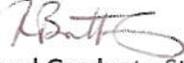




Date: March 16, 2016

To: Janice S. Blum, Ph.D.
Associate Vice Chancellor for Graduate Education at IUPUI
Associate Dean of the University Graduate School, Indiana University

From: Randy R. Brutkiewicz, Ph.D. 
Associate Dean for Research and Graduate Studies, IU School of Medicine

Re: Updates to the Business of Biomedical Sciences doctoral minor

This memo requests changes to the Business of Biomedical Sciences doctoral minor, originally approved by the IUPUI Graduate Affairs Committee (GAC) in May 2014. Since offering the minor, one of the courses offered for the minor (LAW-D/N 698 - Intellectual Property of Pharmaceutical Products and Medical Devices) was not being regularly offered due to staffing issues. The need to accommodate a student's minor plan of study prompted the Graduate Division to re-evaluate the course requirements. As a result, after consultation with our colleagues in the McKinney School of Law, we have replaced the requirement for students to take D/N 698 with the option for students in the minor to choose one of four courses, and D/N 698 is one of the four options.

Previous Requirements:

Required Courses (7 credits total):

- GRAD-G718--Research in Biomedical Science (2 cr.)
- BUS-X518--Global Trends and Events (1.5 cr.)
- BUS-X519--Business of Life Sciences (1.5 cr.)
- GRAD-G672--Translational Research and Entrepreneurship (2 cr.)
- LAW-D/N 698--Intellectual Property of Pharmaceutical Products and Medical Devices (2 cr.)

New Requirements:

Required Courses (7 credits total):

- GRAD-G718--Research in Biomedical Science (2 cr.)
- BUS-X518--Global Trends and Events (1.5 cr.)
- BUS-X519--Business of Life Sciences (1.5 cr.)
- GRAD-G672--Translational Research and Entrepreneurship (2 cr.)

Choose one of the following courses (2 credits total):

- LAW-D/N 693 - Life Sciences Compliance Law (2 or 3 cr.)
- LAW-D/N 698--Intellectual Property of Pharmaceutical Products and Medical Devices (2 cr.)
- LAW-D/N 635 - Drug Innovation and Competition Law (2 or 3 cr.)
- LAW-D/N 838 - Bioethics and Law (2 or 3 cr.)

OFFICE OF THE DEAN

GRADUATE DIVISION

Medical Science 207
635 Barnhill Drive
Indianapolis, Indiana
46202-5120

317-274-3441
Fax: 317-278-5211

INDIANA UNIVERSITY



Attached is our internal doctoral minor information sheet, for your records. If you have any questions, please contact me at rbrutkie@iupui.edu.

SCHOOL OF MEDICINE

Randy Brutkiewicz, Ph.D.
Associate Dean for Research and Graduate Studies
IU School of Medicine – Graduate Division

RRB/lae

OFFICE OF THE DEAN

GRADUATE DIVISION

Medical Science 207
635 Barnhill Drive
Indianapolis, Indiana
46202-5120

317-274-3441
Fax: 317-278-5211

Doctoral Minor: Business of Biomedical Sciences

Minor Contact: Randy R. Brutkiewicz, PhD

Minor Description

The “Business of Biomedical Sciences” minor will allow our trainees to be highly competitive for the careers in the 21st century biomedical workforce that require doctoral education. We take advantage of the existing structure of the IBMG Program for PhD study for the minor, but this minor is not restricted to School of Medicine graduate students. The nine credit “Business of Life Sciences” minor requires that students utilize existing courses in the Schools of Business, Law and Medicine. These courses are listed below in the doctoral minor plan of study.

Plan of Study

Required Courses (7 credits total):

- GRAD-G718--Research in Biomedical Science (2 cr.)
- BUS-X518--Global Trends and Events (1.5 cr.)
- BUS-X519--Business of Life Sciences (1.5 cr.)
- GRAD -G672--Translational Research and Entrepreneurship (2 cr.)

Choose one of the following courses (2 credits total):

- LAW-D/N 693 - Life Sciences Compliance Law (2 or 3 cr.)
- LAW-D/N 698--Intellectual Property of Pharmaceutical Products and Medical Devices (2 cr.)
- LAW-D/N 635 - Drug Innovation and Competition Law (2 or 3 cr.)
- LAW-D/N 838 - Bioethics and Law (2 or 3 cr.)

Admission Requirements

To be admitted to the Ph.D. minor in Business of Biomedical Sciences, you must be a currently enrolled doctoral student in good academic standing in any IU or IUPUI school.

