

BRAMS/BRAMS Applied Student Handbook 2018-19

Biomedical Regulatory Affairs Master of Science Program

*School of Pharmacy,
Professional & Continuing Education
University of Washington*

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2018-2019 Student Guide

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Curriculum Overview

The curriculum spans the process of taking a medical product — drug, device or biologic — from research and development to market and post-market. Instructors cover topics such as clinical trials management, product testing, risk management, technical writing and international regulatory affairs.

At the end of the program, you'll be able to:

- Guide new medical products through regulatory compliance, clinical trials and quality assurance
- Understand and access regulations, guidelines, standards and application procedures used by the U.S. Food and Drug Administration, the International Conference on Harmonisation, and the International Organization for Standardization
- Identify, analyze and apply business and economic factors important to regulatory affairs for the pharmaceutical and medical device industries
- Identify and manage medical risk
- Write effective, accurate technical documents and reports

You'll also be prepared to earn professional certifications, including those from the Regulatory Affairs Professionals Society and the Association of Clinical Research Professionals.

Courses

Students in the part-time option complete 14 courses, for a total of 45 credits. In addition to that same coursework, students in the full-time option take at least seven additional credits of electives of their choosing, for a minimum of 52 credits.

Both part-time and full-time students participate in a nine-credit practicum, a hands-on experience in regulatory affairs at a Seattle-area company or institution.

For the Applied (Full-time) cohort, you will work with d Stephanie O. Guerrero to determine course electives prior to each quarter.

Course sequence

Year One

Autumn

PHARM 516: Introduction to Biomedical Regulatory Affairs

PHRMRA 524: Introduction to Clinical Trials

PHRMRA 536: Skills for the Regulatory Affairs Professional

Winter

PHARM 517: Product Development & Manufacturing Systems

PHRMRA 525: Implementation & Conduct of Clinical Trials

PHRMRA 546: Technical Writing for Biomedical Regulatory Affairs

Spring

PHARM 518: Product Testing, Evaluation & Post-Market Issues

PHRMRA 526: Project Management & the Business of Clinical Trials
PHRMRA 550: Advanced Technical Writing for Biomedical Regulatory Affairs

Summer (Optional)

PHRMRA 548: Practicum

Year Two

Autumn

PHRMRA 527: International Regulatory Affairs
PHRMRA 528: Medical Risk Analysis & Management
PHRMRA 548: Practicum

Winter

PHRMRA 545: Statistical Topics for Biomedical Regulatory Affairs Professionals
PHRMRA 548: Practicum
PHRMRA 554: Advanced Medical Products Regulation I

Spring

PHRMRA 548: Practicum

Practicum

The Biomedical Regulatory Affairs practicum provides a practical experience for students, allowing them to develop or expand skills in shepherding new medical products (drug, device and biologic) through regulatory, clinical, and quality assurance aspects. Students work on projects of their own devising under guidance of a preceptor from the practicum site.

Types of Practicum projects:

- Devising regulatory strategy for a device.
- Assisting in preparation of applications or reports to FDA, EMA.
- Auditing SOPs for compliance to foreign country requirements.
- Developing on-line training for academics planning clinical trials.
- Developing medical product information site for the public.

Students in both the part-time and full-time options complete a practicum. In this course, you'll get valuable hands-on experience shepherding a new medical product through aspects of the regulatory affairs process at a Seattle-area company or institution. Most students identify their practicum site through individual interests and networking, though placement assistance is available.

Practicum has two parts: a regulatory project you will perform for a company or institution and documentation of that project for the BRAMS program. You'll spend an average of three quarters on practicum, working on your project under the guidance of an on-site preceptor and the practicum course masters, and documenting the project.

There are no regular classroom sessions but students are required to meet with the practicum course masters each quarter and to attend practicum presentations by other students.

At the end of your practicum, you'll produce a final report and presentation for BRAMS faculty, preceptors, and students.

Registration

Please visit the “How to Register” page at <https://www.degreereg.uw.edu/user-guide/> for a step-by-step guide to the registration process. You will receive a quarterly email detailing the courses you need to register for, their Schedule Line Numbers (SLN), time and place for the class meetings, and the instructor's name.

Once enrolled, if you do not maintain continuous enrollment by either registering for classes or going on official On-Leave status for each quarter (excluding summer), you will lose graduate student status. To return to your graduate program, you will need to request reinstatement to your department and the Graduate School, and pay the \$250 reinstatement fee. See more here: <https://grad.uw.edu/policies-procedures/general-graduate-student-policies/reinstatement/>. For questions, please contact Stephanie O. Guerrero at stephieg@uw.edu.

UW NetID

If you are new to the University of Washington, you received your UW Student ID number and PAC (Personal Access Code) when you confirmed your intent to attend. Your Student ID number is necessary for you to register for courses; you also need this number to gain access to UW library and other resources available to UW students. Students new to the University of Washington will also be eligible for a Student ID Card (“Husky Card™”).

For access to online resources, you will use your UW Student ID to set up your UWNetID, the tool that you need for accessing materials restricted to members of the UW community. You can learn more about setting up your UWNetID at <https://itconnect.uw.edu/security/uw-netids/about-uw-netids/>.

