UAB SCHOOL OF HEALTH PROFESSIONS
The University of Alabama at Birmingham

Department of Clinical and Diagnostic Sciences
Biotechnology Regulatory Affairs Graduate Certificate

2023-2024
STUDENT HANDBOOK

UAB // SHP

UAB SCHOOL OF HEALTH PROFESSIONS

CLINICAL & DIAGNOSTIC SCIENCES

BIOTECHNOLOGY REGULATORY AFFAIRS CERTIFICATE

2023-2024 ACADEMIC HANDBOOK

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7/31/2023

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Date

9/08/2023

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Dean, School of Health Professions

Date

Table of Contents

Table of Contents

INTRODUCTION

DEAN'S WELCOME MESSAGE

Welcome to the University of Alabama at Birmingham School of Health Professions! We are pleased you chose to join one of our many excellent programs, which in combination have established us as a national leader in health professions education.

We are home to one of the largest health professions schools in the nation with more than 30 programs at the certificate, baccalaureate, master's, and doctoral levels, with more than 2,000 undergraduate and graduate students enrolled.

Moving into a post-COVID environment is a new start for everyone in health care, and you are in the best place to begin your personal journey toward joining this dynamic field. We are all committed to providing you a world-class education, and to support your pursuit of knowledge and your strong desire to serve others as a healthcare professional.

The pandemic has challenged all of us in many ways, and your entry into one of our professional programs demonstrates one of the most precious personal qualities one can have: resilience. That resilience has brought you here today and will continue to serve you well during your journey at UAB.

We recognize that healthcare needs - even outside of a pandemic - are constantly changing. That is why we continue to add innovative programs to our academic portfolio, and to enhance and revitalize ongoing programs. We also offer graduate programs you will only find in Alabama at UAB, such as Genetic Counseling, Nuclear Medicine and Molecular Imaging, Low Vision Rehabilitation, Health Physics, Healthcare Quality and Safety, doctoral-level Rehabilitation Science, and Biomedical and Health Sciences.

Our degrees and programs are fully accredited by their respective professional organizations. This means you will be eligible for licensure, national certification or registrations and enjoy being in high demand within the job market. Our first-time student exam pass rate on many credentialing exams is an astounding 98 percent or higher.

Graduating from the School of Health Professions means you will acquire an esteemed degree, have a host of job opportunities in healthcare – an industry that continues to grow rapidly – and be well prepared to make a difference in your community. We look forward to maintaining our relationship with you when you join our alumni community.

Our alumni give advice to current students that is worth repeating: "learn your craft, be a better professional for your patients, be open minded to future possibilities, and remember to have a healthy work/ life balance".

I look forward to seeing you grow in your respective fields and watching you become the leader we know you can be.

Andrew J. Butler, PhD, FAPTA

OVERVIEW OF THE SCHOOL OF HEALTH PROFESSIONS

A leader in federally funded research, the UAB School of Health Professions (SHP) is one of the largest academic institutions of its type in the United States and currently boasts several nationally ranked programs. What began in the 1950s as a collection of training programs in various para-professional disciplines has grown into an internationally recognized center of academic excellence.

The SHP initially took shape in 1969 as UAB gained autonomy within the University of Alabama System. Originally christened the School of Community and Allied Health Resources (SCAHR), the school incorporated the School of Health Services Administration and the Division of Allied Health Sciences from the College of General Studies with parts of the Department of Public Health and Epidemiology from the medical school. An innovative facility designed to meet the growing needs of the health care industry, the SCAHR was divided into four academic divisions that functioned like regular academic departments: Health Services Administration, Public Health and Environment, Allied Health Sciences, and the Regional Technical Institute for Health Occupations.

Throughout the 1970's and 80's the school's offerings were amended to reflect the changing health care industry. As a result of the changes, SCAHR became the School of Public and Allied Health (SPAH). Next it became the School of Community and Allied Health (SCAH) and later the School of Health Related Professions (SHRP). During this time, the school added several new areas of study including a nationally ranked program in Nutrition Sciences. Through the leadership and guidance of early visionaries, the school experienced unparalleled success, which continues to date.

Today, the School of Health Professions is comprised of more than 30 programs – at the certificate, baccalaureate, master's, and doctoral levels – across five academic departments: Clinical and Diagnostic Sciences, Health Services Administration, Nutrition Sciences, Occupational Therapy, and Physical Therapy. The school is housed in three buildings, the Susan Mott Webb Nutrition Sciences Building, the Learning Resource Center Building, and the School of Health Professions Building (SHPB).

With more than 2,200 faculty, staff, and students, SHP is one of six schools comprising the world-renowned UAB Academic Health Center. Students have access to vast academic resources, state-of-the-art facilities, and progressive research.

SHP is proud of many accomplishments including:
- U.S. News & World Report ranks SHP programs in the nation's top 25
- Research funding is over $14 million and growing
- The school is at the top of the list in research funding from the National Institutes of Health for schools of its type and has been either first or second in funding received since 1969

Under the current leadership of Dean Andrew Butler, the school has never been stronger or better positioned as a national leader in health professions education.

