



ESTABLISHING GRADUATE CERTIFICATES
ARIZONA STATE UNIVERSITY
GRADUATE EDUCATION

This form should be used by programs seeking to establish a new graduate certificate. All sections should be completed.

The graduate certificate is a programmatic or linked series of courses in a single field or in one that crosses disciplinary boundaries. The graduate certificate facilitates professional growth for people who already hold the baccalaureate degree, and it may be freestanding or linked to a degree program. The graduate certificate enables the university to respond to societal needs while promoting university cooperation with corporate, industrial, and professional communities.

Submit the completed and signed (chairs, unit deans) proposal to the **Office of Graduate Academic Programs** in Graduate Education. Mail code: 1003 and electronic copies to eric.wertheimer@asu.edu or amanda.morales-calderon@asu.edu.

Please type.

Contact Name(s): Cris Wells	Contact Phone(s): 602-496-0864
College: College of Nursing and Health Innovation (CONHI)	
Department/School:	
Name of proposed Certificate: Biospecimen Repository Administration	
Requested Effective Term and Year: (e.g. Fall 2014) Fall 2015	
Do Not Fill in this information: <u>Office Use Only</u>	
CIP Code:	

1. OVERVIEW. Below, please provide a brief overview of the certificate, including the rationale and need for the program, potential size and nature of the target audience, information on comparable programs (at ASU and/or peer institutions), how this program would relate to existing programs at ASU, and any additional appropriate information.

Biomedical researchers have long used biological samples to study the human condition and to develop better methods of preventing, diagnosing and treating disease. However, with the advances in bio-molecular technology, biomedical informatics, and the drive toward personalized medicine, the importance of quality, accessible, and ethically-obtained samples has become critical. This Graduate Certificate in Bio-specimen Repository Administration addresses the best practices and core values of bio-specimen repository oversight.

Because the field is emerging, best practices for education and training for bio-specimen leadership have not yet been established. Currently there are no other certificate or degree programs at U.S. colleges or universities in Bio-specimen Repository Administration, although there may be as many as 20,000 bio-specimen repositories in the United States alone. The idea for this proposed certificate originated from a local community scientist who suggested that a group of courses directed toward managers and supervisors in the specimen industry would lead to higher overall quality in samples and the industry. Subsequently, we surveyed local Arizona (bio-specimen) leaders to obtain their feedback on a Bio-specimen Repository Administration Certificate. The results of the survey were overwhelmingly positive, reflecting strong local support and offering suggestions for potential courses.

The target audience for this certificate is research administrators, biotechnology managers, hospital laboratory managers, translational researchers, pharmaceutical project managers, bioengineers, nurses, physicians, and other professionals who collect, store, and/or disburse biological samples. Because this certificate is targeted at professionals who will be working in the bio-specimen industry, the proposed certificate will be offered in an online format to be geographically available to national and international audiences. The targeted audience is in the range of 15-20K professionals. The academic unit is poised for growth to initiate and sustain this targeted audience. Strategic plans include staggered faculty and staff hiring to complement and support this program.

This program will be offered through the Clinical Research Management program as a separate subject-matter pathway for students who are focusing their career in basic, translational, or laboratory science and need the skills for oversight of biospecimen handling, strategy, and operations. This certificate offers students within other science,

engineering, and business programs an opportunity to expand their marketability and skillset to excel in their primary business or science degree or role.

2. ADMINISTRATION AND RESOURCES

- A. How will the proposed certificate be administered (including recommendations for admissions, student advisement, retention etc.)? Describe the administering body in detail, especially if the proposed certificate is part of a larger interdisciplinary agenda. How will the graduate support staffing needs for this proposed certificate program be met?**

The proposed certificate will be administered under the Clinical Research Management (CRM) program by the director of the CRM program. It will follow the same processes and procedures as the current Clinical Research Management Graduate Certificate for admissions, advisement and retention. To meet our current and anticipated needs, we have recruited a part-time academic success specialist whose role may expand to full time as the certificate program grows.