Your UWNetID allows you to access your MyUW page from which you can check your personal UW information such as student grades. You will also be able to turn on UW email accounts with forwarding options, along with other computer services (dial-in modems, lab access, research computing, Web publishing). Your UWNetID remains the same throughout your life, no matter what associations (student, faculty, staff, alumni, or other affiliate) you have with the UW. For more information go to <https://itconnect.uw.edu/security/uw-netids/about-uw-netids/>.

MyUW

MyUW is your personal portal to University of Washington information. It is an easy-to-use tool for finding the resources you need to fulfill your goals at the University. You can "personalize" MyUW to fit your needs by including or excluding the services you see listed, adding bookmarks to your favorite links, and choosing the background and accent colors you prefer.

The people who bring you MyUW are committed to respecting your privacy and to protecting it within the constraints imposed by state and federal law. Information you supply to MyUW is used only to personalize your Web page. The UW does not share or sell your personal information for commercial purposes. Your personal information is not disclosed unless such action is necessary to comply with the law, to protect UW property, or to enforce UW policy.

For security, your UWNNetID and password and all functions of MyUW that contain sensitive information are encrypted before they are transmitted across the network. For more detailed information, please read the MyUW Policy on Privacy at <http://www.washington.edu/online/privacy/>

MyUW: access for some services, but not for others

The University of Washington electronic infrastructure allows students with a UWNNetID to access a great deal of information and a variety of resources via the MyUW icon on the UW home page. Students in the Biomedical Regulatory Affairs program can use MyUW for some of these same resources, **but not for all of them.**

The following table summarizes where Biomedical Regulatory Affairs students will go to obtain certain information:

My UW	Bettina Schifferl/UW PCE, bett@uw.edu
My Financial Aid Status (e.g., account balance)	Registration issues and questions
Schedule info (what courses am I registered for?)	Issues with OR Pay my tuition bill: 206-543-2310 (UW PCE Registration Staff)
Official or Unofficial transcript	Withdraw from a course
Access to Library resources	Change my address
	Where to buy textbooks

Family Educational Rights and Privacy Act (FERPA)

The Family Educational Rights and Privacy Act (FERPA) of 1974 protects the privacy of your educational records. However, the following information is considered public or "directory" information and may be released to anyone unless you request that you do not wish any information released: name, telephone number, major field of studies, dates of attendance, degrees and awards received, full- or part-time enrollment status, educational institutions attended, and for athletes, date of birth. To request no release of "directory" information, contact UW Professional & Continuing Education at 800-543-2320 or 206-543-2310. Students may

choose in their MyUW accounts whether to keep directory information public or private. If you should choose not to release information, please remember that no one, including future potential employers, will be given any information about you, including the fact that you have completed your degree.

Tuition and Fees

Tuition and Registration Fee

Current tuition for the 2018-19 is \$845 per credit. A nonrefundable \$45* fee is paid each quarter at the time of registration.

Technology Fee

The technology fee supports the improvement of technology used by the students at the University of Washington campuses. The Student Technology Fee Committee determines the expenditure of this fee. Students at the UW lead the committee which allocates money for technology resources for general student use. Paid Autumn, Winter, and Spring quarters, and based on the number of credits taken, the technology fee for graduate students in the Biomedical Regulatory Affairs program is approximately \$40 per quarter.*

Services & Activities fee

This fee supports student activities and programs such as ASUW and GPSS Activities, Student Publications, Student Loan Fund, Hall Health Primary Care Center, recreational sports programs, childcare, student legal services, Ethnic Cultural Center, Student Union facilities and UW CARES. It also subsidizes your UPASS (Required). Paid each quarter and based on the number of credits taken, the Services & Activities fee for graduate students in the Biomedical Regulatory Affairs program ranges from \$38 to \$238 per quarter.*

* Fees may be subject to change.

Quarterly UPass Purchase

Your Student Activities Fee includes a (mandatory) UPASS each quarter. Including the UPASS payment into the SAF is to encourage students to take public transportation. You cannot “opt out” of the UPASS. More information on this is at: [https://facilities.uw.edu/transportation/?ref=.](https://facilities.uw.edu/transportation/?ref=)

Your UPASS will automatically expire if you do not register 9 days prior to the start of a new term.

Withdrawal/Refund Policies

If you register for classes and find that you are unable to attend the University, it is your responsibility to withdraw. Withdrawals, refunds and changes are handled through UWPCE Registration Services. Please carefully follow deadlines detailed in your Registration mailing for refunds and course changes. To request any of these options, you may:

- request the change in person at UW Professional & Continuing Education, or

- submit a request in writing (with a signature) via US mail to: UW Professional & Continuing Education Registration Services, 4311 – 11th Ave. NE, Seattle, WA 98105-4608, or
- fax your request to 206-685-9359, or
- send an email request to c2reg@uw.edu, stephieg@uw.edu and bett@uw.edu. (Please use your UW email when making this request).

Grading

In reporting grades for graduate students, units that offer graduate degrees use the system described below. Grades are entered as numbers, the possible values being between 4.0, decreasing by one-tenth until 1.7. Grades below 1.7 are recorded as 0.0 by the Registrar and no credit is earned. A minimum of 2.7 is required in each course that is counted toward a graduate degree. A minimum GPA of 3.00 is required for graduation. Students whose cumulative or quarterly GPA falls below a 3.0 must meet with Tom Hazlet to discuss performance expectations and a timetable for correction of deficiencies.

