to the Ph.D. Program in Clinical Pharmacology, School of Medicine and the Department of Pediatrics, Division of Clinical Pharmacology at the University of Utah. Applicants should have a strong interest in the clinical pharmacology research and teaching. Applicants should also have a master's or clinical doctoral degree. Exceptional students with a bachelor's degree and compelling clinical research experience in health sciences will be considered. (see Section IV: Program and Student Assessment).

Student Advisement

Upon admission into the doctoral program, each student will be matched with a faculty advisor. This faculty advisor will assist the student in developing a plan of study and will help the student to choose members of his/ her supervisory committee.

Justification for Graduation Standards and Number of Credits.

The total number of credit hours required by the doctoral program in Clinical Pharmacology (minimum 64 credits), examination processes and dissertation evaluation are consistent with other Ph.D. programs at the

University of Utah.

External Review and Accreditation.

The Ph.D. program in Clinical Pharmacology is not subject to external review and accreditation, except as required for the University of Utah's Northwest Accreditation process.

Projected Enrollment.

We will admit a maximum of two students per year.

Expansion of Existing Program

Not applicable

Consistency with Institutional Mission

Explain how the program is consistent with the institution's Regents-approved mission, roles, and goals. Institutional mission and roles may be found at highered utah.org/policies/policyr312/ .

The mission of the Ph.D. program in Clinical Pharmacology is consistent with the University of Utah mission statement:"… generate and share new knowledge, discoveries, and innovations, and we engage local and global communities in promoting education, health, and quality of life, " and strategic goals: 1) "Promote student success to transform lives"; 2) "Develop and transfer new knowledge." The major focus of the Ph.D. program in Clinical Pharmacology is on the third strategic goal of the University of Utah "Engage communities to improve health and quality of life." Additionally, the Ph.D. program in Clinical Pharmacology will be focusing on providing "transformative and innovative health care", improving existing standards of care and inventing new methods of treatment for adult patients, pregnant women, neonates, and children, adolescent, and elderly patients.

Section III: Needs Assessment

Program Rationale

Describe the institutional procedures used to arrive at a decision to offer the program. Briefly indicate why such a program should be initiated. State how the institution and the USHE benefit by offering the proposed program.

The main reason why faculty members of the Division of Clinical Pharmacology decided to initiate a Ph.D. program in Clinical Pharmacology is:

1. Nowadays, all medical fields are moving towards personalized medicine where clinical pharmacology, in particular, pharmacogenomics, pharmacometrics, developmental pharmacology will play critical roles.
2. Every year we have several students approaching Division of Clinical Pharmacology faculty members with inquiries regarding Ph.D. in Clinical Pharmacology. Until now, we had to refer these students to the University of Utah Ph.D. programs in Economics, Biomedical Informatics or Public Health, and Pharmacotherapy Outcomes Research and Health. While these programs prepare fine specialists, they cannot offer special courses and research projects which can be offered by Clinical Pharmacology specialized program.

Additionally, Ph.D. program in Clinical pharmacology should be initiated since there is no specialized Ph.D. program in Clinical Pharmacology within the SOM, University of Utah and Utah System of Higher Education, and there is a high demand in doctoral degree medical professionals (see labor market analysis below); and most importantly Ph.D. graduates of this Program can contribute a great deal to the translational research in the area of personalized medicine.

Labor Market Demand

Provide local, state, and/or national labor market data that speak to the need for this program. Occupational demand, wage, and number of annual openings information may be found at sources such as Utah DWS Occupation Information Data Viewer (jobs.utah.gov/jsp/wi/utalmis/gotoOccinfo.do) and the Occupation Outlook Handbook (www.bls.gov/oco).

The best occupational areas for Clinical Pharmacology Ph.D. program graduates will be interdisciplinary work with clinicians at the University of Utah Hospital and Clinics and/or standalone hospitals to optimize or personalize medical care for patients. Additionally, graduates can successfully work as investigators in the area of translational research at the academic and pharma industry settings. While jobs.utah.gov website does not present outlook for such narrow area of expertise, but labor outlook for the best fit occupation such as "Medical Scientists, Except Epidemiologists" looks very optimistic (five stars for Salt Lake metro area and nationwide). Median annual salary for such specialists with a doctoral degree and no experience in Salt Lake metro area is $77,680; statewide - $80,400; and nationwide - $82,240. Utah DWS has currently (March 2017) 79 job orders in "Medical Scientists, Except Epidemiologists" category. Projected job growth in this category is ~4% statewide

Student Demand

Provide evidence of student interest and demand that supports potential program enrollment. Use Appendix D to project five years' enrollments and graduates. Note: If the proposed program is an expansion of an existing program, present several years enrollment trends by headcount and/or by student credit hours that justify expansion.

Although the exact numbers of students who desire Ph.D. level training in Clinical Pharmacology are difficult to tabulate, former and current students who desire Ph.D. level training in Clinical Pharmacology were referred to the University of Utah Ph.D. programs in Economics, Biomedical Informatics or Public Health, and Pharmacotherapy Outcomes Research and Health.

Similar Programs

Are similar programs offered elsewhere in the USHE, the state, or Intermountain Region? If yes, identify the existing program(s) and cite justifications for why the Regents should approve another program of this type. How does the proposed program differ from or compliment similar program(s)?

There are no similar programs within the USHE.

Collaboration with and Impact on Other USHE Institutions

Indicate if the program will be delivered outside of designated service area; provide justification. Service areas are defined in higheredutah.org/policies/policyr315/ . Assess the impact the new program will have on other USHE institutions. Describe any discussions with other institutions pertaining to this program. Include any collaborative efforts that may have been proposed.

The University of Utah has the only School of Medicine and Division of Clinical Pharmacology, Department of Pediatrics among the institutions in the USHE focusing on translational research in *Clinical Pharmacology*. There will be no impact on other USHE Institutional programs. Clinical Pharmacology Program will be closely collaborating with Departments of Pharmacotherapy and Pharmacology & Toxicology, College of Pharmacy within the University of Utah. Ph.D. students will attend some courses offered by the College of Pharmacy.

External Review and Accreditation

Indicate whether external consultants or, for a career and technical education program, program advisory committee were involved in the development of the proposed program. List the members of the external consultants or advisory committee and briefly describe their activities. If the program will seek special professional accreditation, project anticipated costs and a date for accreditation review.

The Ph.D. program in Clinical Pharmacology is not a subject to external review and accreditation, except as required for the University of Utah's Northwest Accreditation process. The department's graduate programs abide by the University of Utah Graduate School periodic (6 years) review process that includes both campus and external university reviewers (see Section IV: Program and Student Assessment).

Section IV: Program Details

Graduation Standards and Number of Credits

Provide graduation standards. Provide justification if number of credit or clock hours exceeds credit limit for this program type described in R401-3.11, which can be found at higheredutah.org/policies/R401.

Credits

The Ph.D. degree requires core graduate credits, a minimum of 64-course credits including 14 doctoral thesis credits. Students will design their educational program with the guidance of their advisors.

Examinations

Students must pass one written preliminary examination and one preliminary oral examination before writing the dissertation. The final examination processes and dissertation evaluation are consistent with other Ph.D. programs at the University of Utah.

Admission Requirements

List admission requirements specific to the proposed program.

The graduate school must admit applicants for admission to the Program in Clinical Pharmacology, School of Medicine and the Department of Pediatrics Division of Clinical Pharmacology at the University of Utah. Applicants should have a strong interest in Clinical Pharmacology research and teaching. Applicants should also have a master's or clinical doctoral degree.

Exceptional students with a bachelor's degree and compelling clinical research experience in health sciences will be considered.

The following information must be submitted to the graduate school:

1. Graduate admission application
2. Official transcripts of undergraduate and graduate coursework
3. For international students, a Test of English as a Foreign Language (TOEFL) score.