Application Procedure

Students who would like to apply to the Ph.D. minor in the Business of Biomedical Sciences must submit an email to Dr. Randy Brutkiewicz, Associate Dean for Research and Graduate Studies, and contact for this minor, the following:

- Documentation of the approval of the student’s pursuit of this minor by his/her PI and advisory committee
- A one-page personal statement explaining the student’s reason for pursuing this minor, including the relevance of the minor to their program and goals

Accepted students will be notified promptly via email by the minor contact.

Grading Policy

A minimum of B (3.0) is required in each course that is to count toward the minor. If a minimum of B (3.0) is not earned in a course, that course must be retaken. A course may be retaken only once. Students who fail to achieve the minimum grade of B (3.0) the second time they take a course, will not be able to earn this Ph.D. minor.

Qualifying Exam

The Ph.D minor in Business of Biomedical Science does not require a Qualifying Exam

Course Descriptions – Business of Biomedical Science Doctoral Minor

IUSM Graduate Division Courses

1. **GRAD-G718 = Research in Biomedical Science (2 cr.)**
A laboratory research rotation course. Allows incoming basic science doctoral graduate students in the School of Medicine programs to take research rotations in laboratories affiliated with all of the school graduate programs.
2. **GRAD - G672 – Translational Research and Entrepreneurship (2 cr.)**
Offered through the Indiana Clinical and Translational Sciences Institute (CTSI).

Kelley School of Business Courses

1. **BUS-X518 - Life Sciences Global Events and Trends (1.5 cr.)**
This course exposes students to a variety of trends driving change within the life sciences industry. Topics to be reviewed include increasing worldwide cost pressures, shifts in population demographics, regulatory compliance and approvals, privacy and data protection, emerging market opportunities and ethical issues currently being faced. Discussions will include how different companies are responding to these trends.
2. **BUS-X519 - The Life Sciences Industry from Research to Patient (1.5 cr.)**
This course introduces students to the different parts of the life sciences industry and highlights some of the challenges and opportunities currently being faced. Sections of the industry included are basic science, medical devices, pharmaceuticals/ generic/biologics, distributors, health care providers, insurers, contract services and specialized suppliers. The business of life sciences is made more successful when those involved in the industry recognize and understand the value added at each stage. A Kelley student interested in a life science career will benefit from a deeper understanding of how the whole value chain/network functions.

McKinney School of Law Courses

1. **LAW-D/N 693 - Life Sciences Compliance Law (2 or 3 cr.)** The course examines law and regulation pertaining to the initiation of research projects involving human and animal subjects by both universities and manufacturers. It examines the pertinent government regulations, guidance documents and enforcement initiatives forming the framework for the conduct of clinical trials and focuses upon the practical aspects of clinical trial contracting, application of regulatory guidelines, quality system compliance and corresponding documentation requirements. The course will provide experience in drafting and negotiating clinical trial contract provisions, addressing publication rights, intellectual property ownership, indemnification and confidentiality.
2. **LAW-D/N 698 - Intellectual Property of Pharmaceutical Products and Medical Devices (2 or 3 cr.)** This seminar/course will offer a detailed and high-level analysis of intellectual property law as it applies to medical devices and medical therapeutics, including pharmaceuticals, genetics, proteomics, etc. Topics to be covered are patent law, copyright law and trademark law, as well as some discussion of their potential anticompetitive effects in the biomedical industry. Coursework or related experience in intellectual property, patent law or copyright law is required to enroll. No background in pharmaceuticals or medical technology will be necessary, but some knowledge of any of the life sciences or of chemistry will be helpful. Students will be expected to write and present a research paper of adequate length to satisfy the advanced writing requirement when the course is taught as a seminar. This course may be taught either as a seminar or as a regular course.

3. **LAW-D/N 635 - Drug Innovation and Competition Law (2 or 3 cr.)** provides and understanding of the processes by which pharmaceutical exclusivity is obtained and challenged on a global scale. The course examines the interplay between patents, data package exclusivity, pediatric exclusivity, and orphan drug exclusivity; and surveys the procedural and substantive aspects of US Hatch-Waxman litigation, drug reimportation/parallel trade, and exceptions to exclusivity. Finally, it addresses the influence of public policy on the evolution of pharmaceutical exclusivity law.

4. **LAW-D/N 838 - Bioethics and Law (2 or 3 cr.)** D/N 838 examines how the law in bioethics is shaped by the interplay of ethical principles, medical considerations, and social forces. Topics that will be covered include: the refusal of life-sustaining treatment, physician-assisted suicide, organ transplantation, abortion, the balance between individual liberty and protection of the public health, access to health care, and rationing of health care. An important theme of the course will be to consider the extent to which individuals have--and should have--control over medical decision making.