School of Health Professions Contact Information

In addition to your program director and program faculty, the following individuals may be able to provide assistance with questions and issues related to your school and program activities.

Kristin Chapleau, Director of Student Services and Advising

205-996-4721; kjohnsto@uab.edu

Jennifer Christy, Assistant Dean for Faculty Affairs

205-934-5903; jbraswel@uab.edu

Mary Foster, Dean's Executive Assistant

205-934-5149; fostermg@uab.edu

Samantha Giordano-Mooga, PhD, Director of Undergraduate Honors Program

205-996-1399; sgiordan@uab.edu

Melanie Hart, PhD, Associate Dean for Academic and Faculty Affairs

205-934-7528; mhart2@uab.edu

Kevin Storr, Director of Communications

205-934-4159; storr@uab.edu

Lee Test, Director of Academic and Faculty Operations

205-975-8034; ltest@uab.edu

Marci Willis, Director, Learning Resource Center

205-934-9472; mbattles@uab.edu

SECTION 1 – SCHOOL AND UNIVERSITY INFORMATION

ACADEMIC CALENDAR

All dates related to registration, payments of tuition and fees, drop/add dates, other administrative requirements, and official school holidays are recorded on the UAB Academic Calendar available at www.uab.edu/academiccalendar.

ACADEMIC INTEGRITY CODE

The University established a new Academic Integrity Code effective August 23, 2021. This Code, which applies to undergraduate, graduate, and professional students as well as all academic activities, defines academic misconduct and outlines procedures for breaches of the code. Policies are established for resolution of charges of academic misconduct, and these processes are managed by the Academic Integrity Coordinator (AIC). In the School of Health Profession, the AIC is the Senior Associate Dean for Academic and Faculty Affairs, the office is located in SHPB 660. The full text of the Academic Integrity Code is available at: https://www.uab.edu/one-stop/policies/academic-integrity-code.

ADVISING

Undergraduate student advising is provided through the Student Services and Advising unit, which is housed in the SHPB 230 suite of offices, near the elevators on the 2nd floor. Walk-ins are accepted, but appointments are preferred. Contact information for individual advisors is listed below.

> Anrika Steen, Academic Advisor III, SHPB 424E – 996-1689; anrikam@uab.edu
>
> Eileen Hatfield, Academic Advisor II, SHPB 230 – 205-934-4185; mehatfie@uab.edu
>
> Chris Smith, Academic Advisor III, SHPB 230 – 205-934-5974; cjsmith1@uab.edu
>
> Adam Pinson, Academic Advisor III, SHPB 424A – 205-996-6789; apinson@uab.edu

Graduate student advising is provided through the SHP graduate programs.

AMBASSADORS

Ambassadors help to spread awareness of the School of Health Professions and its multifaceted undergraduate and graduate programs, serving as liaisons between the department and university-wide student organizations, serve as a student voice in school and university committees, and with the timely goal of creating a sense of community for all SHP students. The SHP Ambassadors help to support the programs within the school that will impact recruitment and retention initiatives.

AskIT

AskIT is the technology help desk for faculty, staff, and students. They provide free support via telephone, email, or in-person. You will be asked to supply your BlazerID when you request assistance.

Phone: (205) 996-5555 Email: askit@uab.edu   Website: https://uabprod.service-now.com/service_portal

ATTENDANCE

Class attendance is expected in all SHP programs. Specific class, laboratory or clinical site attendance requirements may be more stringent than university guidelines. Refer to the program requirements in this handbook and in course syllabi for policies. The UAB policy for undergraduates follows.

The University of Alabama at Birmingham recognizes that the academic success of individual students is related to their class attendance and participation. Each course instructor is responsible for establishing policies concerning class attendance and make-up opportunities. Any such policies, including points for attendance and/or participation, penalties for absences, limits on excused absences, total allowable absences, etc., must be specified in the course syllabus provided to students at the beginning of the course term. Such policies are subject to departmental oversight and may not, by their specific prescriptions, negate or circumvent the accommodations provided below for excused absences.

The University regards certain absences as excused and, in those instances, requires that instructors provide an accommodation for the student who misses assignments, presentations, examinations, or other academic work of a substantive nature by virtue of these excused absences. Examples include the following:

Absences due to jury or military duty provided that official documentation have been provided to the instructor in a timely manner in advance.

Absences of students registered with Disabilities Services for disabilities eligible for "a reasonable number of disability-related absences" provided students give their instructors notice of a disability-related absence in advance or as soon as possible.

Absences due to participation in university-sponsored activities when the student is representing the university in an official capacity and as a critical participant, provided that the procedures below have been followed:

Before the end of the add/drop period, students must provide their instructor a schedule of anticipated excused absences in or with a letter explaining the nature of the expected absences from the director of the unit or department sponsoring the activity.

If a change in the schedule occurs, students are responsible for providing their instructors with advance written notification from the sponsoring unit or department.

Absences due to other extenuating circumstances that instructors deem excused. Such classification is at the discretion of the instructor and is predicated upon consistent treatment of all students. In these instances, instructors must devise a system for reasonable accommodation including, for example, policies allowing for dropped exams/quizzes, make-up exams, rescheduling of student classroom presentations or early or later submission of written assignments.