The following information must be submitted to the Division of Clinical Pharmacology, Pediatrics Department.

1. A current *Curriculum Vitae*
2. Report of the Graduate Record Exam taken within the past five years
3. A written statement (less than 1000 words) of research experience and interests, and long-term career goals
4. 3-5 letters of recommendation from individuals with knowledge of the applicant's potential for success in a doctoral program

Admission to the Doctoral Program in Clinical Pharmacology will require:

1. Acceptance to the graduate school at the University of Utah
2. A minimum grade point average of 3.0 in all college work and a record of the Graduate Record Exam
3. Availability of faculty mentor resources that match the student's research interests
4. TOEFL score of at least 550, if applicable.

Curriculum and Degree Map

Use the tables in Appendix A to provide a list of courses and Appendix B to provide a program Degree Map, also referred to as a graduation plan.

Section V: Institution, Faculty, and Staff Support

Institutional Readiness

How do existing administrative structures support the proposed program? Identify new organizational structures that may be needed to deliver the program. Will the proposed program impact the delivery of undergraduate and/or lower-division education? If yes, how?

The Division of Clinical Pharmacology, Pediatrics at the University of Utah is actively developing division with a high level of productivity. The division was offering clinical pharmacology fellowship program for more than 6 years. Ten fellows successfully graduated from this program. In the past year, the division chief and faculty members have advanced fellowship program to the standards of accredited with American Board of Clinical Pharmacology training programs. The program was ranked very high by the American Board of Clinical Pharmacology following an onsite visit this year. In 2017, Utah Clinical Pharmacology Fellowship program became accredited as Clinical Pharmacology training program. A number of faculty members have received inquiries on whether a doctoral program is available in Clinical Pharmacology. The division faculty members, therefore, considered the creation of a Ph.D. program one of the main objectives for the next two years.

The size of the division faculty body was one of consideration in determining division readiness to offer a doctoral degree. The division of Clinical Pharmacology currently has 1 tenure-track, 5 research track, 2 adjunct (both tenure-track) and 2 emeritus faculty. Four division faculty are adjunct faculty of other departments. The faculty members have established collaborative relationships with faculty members and research programs in other departments, providing a diversity of opportunities for mentoring and access to research facilities. The division faculty members actively collaborate with faculty of the Department of Pediatrics, Internal Medicine, the Department of Family and Preventative Medicine, the Department of OBGYN and most important faculty members of the College of Pharmacy, Department of Pharmacotherapy. Many of these collaborating faculty members participate in the fellow training within Clinical Pharmacology fellowship program and have expressed interest in contributing to the training and mentorship of our Ph.D. students.
The Department of Pediatrics will initially limit enrollment in the doctoral program to no more than two new students per year (1 student will be jointly funded by the Division of Clinical Pharmacology, Pediatrics and the Department of Pharmacotherapy, College of Pharmacy).

To increase interaction of Clinical Pharmacology program Ph.D. students with their peers at the College of Pharmacy, all Ph.D. students will be advised to take one or more College of Pharmacy courses aimed to facilitate interaction between students (e.g., Journal clubs, research seminars, and Clinical seminars. Additionally, program students will be attending national clinical pharmacology meetings as well as locally organized workshops where students will be able to present their work and interact with other Ph.D. students and national and international experts in clinical pharmacology.

Faculty

Describe faculty development activities that will support this program. Will existing faculty/instructions, including teaching/ graduate assistants, be sufficient to instruct the program or will additional faculty be recruited? If needed, provide plans and resources to secure qualified faculty. Use Appendix C to provide detail on faculty profiles and new hires.

The selection of faculty for the Ph.D. Program in Clinical Pharmacology was based on the interdisciplinary research expertise as evident by their peer-reviewed publications, mentorship experience, and ongoing and previous developmental and clinical pharmacology related research collaborations. The foundation for the training program curriculum and research training opportunities is provided by the Division of Clinical Pharmacology faculty members with expertise in several key areas: developmental pharmacology, clinical pharmacology of special populations, clinical trial design and conduct, pharmacogenomics, pharmacometrics, immunotherapy, biostatistics, biomedical informatics, and translational research.

Several faculty members have received institutional, regional, national and international awards for their research efforts. Our faculty represent senior leadership in numerous national and international professional societies including: the American College of Clinical Pharmacology, Academic Pediatric Association, International Association of TDM and Clinical Toxicology, American Society for Clinical Pharmacology and Therapeutics, International Society of Pharmacometrics, American Association of Pharmaceutical Scientists, ESDPPP - European Society for Developmental Perinatal and Pediatric Pharmacology, and Society for Pediatric Research. The demonstrated excellence in scholarship of the division ensures that potential Ph.D. students will be immersed in a productive scholarly environment.

The following faculty pool, which includes regular, research and clinical track faculty members, will be used to select advisors of the Clinical Pharmacology Ph.D. program students:

Faculty of the Division of Clinical Pharmacology

Dr. Catherine MT Sherwin Ph.D., MSc., FCP (tenured, core faculty)

Dr. Robert Marshall MD (core faculty)

Dr. James Steven Leeder, PharmD, Ph.D. (core faculty)

Dr. Alfred H Balch Ph.D. (core faculty)

Dr. Elena Yu Enioutina M.D., Ph.D. (core & research faculty)

Dr. Anthony Temple M.D. (core faculty)

Dr. Christopher A. Reilly Ph.D. (tenure-track, research faculty)

Dr. Joseph Rower Ph.D. (research faculty)

Dr. Jonathan Constance Ph.D. (research faculty)

Dr. Xiaoxi Liu Ph.D. (research faculty)

Dr. Diana Brixner, RPh, Ph.D., FAMCP (tenure-track, research faculty)

Faculty of Other Departments of SOM, University of Utah

Dr. Robert D. Christensen, M.D. (tenured, clinical faculty)

Dr. Andrew Pavia, M.D., (tenured, clinical faculty)

Dr. Emily Thorell, M.D. M.S.C.I (clinical faculty)

Dr. Andrew C. Harris, M.D. (clinical faculty)

Dr. Elizabeth Ann Raetz, M.D (clinical faculty)

Dr. Shannon Saldaña, MS, PharmD, BCPP, BCPS (clinical faculty)

Dr. Richard Martini, MD (clinical faculty)

Dr. Erin Clark, MD, (clinical faculty)

Dr. Michael W. Varner, MD (tenured, clinical faculty)

College of Pharmacy Pharmacology & Toxicology Department

Dr. Mario E. Alburges, Ph.D. - Research Associate Professor

Dr. Louis R. Barrows, Ph.D. - Professor

Dr. Andrea Bild, Ph.D. - Associate Professor

Dr. Donald K. Blumenthal, Ph.D. - Associate Dean for Interprofessional Education and Assessment

Dr. Marco Bortolato, Ph.D. - Associate Professor

Dr. William R. Crowley, Ph.D. - Professor

Dr. Kristen A. Keefe, Ph.D. - Professor

Dr. Mei Yee Koh, Ph.D. - Assistant Professor

Dr. David E. Moody, Ph.D. - Director, Center for Human Toxicology; Research Professor

Dr. Philip J. Moos, Ph.D. - Associate Professor

Dr. Roy M. Smeal, Ph.D. - Research Assistant Professor

Dr. Misty D. Smith, Ph.D. - Research Assistant Professor

Dr. John M. Veranth, MBA, Ph.D. - Research Associate Professor

Dr. Peter J. West, Ph.D. - Research Assistant Professor

Dr. Karen Wilcox, Ph.D. - Chair Department of Pharmacology & Toxicology; Professor

Dr. Cameron Metcalf, Ph.D. - Research Assistant Professor

Pharmacotherapy Department

Dr. Jennifer L. Babin, Pharm.D., Pharm.D., Assistant Professor (Clinical)