Please review the University of Washington grading system here, https://www.washington.edu/students/genclat/front/Grading_Sys.html.

I Incomplete

An incomplete may be given only when the student has been in attendance and has done satisfactory work to within two weeks of the end of the quarter and has furnished proof satisfactory to the instructor that the work cannot be completed because of illness or other circumstances beyond the student's control. To obtain credit for the course, a student must successfully complete the work and the instructor must submit a grade. In no case may an incomplete be converted into a passing grade after a lapse of two years or more. An incomplete received by the graduate student does not automatically convert to a grade of 0.0 but will remain a permanent part of the student's record.

N No grade

Used only for hyphenated courses and courses numbered 600 (Independent Study and Research), 601 (Internship), 700 (Thesis), 750 (Internship), and 800 (Dissertation). An N grade indicates that satisfactory progress is being made, but evaluation depends on completion of the research, thesis, internship, or dissertation, at which time the instructor or Supervisory Committee Chairperson should change the N grade(s) to one reflecting the final evaluation.

The BRAMS program's PHRMRA 548 is a CR/NC course which qualifies for use of an N grade. An N is awarded when progress is being made but goals for the quarter were not completed. This appears as an N on the transcript and the instructor replaces it with a CR (credit received) when the goals are achieved.

Satisfactory Progress

In order to remain in the program, students must maintain satisfactory progress toward their degree. This includes remaining on a trajectory to complete the program within two years as well as maintaining a minimum GPA of 3.0 with no course grade below 2.7. Students who do not maintain satisfactory progress will be warned, then placed on probation, and if the situation is not remedied, will be dismissed from the program.

Please reference the UW Graduate School's Memorandum 16: Unsatisfactory Performance and Progress, <https://grad.uw.edu/policies-procedures/graduate-school-memoranda/memo-16-unsatisfactory-performance-and-progress/>.

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BRAMS Academic Progress Policy

Our goal in the BRAMS program is to encourage each student to complete his or her classes and practicum in a reasonable period of time. UW allows six years from initial enrollment for completion of an MS degree but BRAMS students typically finish the program in their second, or occasionally their third, year. This policy describes expectations for academic progress and provides the faculty with a mechanism to identify students who may need attention to succeed.

We recognize that orderly progress can be delayed by circumstances outside a student's control (e.g., extended illness). Such circumstances will be considered on a case-by-case basis when progress is evaluated.

The procedure follows the University of Washington Graduate School's guidelines in Memo 16: Unsatisfactory Performance and Progress. Evaluation of progress will take into consideration an individual student's situation and the magnitude of deficiency. Expectations for student performance include: 1) achievement of a passing grade in all required courses (2.7 or better), 2) maintenance of a minimum GPA of 3.0, cumulatively and for each quarter of coursework, and 3) satisfactory practicum progress and performance.

Unsatisfactory progress in any one of these areas may result in the following actions:

First time	Probation
Second time	Final probation
Deficiency not corrected after final probation	Drop

All recommended actions will be communicated to the Graduate School. They also appear on a student's unofficial transcript but are not included on the official transcript.

Responsibility for monitoring progress

1. Failing grade in a course

Grades will be monitored on a quarterly basis by the Program Director and Counseling Services Coordinator.

2. Unsatisfactory GPA

GPA's will be monitored on a quarterly basis by the Program Director and Counseling Services Coordinator.

3. Unsatisfactory practicum progress

Practicum has two components. For the first, the student performs a regulatory project for a practicum site, with direction from a preceptor. For the second, the student documents the project for the BRAMS program. Timely progress in both components is required, as measured by completion of tasks on schedule. Progress will be monitored by the Practicum coursemasters. Any concerns with progress and steps needed for improvement will be conveyed to students in writing.

Examples of unsatisfactory progress

[Examples of unsatisfactory progress in numerically graded courses](#)

- Student fails to earn a grade of 2.7 or better
- Students fails to maintain a GPA of 3.0 or better

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Examples of unsatisfactory progress with a practicum project

- Student does not communicate with preceptor according to agreed plan
- Student does not pursue agreed project
- Student fails to provide drafts or reports according to agreed schedule
- Student does not maintain normal collegial relationships with others at site
- Preceptor reports student's work is substandard
- Progress is delayed by student inaction

The student should contact the coursemasters promptly if progress is adversely affected by the preceptor, project, or site. For example, a lack of regular communication with the preceptor could be due to either the student or the preceptor failing to respond to the other in a timely way.

Examples of unsatisfactory progress with practicum documentation

- Student does not communicate regularly with coursemasters, according to syllabus
- Student documents are not posted and revised in a timely manner
- Document quality is lacking, for example
 - incomplete or insufficient answers to questions
 - incomplete or insufficient revisions
 - multiple errors in technical writing skills
- Subsequent documents repeat the same errors
- Regulatory considerations are inaccurately or incompletely described, and this is not corrected in subsequent revision
- Presentation is significantly substandard
 - student is unfamiliar with the content of the talk
 - student does not know or cannot adequately explain regulatory background and rationale for the project

The coursemasters will solicit information on student progress with the project from the preceptor each quarter. The coursemasters will evaluate progress with project documentation.

Scenarios of unsatisfactory progress

1) Coursework

First Time - Probation	Student earns a 2.6 in an Autumn Quarter class.
Second Time - Final Probation	Student has a GPA less than 3.0 in Winter Quarter.
Third Time - Dismissal	Student has a GPA less than 3.0 in Spring Quarter.