- B. What are the resource implications for the proposed certificate, including projected budget needs? Will new books, library holdings, equipment, laboratory space and/or personnel be required now or in the future? If multiple units/programs will collaborate in offering this certificate, please discuss the resource contribution of each participating program. Letters of support must be included from all academic units that will commit resources to this certificate program.**

The proposed certificate will be administered with resources and support already in place for the MS in Clinical Research Management. Additional faculty with bio-specimen expertise will be needed to build and teach the program. This will impact the budget, and has been accounted for within the budget.

3. ADMISSIONS PROCEDURES AND CRITERIA

- A. Admission criteria – Applicants must meet the admissions criteria for Graduate Education. Please also include any other additional admission requirements, e.g. type of undergraduate degree, minimum GPA, tests and/or entry-level skills that are required for this certificate program.**

http://graduate.asu.edu/sites/default/files/GraduatePolicies_1.pdf

Degree(s):

- Bachelor degree in any business, science, engineering, nursing, health-related, medicine, math, or technology field.
- Or
- Bachelor degree in any other field (not mentioned above) with more than 6 months vocational experience in the bio-specimen repository administration field

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. Minimum of 3.00 cumulative GPA (scale is 4.0 = A) in the applicable Master's degree.

English Proficiency Requirement for International Applicants: (See Graduate Education policies and procedures) (http://graduate.asu.edu/admissions/international/english_proficiency):

Same as Graduate Education Policy

Required Admission Examinations: GRE GMAT Millers Analogies None required

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

- Fall Deadline (month/year): June 2015
 Spring Deadline (month/year): October 2015

C. Projected annual admission/enrollment

How many students will be admitted immediately following final approval of the certificate? What are enrollment projections for the next three years?

Upon final approval, it is anticipated that 8-10 students will be admitted immediately (Fall 2015). Enrollment projections for the following 3 years include:

- Fall/Spring 2016-17: 15-20 students
- Fall/Spring 2017-18: 20-23 students
- Fall/Spring 2018-19: 23-35 students

4. ACADEMIC REQUIREMENTS

A. Minimum credit hours required for certificate (15 credit hour minimum)

15 credit hours

B. Please describe the primary course delivery mode, (e.g., online, face-to-face, off-site etc.). Please note: If this proposed initiative will be offered completely online, clearly state that in this section.

This certificate will be offered completely online.

C. As applicable, please describe culminating experience required (e.g., internship, project, research paper, capstone course, etc.)

Not applicable

D. What knowledge, competencies, and skills (learning outcomes) should graduates have when they complete this proposed certificate program? Examples of program learning outcomes can be found at (<https://uoeee.asu.edu/program-outcomes>).

- Students graduating from the Graduate Certificate in Bio-specimen Repository Administration will be able to:
 - Evaluate the long-term ethical implications of ownership, privacy and commercial distribution of bio-specimen samples and data.
 - Delineate the environmental and personal safety concerns related to the collection, maintenance and disbursement of biological samples.
 - Design a hiring, training, and development plan for the start-up, maintenance, and disbursement cycles of a bio-specimen repository.
 - Create standard operating procedures based on industry “best practices.”
 - Assess the ethical, legal and social implications that influence bio-specimen repository stakeholders.
 - Develop a cost-benefit analysis for bio-specimen resource management and operations.
 - Plan for the long-term sustainability of a bio-specimen repository.
 - Critique the secondary use of biomaterials and the ethical issues that impact such use.
 - Justify the scientific foundations for the collection and utilization of bio-specimens.

E. How will students be assessed and evaluated in achieving the knowledge, competencies, and skills outlined in 4.D. above? Examples of assessment methods can be found at (<http://www.asu.edu/oue/assessment.html>).