Dr. Brandon Bellows, PharmD, MS Research Assistant Professor

Dr. Joseph E. Biskupiak, Ph.D., MBA - Research Professor

Dr. Barbara Insley Crouch, PharmD, MSPH - Professor (Clinical) & Executive Director of Utah Poison Control Center

Dr. Karen M. Gunning, PharmD - Professor (Clinical)

Dr. Holly E. Gurgle, PharmD, BCACP, CDE - Assistant Professor (Clinical)

Dr. Joanne LaFleur, PharmD, MSPH - Associate Professor

Dr. Krystal L. Moorman, PharmD - Assistant Professor (Clinical) & PEP Director

Dr. Mark A. Munger, PharmD, FCCP - Professor & Associate Dean

Dr. Nancy A. Nickman, MS, Ph.D. - Professor

Dr. Heather A. Nyman, PharmD, Assistant Professor (Clinical)

Dr. Patricia L. Orlando, PharmD - Associate Professor (Clinical)

Dr. Hanna P. Raber, PharmD, BCPS, TTS - Assistant Professor (Clinical)

Dr. Jim Ruble, PharmD, JD - Associate Professor (Clinical)

Dr. Laura Shane-McWhorter, PharmD, BCPS, FASCP, CDE, BC-ADM - Professor (Clinical)

Dr. Katie L. Traylor, PharmD - Assistant Professor (Clinical)

Dr. Linda S. Tyler, PharmD - Professor (Clinical); Associate Dean, Pharmacy Practice; Chief Pharmacy Officer

Dr. Kyle M. Turner, PharmD - Assistant Professor (Clinical)

Dr. David C. Young, PharmD - Professor (Clinical)

Pharmaceutics & Pharmaceutical Chemistry

Dr. Mingnan Chen, Ph.D. - Assistant Professor

Dr. James N Herron, Ph.D. - Associate Professor

Dr. Carol Lim, Ph.D. - Professor

Dr. Shawn C Owen, Ph.D. - Assistant Professor

Dr. Shuyun Dong, Ph.D. - Research Assistant Professor

Dr. Jiyuan (Jane) Yang, Ph.D. - Research Professor

Dr. Sivaprasad Sukavaneshvar, Ph.D. - Research Assistant Professor

Dr. Youngsook Lee, Ph.D. - Research Assistant Professor

Dr. Yoshikazu Kumashiro, Ph.D. -Research Assistant Professor

Dr. Andrew Dixon, Ph.D. - Research Assistant Professor

Staff

Describe the staff development activities that will support this program. Will existing staff such as administrative, secretarial/ clerical, laboratory aides, advisors, be sufficient to support the program or will additional staff need to be hired? Provide plans and resources to secure qualified staff, as needed.

No additional professional staff would be needed to support the doctoral program in the department. As a limited number of students to be admitted to the program initially, the existing staff in the Department of Pediatrics, Division of Clinical Pharmacology will be able to provide support to the program.

Student Advisement

Describe how students in the proposed program will be advised.

Upon admission into the doctoral program, each student will be matched with a faculty advisor. This faculty advisor will assist the student in developing a plan of study and will oversee the composition of a supervisory committee that will be identified after the student's first year in the program. The Supervisory Committee must be approved by the Graduate Committee and the Division Chief of Clinical Pharmacology, Pediatrics. The Supervisory Committee will be responsible for providing additional advisement to the student throughout his or her course of study.

Library and Information Resources

Describe library resources required to offer the proposed program if any. List new library resources to be acquired.

Library resources required for a doctoral program include access to clinical pharmacology journals and other textbooks and reference material related to clinical pharmacology, pharmacogenomics, pharmacometrics, immunotherapy, biostatistics, biomedical informatics, and translational research. The

existing resources of the Eccles Health Science Library are adequate for support of this doctoral program.

Projected Enrollment and Finance

Use Appendix D to provide projected enrollment and information on related operating expenses and funding sources.

Section VI: Program Evaluation

Program Assessment

Identify program goals. Describe the system of assessment to be used to evaluate and develop the program.

This program is not subject to accreditation from any agency. As a graduate program at the University of Utah, the program will be subject to review by the Graduate Council. Also, the School of Medicine will evaluate the program as it currently evaluates the programs in other departments within the college.

This includes:
The faculty members of the Department of Pediatrics will use these assessment tools to conduct an internal review of the Program on an annual basis. Until the Program matures, this review will be conducted informally as a meeting of the core faculty of the Ph.D. program.

Student Standards of Performance

List the standards, competencies, and marketable skills students will have achieved at the time of graduation. How and why were these standards and competencies chosen? Include formative and summative assessment measures to be used to determine student learning outcomes.

Graduates of the Ph.D. program will have specific knowledge in several key areas: developmental pharmacology, clinical pharmacology of special populations (pediatrics, geriatrics, and pregnancy), clinical trial design and conduct, pharmacogenomics, pharmacometrics, immunotherapy, biomedical informatics, and translational research. These graduates will become researchers, scholars, teachers, thinkers, and planners in academia, government, and industry. The graduates will have the skills required to lead in Universities and other settings where clinical pharmacology is practiced and taught. Students will acquire these skills through the completion of the graduation requirements. These are:

1. Coursework: Students in the Ph.D. program will be expected to complete coursework:
    - Introduction to Clinical Pharmacology
    - Introduction to Pharmacokinetic and Pharmacodynamic
    - Implementation of Clinical Trials
    - Principles and Practice of Pharmacometrics
    - Clinical Pharmacology in Special Populations
    - Journal Club - Pharmacometrics and Clinical Pharmacology
    - Research in Clinical Pharmacology
    - Special Seminar Series in Clinical Pharmacology

2. Supervisory Committee: This committee and the Division Chief of Clinical Pharmacology will approve electives, approve and judge the qualifying examination and approve dissertation subject, final written dissertation and judge the final oral examination.

3. Qualifying Examinations: At the end of the required coursework, students will take a qualifying examination that assesses their knowledge within their specific discipline

4. Dissertation: After successful completion of the Qualifying Examination and advancement to candidacy, students will develop a proposal for the dissertation, complete and defend the research.

5. Learning Outcomes & Assessments: The aim of the Expected Learning Outcomes (ELOs) described below is to provide clarity and accountability for both faculty members and students concerning the goals and outcomes of the undergraduate major in Family, Community, and Human Development. ELOs can be useful in constructing the

overall curriculum as well as improving it.

a. Demonstrate an understanding of fundamental principles in clinical pharmacology such as drug pharmacokinetics and pharmacodynamics in humans, drug effectiveness, drug-drug interactions and adverse drug reactions, fundamentals of drug and drug metabolite analysis and methods therapeutic drug monitoring, clinical pharmacology of special populations.
Assessment: Students must actively participate in the discussion of lectures and materials presented by the lecturers of the PED 4500 and PED 7700 and write a ½ page essay discussing questions posted for each lecture on the course website.
An understanding of basic Principals of Pharmacokinetic and Pharmacodynamic Modeling (PED7600), implementation of clinical trials (PCTH 7460 /MDCRC 6470) and will be assessed similarly as described above.

b. Demonstrate an ability to describe, understand, and critically analyze scientific publications in the area of clinical pharmacology.
Assessment: Each student will be required to attend the Journal club course, and provide feedback to the course master on the manuscript presented by his/her peers or postdoctoral fellows and present twice per year peer-reviewed clinical pharmacology related manuscripts (course PED7800).

c. Demonstrate an ability to design, conduct experiments, analyze results and present these results.
Assessment: Each student will be required to present his/her research project work twice per year to their peers, postdoctoral fellows, and Clinical Pharmacology faculty members. Students, fellows, and faculty will critically evaluate the research design and results presented by the student and discuss potential strengths and pitfalls (PED 7810).
Results of the research project will also be discussed by the student twice per year with his/her Supervisory Committee.