2) Practicum

First Time - Probation	Student fails to maintain regular contact with coursemasters.
Second Time - Final Probation	Preceptor reports substandard work.
Third Time - Dismissal	Quality or timeliness of work remains a problem.

A combination of problems with coursework and practicum may also trigger these steps.

Plagiarism may contribute to a delay in student progress. However, it is covered by UW policies on misconduct so it is not discussed in this policy.

Students may appeal these procedures to the BRAMS Director. For further appeals, follow Graduate School Memorandum 33, Academic Grievance Procedure (<https://grad.uw.edu/policies-procedures/graduate-school-memoranda/memo-16-unsatisfactory-performance-and-progress/>).

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Academic Grievance Procedure

Graduate students who believe they have been subjected to unfair treatment in the administration of academic policies may, except as noted in the procedure, seek resolution of their complaints under this Academic Grievance Procedure. Please reference this procedure in Memo 33, <https://grad.uw.edu/policies-procedures/graduate-school-memoranda/memo-33-academic-grievance-procedure/>

Electives

Some students choose to take elective courses as part of their education. If a student wishes to take an elective course, s/he is allowed to do so as long as the course meets the program and university requirements for electives. If you would like to take an elective, please contact Stephanie O. Guerrero, stephieg@uw.edu. Elective courses will not take the place of required courses in the program.

For the BRAMS Applied students who MUST take elective courses to meet the minimum 10 credits per quarter per the UW Graduate School requirements for full-time students, you will work with Stephanie O. Guerrero to determine course electives prior to each quarter.

UW Student Academic Responsibility Policy

Students enrolled in UW courses are expected to observe the code of academic responsibility required of University of Washington students. Violation of this code will result in various penalties, including a failing grade in the course and, in some cases, disciplinary actions. Instances of academic dishonesty for credit courses will be handled by the University of Washington Committee on Academic Conduct. Academic dishonesty includes plagiarism, defined as offering the language or ideas of someone else as one's own. Plagiarism may range from failure to credit isolated formulas, sentences or paragraphs to copying entire articles from books, periodicals, speeches or the writings of other students. If evidence of academic misconduct is established, students will be given a failing grade for the course and any refund of tuition fees will be denied. To view the complete Academic Honesty policy, please consult the following link: <http://depts.washington.edu/grading/pdf/AcademicResponsibility.pdf>

Plagiarism resources:

- Purdue Online Writing Lab, <https://owl.english.purdue.edu/owl/resource/589/1/>
- Harvard Guide to Using Sources, <https://usingsources.fas.harvard.edu/>
- Indiana University — Plagiarism: What It Is and How to Recognize and Avoid It, <https://www.indiana.edu/~academy/firstPrinciples/choice.html>
- Avoiding Plagiarism: A Guide for Graduate Students at Virginia Tech, http://graduateschool.vt.edu/content/dam/graduateschool_vt_edu/graduate-honor-system/avoiding-plagiarism-short-guide.pdf
- University of Michigan — Library Guide for International Students: What is Plagiarism?,

- <http://libguides.umflint.edu/internationalstudents/plagiarism>
UCLA Graduate Writing Center - Citation Practices and Academic Integrity, <https://gwc.gsrc.ucla.edu/Resources/Citation-Practices>

Maintaining Your Status in the Program

To maintain your graduate status, you must be enrolled on a full-time, part-time or official On-Leave basis from the time of first enrollment in the Graduate School until completion of all requirements for the graduate degree. Summer quarter registration is not a requirement of the Graduate School, but many students do register for some of their practicum credits during the summer between the first and second year. If you anticipate any difficulties with maintaining ongoing registration, please contact

Stephanie O. Guerrero at stephieg@uw.edu to assist you with arranging for On-Leave status. For more information on this policy, see <https://grad.uw.edu/policies-procedures/graduate-school-memoranda/memo-9-on-leave-policy-to-maintain-graduate-student-status/>.

UW Rules and Regulations

Students are expected to follow University rules and regulations. The University and UW Professional & Continuing Education reserve the right to change the fees, rules, and calendar regulating registration and instruction, and to change other regulations affecting the student body. Changes go into effect as determined by university authorities. These changes apply to prospective students and those who are registered in credit and UW Online Learning courses. The University can withdraw courses at any time.

Financial Aid

Long-term student loans are available to help with tuition and fees. Since the program is fee-based, it is not eligible for State funding, but other funding sources are available.

The BRAMS program has limited financial aid available for students who meet certain specific criteria:

Financial aid, supplied by the Biomedical Regulatory Affairs Master of Science Program Budget, may be supplied to students who meet the following qualifications:

- 1) Aid is only available to students in Spring quarter of their second year
- 2) Must currently be receiving financial aid from another source
- 3) Must be in good standing in the program, and on schedule to graduate with the cohort*
- 4) Must be enrolled for 3 or fewer Practicum credits (PHRMRA 548) only during their final spring quarter

*Exception: a student may receive aid during Spring quarter of the second year and still take their final Practicum credits during the following Summer quarter; however, there will be no aid available for any credits taken during summer.

Financial Aid in the amount to cover no more than three credits plus all associated fees will be disbursed **ONLY** to students meeting the above criteria.

