

Herness, Scott

From: Neidecker, Marjorie <Marjorie.Neidecker@osumc.edu>
Sent: Tuesday, December 1, 2015 1:37 PM
To: Montalto, Catherine
Cc: Herness, Scott
Subject: RE: Proposal for Minor in Applied Clinical and Preclinical Research
Attachments: COM Clinchot letter of support 2015.12.pdf; CON Anderson letter of support 2015.11.16.pdf; COO Zadnik letter of concurrence 2015.11.10.pdf; COP Carnes letter of support 2015.11.16.pdf

Catherine,

Please find attached emails of support from the four colleges your requested. Let me know if you if you need anything else from me. I look forward to moving the proposal to the next approval step!

Warm regards,
Margie



Marjorie Neidecker, PhD MEng RN CCRP

Director, Master of Applied Clinical and Preclinical Research

Assistant Professor - Clinical, [Colleges of Nursing and Pharmacy](#)

Adjunct Assistant Professor, [College of Medicine, Dept. of Biological Chemistry and Pharmacology](#)

5072C Graves Hall, 333 W. 10th Ave., Columbus, OH 43210

614-247-6181 Office / 614-302-3904 Mobile

neidecker.1@osu.edu macpr.osu.edu

From: Montalto, Catherine [montalto.2@osu.edu]
Sent: Monday, November 09, 2015 12:06 PM
To: Neidecker, Margie
Cc: Herness, Scott; Montalto, Catherine
Subject: Proposal for Minor in Applied Clinical and Preclinical Research

Good morning Margie,

The Graduate School/Council on Academic Affairs Curriculum Subcommittee met on Friday, November 6, 2015 and reviewed the proposal for the Minor in Applied Clinical and Preclinical Research. The committee found the proposal solid and well prepared. In the spirit of having complete documentation of the proposal as it continues through the review process we have two requests.

1. Please secure a letter of concurrence (or email) from Vision Science, since their course Vision Science 7960 is a course that could be selected to meet the Research Ethics course requirement.
2. Please secure letters of support (or email) from the Dean or appropriate designee for the College of Nursing, the College of Pharmacy, and the College of Medicine.

Once these documents are received the proposal will continue through the review process.

Please let me know if you have questions.

Thank you.

Catherine Montalto

Chair

Graduate School/Council on Academic Affairs Curriculum Subcommittee



Catherine P. Montalto, Ph.D.

Associate Professor

College of Education and Human Ecology Department of Human Sciences

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montalto.2@osu.edu osu.edu

Buckeyes consider the environment before printing.

Herness, Scott

From: Clinchot, Dan <Dan.Clinchot@osumc.edu>
Sent: Thursday, November 19, 2015 12:19 PM
To: Montalto, Catherine
Subject: FW: Proposal for Minor in Applied Clinical and Preclinical Research
Attachments: image004.jpg; image001.png; Applied Clinical and Preclinical Research Minor Advising Sheet.pdf

Dr. Montalto, I have reviewed the attached proposal with our curriculum committee within the College of Medicine and write to document the College of Medicine's full support of the proposed minor. If you require a separate letter please let me know. Thanks, Dan

Daniel M Clinchot, MD
Vice Dean for Education
College of Medicine

From: Montalto, Catherine [montalto.2@osu.edu]
Sent: Monday, November 09, 2015 12:06 PM
To: Neidecker, Margie
Cc: Herness, Scott; Montalto, Catherine
Subject: Proposal for Minor in Applied Clinical and Preclinical Research

Good morning Margie,

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2. Please secure letters of support (or email) from the Dean or appropriate designee for the College of Nursing, the College of Pharmacy, and the College of Medicine.

Once these documents are received the proposal will continue through the review process.

Please let me know if you have questions.

Thank you.



Chair

Graduate School/Council on Academic Affairs Curriculum Subcommittee

RE: Proposal for Minor in Applied Clinical and Preclinical Research

Zadnik, Karla [zadnik.4@osu.edu]

Sent: Tuesday, November 10, 2015 9:17 PM

To: Neidecker, Marjorie

Dear Marjorie--

I approve the minor and would be delighted to have the students enrolled in it take my course, VS 7970.

