ARIZONA STATE UNIVERSITY

PROPOSAL TO ESTABLISH A NEW GRADUATE DEGREE

This template is to be used only by programs that have received specific written approval from the Provost’s office to proceed with internal proposal development and review. A separate proposal must be submitted for each individual new degree program.

DEGREE PROGRAM

College/School(s) offering this degree: College of Nursing and Health Innovation (CONHI)

Unit(s) within college/school responsible for program: Graduate and Advance Practice Programs & Graduate Student Services

If this is for an official joint degree program, list all units and colleges/schools that will be involved in offering the degree program and providing the necessary resources: N/A

Proposed Degree Name: Master of Science in Regulatory Science and Health Safety (MSRSHS)

Master's Degree Type: MS-Master of Science

Proposed title of major: Regulatory Science and Health Safety

Is a program fee required? Yes No x *$750/semester graduate differential tuition

Requested effective term: Select term and year: Fall 2010
(The first semester and year for which students may begin applying to the program.)

PROPOSAL CONTACT INFORMATION
(Person to contact regarding this proposal)

Name: Evelyn L. Cesarotti Ph.D.  Title: Director
Phone: 602-496-0735  email: e.cesarotti@asu.edu

Name: Sandra L. Shire, DMD, MPA  Title: Director
Phone: 602-496-1694  email: Sandra.Shire@asu.edu

DEAN APPROVAL

This proposal has been approved by all necessary unit and College/School levels of review, and the College/School(s) has the resources to offer this degree program. I recommend implementation of the proposed degree program. (Note: An electronic signature, an email from the dean or dean’s designee, or a PDF of the signed signature page is acceptable.)

College Dean Name: Bernadette Melnyk, PhD, RN, CPNP/PMHNP, FNAP, FAAN

College Dean Signature __________________________ Date: March 3, 2010

College Dean name: __________________________ Date: __________
(If more than one college involved)
ARIZONA STATE UNIVERSITY
PROPOSAL TO ESTABLISH A NEW GRADUATE DEGREE

This proposal template should be completed in full and submitted to the University Provost’s Academic Council [mailto:curriculum@asu.edu]. It must undergo all internal university review and approval steps including those at the unit, college, and university levels. A program may not be implemented until the Provost’s Office notifies the academic unit that the program may be offered.

DEGREE PROGRAM INFORMATION

Master’s: MS-Master of Science

Proposed title of major: Regulatory Science and Health Safety (RSHS)

1. PURPOSE AND NATURE OF PROGRAM

   A. Brief program description (This is a catalog type description of no more than 250 words. Include the distinctive features of the program that make it unique. Do not include program or admission requirements.)

   The purpose of this new 39 credit hour MS degree program is to prepare students for careers in the field of Regulatory Affairs. The program will focus on safety, as fundamental to regulatory science, and on leadership development. The MS in RSHS degree uses a multidisciplinary approach to meet the unique needs of regulating bodies and the regulated industry. It encompasses coursework in clinical research, ethics, quality systems, quantitative methods and statistics, leadership and project management in the regulatory field. All MS in RSHS core courses are offered as classroom-based courses. Students will develop skills that incorporate an evidence-based approach to decision-making, clinical research, regulations, and the evaluation of the safety of health products including drugs, medical devices and nutritional products. They will also develop leadership and project management skills.

   The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) Academic Collaboration Program (CACP) is partnering with select institutions of higher learning to develop a work force for the rapidly expanding field of regulatory science. ASU’s College of Nursing and Health Innovation has been selected as a site for their next collaboration. In this collaboration program, up to ten students will be commissioned as officers in the U.S. Public Health Service, supported throughout their program of study and will be hired by the FDA as regulatory professionals upon completion. The program will also recruit up to ten non FDA-funded students who may seek employment with a regulatory agency or with regulated industry upon completion of the degree.

   B. Total credit hours required for the program: 39

   C. Are any concentrations to be established under this degree program? ☐ Yes ☑ No

2. PROGRAM NEED. Explain why the university needs to offer this program (include data and discussion of the target audience and market).