For further information on other financial aid sources, visit the following Web sites:

UW Office of Student Financial Aid <http://www.washington.edu/students/osfa/>
U.S. Department of Education Federal Student Aid <http://www.fafsa.ed.gov/>
VA loans and Veteran's benefits <http://depts.washington.edu/osfaweb/veterans/>
UW Libraries Grants & Funding Information Services
<http://www.lib.washington.edu/commons/services/gfis>
The Graduate School <https://grad.uw.edu/graduate-student-funding/>

Academic Student Services

UW Professional & Continuing Education Registration

UW Professional & Continuing Education Registration Services is located at 4311 - 11th Ave. NE on the main floor. Registration is open from 8 a.m. to 5 p.m. Monday through Friday. Other contact numbers for registration include phone 206-543-2310, 800-543-2320, or 206-543-0898 (TTY), and fax 206-685-9359.

Biomedical Regulatory Affairs

Tom Hazlet thazlet@uw.edu Program Director,
Jean Feagin feagin@uw.edu Practicum Course Master <TOM- we had Jean as Practicum Director last year, so I added Floyd and both with this title. Your thoughts>
Floyd Karp, floyd@uw.edu, Practicum Course Master

Disability Support Services

The Disability Resources for Students (DRS) provides an array of academic support and student services. <http://depts.washington.edu/uwdrs/>

UW Student Counseling Center

Located in Schmitz Hall, the UW Student Counseling Center offers academic, career, and personal counseling services detailed at <http://www.washington.edu/counseling/> If you are experiencing a crisis and need immediate assistance, please call the Crisis Clinic at (206) 461-3222 or (866) 427-4747.

Graduate School

The UW Graduate School website <http://grad.uw.edu/>, lists extensive resources for graduate students including: enrollment statistics, links to the disability services office, financial information, student life, and career resources. Most Graduate School offices are located in the Communications building.

GPSS – Graduate & Professional Student Senate

The University of Washington offers many opportunities for students to gain experience in campus governance. Graduate students can serve as graduate representatives on campus committees or participate in GPSS governance. More information can be found at <http://depts.washington.edu/gpss>.

GO-MAP

The Graduate School is also home to GO-MAP (Graduate Opportunities and Minority Achievement Program), available online at <https://grad.uw.edu/diversity/go-map/> GO-MAP is one of several resources on campus for graduate students of color and traditionally underrepresented groups that address issues of diversity including academic, campus, outreach, recruitment, and community information.

Office of the Vice Provost for Student Life

The Office of the Vice Provost for Student Life is the main conduit for all general student services at the University of Washington. From student groups to counseling services, more information on Student Life is available at <http://www.washington.edu/provost/studentlife/>

Office of Minority Affairs and Diversity

The Office of Minority Affairs (OMA&D) <http://www.washington.edu/omad/> forwards the core mission of diversity at the UW by providing outreach and academic support services to students of all backgrounds. As the academic arm of OMA&D, the Instructional Center (IC) provides academic assistance so students can excel at the University of Washington.

International Student Services (ISS)

For more information on the resources available for international students, please consult the ISS web page: <https://iss.washington.edu/> or call (206) 221-7857 to make an appointment or ask a question.

Information is available to you at the ISS on a variety of topics including:

- Procedures for requesting a replacement I-20, or an F-1 or J-1 visa.
- Extending your I-20 or DS-2019
- OPT/CPT (<https://iss.washington.edu/employment/f1-employment/cpt/>)
- Making an advising appointment and hours the ISS is available for questions.

Women’s Center

The Women’s Center, <http://depts.washington.edu/womenctr/> encourages positive change in public policy by providing educational programs, advising, counseling, and life skills training. The center welcomes both men and women and is located on the fourth floor of Bagley Hall.

UW Events and Calendars

To find out what’s going on around campus, check out the “events” link on the UW home page at <http://www.washington.edu/news/>. Events range from arts performances to lectures. Admission to all museums and galleries on the UW campus (including the Burke Museum and the Henry Art Gallery) is free to UW students. Here you will also find the UW Academic Calendar which contains all information regarding the academic schedule for each quarter.

Husky Card™

Your Husky Card™, <https://hfs.uw.edu/Husky-Card-Services/Husky-Card/Student-Husky-Card> is your University of Washington identification card. All new UW students are issued a card that says “Husky Card” on the front. The Husky Card™ is valid only if it has a current validation sticker on it and the encoded information on the magnetic stripe indicating validity. Enrollment validation stickers are sent each quarter to students with their Registration Confirmation. It is important to keep your Husky Card™ with you at all times while on campus.

Online access to accounts is now available. It’s easy for you to monitor your account, make deposits (friends and relatives can deposit money into your account too), and check balances. See <https://hfs.uw.edu/OLCO/> for details.