AWARDS AND HONOR SOCIETIES

All students in the School of Health Professions are eligible for consideration for the following awards or society memberships.

- Alfred W. Sangster Award for Outstanding International Student – This award is presented annually to an international student in recognition of his or her academic and non-academic achievements.

- Alpha Eta Society – The UAB Chapter of this Society recognizes students registered in the final term of a baccalaureate or graduate health professions program. Inductees must have a cumulative grade point average of 3.0 (4.0 = A) and be in the upper 10% of their program. Nominations are made by program directors in spring and summer terms.

- Cecile Clardy Satterfield Award for Humanism in Health Care – This award is made annually to recognize one outstanding student for humanitarianism, professionalism, and commitment to health care. Nominations are coordinated by program directors, but may also be made by faculty, students, patients, or preceptors.

- Charles Brooks Award for Creativity – This award is made annually in recognition of creative accomplishments such as written publications or artistic contributions which complemented the student's academic activities. Nominations are made by program directors.

- Dean's Leadership and Service Award – Presented to a maximum of three outstanding SHP students annually, this award recognizes leadership to the School, UAB, and the community. Nominations are made by program directors or faculty.

- Phi Kappa Phi – This is the oldest, and most selective, all-discipline honor society in the nation. Membership is by invitation to the top 7.5% of junior students and the top 10% of seniors and graduate students. Nominations are made by program directors.

Please refer to the program section of this handbook for awards and honors available to students in individual programs.

BACKGROUND CHECK

Students in SHP programs are required by policy to undergo a background check using the school's approved vendor, CastleBranch https://discover.castlebranch.com/, at the time of program admission, and again, prior to placement in a fieldwork l rotation. In addition, some sites are requiring the social media background check. This package code is different than the initial package code given. Instructions for requesting the background check and appropriate consent forms are provided to students by their programs. Please refer to the policy section of this handbook for the policy statement.

BLAZERID / BLAZERNET / EMAIL

BlazerID: All students receive a unique identifier, the BlazerID, established at: www.uab.edu/blazerid. Your BlazerID is required for accessing BlazerNET and other campus resources. To activate one's BlazerID, select "Activate Accounts."

BlazerNET is the official portal of the UAB information network and is accessible from any Internet-accessible computer, on- or off-campus. Access BlazerNET from UAB home page www.uab.edu then choose UAB Quicklinks.

Email: uab.edu Monitor your email regularly. Your UAB email is the official communication medium for courses, news, information, and announcements. UAB student email is provided through Microsoft Office 365, a cloud-based system. Students have 50 GB of email space and 25 GB of free file 1 TB storage.

BLAZER EXPRESS

The UAB Blazer Express Transit System provides transportation throughout the UAB campus. With a valid UAB ID badge, students can enjoy fare-free bus transportation. All buses are ADA-accessible and can seat approximately 35 riders. For an updated schedule, route maps, and hours of operation please go to www.uab.edu/blazerexpress/.

BOOKSTORE

There is one bookstore located on the UAB campus, offering a wide variety of products and services to students, including online purchasing and shipping. The bookstore stocks UAB memorabilia and college wear in addition to all required textbooks and course material.

UAB Barnes and Noble Bookstore

> Location: 1400 University Blvd, Hill Student Center, 35233
>
> Hours: M – F 8:00am – 6:00pm | Sat 10:00am – 2:00pm | Sun Closed
>
> Telephone: (205) 996-2665   Website: https://uab.bncollege.com/shop/uab/home

CAMPUS ONECARD

The UAB OneCard is the official university identification card. It is used for personal identification, for entry to campus events and the recreation center, for library checkout, and other UAB services. It also serves as a declining balance card for the UAB meal plans and for Blazer Bucks accounts. Additional information is available at www.uab.edu/onecard.

CAMPUS MAP

UAB's campus map can be found at the following: www.uab.edu/map/

CAMPUS SAFETY

Campus safety procedures and resources can be accessed at https://www.uab.edu/students/home/safety.

CANVAS LEARNING MANAGEMENT SYSTEM

The Canvas Learning Management System is the platform used for managing instructional materials online. Canvas course sites are accessed through BlazerNET or at www.uab.edu/elearning/canvas.

Students should monitor their course sites routinely for communication from faculty and manage course assignments.

CATALOG

The UAB Catalog is published annually and includes UAB's courses, policies, and curricula. Students can link to the Undergraduate or Graduate catalog at www.uab.edu/catalog.

COUNSELING SERVICES

Student Counseling Services offers no cost, confidential counseling for UAB students related to physical, emotional, social, intellectual, or spiritual concerns. Student Counseling Services is located in the Student Health and Wellness Center at 1714 9th Ave. South. For more information, call 205-934-5816 or https://www.uab.edu/students/counseling/.

COVID-19 PRECAUTIONS

The COVID-19 pandemic necessitated many changes in our academic and administrative operating practices. The University continues to consult experts in the field to assess the pandemic and make data-driven decisions to safely pursue our vital mission. Students can view current COVID information and official policies at www.uab.edu/uabunited.