   The bioscience research and medical products industries in Arizona and around the globe increasingly require individuals with graduate level degrees who can conduct business in accordance with regulatory requirements. As the result of increased scrutiny of the development of new health products and the explosion of new products every year, line staff and managers who can interpret the regulations, verify that they were followed, evaluate research data and assure the safety and effectiveness of new products are needed to protect the public health.

   The number of jobs with regulated industry and with regulatory agencies is rapidly expanding in Arizona and throughout the U.S. The U.S. Food and Drug Administration has embarked on a major hiring initiative to protect and promote the public health by creating and filling positions at their headquarters and at district offices. Graduates will be prepared to lead complex reviews and manage
projects in clinical research at domestic and international sites for private industry and regulatory bodies. According to the Arizona’s Bioscience Roadmap developed by Battelle Memorial Institute, bioscience employment has increased 16% over last 4 years and is expected to continue above average growth rate over the next few decades. Center Watch (an international organization focused on providing information services, market intelligence services and medical education solutions for the clinical trials industry) estimates that the clinical research industry is steadily growing at 5-9% yearly, with the largest employment need for high-level clinical research managers, auditors, inspectors and regulatory oversight personnel.

Healthcare professionals and students from diverse science fields may enter the program. It is expected that students will represent a variety of backgrounds including nursing, pharmacy, dentistry, medicine, allied health, medical science, public health, computer science and other technical and scientific backgrounds. There are few Regulatory Science degree programs in the U.S. and none currently exist in the state of Arizona.

3. IMPACT ON OTHER PROGRAMS. List other academic units that might be impacted by the proposed program and describe the potential impact (e.g., how the implementation of this program might affect student headcount/enrollment, student recruitment, faculty participation, course content, etc. in other programs). Attach letters of collaboration/support from impacted programs.

Core courses for the new program are primarily offered by ASU CONHI, specifically in the Master of Healthcare Innovation and Master of Science in Clinical Research Management programs. Other core courses are housed in: Sandra Day O’Connor College of Law, and the Ira A. Fulton Schools of Engineering. Faculty members in departments outside of CONHI have reacted favorably to the addition of these students to their courses. There is no anticipated negative impact on other ASU programs.

Core courses that have previously been available exclusively in an online format will be modified for in-classroom delivery for this degree.

Student recruitment for the FDA-funded positions will be accomplished in collaboration with FDA staff. Based on the FDA’s previous experience with other Center Academic Collaboration Programs, the applicant pool for these limited positions will be very large. It is therefore anticipated that the remaining seats in the program will be filled by students from the large recruitment pool who do not wish to participate in the FDA-sponsored positions (and the subsequent service payback requirement).

Three letters of collaboration/support are attached.

4. PROJECTED ENROLLMENT How many new students do you anticipate enrolling in this program each year for the next five years? Please utilize the following tabular format.

<table>
<thead>
<tr>
<th>5-YEAR PROJECTED ANNUAL ENROLLMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Year (Yr 1 continuing + new entering)</td>
</tr>
<tr>
<td>Number of Students Majoring (Headcount)</td>
</tr>
</tbody>
</table>

Request to implement a new degree program 3/23/2010
5. STUDENT LEARNING OUTCOMES AND ASSESSMENT

   A. List the knowledge, competencies, and skills students should have when they graduate from the proposed degree program. (You can find examples of program Learning Outcomes at [http://www.asu.edu/oue/assessment.html](http://www.asu.edu/oue/assessment.html)).

The Program Completion Objectives (PCOs) are:

1. Assess current regulations that focus on public health, quality and safety, considering the origin and significance of related laws and regulations and their impact on public health.

2. Critique regulatory submissions evaluating the product life cycle to include product design, manufacturing, testing and post-market surveillance.

3. Lead an evidence-based scientific review team, using sound principles of project management to critically analyze a product risk mitigation plan.

4. Examine regulatory science submissions to judge adherence to valid research methods and principles of responsible conduct of research.