--Karla

Karla Zadnik, OD PhD

Dean and Glenn A. Fry Professor in Optometry and Physiological Optics

The Ohio State University

College of Optometry

A400 Starling-Loving Hall, 338 W 10th Ave, Columbus, OH 43210

614-292-6603 Office

614-580-7267 Cell

zadnik.4@osu.edu

From: Neidecker, Marjorie [Marjorie.Neidecker@osumc.edu]

Sent: Tuesday, November 10, 2015 11:46 AM

To: Zadnik, Karla

Subject: Proposal for Minor in Applied Clinical and Preclinical Research

Dr. Dean Zadnik,

The Graduate School/Council on Academic Affairs Curriculum Subcommittee has approved a minor in Applied Clinical and Preclinical Research. We anticipate this minor will be attractive to PharmD students as well as other graduate students in the health sciences. One course that we have proposed as an elective in the minor is in the College of Optometry: Vision Science 7960 Ethics in Biomedical Research.

At this time a letter or email of concurrence is required from the dean or appropriate designee of the College of Optometry in order to include your course in our minor. If you are agreeable, would you please provide a response to this email in support of the minor? I've attached the proposal for the minor.

Thank you very much,
Margie Neidecker

Marjorie Neidecker, PhD MEng RN CCRP

Director, Master of Applied Clinical and Preclinical Research

Assistant Professor - Clinical, **Colleges of Nursing and Pharmacy**

Adjunct Assistant Professor, **College of Medicine, Dept. of Biological Chemistry and Pharmacology**

5072C Graves Hall, 333 W. 10th Ave., Columbus, OH 43210

RE: Proposal for Minor in Applied Clinical and Preclinical Research

Anderson, Cindy M. [anderson.2765@osu.edu]

Sent: Monday, November 16, 2015 8:53 AM

To: Neidecker, Marjorie

Sorry...I spoke with Bern and I am drafting a letter of concurrence on her behalf. If all you need is an email indicating support, consider this evidence. Let me know how to proceed. Cindy

From: Neidecker, Marjorie [mailto:Marjorie.Neidecker@osumc.edu]

Sent: Monday, November 16, 2015 8:25 AM

To: Anderson, Cindy M.

Subject: FW: Proposal for Minor in Applied Clinical and Preclinical Research

Cindy, at your earliest convenience, could you please indicate your support for the minor in Applied Clinical and Preclinical Research by responding to this email? A response of "I am in support" is sufficient. The Graduate School is awaiting emails of support before moving the proposal to the next step.

Thanks,
Margie

Marjorie Neidecker, PhD MEng RN CCRP

Director, Master of Applied Clinical and Preclinical Research

Assistant Professor - Clinical, [Colleges of Nursing and Pharmacy](#)

Adjunct Assistant Professor, [College of Medicine, Dept. of Biological Chemistry and Pharmacology](#)

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From: Neidecker, Marjorie

Sent: Tuesday, November 10, 2015 11:08 AM

To: Anderson, Cindy M.

Subject: Proposal for Minor in Applied Clinical and Preclinical Research

Cindy,

The Graduate School/Council on Academic Affairs Curriculum Subcommittee has approved the minor in Applied Clinical and Preclinical Research. At this time a letter or email of support is required from the dean or appropriate designee of the College of Nursing. Would you please provide a response to this email in support of the minor, or would you like me to forward this request to Dean Melnyk? I've attached the proposal for the minor.