Supervisory Committee will evaluate the student progress and success twice per year based on the performance on the questions developed to assess the learning outcomes. A report including recommendations for action will be generated by the committee and presented to the Division of Clinical Pharmacology, Chair of the Graduate Committee, Catherine Sherwin. Additionally, Dr Sherwin will meet with members of the Graduate Committee and discuss student's progress. After that, the Chair or one of the members of the Graduate Committee will meet with the student and discuss student progress and present the Graduate Committee recommendations.

Appendix A: Program Curriculum

List all courses, including new courses, to be offered in the proposed program by prefix, number, title, and credit hours (or credit equivalences). Indicate new courses with an X in the appropriate columns. The total number of credit hours should reflect the number of credits required to be awarded the degree.

For variable credits, please enter the minimum value in the table for credit hours. To explain variable credit in detail as well as any additional information, use the narrative box at the end of this appendix.

Course Number	NEW Course	Course Title	Credit Hours
General Education Courses (list specific courses if recommended for this program on Degree Map)			
		General Education Credit Hour Sub-Total	
Required Courses			
PED 7800		Journal Club – Pharmacometrics and Clinical	3
PED 7810		Research in Progress, Clinical Pharmacology	3
PED 7820		Special Seminar Series in Clinical Pharmacology	3
PCTH 7460 /MDC		Implementation of Clinical Trials	2
PED 7700		Clinical Pharmacology in Special populations	2
PCTH 5114		US Health Care Policy	
MDCRC 6150		Foundations in Personalized Health Care	2
BMI 6030		Foundations of Bioinformatics	2
PED 5400	X	Introduction to Clinical Pharmacology	2
PEDXXXX*	X	Introduction to Pharmacokinetic and Pharmacodynamic	1
		Required Course Credit Hour Sub-Total	20
Elective Courses			
FPMD 7120		Linear and Logistic Regression Models	3
FPMD 7140		Applied Multivariate Data Analysis	3
FCS 5969		Survival Analysis	
FPMD 6101		SAS Programming	
FPMD 6305		Advanced Methods of Epidemiologic	
PCTH 7315		Clinical Toxicology	
PCTH 7512		Pediatrics Clerkship	
PCTH 7513		Neonatology Clerkship	
PCTH 7532		Investigational Drug Service Clerkship Pharm	
PCTH 7710		Data Mining	3
PCTH 7150		Pharmacotherapy Outcomes Research I	3
PCTH 7750		Pharmacotherapy Outcomes Research II	
PCTH 7341		Problems in Pharmacotherapy	3
PHCEU 7011		Fundamental Pharmacokinetics	
PHCEU 7316		Applied Clinical Pharmacokinetics	2
PHCEU 7510		Pharmacokinetic Approaches to Drug Delivery	
PHCEU 7315		Biopharmaceutics and Pharmacokinetics	2
BMI 6030		Foundations of Bioinformatics	
FPMD 6106		Categorical Data Analysis	3

Course Number	NEW Course	Course Title	Credit Hours
FPMD 6101		Data Analysis using SAS	
FPMD 7310		Advanced Research Design	
FPMD 6305		Advanced Methods Epidemiology Research	
FPMD 7130		Longitudinal Data Analyses	
FPMD 6400		Public Health Administration & Policy	
PH TX 7890		Research Seminar	1
PCTH 6890		Research Seminar I	1
PCTH 6891		Research Seminar II	
PCTH 7100		Clinical Pharmacy Seminar	1
PCTH 7890		Research Seminar I	
PCTH 7891		Research Seminar II	
		Elective Credit Hour Sub-Total	25
		Core Curriculum Credit Hour Sub-Total	45

Are students required to choose an emphasis? X *Yes or* *No*

Course Number	NEW Course	Course Title	Credit Hours
Name of Emphasis:		Pharmacometrics	
FPMD 6101		SAS Programming	3
PED 7600		Principles and Practice of Pharmacometrics	2

Emphasis Credit Hour Sub-Total	5
Total Number of Credits to Complete Program	50

Course Number	NEW Course	Course Title	Credit Hours
Name of Emphasis:		Comparative Effectiveness Research	
PCTH 7750		Pharmacotherapy Outcomes Research II	3
FPMD 6305		Advanced Methods of Epidemiologic	2

Course Number	NEW Course	Course Title	Credit Hours

Emphasis Credit Hour Sub-Total	5
Total Number of Credits to Complete Program	50

Program Curriculum Narrative

Describe any variable credits. You may also include additional curriculum information.

***** Proposed required courses (start Fall semester 2017)

Additionally, students may be asked to attend NIH Remote Courses (not credited):

1. NIH "Principles of Pediatric Clinical Pharmacology" course (Oct -April) http://www.cvent.com/events/principles-of-pediatric-clinical-pharmacology-course/event-summary- f0b882cb929247d6af5929c299a6ed5f.aspx

2. Introduction to the Principles and Practice of Clinical Research (IPPCR) (Oct -April) http://www.cc.nih.gov/training/training/ippcr.html

The proposed Ph.D. program in Clinical Pharmacology will have emphasis: a) Pharmacometrics, and b) Comparative Effectiveness Research.

Appendix B: Course Descriptions

PCTH 7460 /MDCRC 6470 - Implementation of Clinical Trials (2 credits): Course explores the use of statistical modeling of analysis of health and medical data. Expanding upon the foundation laid in Biostatistics I, this course focuses on the analysis of complex data using a variety of regression and analysis of variance techniques, including linear regression, logistic regression, proportional hazards regression, Poisson regression, fixed effects analysis of variance, and repeated measures analysis of variance.

PED 7600 - Principles and Practice of Pharmacometrics (2 credits): Enrollment Requirement: Prerequisites: Introductory Statistics Course. This course provides an extensive overview of topics in population pharmacokinetics and pharmacodynamic models, Monte Carlo simulation, and best practices. Instruction combines didactic lectures with hands-on exercises using R, Monolix, SimCyp, and NONMEM.

PED 7700 - Clinical Pharmacology in Special Populations (2 credits): This course establishes a foundation for understanding the clinical significance of the pharmacological effects of drugs across different stages of life and human development.

PED 7800 - Journal Club - Pharmacometrics and Clinical Pharmacology (1 credit): This course will review the fundamentals and applications of pharmacometrics and clinical pharmacology with an emphasis on literature-based understanding and critique of topics associated with the field of pharmacometrics and clinical pharmacology, and this provides a unique opportunity to review new research methods and approaches. The purpose of this journal club is to familiarize students/trainees with the latest topics in pharmacometrics and clinical pharmacology as they relate to clinical research.

PED 7810 - Research-in-Progress, Pharmacometrics, and Clinical Pharmacology (1 credit): This course will represent an opportunity for staff, fellow and graduate students to present their in-progress research. This will facilitate learning by the audience, as they familiarize themselves with current work by pharmacometricians and clinical pharmacologists, and will benefit the presenters as they receive peer feedback as well as input from senior faculty members.

PED 7820 - Special Seminar Series in Clinical Pharmacology (1 credit): This course will consist of presentations by specialists in clinical pharmacology, maternal-fetal medicine, neonatology, pediatric infectious diseases, pediatric oncology, drug toxicology/poisoning and animal modeling. The purpose of the course is to raise awareness of relevant topics associated with various pediatric clinical conditions, topics or research and the state of research in these areas.

PED 5400 - Introduction to Clinical Pharmacology (2 credit): This course is a covers the fundamentals of clinical pharmacology as a translational scientific discipline focused on rational drug development and utilization in therapeutics. The course provides an introductory review of pharmacokinetics, drug metabolism and transport, pharmacogenetics, and drug discovery and development.

PED XXXX - Introduction to Pharmacokinetic and Pharmacodynamic Modeling (1 credit): Introduction to Pharmacokinetic and Pharmacodynamic Modeling

Degree Map

Degree maps pertain to undergraduate programs ONLY. Provide a degree map for proposed program. Degree Maps were approved by the State Board of Regents on July 17, 2014 as a degree completion measure. Degree maps or graduation plans are a suggested semester-by-semester class schedule that includes prefix, number, title, and semester hours. For more details see http://higheredutah.org/pdf/agendas/201407/TAB%20A%202014-7-18.pdf (Item #3).