5. Defend conclusions developed in regulatory reviews using sound oral and written communication techniques.

6. Lead the transformation of traditional organizational cultures into a culture of innovation.

7. Examine quality systems and standards and their impact on public safety and the protection of health care providers.

8. Select effective strategies to maintain currency in one’s specialty field to contribute to transdisciplinary teams.

9. Optimize technology-enabled regulatory science strategies and practices.

Students enrolled in the program will develop an in-depth understanding of existing regulatory practices and the context in which regulations evolve. Students will develop leadership and project management skills that incorporate an evidence-based approach to decision-making as they will build on course work in the field of Clinical Research and apply their knowledge to develop, test and market products in the regulatory arena.

Graduates will be prepared to lead complex regulatory reviews and manage projects in clinical research at domestic and international sites. Potential employers include drug, device, and other product developers, regulatory agencies, healthcare institutions, academic medical institutions, and national and international contract research organizations. They will qualify for positions in regulatory affairs and clinical research operations, as well as regulatory review officers and investigational and inspectional auditors.

Assessment methods will capture success in meeting the competencies and skills identified in the Learning Outcomes.
B. **Describe the plan and methods to assess** whether students have achieved the knowledge, competencies and skills identified in the Learning Outcomes. (You can find examples of assessment methods at [http://www.asu.edu/oue/assessment.html](http://www.asu.edu/oue/assessment.html)).

Assessment methods will capture success in meeting the competencies and skills identified in the Learning Outcomes. The plan includes classroom assignments and exams; a two semester internship or field experience; course projects and a capstone project. Examples of these assessment tools in specific courses include: HCR 563 Clinical Research Management and Regulatory Affairs, students develop a complete plan for a clinical trial; for HCR 558, Technical Writing for the Regulatory Professional, students will be assigned a role in a mock FDA Advisory Panel Meeting for which they will have to create, present and defend a position based on the role that has been identified for them.

An indirect method of assessment will be based on employment in the regulatory field after the completion of the degree program.

a. Direct Measure: Successful completion of 3-credit internship at FDA, other regulatory agency or industry.

b. Direct Measure: Oral defense of capstone paper summarizing the project conducted during the required internship.

6. **ACCREDITATION OR LICENSING REQUIREMENTS (if applicable).** Provide the names of the external agencies for accreditation, professional licensing, etc. that guide your curriculum for this program, if any. Describe any requirements for accreditation or licensing.

None currently exist

7. **FACULTY, STAFF AND RESOURCE REQUIREMENTS**

   A. **Faculty**

      i. **Current Faculty.** List the name, rank, highest degree, area of specialization/expertise and estimate of the level of involvement of all current faculty who will teach in the program.

         **CONHI Faculty:**
         Kimberly Arcoleo, PhD; Asst. Professor; Clinical Research
         Jack Gilbert, EdD; Director; Healthcare Innovation
         Katherine Kenny, DNP; Clinical Assoc. Professor; Healthcare Innovation
         Linda Mottle, MSM-HSA; Clinical Assoc. Professor; Clinical Research
         Diane Gates, MPH; Faculty Associate; Nursing & Clinical Research
         Laura Szalacha, PhD, Assoc Professor; Biostatistics; Research Design & Methods
         Kathryn Records, PhD; Assoc. Professor; Research
         Crystal Jenkins, MS; Faculty Associate; Healthcare Innovation
         Keith Martin, PhD; Nutrition
         Sandra Shire, DMD; Director; Regulatory Science

         **Sandra Day O’Connor College of Law faculty:**
         David Feigal, MD; Adjunct Professor; FDA Law & Regulations
         Roger Morris, JD; Adjunct Professor; FDA Law & Regulations

         **College of Engineering:**
         George Runger, PhD; Professor; Industrial Engineering

         Faculty listed will teach approximately one course per semester and may be involved in developing capstone projects for students and assisting with the Internship/Field Experience courses.
ii. **New Faculty.** Describe the new faculty hiring needed during the next three years to sustain the program. List the anticipated hiring schedule and financial sources for supporting the addition of these faculty.

The FDA has included a budget item to support two full time faculty positions for this program for at least two years. The funding may be used either for two individuals or to supplement existing faculty at CONHI or at other colleges within the University. The College plans to finalize faculty assignments prior to the start of the Fall 2010 term.

iii. **Administration of the program.** Explain how the program will be administered for the purposes of admissions, advising, course offerings, etc. Discuss the available staff support.