FW: Proposal for Minor in Applied Clinical and Preclinical Research

Clinchot, Dan

Sent: Tuesday, December 01, 2015 1:22 PM
To: Neidecker, Marjorie
Cc: LaFramboise, Sidonia
Attachments: image004.jpg (2 KB) ; image001.png (4 KB) ; Applied Clinical and Precl~1.pdf (201 KB)

Marjorie, I sent the e-mail below to Dr. Montalto on November 19th. I am not sure what else you are looking for as you indicated that I could send an e-mail. If you would like me to write a letter instead let me know but I am not sure what you are asking for as I believe I did what you requested. Thanks Dan

From: "Clinchot, Dan" <Dan.Clinchot@osumc.edu>
Date: Thursday, November 19, 2015 at 12:18 PM
To: "montalto.2@osu.edu" <montalto.2@osu.edu>
Subject: FW: Proposal for Minor in Applied Clinical and Preclinical Research

Dr. Montalto, I have reviewed the attached proposal with our curriculum committee within the College of Medicine and write to document the College of Medicine's full support of the proposed minor. If you require a separate letter please let me know. Thanks, Dan

Daniel M Clinchot, MD
Vice Dean for Education
College of Medicine

From: Montalto, Catherine [montalto.2@osu.edu]
Sent: Monday, November 09, 2015 12:06 PM
To: Neidecker, Margie
Cc: Herness, Scott; Montalto, Catherine
Subject: Proposal for Minor in Applied Clinical and Preclinical Research

Good morning Margie,

The Graduate School/Council on Academic Affairs Curriculum Subcommittee met on Friday, November 6, 2015 and reviewed the proposal for the Minor in Applied Clinical and Preclinical Research. The committee found the proposal solid and well prepared. In the spirit of having complete documentation of the proposal as it continues through the review process we have two requests.

1. Please secure a letter of concurrence (or email) from Vision Science, since their course Vision Science 7960 is a course that could be selected to meet the Research Ethics course requirement.
2. Please secure letters of support (or email) from the Dean or appropriate designee for the College of Nursing, the College of Pharmacy, and the College of Medicine.

Once these documents are received the proposal will continue through the review process.

Please let me know if you have questions.

Thank you.



Chair
Graduate School/Council on Academic Affairs Curriculum Subcommittee

Re: Proposal for Minor in Applied Clinical and Preclinical Research

Carnes, Cynthia [carnes.4@osu.edu]

Sent: Monday, November 16, 2015 8:22 AM
To: Neidecker, Marjorie
Attachments: image004.jpg (2 KB) ; image001.png (4 KB)

I am in support.

Cynthia Carnes

On Nov 16, 2015, at 7:55 AM, Neidecker, Marjorie <Marjorie.Neidecker@osumc.edu> wrote:

Cynthia, at your earliest convenience, could you please indicate your support for the minor in Applied Clinical and Preclinical Research by responding to this email? The Graduate School is awaiting emails of support before moving the proposal to the next step.

Thanks,
Margie

Marjorie Neidecker, PhD MEng RN CCRP
Director, Master of Applied Clinical and Preclinical Research

Assistant Professor - Clinical, [Colleges of Nursing and Pharmacy](#)
Adjunct Assistant Professor, [College of Medicine, Dept. of Biological Chemistry and Pharmacology](#)
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From: Neidecker, Marjorie
Sent: Tuesday, November 10, 2015 11:08 AM
To: Carnes, Cynthia
Subject: FW: Proposal for Minor in Applied Clinical and Preclinical Research

Cynthia,

The Graduate School/Council on Academic Affairs Curriculum Subcommittee has approved the minor in Applied Clinical and Preclinical Research. At this time a letter or email of support is required from the dean or appropriate designee of the College of Pharmacy. Would you please provide a response to this email in support of the minor, or would you like me to forward this request to Dean Mann? I've attached the proposal for the minor.

Thanks,

Kathy and Scott,

Scott, I've entered the Minor in Applied Clinical and Preclinical Research in the curriculum system as you instructed. Kathy, so that you have some background, the minor was developed in consultation with Cynthia Carnes, and the MACPR graduate studies committee has approved it. The CON graduate studies committee AND faculty approved the minor, but Cynthia did not see the need to take it through the COP Graduate and Research Committee (GRC) since the MACPR program has its own graduate studies committee. She also didn't feel it was necessary to provide letters of support from the deans. Scott, let me know if that's not the case.