Please cut-and-paste the degree map or manually enter the degree map in the table below.

Appendix C: Current and New Faculty / Staff Information

Part I. Department Faculty / Staff

Identify # of department faculty / staff (headcount) for the year preceding implementation of proposed program.

	# Tenured	# Tenure -Track	# Non -Tenure Track
Faculty: Full Time with Doctorate		3	8
Faculty: Part Time with Doctorate			
Faculty: Full Time with Masters			
Faculty: Part Time with Masters			
Faculty: Full Time with Baccalaureate			
Faculty: Part Time with Baccalaureate			
Teaching / Graduate Assistants			
Staff: Full Time			
Staff: Part Time			

Part II. Proposed Program Faculty Profiles

List current faculty within the institution -- with academic qualifications -- to be used in support of the proposed program(s).

	First Name	Last Name	Tenure (T) / Tenure Track (TT) / Other	Degree	Institution where Credential was Earned	Est. % of time faculty member will dedicate to proposed program.	If "Other," describe
Full Time Faculty							
Part Time Faculty							
	Robert D	Christensen	T	MD	Columbia University College of Physicians and Surgeons	1%	
	Andrew	Pavia	T	MD	Brown University Medicine	3%	
	Emily	Thorell		MD, M.S.C.I	University of Utah Medicine	3%	
	Andrew C	Harris		MD	Case Western Reserve University School of Medicine	1%	
	Elizabeth Ann	Raetz,		MD	University of Wisconsin Medicine	1%	
	Shannon	Saldaña		MS, Pharm[	Idaho State University College of Pharmacy and specializes in medicatio	1%	
	Richard	Martini		MD	University of Nebraska - Omaha Medicine	1%	
	Erin	Clark		MD	Mayo Medical School Medicine	1%	
	Michael W.	Varner		MD	University of Minnesota Medicine	3%	
	Roger	Van Andel	T	DVM	Colorado State University	1%	

Part III: New Faculty / Staff Projections for Proposed Program

Indicate the number of faculty / staff to be hired in the first three years of the program, if applicable. Include additional cost for these faculty / staff members in Appendix D.

	# Tenured	# Tenure -Track	# Non -Tenure Track	Academic or Industry Credentials Needed	Est. % of time to be dedicated to proposed program.

	# Tenured	# Tenure -Track	# Non -Tenure Track	Academic or Industry Credentials Needed	Est. % of time to be dedicated to proposed program.
Faculty: Full Time with Doctorate					
Faculty: Part Time with Doctorate					
Faculty: Full Time with Masters					
Faculty: Part Time with Masters					
Faculty: Full Time with Baccalaureate					
Faculty: Part Time with Baccalaureate					
Teaching / Graduate Assistants					
Staff: Full Time					
Staff: Part Time					

Appendix D: Projected Program Participation and Finance

Part I.

Project the number of students who will be attracted to the proposed program as well as increased expenses, if any. Include new faculty & staff as described in Appendix C.

Three Year Projection: Program Participation and Department Budget						
	Year Preceding Implementation	New Program				
		Year 1	Year 2	Year 3	Year 4	Year 5
Student Data						
# of Majors in Department						
# of Majors in Proposed Program(s)		1	1	1	1	1
# of Graduates from Department						
# Graduates in New Program(s)		2	2	2	2	2

Department Financial Data				
	Department Budget			
		Year 1	Year 2	Year 3
Project additional expenses associated with offering new program(s). Account for New Faculty as stated in Appendix C, "Faculty Projections."	Year Preceding Implementation (Base Budget)	Addition to Base Budget for New Program(s)	Addition to Base Budget for New Program(s)	Addition to Base Budget for New Program(s)
EXPENSES – nature of additional costs required for proposed program(s)				
List salary benefits for additional faculty/staff each year the positions will be filled. For example, if hiring faculty in year 2, include expense in years 2 and 3. List one-time operating expenses only in the year expended.				
Personnel (Faculty & Staff Salary & Benefits)	$0	$0	$0	$0
Operating Expenses (equipment, travel, resources)	$0	$0	$0	$0
Other:	$0	$0	$0	$0
TOTAL PROGRAM EXPENSES		$0	$0	$0
TOTAL EXPENSES	$0	$0	$0	$0
FUNDING – source of funding to cover additional costs generated by proposed program(s)				
Describe internal reallocation using Narrative 1 on the following page. Describe new sources of funding using Narrative 2.				
Internal Reallocation	$0	$0	$0	$0
Appropriation	$0	$0	$0	$0
Special Legislative Appropriation	$0	$0	$0	$0
Grants and Contracts	$0	$0	$0	$0
Special Fees	$0	$0	$0	$0
Tuition	$0	$0	$0	$0
Differential Tuition (requires Regents approval)	$0	$0	$0	$0
PROPOSED PROGRAM FUNDING		$0	$0	$0
TOTAL DEPARTMENT FUNDING	$0	$0	$0	$0
Difference				
Funding - Expense	$0	$0	$0	$0

Part II: Expense explanation

Expense Narrative

Describe expenses associated with the proposed program.

Initially, two Ph.D. student will be enrolled each year. - Students will be paid a stipend of $25,000 per year in accordance with NIH NOT-OD-17-084 recommendations for establishing stipend levels for undergraduate and predoctoral trainees and fellows (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-084.html). The students will be Graduate Research Assistants and will be eligible for Student Tuition Benefit through the Graduate School. The Division will pay any cost of health insurance and tuition not covered by the by the Student Tuition Benefit Subsidized Insurance Plan. There will be no additional costs associated with mentoring Ph.D. students. The time required for mentoring can be absorbed into existing faculty FTE. There are no additional costs for space or equipment as space has been requested in the new Pharmacy building design. All costs associated with student's education, research projects will be covered by the division research grants, Pediatric Research Enterprise and are encountered in the strategic budget of the division.

Part III: Describe funding sources

Revenue Narrative 1

Describe what internal reallocations, if applicable, are available and any impact to existing programs or services.

Not applicable

Revenue Narrative 2

Describe new funding sources and plans to acquire the funds.

Not applicable

School of Medicine
Department of Pediatrics
Clinical Pharmacology
295 Chipeta Way, 1S100
Salt Lake City, UT 84108
801.585.7857

October 16, 2017

To: Dr. David Kieda,
Dean of the Graduate School,
Graduate Council Chair,
University of Utah

Re: Doctorate Degree in Clinical Pharmacology Program (PhD in Clinical Pharmacology) resubmission

Dear Dr. Kieda,

Thank you for meeting with me recently and for your help to prepare our request for reconsideration of our PhD program. After receiving comments from the University Graduate Council on our initial application to approve a doctorate degree program in Clinical Pharmacology at the University of Utah, faculty members of our division and affiliated faculty members within the Department of Pediatrics, other departments in the School of Medicine, and College of Pharmacy have further discussed the viability of the PhD program to be offered through the Division of Clinical Pharmacology. We have worked to resolve and address the program deficiencies, which the Council outlined in our initial PhD program proposal. The Director of the proposed PhD program in Clinical Pharmacology, Dr. Sherwin has met with the Chairs of Pediatrics, Internal Medicine (SoM), Pharmacology/Toxicology, Pharmacotherapy and Pharmaceutics (CoP) and the Executive Director Personalized Health to discuss potential solutions.

Council comments from first submission:
"1. The Graduate Council expressed concerns regarding the very limited size of the proposed program. The small number of students that would be enrolled in proposed program would create a very small cohort group, and a very small number of faculty members would be responsible for the management of the proposed curriculum.