- Masking – Masks are not required in university meetings, events, classrooms or laboratories unless there is a non-COVID environmental health and safety policy or guideline that otherwise requires a mask for the setting or activity performed. Many individuals in our campus community may choose to wear a well-fitting mask. Members of the campus community are encouraged to respect the decisions others make in keeping with UAB's Shared Values.
- If you are not vaccinated, we highly encourage you to obtain the COVID vaccine – students may receive the vaccine at no cost through Student Health Services, at walk-up clinics, or through UAB Medicine. Scheduling information is available at https://www.uab.edu/uabunited/covid-19-vaccine
- If you are vaccinated, please upload an image of your vaccination card through the Student Health Patient Portal at https://studentwellness.uab.edu/login_directory.aspx.
- Students who experience COVID symptoms should not come on campus or clinical sites and should contact Student Health immediately for further instruction.
- Maintain hand hygiene with frequent handwashing and disinfectant solutions.
- Clean your work areas with disinfectant solution regularly.
- Eat only in designated spaces. Student may consume water in classrooms but should comply with any restrictions on food and other beverages that may be in place.

Students should refer to their course syllabus for additional requirements and guidelines.

DIVERSITY, EQUITY, AND INCLUSION (DEI)

Collaboration, integrity, respect and excellence are shared values of our institution and are the core of what it means to be a UAB community member. And a key foundation at UAB is diversity, equity, and

inclusion. At UAB, everybody counts every day. UAB is committed to fostering a diverse, respectful, and inclusive campus environment that values all community members regardless of background and embraces individual differences. UAB values and cultivates equity, diversity, and inclusion in our research, learning, clinical and work environments. Our students, faculty, and staff add diversity to our community through life experiences, perspectives and viewpoints that are enriching for the learning and work environment and are reflective of the students and communities we serve. Because UAB serves a diverse population, ODEI, along with our School of Health Professions initiatives, aims to create an inclusive environment for all UAB faculty, staff, students, and patients through education, training, and awareness programs.

[UAB Office of the Vice President of Diversity, Equity, and Inclusion](#)

[SHP Diversity, Equity, and Inclusion Site](#)

DISABILITY SUPPORT SERVICES (DSS)

"DSS provides an accessible university experience through collaboration with UAB partners. These partnerships create a campus where individuals with disabilities have equal access to programs, activities, and opportunities by identifying and removing barriers, providing individualized services, and facilitating accommodations."

"DSS serves as the university-appointed office charged with providing institution-wide advisement, consultation, and training on disability-related topics which include legal and regulatory compliance, universal design, and disability scholarship."

To apply for accommodations, contact DSS. ***Note****: You must have your Blazer ID and password.*

Telephone: (205) 934-4205 | (205) 934-4248 (TDD)   Fax: (205) 934-8170
Email: dss@uab.edu   Website: www.uab.edu/students/disability/

DRUG SCREENING

By policy, SHP students in programs requiring fieldwork placement (clinical, internship, practicum) are required to undergo a routine drug screen using the school's approved vendor, CastleBranch, www.castlebranch.com, at the time of program admission and again prior to placement in a fieldwork placement. Instructions for requesting the drug screen and appropriate consent forms will be provided to students by their programs. Please refer to the policy section of this handbook for the school and university policy statements. If you have questions, please contact shrp-shpasdnfacaffrs@uab.edu.

EMERGENCIES

Report suspicious or threatening activity to the UAB Police Department immediately. Law officers are available 24 hours, seven days a week. Also, more than 300 emergency blue light telephones connected directly to the police dispatch are located throughout campus.

UAB Police: Dial 911 *from a campus phone*

or call: 205-934-3535 | 205-934-HELP (4357) | 205-934-4434

Emergencies affecting campus are communicated via the following:

- Weather & Emergency Hotline: (205) 934-2165

- University home web page: www.uab.edu
- Webpage: www.uab.edu/emergency
- Announcements on BlazerNET
- Twitter@UABALERT: www.twitter.com/uabalert
- facebook.com/UABALERT
- Cell phone messages and SMS text – register for B-ALERT notices via https://idm.uab.edu/ens/b-alert

FERPA TRAINING

The Family Educational Rights and Privacy Act (FERPA) of 1974 provides protection for all educational records related to students enrolled in an educational program. Information about your rights and protection of your records is available at the following sites: https://sa.uab.edu/enrollmentservices/ferpa/. If you have questions or concerns about FERPA issues, you may email FERPA@uab.edu. All SHP students are required to complete FERPA Training.

FINANCIAL AID

Financial Aid Counselors are available each day in the One Stop Student Services Office located in the Hill Student Center. Additional financial aid information is located at www.uab.edu/financialaid.

FOOD SERVICES

Dining facilities available on campus closest to the SHP buildings include the Commons on the Green – located on the Campus Green, south of 9th Avenue and the Campus Recreation Center. Additional information about meal plans and campus dining facilities is available at www.uab.edu/dining.

GRADUATE SCHOOL

The UAB Graduate School offers doctoral programs, post-master's specialist programs, and master's level programs. Graduate programs in SHP are coordinated through the Graduate School and students must adhere to the Graduate School policies and procedures. Graduate School information for current students is available at www.uab.edu/graduate/. Policies and Procedures for the Graduate School can be located in the Graduate School Catalog 2022-2023 Catalog of Graduate Programs < Catalog | The University of Alabama at Birmingham (uab.edu).