Thank you for reviewing the proposal. I'm looking forward to its final approval, hopefully by the end of autumn semester!

Warm regards,
Margie



Marjorie Neidecker, PhD MEng RN CCRP

Director, Master of Applied Clinical and Preclinical Research
Assistant Professor - Clinical, **Colleges of Nursing and Pharmacy**
Adjunct Assistant Professor, **College of Medicine, Dept. of Pharmacology**
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neidecker.1@osu.edu macpr.osu.edu

Date: June 8, 2015

Subject: Minor in Applied Clinical and Preclinical Research

Dear Dean Herness,

The Graduate Studies Committee of the Master of Applied Clinical and Preclinical Research program has approved the following proposal for which I respectfully request Graduate School approval:

Introduction of a Graduate Minor in Applied and Preclinical Research.

This proposal has been developed with the full support of the Dean of Academic Affairs in the College of Nursing and the Dean of Graduate Studies and Research in the College of Pharmacy.

Sincerely,
Margie Neidecker

Marjorie Neidecker, PhD MEng RN CCRP

Director, Master of Applied Clinical and Preclinical Research
Assistant Professor - Clinical, **Colleges of Nursing and Pharmacy**
Adjunct Assistant Professor, **College of Medicine, Dept. of Pharmacology**
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Graduate Minor in Applied Clinical and Preclinical Research

Rationale:

The Graduate Minor in Applied Clinical and Preclinical Research is comprised of four core courses in the Master of Applied Clinical and Preclinical Research program, with an option to complete one course in another health science college. These courses provide a foundation for the conduct of clinical research and meet the key competencies established by the Consortium of Academic Programs in Clinical Research. Gaining the knowledge and skills to conduct or support clinical research will be an asset to graduate students in the health sciences, life sciences, and social sciences, whether the graduate will become a member of the clinical research team or use the results of clinical research in his/her professional practice. It is anticipated that approximately 10-20 students per year will take advantage of this minor.

OSU Graduate School General Criteria for Graduate Minor (*Graduate School Handbook, Section VIII.4*):

All academic aspects of the Graduate Minor and the Graduate Interdisciplinary Specialization (e.g., program of study, examination requirements) are subject to approval by the graduate programs which offer the Minor and Interdisciplinary Specialization.

The Graduate Minor in Applied Clinical and Preclinical Research was approved by the Master of Applied Clinical and Preclinical Research graduate studies committee on November 21, 2014.

A Graduate Minor involves one program outside a student's major graduate program. A Graduate Minor requires a minimum of 10 hours of graduate-level course work in at least three courses. Twenty hours of graduate level courses is the maximum allowance for Graduate Minors. The student must receive a grade of B or better or S in each course comprising the Graduate Minor. The completed Graduate Minor will appear on the student's transcript.

The Graduate Minor in Applied Clinical and Preclinical Research is comprised of four courses and totals 10-12 credit hours. Students are required to receive a grade of B or better or S in each course.

Operating Procedures

Please refer to the Graduate Minor Procedures Form:

<http://www.gradsch.osu.edu/Depo/PDF/GraduateMinorProgramForm.pdf>.

1. The student completes the graduate minor program form (p.2 on <http://www.gradsch.osu.edu/Depo/PDF/GraduateMinorProgramForm.pdf>), including obtaining his/her advisor's signature. The minor program form is then submitted to the chairperson of the minor program (i.e., Graduate Minor in Applied Clinical Research). This form serves as the application to enroll in the graduate minor.
2. The graduate studies committee chair of the minor program sends a copy of the completed graduate minor program form to the Graduate School and to the graduate studies committee chairperson of the student's primary graduate program. The graduate program offering the minor keeps the original.
3. The graduate studies committee of the minor program will send the student an acknowledgement indicating whether or not the request is approved. The graduate studies committee of the minor program will send a copy to the Graduate School and the student's primary graduate studies committee.
4. The student must adhere to the curriculum of the graduate minor program as indicated on the approved graduate minor program form. If changes in the approved curriculum are necessary, the student must complete a new graduate minor program form following the above steps. Departures

from the approved minor program could lead to the minor not appearing on the student's transcript.