The FDA has included a budget item to support a full time program director and part-time (50%) administrative assistant in addition to two full-time faculty positions for a minimum of two years at which time the program will be re-evaluated by the Agency to assess extension of the program. The director (Dr. Shire) has been hired and is actively developing the program. She, along with a team of CONHI faculty, will meet with staff from the FDA via weekly phone conferences to update the status of program development and establishment. In addition, FDA staff have been appointed as ASU Adjunct Faculty and will travel to Phoenix (FDA sponsored funds) to assist in the admission interviewing process. Dr. Shire reports directly to the Associate Dean for Academic Affairs and is therefore situated with peer programs in the CONHI to assure consistency of academic policies and standards. Student services support including recruitment, admissions, and admission advisement will be provided by CONHI’s graduate program office, which also reports to the Associate Dean.

B. **Resource requirements to launch and sustain the program.** Describe any new resources required for this program’s success such as new staff, new facilities, new library resources, new technology resources, etc.

All costs of the program are covered by the FDA (MOU signed by FDA on file) for the first two years. Another program sponsored by the FDA CACP program is currently being funded for a second cohort and it is expected that will also occur with this program. A concurrent CONHI differential tuition proposal of $750/semester/student has been proposed to provide long-term stability for this and other degrees at the college and has been submitted for 2010 ABOR approval.

Students who want to qualify for FDA-support in this program must meet the requirements for commissioned officers in the US Public Health Service (less than 44 years of age, U.S. citizen, in good health and possess the discipline-specific requirements for commissioning).

Students who are not applying for the Commissioned Corps do not need to meet these additional requirements.

8. **CURRICULAR STRUCTURE OF THE PROPOSED PROGRAM**

A. **Admission Requirements** The requirements listed below are Graduate College requirements. Please modify and/or expand if the proposed degree has additional admissions requirements.

i. **Degree.** Minimum of a bachelor’s degree or a graduate degree from a regionally accredited College or University of recognized standing in a related field such as:

- Biological or life sciences; physical sciences; computer science; biostatistics or statistics; engineering; a healthcare degree or background such as nursing; dentistry; medicine or health sciences; optometry; podiatry; veterinary science; public health; physical therapy; speech pathology; audiology; pharmacy; or dietician.

ii. **GPA.** Minimum of a 3.00 cumulative GPA (scale is 4.0=A) in the last 60 hours of a student’s first bachelor’s degree program.
iii. **English Proficiency Requirement for International Applicants.** If applicable list any English proficiency requirements that are higher than and/or in addition to the Graduate College requirement. (See Graduate College policy and procedures [http://graduate.asu.edu/admissions/international.html#proficiency]: N/A

iv. **Required Admission Examinations.**

- [ ] GRE
- [ ] GMAT
- [ ] Millers Analogies
- [X] None Required

v. **Application Review Terms.** Indicate all terms for which applications for admissions are accepted and the corresponding application deadline dates, if any:

- [X] Fall  Deadline (month/year): 06/2010
- [ ] Spring  Deadline (month/year):
- [ ] Summer  Deadline (month/year):

vi. **Interview by program faculty**  Deadline (month/year): 05/2010

B. **Degree Requirements.** Below provide the curricular requirements for the proposed degree program.

The Master of Science in Regulatory Science and Health Safety is designed as a full-time in-classroom degree that will be completed over two years.

i. **Total credit hours (cr hrs) required for the degree program:** 39

ii. **Core courses.** List all required core courses and total credit hours for the core (required courses other than internships, thesis, dissertation, capstone course, etc). Omnibus number courses can not be used as core courses. Permanent numbers must be requested by submitting course proposal to ACRES for approval.