There are many uses for your Husky Card™ including, but not limited to:

- Utilizing your U-PASS benefits (the U-Pass validation sticker is sent to you with your enrollment validation sticker and Registration Confirmation and should be placed on the back of your Husky Card™).
- Carpool parking – two or more students. Gatehouse-issued carpools and E1 Montlake parking lot carpools require Husky Card™ accounts as well as U-Pass. Gatehouse carpool Husky Card™ account debits are split between two or more carpool member cards.
- Accessing funds from your Husky Card™ Account. Find out all the locations that accepts the Husky Card™ Account by clicking on the official website <https://hfs.uw.edu/Husky-Card-Services/Husky-Card-Account/Participating-Locations>
 - As your library card
 - Gaining admission to events and purchasing tickets
 - Accessing the Intramural Activities Center (IMA)
 - Obtaining discounts on tickets at the UW Arts Ticket Office, at the Golf Driving Range, and the Waterfront Activities Center
 - Obtaining free admission to the Henry Art Gallery and the Burke Museum

To obtain your card, go to the UW student ID Center, located on the ground floor of the Odegaard Undergraduate Library next to the By George Café, between the hours of 8:00 a.m. and 5:00 p.m., Monday through Friday. You will be required to show legal photo identification to obtain your Husky Card™. There is no charge for your first card.

Husky Card FAQs, <https://hfs.uw.edu/Husky-Card-Services/FAQ>.

Library Services

As a student in the Biomedical Regulatory Affairs program you have on-campus and off-campus access to the University of Washington library system. Electronic access is available to many

resources—journals and databases—of interest to BRAMS students. One valuable resource is *Summit*, a library catalog that combines information from Pacific Northwest academic libraries into a single unified database. You can initiate your library account using your UWNetID at <http://catalog.lib.washington.edu/patroninfo>

Connect to UW-restricted resources from off-campus.

Most of the databases, electronic journals and e-books available through the libraries have restricted access for UW faculty, students and staff. If you connect to the Internet via an Internet Service Provider, you will need to use the UW Libraries Proxy server. To start a session with the new proxy, click on the "Off-Campus Access" link in the upper right corner of most pages on the library website or visit <http://offcampus.lib.washington.edu/menu>. This proxy requires that you always start a session to gain access to restricted resources. Another solution, which is more flexible, is to use our proxy bookmarklet. Once the bookmarklet is installed, you do your research and at some point will arrive (unauthenticated) at the content provider's site. Then hit the bookmarklet and it takes you back to that same page, but through the proxy server. More information on our bookmarklet is available at <http://www.lib.washington.edu/help/connect/tools>.

School of Pharmacy Librarian

UW Librarian Terry Ann Jankowski has been designated to assist School of Pharmacy students. Please contact Terry at 206 543-3397 or terryj@uw.edu for her office hours.

Interlibrary Loan

The Interlibrary Loan system provides borrowing, lending, and document delivery services for UW patrons. Current UW students may borrow material or obtain copies of articles not owned by the UW Libraries (items which can be requested through *Summit* will not be borrowed). This service is fully subsidized for UW-related needs. Material for personal or recreational use may be obtained for a fee.

Interlibrary Loan is also a fast, convenient way to get photocopies of articles from journals held in your home campus library. There is a \$7.00 convenience fee charged per journal article. Articles can be delivered by PDF or mailed to your campus box for free. There is an additional \$7.00 charge per article to have them mailed to your home address. If you are a currently enrolled, non-resident (distance learning) student, Interlibrary Loan can mail books owned by UW Libraries or article photocopies to your home address. This may be the most convenient way for you to obtain materials from the Libraries. There is a charge for this service. For more about Interlibrary loans visit <http://www.lib.washington.edu/uworld/>.

To access details about library locations and hours in addition to the resources and services available visit the UW library home page at <http://www.lib.washington.edu/>.

Libraries

Students of the School of Pharmacy will find many of the references needed for classes in either the Health Sciences Library or Suzzallo Library and the specialty libraries located on upper campus.

The Health Sciences Library is located on the second and third floors of the T-Wing, in the Health Sciences Building. This facility contains the largest collection of biomedical literature in

the Pacific Northwest, and also serves as the Pacific Northwest and Regional Health Sciences Library of the National Library of Medicine. This library is open Monday through Thursday 8:00 am to 11:00 pm and Sunday 12:00 pm to 11:00 pm. During interim periods between quarters the hours of operation may be altered slightly.

The library subscribes to a large number of periodicals in the biomedical field. Journals are shelved alphabetically on the main floor of the library. The most recent issues of periodicals are found in the New Acquisitions area. The library also maintains a Reserve Reading Desk where specific course readings are available for a two hour reserve. The Reserve Desk is located on the second floor of the library (the third floor in the building).

In addition to providing reference material for students, the library also serves as a good place for studying. Small conference rooms have been designated as audiovisual rooms containing video and audio playback machinery for various self-learning resource materials.

The Health Sciences Library staff provides tours of the library at the beginning of each quarter for new students and faculty. Students are advised to sign up for one of these tours, as they describe the services of the library in considerably more detail than is possible here.

Suzzallo and Allen Libraries, located in the center of upper campus, contain nearly five million volumes. They provide an unparalleled variety of texts on scientific, economic, and social issues. The UW Libraries Catalog (available on-line) is a fully integrated, computerized system that provides bibliographic information and circulation status for the cataloged holdings of the University Libraries. Suzzallo and Allen Libraries are open 7:30 am to 10:00 pm Monday through Thursday, 7:30 am to 5:00 pm Fridays, and 1:00 pm to 5:00 pm on Saturdays and Sundays. The hours of libraries may change between quarters. For current hours call 543-0140

Computing Services

Tools for Safe and Secure Computing

The Tools for Safe and Secure Computing page gives you quick access to a basic set of software tools for fighting viruses, doing secure file transfer and terminal sessions, and other common tasks. All of the tools linked on this page are available at no cost to you, either because they are freeware or because the UW has paid for the right for you to use them.