2. The Graduate Council felt the program could have larger impact and better learning outcomes if a program faculty for the proposed degree was established. The Graduate Council voted to table the proposal until options for establishing a larger program faculty are explored. The proposers are requested to meet with Graduate School Deans to develop an action plan in response to the Graduate Council's concerns."

Below is a summary of our response to the council comments.
Related to concern in the cohort size, we have given much consideration on how to increase the impact of our program and how to improve learning outcomes for our future students:

Point 1: Initially, each year we are planning to enroll two students. While it appears that the student cohort is small, as two students will be admitted every year the cohort will grow, after 3 years, there will potentially be 6 students in our program. In order for students not to feel "isolated" and to increase their exposure to basis pharmacology and toxicology, pharmacotherapy research and other pharmaceutical disciplines, we have expanded the proposed curriculum and added additional elective several courses. These include "Research Seminars" taught by College of Pharmacy faculty members. These activities will allow our students to interact with their peers at the College of Pharmacy and also to present their work to their peers and get feedback from other researchers outside the field of clinical pharmacology. Additionally, our students will be presenting their work at local/regional conferences, national, international and workshops as appropriate. This will also increase their interaction and networking with PhD students from other universities and nationally recognized experts in the field of clinical pharmacology. The Division of Clinical Pharmacology initiated a regional group 6 years ago that includes all medical and pharmacy schools in the mountain west, which meets annually and has a strong student focus to encourage networking and collaborations. This is just one of the examples of initiatives that the Division provides students.

Point 2: You will see from the letters of support we have submitted, we have a large amount of support from the College of Pharmacy, including from the Dean. We have added to the application a list of potential faculty members from departments within the School of Medicine and College of Pharmacy who have expressed interest in participating in our PhD program as potential student mentors, or members of the

Supervisory Committee. Part of our program requires at least one rotation in a lab/group outside of the division of clinical pharmacology. Similar to our recently accredited Clinical Pharmacology Fellowship program, it will be required that students have appropriate mentors either clinical and research based from outside the Division of Clinical Pharmacology on their committees. These mentors may be topic specific or required based on the students main research focus. Following a number of meetings we know we have the support as needed from other faculty for our students as our program develops.

Lastly, this proposed PhD in Clinical Pharmacology if approved will be the only program of its kind in the USHE, Utah and Intermountain regions. We to build on the success of our Fellowship, which is also the only one of its kind within the Mountain West region and has attracted national attention for the University of Utah. If our program is approved, it will provide an opportunity for more students to obtain a PhD degree in Clinical Pharmacology and provide more experts who have the knowledge and training to improve current treatment regimens, decrease costs, improve health outcomes and move towards personalizing (precision medicine) treatments for every patient treated – which helps achieve the are goals of the University of Utah Health

Sincerely,

Catherine Sherwin, BSs (Hons), PhD, BN, MSCI
Associate Professor of Pediatrics
Division Chief of Pediatric Clinical Pharmacology
Department of Pediatrics
University of Utah School of Medicine
295 Chipeta Way, Williams Building
Salt Lake City, UT 84108
801.587.7404
Catherine.Sherwin@hsc.utah.edu

HEALTH
UNIVERSITY OF UTAH

Academic Affairs &
Faculty Development
26 S. 2000 E., HSEB 5515
Salt Lake City, UT 84112
Office 801-585-6283
Fax 801-581-3338

October 12, 2017

Graduate Council
302 Park Building
201 South Presidents Circle
Salt Lake City, UT 84112

Re: PhD program in Clinical Pharmacology

Dear Council Members,

It is my pleasure to support the application for a Doctor of Philosophy (PhD) program in Clinical Pharmacology in the Division of Clinical Pharmacology, Department of Pediatrics, School of Medicine at the University of Utah. I had involvement in the accreditation process of the Division of Clinical Pharmacology's recently accredited Utah Clinical Pharmacology Fellowship Program. The proposed PhD program is the natural development of the strategic plan to further develop the educational program provided by this research and educational focused division under the leadership of Catherine Sherwin, PhD, FCP.

The Division of Clinical Pharmacology is a unique division with a diverse group of faculty with research focused in various areas of clinical pharmacology including personalized (precision) medicine, pharmacogenomics, pharmacometrics and translational medicine. Their research aims to help treat patients based on their individual therapeutic needs and to reduce costs associated with therapeutics. Students who would graduate from this proposed PhD program in Clinical Pharmacology would be highly competitive for positions within the pharmaceutical industry, the FDA, and academic institutions. The program will focus on training students in the pharmacology associated with special populations, which includes neonates, children, and pregnant women. The availability of this PhD program will be of considerable value to the Department of Pediatrics and the University of Utah.

I fully support this proposed PhD program in Clinical Pharmacology and believe that it will strengthen the existing clinical programs within School of Medicine and support the University of Utah Health focus towards an integrated health system.

Sincerely,

Wyatt Rory Hume, DDS, PhD
Associate Vice President for Academic Affairs and Education

UNIVERSITY OF UTAH
COLLEGE OF PHARMACY
L. S. SKAGGS PHARMACY INSTITUTE

Pharmacotherapy Outcomes
Research Center

April 10, 2017

Catherine M.T. Sherwin, Ph.D., MSc., FCP
Assistant Professor, Pediatrics and Pharmacy
Chief Division of Clinical Pharmacology
Director Utah Clinical Pharmacology Fellowship Program
Director Pharmacometrics, Clinical Trials Office
Department of Pediatrics,
University of Utah School of Medicine
295 Chipeta Way
Salt Lake City, UT 84108

Re: Proposed Ph.D. Program in Clinical Pharmacology in the School of Medicine

Dear Dr. Sherwin:

I express my full support for your pursuit of a PhD program in Clinical Pharmacology. Considering that clinical pharmacology is becoming a cornerstone of personalized medicine, I believe that the proposed PhD program is a much needed addition to the University of Utah School of Medicine curriculum.

You and your division faculty members have excellent scholarly records and outstanding skills teaching, as exemplified by your Utah Clinical Pharmacology Fellowship Program. Fellows completing your program have become true research leaders in academia and are in a high demand by pharmaceutical companies. I anticipate the same quality of training and results from the proposed PhD program.

For a number of years, the Department of Pharmacotherapy, Outcome Research Center and the Division of Clinical Pharmacology, Department of Pediatrics have closely collaborated. We have a strong history of mentorship. As one example, we have mentored graduate students in the Technology Oriented Comparative Effectiveness Research (TOCER) scholars program and with your active support, we have held formal biannual meetings with the TOCER scholar. We have also collaborated on multiple projects, where graduate students were mentored in crystalizing their analytical and research skills. Additionally, we recently supervised two graduate students on a project evaluating the cost effectiveness of TP53 mutation testing in newborns. This project is in its final stages, and a manuscript is currently under revision. A final example is our collaborative project identifying polypharmacy populations at risk for pharmacogenetic interactions treated in the University of Utah Healthcare System.

30 South 2000 East, Room 4410
Salt Lake City, UT 84112-5820
Phone 801-585-3092

The division has an excellent reputation for educating and mentoring graduate students in the area of clinical pharmacology. In the past 6 years, under you, the division has had 5 PhD graduate students in partnership with the College of Pharmacy, with 3 of those students receiving American Foundation for Pharmaceutical Education (AFPE) Pre-Doctoral Fellowships. One of those students, Casey Tak is jointly supervised between our two groups. This demonstrates the strong relationship and the success we have had combining our programs.

I am very pleased by our interactions with your division and I truly hope that the formalization of a PhD program in clinical pharmacology will provide additional opportunities for students and collaboration. I wish you luck with your application.