Two program outcomes, one measure for each outcome and one performance criterion is found below:

Outcome 1	Design a hiring, training, and development plan for the start-up, maintenance, and disbursement cycles of a bio-specimen repository.
Measure 1.1 (Direct)	HCR 546 Management of Bio-specimen Repository Operations Assignment: "Operations" exercise where students will define job titles, use timeline software, and map a training schedule for repository employees.
Performance Criterion 1.1	At least 80 percent of students will earn 90% or higher on their "operations" exercise.
Measure 1.2 (Indirect)	At least 60% of alumni who are surveyed will indicate that their job performance has included a successful development plan for the start-up, maintenance, and/or disbursement of a bio-specimen repository.
Outcome 2	Create standard operating procedures based on industry "best practices."
Measure 2.1 (Direct)	HCR 545, Foundations of Bio-specimen Repository Administration or HCR 547, Bio-specimen Resource and Technology Management Assignment: Write a standard operating procedure for the evaluation of a new piece of technology for purchase or replacement.
Performance Criterion 2.1	At least 70 percent of students will earn 85% or higher on their standard operating procedures assignment.
Measure 2.2 (Indirect)	At least 70% of employer surveys will indicate that Certificate graduates are successful in meeting industry "best practices" in creating standard operating procedures.

F. Please state the satisfactory student academic progress standards and guidelines (including any time limits for completion).

Students will fulfill Graduate Education satisfactory academic progress standard of completing the certificate program courses with a GPA of 3.0 and all coursework completed within 6 years.

G. Will this proposed certificate program allow sharing of credit hours from another ASU degree program to be used as part of this certificate program?

We are not planning to share credits from another ASU degree program.

H. Below, please list all required and elective courses in the appropriate boxes (you may attach additional pages if necessary).

Please ensure that all new core course proposals have been submitted to the Provost's office through the Curriculum ChangeMaker online course proposal submission system before this initiative is put on the University Graduate Council and CAPC agendas. Please note: a minimum of 2/3 of the courses required for a graduate certificate must be at the 500-level or above.

<u>Required Courses</u>			<u>Credit Hours</u>
<i>(Prefix & Number)</i>	<i>(Course Title)</i>	<i>(New Course?) Yes or No?</i>	<i>(Insert Section Sub-total)</i> 15
HCR 545	Foundations of Bio-specimen Repository Administration	Yes	3


HCR 546	Management of Bio-specimen Repository Operations	Yes	3
HCR 547	Bio-specimen Resource and Technology Management	Yes	3
HCR 548	Regulation and Ethics in Bio-specimen Repository Administration	Yes	3
HCR 549	Scientific Innovation and Bio-specimen Repository Administration	Yes	3
<u>Electives</u>			<u>Credit Hours</u>
<i>(Prefix & Number)</i>	<i>(Course Title)</i>	<i>(New Course?) Yes or No?</i>	(Insert Section Sub-total)
Not Applicable			
<u>Culminating Experience (if applicable)</u>			<u>Credit Hours</u> (Insert Section Sub-total)
Not Applicable			
Total required credit hours			15


5. PRIMARY FACULTY PARTICIPANTS - Please list all primary faculty participants for the proposed certificate, including home unit and title. You may attach additional pages if necessary.		
Name	Home Unit	Title
Cris Wells, EdD, MBA	Clinical Research Management	Director, Clinical Research Management Programs/Associate Clinical Track Professor
Sandra Shire, DMD, MPA	Clinical Research Management	Associate Clinical Track Professor
JoAnn Pfeiffer, DrSC	Clinical Research Management	Faculty Associate

Note: Strategic plans include staggered faculty and staff hiring to complement and support this program.

<p>6. REQUIRED SUPPORTING DOCUMENTS (Please label accordingly, i.e., Appendix or Attachment A, B, etc.)</p> <p>Please include the following with your proposal:</p> <ul style="list-style-type: none"> A. Sample plans of study for students in the proposed program – See Appendix A B. Statements of support from all deans and heads of impacted academic units - See Appendix B

7. APPROVALS - If the proposal submission involves multiple units, please include letters of support from those units.

DEPARTMENT CHAIR or SCHOOL DIRECTOR (PRINT/TYPE) Brenda Morris, EdD, RN, CNE	
SIGNATURE 	DATE 9/10/2014

DEAN (PRINT/TYPE) Teri Pipe, PhD, RN	
SIGNATURE 	DATE 9/9/14 9/10/2014

The following section will be completed by Graduate Education following the recommendations of faculty governance bodies.

VICE PROVOST FOR GRADUATE EDUCATION	
SIGNATURE	DATE

Please note: Proposals for new certificates also require the review and recommendation of approval from the University Graduate Council, Curriculum and Academic Programs Committee (CAPC), the Academic Senate, and the Office of the Provost before they can be put into operation.