5. Upon completion of the minor program, the student must submit the graduate minor transcript designation form (p.3 on <http://www.gradsch.osu.edu/Depo/PDF/GraduateMinorProgramForm.pdf>) to the graduate studies committee chair of the minor program.

Coursework

Department	Course #	Course Title	Credit Hours	Semesters Offered	Delivery Mode	Semester (taken or planned)	Grade
Required Courses (9 credits)							
Nursing/Pharmacy	7770	Fundamentals of Medical Product Development and Regulation	3	Autumn, Spring	Online		
Nursing/Pharmacy	7782	Research Design and Methods for Clinical and Preclinical Research	3	Autumn, Spring	Online		
Nursing/Pharmacy	7405	Management of Clinical and Preclinical Studies (prerequisite: Nursing/Pharmacy 7770)	3	Spring, Summer	Online		
Research Ethics Course – SELECT ONE (1-3 credits)							
Nursing	7781	Responsible Conduct of Research	3	Autumn, Spring	Online		
Pharmacology	7510	Professional and Ethical Issues in Biomedical Sciences	2	Spring	Face-to-face		
Pharmacy	8520	Research Ethics	1	May session	Face-to-face		
Vision Science	7960	Ethics in Biomedical Research	2	Autumn	Face-to-face		

Course Descriptions

Required Courses	
Nursing/Pharmacy 7770 3 credits Autumn/Spring online	Fundamentals of Medical Product Development and Regulation Function of clinical research in medical product development and the regulatory process of new medical products. Laws and regulations concerning the development, testing, commercialization, and total product life cycle for medical products. Regulations governing the conduct of clinical research, including study sponsors, investigators, and Institutional Review Boards. Prerequisites: none.
Nursing/Pharmacy 7782 3 credits Autumn/Spring online	Research Design and Methods for Clinical and Preclinical Research Study of research design and methods used in clinical and preclinical research. Measurement issues, bias and confounding, statistical considerations, evaluation of published clinical and preclinical research designs, and protocol and proposal development. Prerequisites: none.
Nursing/Pharmacy 7405 3 credits Spring/Summer online	Management of Clinical and Preclinical Studies Operational planning of clinical trials including budgeting, study timeline, site evaluation and selection, study initiation, content and timing of monitoring visits, quality assurance, study closure procedures. Introduction to database design, data management, quality assurance, and technology assessment in clinical research administration. Prerequisite: Nursing/Pharmacy 7770.

Research Ethics Course – SELECT ONE	
<p>Nursing 7781 3 credits Autumn/Spring online, face-to-face as needed</p>	<p>Responsible Conduct of Research Concepts and policies for the responsible conduct of research (RCOR), Institutional Review Boards, and dissemination of findings. Prerequisites: grad standing.</p>
<p>Pharmacology 7510 2 credits Spring Face-to-face</p>	<p>Professional and Ethical Issues in Biomedical Sciences A discussion course based on case scenarios dealing with ethical issues facing biomedical researchers, such as publishing practices, confidentiality, mentoring. Prereq: Grad standing, and enrollment in Biomedical Sciences program. This course is graded S/U.</p>
<p>Pharmacy 8520 1 credit May session Face-to-face</p>	<p>Research Ethics Basic concepts of integrity in the process of research. The course fulfills NIH requirement for research ethics. Repeatable to a maximum of 20 cr hrs. This course is progress graded (S/U).</p>
<p>Vision Science 7960 2 credit hours Autumn Face-to-face</p>	<p>Ethics in Biomedical Research Provides a general understanding of the issues surrounding the ethical conduct of science including issues related to research involving human subjects, scientific misconduct, and authorship of scientific papers. Real-life case studies will be used.</p>