Sincerely,

Diana Brixner, PhD, RPh
Professor
Department of Pharmacotherapy
Executive Director Outcomes Research Center
College of Pharmacy
http://www.pharmacy.utah.edu/pharmacotherapy
Director of Outcomes
Program in Personalized Health Care
University of Utah
http://healthsciences.utah.edu/phc/
office: +1 (801) 581-3182
diana.brixner@utah.edu

UNIVERSITY OF UTAH
COLLEGE OF PHARMACY
L. S. SKAGGS PHARMACY INSTITUTE
Department of Pharmacotherapy

April 4, 2017

To: Catherine M.T. Sherwin, Ph.D., MSc., FCP
Assistant Professor, Pediatrics and Pharmacy
Chief Division of Clinical Pharmacology
Director Utah Clinical Pharmacology Fellowship Program
Director Pharmacometrics, Clinical Trials Office
Department of Pediatrics,
University of Utah School of Medicine
295 Chipeta Way
Salt Lake City, UT 84108, USA

Re: Proposed PhD. Program in Clinical Pharmacology in the School of Medicine

Dear Dr. Sherwin,

I am pleased to support the proposed PhD program in Clinical Pharmacology, which will be administered by the Division of Clinical Pharmacology, Department of Pediatrics at the University of Utah School of Medicine.

The Department of Pharmacotherapy trains high-quality specialists as practitioners at hospital and retail pharmacies as well as researchers in both the academic and industry setting. The Department of Pharmacotherapy values its established, close collaboration with your division. We have similar goals in delivering best therapeutic care to the patients, staying on the cutting edge of pharmaceutical science and promoting personalized care for every patient in the University Healthcare System.

Considering the great need for both clinical pharmacologists and translational research scientists as well as the lack of a PhD program specializing in clinical pharmacology at the School of Medicine, I believe that this is an opportune time to offer this program. Please let me know whether you need further assistance in initiating this program.

Sincerely,

Prof. Karen Gunning, PharmD, BCPS
Interim Chair of the Department of Pharmacotherapy

30 South 2000 East, Room 4410
Salt Lake City, UT 84112-5820
Phone 801-585-3092

UNIVERSITY OF UTAH
SCHOOL OF MEDICINE

Department of Pediatrics

EDWARD B. CLARK, M.D.
Wilma T. Gibson Presidential Professor
Chair of Pediatrics, The University of Utah
Associate Vice President, Clinical Affairs
President, University of Utah Medical Group

April 4, 2017

To: Catherine M.T. Sherwin, Ph.D., MSc., FCP
Assistant Professor, Pediatrics and Pharmacy
Chief Division of Clinical Pharmacology
Director Utah Clinical Pharmacology Fellowship Program
Director Pharmacometrics, Clinical Trials Office
Department of Pediatrics,
University of Utah School of Medicine
295 Chipeta Way
Salt Lake City, UT 84108, USA

Re: Proposed Ph.D. Program in Clinical Pharmacology in the School of Medicine

Dear Dr. Sherwin,

I fully support the creation of a Ph.D. Program in Clinical Pharmacology in the Division of Clinical Pharmacology, Department of Pediatrics, School of Medicine, at the University of Utah. As clinical pharmacology plays an essential role in drafting treatment algorithms for personalized medicine, I believe the initiation of this program will be of considerable value to the Department of Pediatrics and the University of Utah as a whole.

The Division of Clinical Pharmacology is excellently positioned to offer this degree. In addition to being provided coursework focused in the area of clinical pharmacology, students will be mentored by experienced faculty members and researchers in the field of pharmacokinetics and pharmacodynamics, pharmacometrics, pharmacogenomics, and special population pharmacology. This will allow students to acquire specialized knowledge in the area of pharmacology for adult patients, pregnant women, neonates, children and elderly populations. Each student will also have the opportunity to undertake guided research, ultimately providing them with a mechanism to apply knowledge, utilize skills, and have significant experiences, which will prepare to become leaders in the area of clinical pharmacology and translational research.

The division has an excellent reputation for educating and mentoring graduate students in the area of clinical pharmacology. In the past 6 years, under your direction, the division has had 5 PhD graduate students in partnership with the College of Pharmacy, with 3 of those students receiving American Foundation for Pharmaceutical Education (AFPE) Pre-Doctoral Fellowships. The division also has an outstanding reputation for training postdoctoral fellows, where that program provides each fellow with a designated primary mentor and supervision by an Advisory Committee. As a member of the Executive Committee of Utah Clinical Pharmacology Fellowship Program, I know this fellowship program has substantially advanced under your leadership and is currently being considered for accreditation by American Board of Clinical Pharmacology programs. I expect that your application for formal accreditation will be approved by American Board of Clinical Pharmacology in the near future.

P.O. Box 581289
Salt Lake City, Utah 84158 (mailing)

295 Chipeta Way, 2S010
Salt Lake City, Utah 84108 (campus)
Phone: 801-587-7415
Email: ed.clark@hsc.utah.edu

All faculty and adjunct faculty members of the division have great scholarly records, have published numerous peered-reviewed manuscripts in leading national and international journals, and actively teach courses within the Department of Pediatrics and jointly with other departments in clinical and basic pharmacology (including pharmacometrics, and clinical pharmacology) of special populations. I am impressed with the interactions of your faculty throughout the department. The division of Clinical Pharmacology is widely known to have close collaborations with other divisions in the department of pediatrics as well as other departments within the School of Medicine.

In my role as Chairman of the Department of Pediatrics, I support the development and formalization of a specific Ph.D. Program in Clinical Pharmacology. You have the full support of the department.

Sincerely,

Edward B. Clark, MD
Wilma T. Gibson Presidential Professor
Associate Vice President of Clinical Affairs
President, University of Utah Medical Group
Chair, Department of Pediatrics

April 4, 2017

To: Catherine M.T. Sherwin, Ph.D., MSc., FCP
Assistant Professor, Pediatrics and Pharmacy
Chief Division of Clinical Pharmacology
Director Utah Clinical Pharmacology Fellowship Program
Director Pharmacometrics, Clinical Trials Office
Department of Pediatrics,
University of Utah School of Medicine
295 Chipeta Way
Salt Lake City, UT 84108, USA

Re: Proposed Ph.D. Program in Clinical Pharmacology in the School of Medicine

Dear Dr. Sherwin,

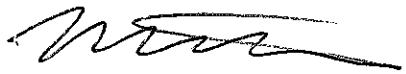
I am pleased to write this letter giving my support to the Division of Clinical Pharmacology, Department of Pediatrics, School of Medicine at the University of Utah in requesting to create a PhD program in Clinical Pharmacology.

I was recently introduced to the Division of Clinical Pharmacology during my talk at the Clinical Pharmacology Fellowship Program Distinguished Speakers seminar series. In the short time we have been acquainted, I have been impressed by you and your division. I believe you and your faculty have great experience in organizing successful educational materials for students and fellows. Specifically notable is the fellowship training program you oversee, which provides meaningful education, experience, and mentoring. Faculty members of your division appear to have outstanding scholarly records. I know that you and other members of the division actively collaborate with many researchers at the College of Pharmacy and participate in teaching pharmacology courses, both as lecturers and invited speakers.

Currently, there is not a PhD degree in Clinical Pharmacology offered at the University of Utah School of Medicine. The College of Pharmacy offers doctoral education in many pharmacy disciplines, but not in the specific area of clinical pharmacology. Currently students looking for training in clinical pharmacology must undertake a degree through the College of Pharmacy, which does not allow for specification of their comprehensive training and experience in clinical pharmacology. The introduction of this Ph.D. program will offer an unique opportunity for these students to continue their education at the University of Utah.

I appreciate the close collaboration you have with the College of Pharmacy and truly welcome the formalization of the PhD program in Clinical Pharmacology. I expect your program will increase collaborations with your division faculty members, fellows and students. As able and available College of Pharmacy faculty members will be happy to serve on your PhD student's supervisory committees in areas of mutual interest.