GRADUATION

All students must complete an application for degree six months prior to graduating and not later than the deadline in the academic calendar. https://www.uab.edu/commencement/faqs. The University holds commencement every semester. Check the commencement website for the most current information: https://www.uab.edu/commencement/.

MEDICAL CLEARANCE

SHP students in programs that are on campus (not fully online), are required to receive medical clearance at the time of program admission. UAB Student Health Services utilizes a secure web-based process for the storage of required documents accessed through BlazerNET. More information is available at the Student Health Services website: www.uab.edu/students/health/medical-clearance/immunizations.

IMMUNIZATION POLICY

To provide a safe and healthy environment for all students, faculty and staff at the University of Alabama at Birmingham (UAB), first-time entering students, international students and scholars, and students in clinical & non-clinical programs, provide proof of immunization against certain diseases: https://secure2.compliancebridge.com/uab/portal/getdoc.php?file=322

INSURANCE WAIVERS

To ensure that all students have adequate health care coverage, including ongoing primary and specialty care, the University of Alabama at Birmingham (UAB) requires all students to have major medical health insurance. Students can provide proof of their own private coverage or be enrolled in the Student Health Insurance Plan. The plan is a 1-year commercial policy provided by United HealthCare and is re-negotiated annually. This policy is a comprehensive health insurance policy at an affordable cost that is specifically designed to meet the needs of UAB Students. If you are required to have insurance but have sufficient coverage on another plan and wish to opt out of the Student Health Insurance Plan, you are required to submit a waiver to Student Health Services at the beginning of every semester. More information including submitting a waiver can be found at this website: https://www.uab.edu/students/health/insurance-waivers/waivers

HIPAA TRAINING

The Health Insurance Portability and Accountability Act includes significant requirements for protecting individual privacy of health information. All students in the School of Health Professions must complete an online tutorial and be tested on HIPAA regulations at the time of program admission. A BlazerID is required to access the training site, located at www.uab.edu/learningsystem. Compliance with the training requirement is monitored monthly.

INSTITUTIONAL REVIEW BOARD FOR HUMAN USE (IRB)

Student researchers must comply with all requirements for protection of human subjects. Detailed information is available on the IRB website www.uab.edu/irb.

INTELLECTUAL PROPERTY

Intellectual property refers to an asset that originated conceptually, such as literary and artistic works, inventions, or other creative works. These assets should be protected and used only as the creator

intends. Training materials defining inventor status, patent criteria, and other intellectual property issues is available at www.uab.edu/research/administration/offices/OSP/Pages/Training.aspx.

LACTATION CENTERS

Through the work of the UAB Commission on the Status of Women, the University has provided several lactation centers for students, faculty, and staff across the campus. Locations of the centers are available at https://www.uab.edu/titleix/pregnancy-parenting/campus-community-support/lactation-centers. The School of Health Professions' lactation room is in the Susan Mott Webb Nutrition Sciences Building at 1675 University Boulevard, room 219A. Female students enrolled in the School of Health Professions have access to the room via their student ID/OneCard. If you cannot access the room, contact the building administrator, Julia Tolbert-Jackson at (205) 934-4133.

LIBRARIES AND LEARNING RESOURCE CENTER

UAB's libraries house excellent collections of books, periodicals, microforms, and other media. Students have online remote access to catalogs and online collections. Computers are available for student use during regular hours of operation. https://library.uab.edu/locations

SHP Learning Resource Center (LRC)

The School of Health Professions Learning Resource Center (LRC) provides a unique set of enterprise solutions that promote an exciting, intriguing, and innovative learning environment. It provides a state-of-the-art media studio; audio/visual support; and information technology management of public, classroom, and testing labs.

> Location: 1714 9th Avenue S.
> Phone: (205) 934-5146
> Email: shplrc@uab.edu

Lister Hill Library of the Health Sciences

This is the largest biomedical library in Alabama, and one of the largest in the south. Located across the crosswalk from the School, the LHL has extension libraries in University Hospital and The Kirklin Clinic. Dedicated librarians hold "office hours" in the Learning Resource Center weekly.

> Location: 1700 University Boulevard
> Website: https://library.uab.edu/locations/lister-hill
> Phone: (205) 975-4821

Mervyn H. Sterne Library

A collection of more than one million items supporting teaching and research in the arts and humanities, business, education, engineering, natural sciences and mathematics, and social and behavioral sciences.

> Location: 913 13th Street South
> Website: https://library.uab.edu/locations/sterne
> Phone: (205) 934-6364 (Reference) | (205) 934-4338 (User Services)

NON-ACADEMIC MISCONDUCT POLICY

The Student Conduct Code promotes honesty, integrity, accountability, rights, and responsibilities expected of students consistent with the core missions of the University of Alabama at Birmingham. This Code describes the standards of behavior for all students, and it outlines students' rights, responsibilities, and the campus processes for adjudicating alleged violations. Behavior that violates UAB standards of conduct listed within the Student Conduct Code and elsewhere will be subject to disciplinary action through the appropriate conduct process. Whether it is determined that an individual or group is responsible for the violation(s), either by direct involvement or by condoning, encouraging, or covering up the violation, appropriate response will occur with respect to the individual(s) and/or group involved.