***Total cr hrs for required core courses:** 33 NEW Courses have been submitted to ACRES

<table>
<thead>
<tr>
<th>Course prefix &amp; number</th>
<th>Course Title</th>
<th>Credit hours</th>
<th>New course?</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCR 563</td>
<td>Clinical Research Management and Regulatory Affairs</td>
<td>3</td>
<td>Y N</td>
</tr>
<tr>
<td>LAW 691</td>
<td>Topic: FDA Regulation</td>
<td>3</td>
<td>Y N</td>
</tr>
<tr>
<td>MHI 538</td>
<td>Innovation and the Individual</td>
<td>3</td>
<td>Y N</td>
</tr>
<tr>
<td>HCR 561</td>
<td>Responsible Conduct of Research</td>
<td>3</td>
<td>Y N</td>
</tr>
<tr>
<td>HCR 557</td>
<td>Quantitative Research and Design Methods for Clinical Research and Regulatory Science</td>
<td>3</td>
<td>Y N</td>
</tr>
<tr>
<td>HCR 558</td>
<td>Technical Writing for the Regulatory Professional</td>
<td>3</td>
<td>Y N</td>
</tr>
<tr>
<td>HCR 569</td>
<td>Applied Principles of Data Management &amp; Inferential Statistics in Healthcare Research</td>
<td>3</td>
<td>Y N</td>
</tr>
<tr>
<td>HCR 568</td>
<td>Healthcare Project Management</td>
<td>3</td>
<td>Y N</td>
</tr>
<tr>
<td>NTR 442</td>
<td>Advanced Food Development</td>
<td>3</td>
<td>Y N</td>
</tr>
<tr>
<td>IEE 571</td>
<td>Quality Management</td>
<td>3</td>
<td>Y N</td>
</tr>
<tr>
<td>HCR 565</td>
<td>Clinical Research Operations</td>
<td>3</td>
<td>Y N</td>
</tr>
</tbody>
</table>

(Please expand table as needed. Right click in white space of last cell. Select “Insert Rows Below”)
iii. Elective Courses

Total cr hrs for program electives: 0

Provide a sample list of elective courses:

<table>
<thead>
<tr>
<th>Course prefix &amp; number</th>
<th>Course title</th>
<th>Credit hours</th>
<th>New course?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Y [ ] N [ ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Y [ ] N [ ]</td>
</tr>
</tbody>
</table>

(Please expand table as needed. Right click in white space of last cell. Select “Insert Rows Below”)

iv. 400-Level Courses. No more than 6 credit hours of 400-level coursework can be included on graduate student program of study.

1. Are 400-level ASU courses allowed on student program of study for this degree? ☒ Yes ☐ No

2. If yes, how many credit hours? 3

v. Additional Requirements (if applicable). Provide a brief description of any additional requirements (e.g. internships, clinicals, field study, etc.)

A Regulatory Science Internship/Field Experience will be required for this program. FDA-sponsored students will conduct the internship at FDA Headquarters during the summer session between year I and year II. Other students will conduct the Internship/Field Experience at a location determined by faculty in collaboration with students and area agencies. Currently, CONHI maintains over 600 clinical site affiliation agreements throughout Arizona and the U.S. The Internship/Field Experience will be monitored and supervised by COHNI faculty and qualified mentors at each facility. The Internship/Field Experience will carry through the second year and the course will be listed as a two credit course during the summer and as a one credit course in the fall of year II. The purpose of the Internship/Field Experience will be to expose students to the work of regulatory professionals, to develop a project that may be used for the capstone experience and to assist them in identifying appropriate career choices.

Total cr hrs for other required courses: 3

List course info for any additional requirements (e.g. internships, clinicals, field study, etc.)

<table>
<thead>
<tr>
<th>Course prefix &amp; number</th>
<th>Course title</th>
<th>Credit hours</th>
<th>New course?</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCR 559</td>
<td>Internship for Regulatory Science *</td>
<td>2</td>
<td>Y ☒ N [ ]</td>
</tr>
<tr>
<td>HCR 559</td>
<td>Internship for Regulatory Science*</td>
<td>1</td>
<td>Y ☒ N [ ]</td>
</tr>
</tbody>
</table>

(Please expand table as needed. Right click in white space of last cell. Select “Insert Rows Below”)

*Internship will be completed over a two semester period, for 2 and 1 credit hours respectively. Courses have been submitted to ACRES

vi. Culminating experience for the proposed program (please check all that apply and provide requested information): 3 credit hours

<table>
<thead>
<tr>
<th>Required?</th>
<th>Brief description of the applied project or the capstone course, as applicable.</th>
<th>Course prefix and number</th>
<th>Credit hours</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>HCR 560 Regulatory Science Capstone*</td>
<td>3</td>
</tr>
</tbody>
</table>

Thesis (master’s only)

Applied Project (master’s only)

Capstone course (master’s only)

Dissertation (doctoral only)
vii. **Master's program comprehensive exams, please check all that apply** (Please note: for doctoral programs, a written and an oral comprehensive exam are required.)