The final approval notification will come from the Office of the Provost.

GF1112G-89

APPENDIX

OPERATIONAL INFORMATION FOR GRADUATE CERTIFICATES

(This information is used to populate the [Graduate Programs Search](#) website.)

1. Provide a brief (catalog type - no more than 150 words) program description.

This certificate program prepares students to oversee the operations of a bio-specimen repository from a business perspective. This emerging, global field oversees the collection, storage, and disbursement of biological samples for use in basic science, translational, and clinical research. The program curriculum includes ethical and practical considerations of bio-specimen resource management and operations. Students will learn through exercises in case study analysis, process and procedure development, resource evaluation and implementation, and project management. Related business concepts such as cost-benefit analytics and personnel and sustainability of the repository are also covered in the program. Emphasizing principles of ethical and quality practices, this program will prepare students to work in this highly regulated field.

- 2. Campus(es) where program will be offered: ***
- | | | | |
|-------------------------------------|---------------|--------------------------|-------|
| <input type="checkbox"/> | Downtown | <input type="checkbox"/> | Tempe |
| <input checked="" type="checkbox"/> | Online (only) | <input type="checkbox"/> | West |
| <input type="checkbox"/> | Polytechnic | | |

3. Keywords: (List all keywords that could be used to search for this program. Keywords should be specific to the proposed program.)

bio-repository, bio-specimen repository, bio-banking, research administration

4. Area(s) of Interest:

- A.** Select one (1) primary area of interest from the list below that applies to this program.

- [Architecture & Construction](#)
- [Arts](#)
- [Business](#)
- [Communications & Media](#)
- [Education & Teaching](#)
- [Engineering & Technology](#)
- [Entrepreneurship](#)
- [Health & Wellness](#)
- [Humanities](#)
- [Interdisciplinary Studies](#)
- [Law & Justice](#)
- [Mathematics](#)
- [Psychology](#)
- [STEM](#)
- [Science](#)
- [Social and Behavioral Sciences](#)
- [Sustainability](#)

B. Select one (1) secondary area of interest from the list below that applies to this program.

- [Architecture & Construction](#)
- [Arts](#)
- [Business](#)
- [Communications & Media](#)
- [Education & Teaching](#)
- [Engineering & Technology](#)
- [Entrepreneurship](#)
- [Health & Wellness](#)
- [Humanities](#)
- [Interdisciplinary Studies](#)
- [Law & Justice](#)
- [Mathematics](#)
- [Psychology](#)
- [STEM](#)
- [Science](#)
- [Social and Behavioral Sciences](#)
- [Sustainability](#)

APPENDIX A

Sample Plan of Study

2015 Fall Admission

Graduate Certificate in Bio-specimen Repository Administration

Part-Time Students

Fall 2015

HCR 545	Foundations of Bio-specimen Repository Administration	3 credits
HCR 546	Management of Bio-specimen Repository Operations	3 credits
	Total Credits	6 credits

Spring 2016

HCR 547	Bio-specimen Resource and Technology Management	3 credits
HCR 548	Regulation and Ethics in Bio-specimen Repository Administration	3 credits
	Total Credits	6 credits

Summer 2016

HCR 549	Scientific Innovation and Bio-specimen Repository Administration	3 credits
	Total Credits	3 credits

Total Program Credits = 15 credits

APPENDIX B
SUPPORT STATEMENTS

W. P. Carey School of Business

Amy Hillman, Dean

Sent: Friday, October 10, 2014 3:54 PM

Hi Cris,

W. P. Carey School of Business has no objections to your proposed graduate certificate in Biospecimen Repository administration.

Best,
Amy

Amy Hillman, PhD

Dean | Rusty Lyon Chair of Strategy

Arizona State University | W. P. Carey School of Business

amy.hillman@asu.edu | (480) 965-3402

Office: BAC 600

School of Mathematical and Statistical Sciences

Al Boggess, School Director

Sent: Friday, October 10, 2014 4:35 PM

Cris,

I acknowledge receipt of this plan for the certificate and have no objections to its approval.