Undergraduate Non-Academic Policies:
http://catalog.uab.edu/undergraduate/aboutuab/nonacademicpolicies/

Graduate Non-Academic Policies:
http://catalog.uab.edu/graduate/academicprogress/#academicethicsandmisconducttext

ONE STOP STUDENT SERVICES

If you have questions or need assistance with an academic or administrative process, the UAB One Stop is where to go! Advisors will help you solve your problem or do the legwork for you if another UAB resource is needed. One Stop is located in the Hill Student Center, 1400 University Blvd. You may contact the One Stop office by phone or email at (205) 934-4300; 855-UAB-1STP; (855) 822-1787; onestop@uab.edu. Additional information is available at www.uab.edu/onestop.

PARKING

Student vehicles must be registered with UAB Parking and Transportation Services, located at 608 8th Street South. The office is open Monday – Friday from 7:30 a.m. – 5:00 p.m. Parking is allocated on a first-come, first-served basis. Parking fees are established by location, payable by semester or year, and are billed to the student's account. Additional information is available at www.uab.edu/parking.

PATIENT CARE PARTNERSHIP

Students in health professions programs learn general information about the health care industry as well as knowledge and skills specific to their chosen profession. The American Hospital Association (AHA) (www.aha.org) is an excellent resource for industry information. One role fulfilled by the AHA is that of patient advocate. The Patient Care Partnership brochure (link below) outlines rights and responsibilities of patients during hospital stays.

www.aha.org/aha/issues/Communicating-With-Patients/pt-care-partnership.html.

PLAGIARISM AND TURNITIN

Plagiarism is academic misconduct that will result in a grade of zero and may result in dismissal from the School of Health Professions and UAB (see Academic Integrity Policy). All papers submitted for grading in

any SHP program may be reviewed using the online plagiarism monitoring software. Please note that all documents submitted to Turnitin.com are added to their database of papers that is used to screen future assignments for plagiarism.

RECREATION CENTER

The Campus Recreation Center, located at 1501 University Blvd, Birmingham, AL 35294, is open to faculty, staff, students, and their families. A valid student identification card or membership card is required for access. Facilities include basketball courts, racquetball courts, weight rooms, swimming pools, exercise rooms, and indoor track. Check the website for information about hours and services at www.uab.edu/campusrecreation.

SCHOOL OF HEALTH PROFESSIONS SCHOLARSHIPS

The SHP has several scholarship opportunities for students enrolled in SHP programs. The Scholarship Committee, comprised of faculty and administrators, review and select awardees.

Scholarships available to students in any SHP program are the following:

Carol E. Medders Endowed Scholarship – Funding for students enrolled in a graduate program in the School of Health Professions. Awards are based on academic achievement and unmet financial need.

Ethel M. and Jessie D. Smith Endowed Nursing and Allied Health Scholarship – Funding for students enrolled in SHP programs with GPA 3.0 or above and unmet financial need. Student must be a resident of the state of Alabama at the time of enrollment.

Lettie Pate Whitehead Foundation Scholarship – Funding for female students from selected states (AL, FL, GA, LA, MS, NC, SC, TN) enrolled in SHP programs. Award amounts are variable and are based on unmet financial need.

National Alumni Society Dean's Scholarship – Funding from the UAB National Alumni Society for two scholarships per year, one to a graduate student and one to an undergraduate student.

Sandra Dunning Huechtker Endowed Memorial Award – Funding for students enrolled in SHP program with GPA 3.0 or above and unmet financial need.

SHP Dean's Scholarship – Funding to recruit or retain outstanding students. Awards are based on academic achievement, and unmet financial need.

You may visit the UAB School of Health Professions Scholarship page to learn more https://www.uab.edu/shp/home/about-us/shp-scholarships. Application announcements are made by the Office of Academic and Faculty Affairs. Many programs in SHP also have scholarships available to currently enrolled students in those programs. Please see the program section of this handbook for that information.

SOCIAL MEDIA

Social media can serve as useful communication tools. However, health professions students should use the forums judiciously. The school's official sites are the following:

- Twitter: https://twitter.com/UAB_SHP
- Facebook: www.facebook.com/UABSHP
- YouTube: www.youtube.com/uabshp
- Vimeo: http://vimeo.com/uabshp
- LinkedIn: UAB SHP LinkedIn
- Website: www.uab.edu/shp

UAB Social Media Guidelines are outlined at https://www.uab.edu/toolkit/social/guidelines.

STUDENT ADVOCACY, RIGHTS AND CONDUCT (SARC)

Student Advocacy, Rights and Conduct (SARC) is responsible for upholding the integrity and purpose of the university through the fair and consistent application of policies and procedures to students' behavior to ensure a community that respects the dignity and right of all persons to reach their highest potential. SARC delivers programs and services in order to promote student safety and success, the pursuit of knowledge, respect for self and others, global citizenship, personal accountability and integrity, and ethical development. More about SARC can be found here: Student Advocacy, Rights & Conduct - Student Affairs - News | UAB. The UAB student conduct code may be accessed online: Student Conduct Code (uab.edu).