- [ ] Written comprehensive exam required
- [ ] Oral comprehensive exam required
- [x] No comprehensive exam required

viii. **Committee:** Required Number of Thesis or Dissertation Committee Members (must be at least 3 including chair or co-chairs): N/A

ix. **Foreign Language Exam.**

Foreign Language Examination(s) required? [ ] Yes [x] No

If yes, list all foreign languages required:

x. **Course Prefix(es)** Provide the following information for the proposed graduate program.

a. Will a new course prefix(es) be required for this degree program?
   - [ ] Yes [x] No

b. If yes:
   - Complete the New Prefix Request Form for each new prefix. This form can be located on the Office of the Executive Vice President and Provost of the University Curriculum Development website at <http://provost.asu.edu/curriculum>.
   - Submit the completed form to Nancy Kiernan at nkiernan@asu.edu in the Office of the Executive Vice President and Provost of the University.

xi. **New Courses Required for Proposed Degree Program.** Provide course prefix, number, title, and credit hours and description for any new courses required for this degree program.

*Please note that all new courses have been submitted to ACRES.*

HCR 558 Technical Writing for the Regulatory Professional (3 credit hours). This course presents techniques to encourage plain language in written documents. Students practice information gathering, logical argument development, effective use of exhibits, and formal and informal regulatory communication.

HCR 559 Regulatory Science Internship (1-3 credit hours). An internship in the field at a regulatory agency or in a regulated industry.

HCR 557 Research and Design Methods for Clinical Research and Regulatory Science (3 credit hours) Examines multiple research approaches in clinical and health policy research from a quantitative perspective.

HCR 560 Regulatory Science Capstone (3 credit hours) Culmination course integrating all components of regulatory core courses demonstrating knowledge and competency in the field of regulatory science.
Good Morning:
I am forwarding the proposal for our MS in Regulatory Science and Health Safety as well as the Support Letters that are required. This is an incredible program and I send this with my complete and total support. Please let us know if you require anything further.

Warm regards,
Bern

Bernadette Melnyk, PhD, RN, CPNP/PMHNP, FAAN, FNAP
Dean and Distinguished Foundation Professor in Nursing
Arizona State University
College of Nursing & Health Innovation
500 N. 3rd Street
Phoenix, AZ 85004
602-496-2200 (Phone)
602-496-0873 (Fax)
Associate Editor, Worldviews on Evidence-Based Nursing

Dream. Discover. Deliver
Dear Sandra,

The Ira A. Fulton Schools of Engineering is in support of your new Master’s program in Regulatory Science and Health Safety at the College of Nursing and Health Innovation. We also support all of the new courses listed below. I wish you the best with your new program.

The new courses are:

- Proposed New Course Prefix/Number: HCR 557
  Title: Quantitative Research Design Methods for Clinical Research and Regulatory Science
  I have no objection to the proposed course.

- Proposed New Course Prefix/Number: HCR 558
  Title: Writing for the Regulatory Professional
  I have no objection to the proposed course.

- Proposed New Course Prefix/Number: HCR 559
  Title: Internship in Regulatory Science
  I have no objection to the proposed course.

- Proposed New Course Prefix/Number: HCR 560
  Title: Capstone in Regulatory Science
  I have no objection to the proposed course.

Sincerely,

-d2-

Deirdre R. Meldrum, Ph.D.
Dean, Ira A. Fulton Schools of Engineering
Director, Center for Ecogenomics, Biodesign Institute
Professor of Electrical Engineering in School of Electrical, Computer, & Energy Engineering
Arizona State University
P.O. Box 879309
Tempe, AZ 85287-9309
tel: 480-965-9235
Leading engineering discovery and innovative education for global impact on quality of life.