Al Boggess

The Biodesign Institute

Raymond DuBois, Executive Director

Sent: Thursday, October 16, 2014 11:18 AM

I am in total support.....

R

Ira A. Fulton Schools of Engineering

Paul Johnson, Dean

Sent: Thursday, October 16, 2014 11:46 AM

Hi Cris -

Sorry to be slow. I've been traveling.

The Fulton Schools is supportive of the proposed certificate.

Good luck!

PCJ

ASU Online (Phil Regier's office)

Phil Regier, Dean, Executive Vice Provost

Sent: Thursday, October 16, 2014 7:36 AM

Cris, thanks for the email.

I support advancing the Graduate Certificate in Biospecimen Repository Administration to the Graduate Council for their review and support.

Phil Regier

School of Life Sciences

Bertram Jacobs, Interim Director

Sent: Wednesday, October 15, 2014 11:02 AM

Dear Cris,

This looks like an interesting program. I am supportive.

Bert Jacobs

College of Health Solutions

Julie Liss, Associate Dean

Sent: Monday, August 11, 2014



August 11, 2014

Dr. Eric Wertheimer:

The College of Health Solutions supports the creation of the graduate certificate in Biospecimen Repository Administration. It does not duplicate any of the programs in CHS and should be a fine addition for the College of Nursing and Health Innovation.

Sincerely,

A handwritten signature in black ink, appearing to read "Julie Liss". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Dr. Julie Liss
Associate Dean, College of Health Solutions

(NEW GRADUATE INITIATIVES)

PROPOSAL PROCEDURES CHECKLIST

Academic units should adhere to the following procedures when requesting new curricular initiatives (degrees, concentrations or certificates).

Obtain the required approval from the Office of the Provost to move the initiative forward for internal ASU governance reviews/approvals.

- Establishment of new curricular initiative requests; degrees, concentrations, or certificates
- Rename requests; existing degrees, concentrations or certificates
- Disestablishment requests; existing degrees, concentrations or certificates

Submit any new courses that will be required for the new curricular program to the Curriculum ChangeMaker online course approval system for review and approval.

- Additional information can be found at the Provost's Office Curriculum Development website: [Courses link](#)
- For questions regarding proposing new courses, send an email to: courses@asu.edu

Prepare the applicable proposal template and operational appendix for the proposed initiative.

- New degree, concentration and certificate templates (contain proposal template and operational appendix) can be found at the Provost's Office Curriculum Development website: [Academic Programs link](#)

Obtain letters or memos of support or collaboration. (if applicable)

- When resources (faculty or courses) from another academic unit will be utilized
- When other academic units may be impacted by the proposed program request

Obtain the internal reviews/approvals of the academic unit.

- Internal faculty governance review committee(s)
- Academic unit head (e.g. Department Chair or School Director)
- Academic unit Dean (will submit approved proposal to the curriculumplanning@asu.edu email account for further ASU internal governance reviews (as applicable, University Graduate Council, CAPC and Senate)

Additional Recommendations - All new graduate programs require specific processes and procedures to maintain a successful degree program. Below are items that Graduate Education strongly recommends that academic units establish after the program is approved for implementation.

Set-up a Graduate Faculty Roster for new PhD Programs – This roster will include the faculty eligible to mentor, co-chair or chair dissertations. For more information, please go to http://graduate.asu.edu/graduate_faculty_initiative.

Establish Satisfactory Academic Progress Policies, Processes and Guidelines – Check within the proposing academic unit and/or college to see if there are existing academic progress policies and processes in place. If none have been established, please go to http://graduate.asu.edu/faculty_staff/policies and scroll down to the **academic progress review and remediation processes** (for faculty and staff) section to locate the reference tool and samples for establishing these procedures.

Establish a Graduate Student Handbook for the New Degree Program – Students need to know the specific requirements and milestones they must meet throughout their degree program. A Graduate Student Handbook provided to students when they are admitted to the degree program and published on the website for the new degree gives students this information. Include in the handbook the unit/college satisfactory academic progress policies, current degree program requirements (outlined in the approved proposal) and provide a link to the Graduate Policies and Procedures website. Please go to http://graduate.asu.edu/faculty_staff/policies to access Graduate Policies and Procedures.