Sincerely,



Dr. Randall T. Peterson, PhD
L.S. Skaggs Presidential Endowed Professor
Dean, College of Pharmacy, University of Utah

UNIVERSITY OF UTAH
HEALTH SCIENCES

Vivian S. Lee, M.D., Ph.D., M.B.A.
A. Lorris Betz Senior Vice President for Health Sciences
Dean, School of Medicine
CEO, University of Utah Health Care

April 7, 2017

Graduate Council
302 Park Building
201 South Presidents Circle
Salt Lake City, UT 84112

Re: PhD program in Clinical Pharmacology

Dear Council Members,

I am pleased to support the formalization of a Doctor of Philosophy (PhD) program in Clinical Pharmacology in the Division of Clinical Pharmacology, Department of Pediatrics, School of Medicine at the University of Utah. This year, University of Utah Health Care system was ranked Number 1in the nation for quality among university hospitals, and is the most innovative and transformative health care system in the nation. As such, our system leadership recognizes the need of transforming current health care and moving towards the personalization of medicine for each patient seen by healthcare professionals at University hospitals and clinics.

Faculty members and researchers in the Division of Clinical Pharmacology are actively involved in researching the best options for treating patients based on their individual therapeutic needs. Students graduating from the proposed PhD program in Clinical Pharmacology would contribute significantly to the development of personalized treatment in adult patients as well as special populations, which includes neonates, children, and pregnant women. I believe the initiation of this program will be of considerable value, not only to the Department of Pediatrics, but to the University of Utah as a whole.

I fully support the creation of a PhD program in Clinical Pharmacology and believe that it will strengthen the existing clinical programs within School of Medicine and support the University of Utah Health Care system toward precision medicine.

Sincerely,

Vivian S. Lee, MD, PhD, MBA,

Clinical Neurosciences Center 5201
175 North Medical Drive East
Salt Lake City, Utah 84132-5901

Phone: (801) 581-7480
E-mail: vivian.lee@hsc.utah.edu
Twitter: @vivianleemd
Blog: www.vivianleemd.org

The University of Utah
Pharmacology & Toxicology
30 S 2000 E RM 201 Salt Lake City, Utah 84112 (801) 581-6287 FAX (801) 585-5111

April 4, 2017

To: Catherine M.T. Sherwin, Ph.D., MSc., FCP
Assistant Professor, Pediatrics and Pharmacy
Chief of Division of Clinical Pharmacology
Director of the Utah Clinical Pharmacology Fellowship Program
Director of Pharmacometrics, Clinical Trials Office
Department of Pediatrics,
University of Utah School of Medicine
295 Chipeta Way
Salt Lake City, UT 84108, USA

Re: Proposed Ph.D. Program in Clinical Pharmacology in the School of Medicine

Dear Catherine,

I am pleased to offer support for the establishment of a Doctor of Philosophy (PhD) program in Clinical Pharmacology. From my experience, the need for personalization of treatments and, concurrently, the necessity for researchers with advanced training is growing, particularly in pediatric and adolescent patients, pregnant women and elderly populations. You and the researchers in your division are instrumental in multiple areas of clinical pharmacology including pharmacometrics and modeling of pharmacologic processes in special population patients. Not only is your group one of a limited number of clinical pharmacology groups actively publishing research findings in peer-reviewed journals, but your research has national and international impact and is highly rated by your colleagues. I appreciate the collaborations between the Department of Pharmacology and Toxicology and the Division of Clinical Pharmacology, Pediatrics. Many divisional Clinical Pharmacology faculty members have taught in courses offered in the Department of Pharmacology and Toxicology, both as lecturers and guest speakers.

Your division has an excellent reputation for educating and mentoring graduate students in the area of clinical pharmacology. In the past 6 years, under you, the division has had 5 PhD graduate students in partnership with the College of Pharmacy, with 3 of those students receiving American Foundation for Pharmaceutical Education (AFPE) Pre-Doctoral Fellowships. In connection with the Department of Pharmacology & Toxicology there have been 3 students jointly supervised between our two groups. This demonstrates the strong relationship and the success we have had combining our programs.

I anticipate that the newly established PhD program in Clinical Pharmacology will expand our collaboration and provide more opportunities to work together. Please let me know if there are further ways in which our department can assist you in establishing this program.

Sincerely,

Karen S. Wilcox, Ph.D.
Chair of the Department of Pharmacology and Toxicology

UNIVERSITY OF UTAH
SCHOOL OF MEDICINE

To: Graduate Council
302 Park Building
201 South Presidents Circle
Salt Lake City, UT 84112

Re: PhD program in Clinical Pharmacology

Dear Council Members,

I am pleased to support the formalization of a Doctor of Philosophy (PhD) program in Clinical Pharmacology in the Division of Clinical Pharmacology, Department of Pediatrics, School of Medicine at the University of Utah. University of Utah Health Care system ranks in the top 10 in quality among university hospitals and is the most innovative and transformative health care system in the nation. As such, our system leadership recognizes the need of transforming current health care and moving towards the personalization of medicine for each patient seen by healthcare professionals at University hospitals and clinics.

Faculty members and researchers in the Division of Clinical Pharmacology are actively involved in researching the best options for treating patients based on their individual therapeutic needs. Students graduating from the proposed PhD program in Clinical Pharmacology would contribute significantly to the development of personalized treatment in adult patients as well as special populations, which includes neonates, children, and pregnant women. I believe the initiation of this program will be of considerable value to the Department of Pediatrics and the University of Utah as a whole

I fully support the creation of a PhD program in Clinical Pharmacology and believe that it will strengthen the existing clinical programs within School of Medicine and support the University of Utah Health Care system push toward precision medicine.

Sincerely,

Wayne Samuelson, MD
Interim Dean School of Medicine

Office of the Dean
School of Medicine
30 North 1900 East
Salt Lake City, Utah 84132-2101
Phone 801-581-7201
Fax 801-585-3300

HEALTH
UNIVERSITY OF UTAH

Spencer S. Eccles Health Sciences Library
10 North 1900 East, Bldg 589
Salt Lake City, Utah 84112
http://library.med.utah.edu

March 31, 2017

Catherine M.T. Sherwin, Ph.D., MSc., FCP
Assistant Professor, Pediatrics and Pharmacy
Chief Division of Clinical Pharmacology
Director Utah Clinical Pharmacology Fellowship Program
Director Pharmacometrics, Clinical Trials Office
Department of Pediatrics,
University of Utah School of Medicine
295 Chipeta Way
Salt Lake City, UT 84108, USA

Re: Proposed Clinical Pharmacology Ph.D. Program in the School of Medicine

Dear Catherine:

I fully support the creation of a Clinical Pharmacology Ph.D. Program in the School of Medicine. The Spencer S. Eccles Health Sciences Library is committed to fostering the growth and development of students through the provision of information, teaching life-long learning strategies, and encouraging innovation and discoveries.

Eccles Library faculty and staff provide access to a wealth of information resources and tools designed to support learners, researchers, and educators in clinical pharmacology, therapeutics, toxicology, trial design, pharmacometrics, and biostatistics. We also offer personalized learning opportunities and literature-based research assistance, plus course-integrated information discovery and management education. We are also happy to assist with supporting any innovation-related information needs that might surface.

Access to collections of the Marriott Library, Faust Law Library, and a nationwide network of health sciences libraries are available through cooperative agreements, interlibrary loan and on-demand journal article suppliers. Our faculty embrace the opportunity to interact with faculty and students in the Clinical Pharmacology Ph.D. Program. We would be delighted to collaborate on courses teaching information use, searching, or management methodologies.

Again, I am delighted to have this opportunity to express my support for your Ph.D. program's establishment, and I look forward to its success and many rewarding partnerships.

Sincerely,

Jean Shipman

Jean P. Shipman, MSLS, AHIP, FMLA
Librarian
Executive Director, Knowledge Management &
Spencer S. Eccles Health Sciences Library
Director for Information Transfer, Center for Medical Innovation
Clifford C. Snyder Endowed Chair