From: Sandra Shire
Sent: Thursday, February 25, 2010 9:18 AM
To: Deirdre Meldrum
Cc: Susan Draughn; Evelyn Cesarotti
Subject: Request Letter of Support

Dean Meldrum,

As you may know, we are developing a new Master’s program in Regulatory Science and Health Safety at the College of Nursing and Health Innovation. I am writing to seek your support for the program which will proceed to the University Senate for review on March 11th. With this compressed timeline in mind, would you kindly provide a letter of support (it may be in the form of a response to this email message.)

The new courses are listed below. It would be helpful for you to also endorse the program, overall. For your information, I have cut-and-pasted the curriculum table, below, as it will be presented to the Senate.

Please don’t hesitate to contact me if you have any questions, and thank you for a prompt reply to this request.

Best regards,
Sandy Shire

**Total cr hrs for required core courses: 33**

<table>
<thead>
<tr>
<th>Course prefix &amp; number</th>
<th>Course Title</th>
<th>Credit hours</th>
<th>New course?</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCR 563</td>
<td>Clinical Research Management and Regulatory Affairs</td>
<td>3</td>
<td>Y N</td>
</tr>
<tr>
<td>LAW 691</td>
<td>Topic: FDA Regulation</td>
<td>3</td>
<td>Y N</td>
</tr>
<tr>
<td>MHI 538</td>
<td>Innovation and the Individual</td>
<td>3</td>
<td>Y N</td>
</tr>
<tr>
<td>HCR 561</td>
<td>Responsible Conduct of Research</td>
<td>3</td>
<td>Y N</td>
</tr>
<tr>
<td>HCR 557</td>
<td>Quantitative Research and Design Methods for Clinical Research and Regulatory Science</td>
<td>3</td>
<td>Y N</td>
</tr>
<tr>
<td>HCR 558</td>
<td>Technical Writing for the Regulatory Professional</td>
<td>3</td>
<td>Y N</td>
</tr>
<tr>
<td>HCR 569</td>
<td>Applied Principles of Data Management &amp; Inferential Statistics in Healthcare Research</td>
<td>3</td>
<td>Y N</td>
</tr>
<tr>
<td>HCR 568</td>
<td>Healthcare Project Management</td>
<td>3</td>
<td>Y N</td>
</tr>
<tr>
<td>NTR 442</td>
<td>Advanced Food Development</td>
<td>3</td>
<td>Y N</td>
</tr>
<tr>
<td>IEE 571</td>
<td>Quality Management</td>
<td>3</td>
<td>Y N</td>
</tr>
<tr>
<td>HCR 565</td>
<td>Clinical Research Operations</td>
<td>3</td>
<td>Y N</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Course prefix &amp; number</th>
<th>Course title</th>
<th>Credit hours</th>
<th>New course?</th>
</tr>
</thead>
</table>

2
The new courses are:

Proposed New Course Prefix/Number: HCR 557
Title: Quantitative Research Design Methods for Clinical Research and Regulatory Science

I have no objection to the proposed course.

I object to the proposed course.

Reasons for objection and/or other comments/recommendations:

Proposed New Course Prefix/Number: HCR 558
Title: Writing for the Regulatory Professional

I have no objection to the proposed course.

I object to the proposed course.

Reasons for objection and/or other comments/recommendations:

Proposed New Course Prefix/Number: HCR 559
Title: Internship in Regulatory Science

I have no objection to the proposed course.

I object to the proposed course.

Reasons for objection and/or other comments/recommendations:

Proposed New Course Prefix/Number: HCR 560
Title: Capstone in Regulatory Science

I have no objection to the proposed course.

I object to the proposed course.
Reasons for objection and/or other comments/recommendations:

Sandy Shire, DMD, MPA
CAPT (Ret) USPHS
Director, MS in Regulatory Science and Health Safety Program
Arizona State University
College of Nursing and Health Innovation
500 N. 3rd Street
Phoenix, Arizona 85004

Tel: 602-496-1694
Sandra.Shire@asu.edu
New Course Impact Form

Date: January 22, 2010
To: Gary Marchant
Unit: Law
From: Sandra Shire

As a step in the procedures governing new course approval, the attached course proposals are provided for your review and response. Please complete this form and return to Susan Draughn.

Proposed New Course Prefix/Number: HCR 557
Title: Quantitative Research Design Methods for Clinical Research and Regulatory Science

☐ I object to the proposed course.