<http://www.washington.edu/itconnect/security/tools/>.

Hot Spots on Campus

Wireless connectivity is available in most indoor and outdoor locations on the UW campuses. For a current list of wireless locations and instructions on connecting, visit

<http://www.washington.edu/itconnect/connect/uw-networks/campus-wi-fi/locations/>

Computer Labs

A number of computer labs are available on campus for student use.

Odegaard Learning Commons is the general access lab and offers a variety of hardware and software, including laser printing. See the website for hours of operation http://catalyst.washington.edu/learning_spaces/computing_commons.html

The Access Technology Center (ATC) provides resources to improve access to computing resources. The computers, software, and special equipment in the lab provide access for users with disabilities: common speech recognition software as a writing tool, tools to make the reading and writing process easier, accessories to make computer use more comfortable, and the capability to create and produce documents in alternative formats. The ATC is located in the Mary Gates Hall Room 064. <http://www.washington.edu/itconnect/learn/accessible/atc/> Contact the ATL Voice/TTY 206-685-4144 or email atcenter@uw.edu.

Health and Safety Services

Health Insurance & Benefits

The UW no longer offers student health insurance for US residents. International students are still required to buy UW health insurance. International Student Health Insurance Plan (ISHIP) information can be found here, <https://www.washington.edu/ship/international-student-insurance-health-plan/>. The Graduate Appointee Insurance Program (GAIP) <https://hr.uw.edu/benefits/insurance/health/graduate-appointees/gaip-eligibility-coverage-overview/> pays for medical, dental, and vision coverage if you hold a Graduate Student Service appointment or receive external funding.

Drop-in Health Centers

The University of Washington offers several drop-in health centers that are open to all UW students, faculty, and staff. Hall Health, <http://depts.washington.edu/hhpccweb/>, offers primary care services including immunization shots (needed for admission), family and mental health, and sports medicine clinic.

UW Student Counseling Center

Located in Schmitz Hall, the UW Student Counseling Center, <http://www.washington.edu/counseling/> offers academic, career, and personal counseling services. If you are experiencing a crisis and need immediate assistance, please call the Crisis Clinic at 206-461-3222 or 866-427-4747

Husky Nightwalk

The hours of operation for these uniformed security guards are 6:00 pm-2:00 am, 7 days week. Although aiding primarily on foot, the guards have a minivan available to assist when needed. In addition, they are equipped to help people, with proper identification, who cannot get into their offices, areas or vehicles. They also can assist with jump starts for dead batteries, and are extra eyes and ears in parking lots and other UW facilities. When members from the campus community need help, call 206-685-WALK (9255). For more information visit <http://www.washington.edu/admin/police/security/>.

Night Ride

The UW Transportation office provides transportation from campus to destinations within one

mile at night during all quarters except summer. The service is free for UPass holders and \$1.00 per ride for those without a UPass.

<http://www.washington.edu/facilities/transportation/uwshuttles/nr>

UW Police

If you need the assistance of UW Campus Police for non-emergency matters, please contact them at 206-543-9331. If you are on a campus phone and have an emergency, please call 911. For more about the UW campus police visit

<http://www.washington.edu/admin/police/index.shtml>.

Parking and Local Transportation

Campus Parking

Parking is often a challenge around the UW campus. If you drive up to a gatehouse for on-campus parking, the cost is \$15.00 for all day (prorated if you stay less than four hours, and possibly more for next year). Most street parking is metered with a two-hour maximum. If you arrive at the campus after 5:00 pm, parking is \$5.00 for the evening with the exception of the Central Garage which charges \$10.00.

<http://www.washington.edu/admin/parking/studtTOC.html>

Local Metro Transit

Your U-Pass (\$84.00 per quarter)* provides full fare coverage for the Metro Transit bus, Community Transit, Light Rail, the Kitsap ferry, the Sounder commuter train service, and discounted carpool parking. Once enrolled, you will automatically receive the quarterly U-Pass and validation sticker. (However, you will need to register at least 9 calendar days before the start of a new term to avoid an interruption in service.) These stickers are to be affixed to your UW student ID card. Note: If you do not want the U-Pass, you are responsible for returning it to campus. Students who do not return the U-pass sticker will be charged for it (\$200)*.

The Metro Online website <http://metro.kingcounty.gov/> provides easy to use resources to plan a trip or look up the bus timetables.

Community Transit (commuter buses that originate outside King County:

www.communitytransit.org

*This rate may increase for the 2017-2018 school year. Please see <http://www.washington.edu/commuterservices/rates.php>, for details.

Campus Maps

Maps showing campus buildings, parking lots and the surrounding streets are located at

<http://www.washington.edu/home/maps/>.

Fitness and Recreation Services

Intramural Activities (IMA) Building

The IMA, located north of Husky Stadium and south of parking lot E1, is the hub of the UW recreational sports programs. UW Students may use the IMA upon presentation of their current quarter Husky ID Card. Facilities include:

Waterfront Activities Center (WAC)

Just south of the UW football stadium, the WAC provides canoe and rowboat rentals. Boat storage is available for private non-motorized boats. The Golf Range has 43 tees, (20 covered), night-lighted, and two chipping and putting greens. The range offers classes monthly.

UW Recreation programs

A broad selection of sports and fitness classes including aquatics, dance, fitness, yoga, martial arts, golf, handball, squash, rock climbing, and tennis are offered throughout the year. The Recreation office also coordinates intramural sports clubs and leagues. For more details about recreation facilities and programs, visit <http://depts.washington.edu/ima/>.

FAQ

The Biomedical Regulatory Affairs Master of Science (BRAMS) program is a partnership among the UW Department of Pharmacy, UW Professional & Continuing Education (UWPCE) and the UW Graduate School. Student admissions and academic content are the primary responsibilities of the Department of Pharmacy. UWPCE is responsible for the logistics and administrative functions of operating the program, i.e., registration, facilitating tuition payments. The Graduate School oversees all the graduate degree programs for the UW, including those administered through UWPCE. It is the Graduate School that offers admission to graduate students, verifies successful completion of the program requirements, and confers the earned degree.

Who can I talk to if I have a complaint?

You can contact Stephanie O. Guerrero, the Counseling Services Coordinator, stephieg@uw.edu, 206-221-6026.

What are the fees for the program?

The per-credit tuition fee for the 2018-2019 school year is \$845 per credit. The program consists of 45 required credits for which the total tuition cost is approximately \$38,025, plus other fees (see page 5). The per-credit cost for all students is the same, whether resident, non-resident or International.

Is this program eligible for the tuition exemption benefit offered to state and UW employees?

No, the tuition benefit exemption applies only to state-funded programs. Since fee-based degree programs receive no state funds, they are not eligible for the tuition exemption benefit.

Why does this program's tuition rate differ from the standard graduate tuition?

This program is not funded by the state of Washington. It is a self-supporting, fee-based program. Tuition differences reflect the administrative costs associated with delivering the program.

May I take other UW courses (courses outside my program) for the purpose of this degree?

Generally, this program does not allow elective credits with the exception of previous certificate students who need to make up academic credits or the full-time students. The student will need to obtain approval from the program advisors before signing up for any classes in this situation. Additionally, students are charged the program tuition rate for any courses that are taken, whether inside or outside the program. International students may be required to take additional courses to fulfill visa requirements; these courses have fewer criteria as far as the program is concerned.

How do I change my address?

You must change your address with two different offices. Please notify UWPCE Registration Services by sending an email to c2reg@uw.edu and the Biomedical Regulatory Affairs program by sending an email to Stephanie O. Guerrero at stephieg@uw.edu. You also need to change your address in your MyUW account.

I'm changing my email address. Should I let you know?

YES! Your UW email address is your most important means of communication with us. Please check it regularly or forward it to an email address which you commonly do check. We rarely send anything via regular mail, so it is imperative that we can communicate with you via email. If you do change your personal email address, we would also appreciate knowing that so we can be assured of being able to contact you. Please send updates to Stephanie O. Guerrero, stephieg@uw.edu.

I have a hold on my student account. What does that mean and how do I clear it?

A hold on your account can be placed by any office within the University system for various reasons. The most common hold for new students is based on failure to prove proof of immunity to measles. The other most common reason for a hold is for fees owed. Students can have holds placed on their account because they owe a fine at the library, didn't return the UPASS (or pay for it), didn't submit their immunization records, didn't submit their transcripts to the Graduate School, didn't pay for a transcript ordered through MyUW, or didn't pay for their student insurance. In addition, any medical facility associated with UW can also place a hold on student records.

If you have a hold on your records, then *you will receive an email from the UWPCE Registration Office which will direct you to Student Fiscal Services*. Please be advised that UWPCE cannot remove this hold for you and cannot register you in courses until it is resolved. To determine if you have a hold on your account, please check your MyUW account. A clear explanation and the way to resolve the hold will appear on your homepage.

Am I a UW graduate student or a UW Professional & Continuing Education graduate student?

You are a UW graduate student, your degree is granted by the University of Washington, and your diploma will say University of Washington. UW Professional & Continuing Education

(UWPCE) is a division of the University of Washington and includes UW Extension, Summer Quarter, Evening Degree, and Distance Learning.

Why is my degree program offered through UW Professional & Continuing Education (UWPCE)?

The degree is what is called a fee-based degree. That means this degree program doesn't receive any funding from the state of Washington so it must function on a self-sustaining basis. By definition, programs not funded by the State must be administered through PCE for accounting purposes.

What is the collaborative relationship between my academic department, UWPCE, and the Graduate School?

Degree programs are a partnership between UWPCE and the academic department. Student admissions and academic content are the primary responsibilities of the academic department. UWPCE offers administration assistance to the department offering the degree. The Biomedical Regulatory Affairs program is offered by the School of Pharmacy. UWPCE is responsible for the logistics and administrative functions of operating the program. The Graduate School oversees all the graduate degree programs for the UW, including those offered through UWPCE. It is the Graduate School that offers admission to graduate students, verifies successful completion of the program requirements, and confers the earned degree.

I still have questions. Whom do I contact?

- Program Administration
Stephanie O. Guerrero, stephieg@uw.edu
- Registration Assistance
Bettina Schifferl, bett@uw.edu
- Program Questions
Paul Detmer, pdetmer@uw.edu
- Program Director
Tom Hazlet, thazlet@uw.edu