Reasons for objection and/or other comments/recommendations:

Proposed New Course Prefix/Number: HCR 558
Title: Writing for the Regulatory Professional

☐ I object to the proposed course.

Reasons for objection and/or other comments/recommendations:

Proposed New Course Prefix/Number: HCR 559
Title: Internship in Regulatory Science

☐ I object to the proposed course.

Reasons for objection and/or other comments/recommendations:

Proposed New Course Prefix/Number: HCR 560
Title: Capstone in Regulatory Science

☐ I object to the proposed course.

Reasons for objection and/or other comments/recommendations:

Signature of Reviewer: 

Gary E. Marchant
From: Ronald O'Donnell  
Sent: Tuesday, January 26, 2010 9:45 AM  
To: Sandra Shire  
Subject: RE: Impact Statement Request

Sandra,

Thanks for the reminder. Please use this email as my impact statement approval from the Doctor of Behavioral Health program for the courses HCR 557, HCR 558, HCR 559 and HCR 560. I have no objections to these courses.

Sincerely,

Ronald R. O'Donnell, Ph.D.  
ASU School of Letters and Science  
Doctor of Behavioral Health Program  
500 N. 3rd Street  
MC:3320, NHI 1  
Phoenix, AZ. 85004-2135

Office: 602-496-1352  
ronald.odonnell@asu.edu  
www.dbh.asu.edu

---

From: Sandra Shire  
Sent: Tuesday, January 26, 2010 9:39 AM  
To: Ronald O'Donnell  
Subject: FW: Impact Statement Request

Hi,

We are hoping to have your impact statement completed in time for our meeting with the Graduate Curriculum Committee which is tomorrow (Wednesday). The materials above were sent out last week but I am re-sending in case you have misplaced the message. If you are able to sign off today on the brief form attached above and return to Susan Draughn (and copy to me, please), I would greatly appreciate it.

Don’t hesitate to contact me if you have any questions,,
I truly appreciate your assistance,
Sandy

Sandy Shire, DMD, MPA  
CAPT (Ret) USPHS  
Director, MS in Regulatory Science and Health Safety Program  
Arizona State University  
College of Nursing and Health Innovation
From: Sandra Shire  
Sent: Friday, January 22, 2010 2:10 PM  
To: Ronald O'Donnell  
Cc: Susan Draughn  
Subject: Impact Statement Request

As you are aware, we are developing a new master of Science in Regulatory Science and Health Safety. As part of the University review process, we are required to solicit impact statements for the four (4) new courses. 
I have attached, for your review, the 4 new syllabi and the new impact form. Please return the completed form to Susan Draughn at your earliest convenience. If you have any questions, feel free to contact me.  
Many thanks for your kind assistance,  
Best regards,  
Sandy

Sandy Shire, DMD, MPA  
CAPT (Ret) USPHS  
Director, MS in Regulatory Science and Health Safety Program  
Arizona State University  
College of Nursing and Health Innovation  
500 N. 3rd Street  
Phoenix, Arizona 85004

Tel: 602-496-1694  
Sandra.Shire@asu.edu
I understand an e-mail will work, so: We have no objections and think the program and these courses will nicely complement what we do.

From: Sandra Shire [mailto:Sandra.Shire@asu.edu]
Sent: Friday, January 22, 2010 2:11 PM
To: robert.denhardt@asu.edu
Cc: Susan Draughn
Subject: Impact Statement Request

As you are aware, we are developing a new master of Science in Regulatory Science and Health Safety. As part of the University review process, we are required to solicit impact statements for the four (4) new courses.
I have attached, for your review, the 4 new syllabi and the new impact form. Please return the completed form to Susan Draughn at your earliest convenience. If you have any questions, feel free to contact me.
Many thanks for your kind assistance,
Best regards,
Sandy

Sandy Shire, DMD, MPA
CAPT (Ret) USPHS
Director, MS in Regulatory Science and Health Safety Program
Arizona State University
College of Nursing and Health Innovation
500 N. 3rd Street
Phoenix, Arizona 85004

Tel: 602-496-1694
Sandra.Shire@asu.edu