STUDENT HEALTH SERVICES

The University provides prevention, counseling, and treatment services to students through Student Health Services located at 1714 9th Avenue South. The clinic is open from 8:00 a.m. – 5:00 p.m. Monday – Thursday; 9:00 a.m. – 5:00 p.m. Friday. Detailed information about services and operating practices is located on the SHS website at www.uab.edu/studenthealth. Appointments may be scheduled by calling 205-934-3580.

TUITION AND FEES

Tuition and fees for the University are published annually under the "Current Students" tab of the UAB website. They may be paid through BlazerNET. SHP programs have specific fees attached to programs, courses, and/ or laboratories. See the school fees at https://www.uab.edu/students/paying-for-college/detailed-tuition-and-fees.

Payment deadlines for each semester are published on the official academic calendar and on the UAB website at www.uab.edu/whentopay/. Please note that failure to meet payment deadlines can result in being administratively withdrawn from courses.

WEATHER

Severe weather situations that may affect the safety of students, faculty, and staff are communicated through the same channels as other emergencies. Severe weather precautions are published at www.uab.edu/emergency/preparedness. Other information sources include:

- Webpage: www.uab.edu/emergency
- Hotline: (205) 934-2165
- B-ALERT System: www.uab.edu/balert
- WBHM Radio (90.3 FM)

WITHDRAWAL FROM COURSE / PROGRAM

Withdrawal from a course or from your program is an official process and should be discussed with your academic advisor and / or program director. Most programs in the School are full-time and the curricula specifically sequenced. Withdrawal from a course may risk your wait time to register for the class again. You might have to wait for a full year before resuming enrollment in the program. Withdrawals are made through the UAB registration system via the Student Resources tab in BlazerNET. Notice of program withdrawal should be given in writing to the program director. Please refer to the following link for additional information on withdrawal guidelines: https://www.uab.edu/students/one-stop/classes/add-drop-and-withdrawal-policy

SECTION 2 – SHP AND UAB POLICIES

SCHOOL OF HEALTH PROFESSIONS POLICIES

BACKGROUND CHECK AND DRUG SCREEN POLICY

With the exceptions noted below, students admitted to clinical and non-clinical programs in the School of Health Professions (SHP) will complete a routine drug screening and criminal background check using the approved vendor (CastleBranch). These screenings should be completed prior to the end of the first term of enrollment. A second routine drug screening and criminal background check using the approved school vendor, or a vendor required by the assigned clinical facility, will be completed prior to placement in assigned fieldwork. Any required additional screenings, and/or those specified by waived programs, will be at the discretion of the program.

Students enrolled in SHP undergraduate programs requiring an internship or other site placement as a component of degree requirements will complete a learning module in the campus learning management system by the end of the first semester of enrollment. They will submit the results of a drug screening and criminal background check from an approved vendor, prior to the end of the semester, immediately preceding the semester for which the internship or site placement occurs.

- School-negotiated fees for these screenings will be the responsibility of the student.

- Students who have completed the screenings as a condition of enrollment in a previous SHP program are waived from the requisite unless the current program of enrollment also includes an internship or fieldwork placement component for degree completion.

- Drug screening and background check results performed by an approved vendor, within the most recent twelve months, may fulfill the SHP requirement

- The rules and regulations governing individual fieldwork placement sites may include additional provisions and/or more stringent guidelines which supersede this policy. Fees for these screenings are the responsibility of the student.

- Should you fail the drug screening, or your background check contains issues that may prevent you from receiving or sitting for licensure, a representative from the Office of the Associate Dean for Academic and Faculty Affairs will contact you. Depending upon the outcome, you may be dismissed from the program. See your program's guidelines regarding specific consequences.

Programs requiring a background check and drug screening by the end of the first semester of enrollment and again, prior to fieldwork placement (if applicable in the program requirements), are the following:

Administration Health Services, PhD
Biomedical Sciences to Biotechnology Fast Track
Biomedical Sciences to Clinical Laboratory Science Fast Track
Biomedical Sciences to Health Physics Fast Track
Biomedical and Health Sciences, MS

Biotechnology, MS

Dietitian Education Program, Graduate Certificate

Genetic Counseling, MS

Health Administration (Residential), MSHA

Health Care Management to Occupational Therapy Doctorate Fast Track

Health Physics, MS

Medical Laboratory Science, MS

Nuclear Medicine & Molecular Imaging Technology, MS

Nutrition Sciences, MS

- – Dietetic Internship Clinical Track
- – Dietitian Education Program
- – Prior Learning Clinical Track
- – Research Track

Nutrition Sciences, PhD

Occupational Therapy Doctorate – (entry level)

Physical Therapy, DPT

Physician Assistant Studies, MSPAS

Rehabilitation Science, PhD

Programs requiring the background check and drug screening learning module during the first semester of enrollment, a criminal background check and drug screening by the end of the semester immediately preceding fieldwork placement or internship (if applicable) are the following:

Health Care Management, BS

Biomedical Sciences, BS

Biobehavioral Nutrition and Wellness, BS

Programs waived from the Background Check and Drug Screening requirement are the following: *

Applied Mixed Methods Research, Graduate Certificate

Biotechnology Regulatory Affairs, Graduate Certificate

Clinical Informatics, Graduate Certificate

Health Administration (International and Executive tracks), MSHA

Health Informatics, MSHI

Healthcare Finance Management, Graduate Certificate

Healthcare Leadership, DSc

HealthCare Leadership, Graduate Certificate

Healthcare Quality and Safety, MS

HealthCare Quality and Safety, Graduate Certificate

Health Service Research, MS

Healthcare Simulation, MS

Nutrition for Community Health, Graduate Certificate

Nutrition Sciences, MS

- – Clinical Track-Prior Learning
- – Lifestyle Management and Disease Prevention Track

Low Vision Rehabilitation, Graduate Certificate
Occupational Therapy Doctorate (Post Professional)
Physical Therapy Residencies (Neurologic, Orthopedic)

Attachments:

- ☐ Procedure for Criminal Background Check and Drug Screening
- ☐ Student Instructions
- ☐ Consent to Drug Testing and Release of Drug Test Results
- ☐ Consent to Criminal Background Check and Release of Results

*Students enrolled in exempt programs who participate in a course(s) incorporating community, corporate or other high impact, out-of-classroom activities such as service learning, capstone projects or other hands-on learning experiences, may be required by placement sites to submit background check and drug screening results. Students are responsible for the fees associated with such screening.

Attachment 1:

Procedure for Criminal Background Check and Drug Screening

1. Program directors (or designees) provide all accepted students with instructions for completing a background check and drug screening.

2. Students request the specified package on the approved SHP vendor website and pay the required fees.

3. Assigned designee(s) in the SHP Office for Academic and Faculty Affairs review and provide compliance reports for programs.

4. In the event a report reveals information which may prevent a student from being placed in a fieldwork rotation or potentially makes them ineligible for professional certification or licensure, the SHP Office of Academic and Faculty Affairs works in conjunction with the program director to notify the student. If such information exists, the student must acknowledge in writing their decision to continue in the program's didactic phase with the understanding that a degree cannot be awarded without completion of required fieldwork placement.

5. Prior to fieldwork placement, program directors (or designees) will provide students with instructions to complete a repeat background check and drug screening. In addition, some sites require a social media background check. The package code for this is different than the initial drug screen and background package code. If a vendor is specified by the placement site or preceptor, the preceptor (or designee) will provide students with instructions.

6. Students are responsible for all additional fieldwork placement requirements.

7. The program director discusses with individual student's implications for information which may inhibit an assigned fieldwork placement.

8. Students provide preceptors or internship supervisors with the required information from the results of their background check and drug screening reports if required.

Attachment 2:

CastleBranch

STUDENT INSTRUCTIONS FOR UNIVERSITY OF ALABAMA AT BIRMINGHAM
SCHOOL OF HEALTH PROFESSIONS

About CastleBranch.com

CastleBranch is a secure platform that allows you to order your background check & drug test online. Once you have placed your order, you may use your login to access additional features of CastleBranch, including document storage, portfolio builders and reference tools. CastleBranch also allows you to upload any additional documents required by your school.

Order Summary

Required Personal Information
- In addition to entering your full name and date of birth, you will be asked for your Social Security Number, current address, phone number, and e-mail address.

Drug Test (LabCorp or Quest Diagnostics)
- Within 24-48 hours after you place your order, the electronic chain of custody form e-chain will be placed directly into your CastleBranch account. This e-chain will explain where you need to go to complete your drug test.

Payment Information
- At the end of the online order process, you will be prompted to enter your Visa or MasterCard information. Money orders are also accepted, but will result in a $10 fee and additional turn-around-time.

Place Your Order

Go to: www.castlebranch.com and enter package code:
AH01 - Background Check and Drug Test
You will be required to enter your program under "Student Information" classification
You will then be directed to set up your CastleBranch profile account.

View Your Results

Your results will be posted directly to your CastleBranch profile account. You will be notified if there is any missing information needed in order to process your order. Although 95% of background check results are completed within 3-5 business days, some results may take longer. Your order will show as "In Process" until it has been completed in its entirety. Your school's administrator can also securely view your results online with their unique username and password. If you have any additional questions, please contact the Service Desk at 888.723.4263 x 7196 or visit the website to submit your question at: https://www.castlebranch.com/contact-us.

Attachment 3:

UAB School of Health Professions

Consent to Drug Testing and Release of Drug Test Results

For and in consideration of my participation in clinical education experiences, I understand that I will be required to submit to drug testing as a prerequisite to my assignment to a clinical site. I hereby consent to be tested for drugs and consent to the release of any such drug test results to the Office of Academic and Faculty Affairs, my Program Director, and the subsequent release of such drug test results to the clinical site to which I am assigned.

I understand that any clinical site to which I am assigned has the right to require additional drug testing as a condition of my placement. I hereby consent to any facility-required drug testing and consent to the release of such drug test results to my Program Director.

_____   _____

Student's Signature   **Date**

_____   _____

Signature of Parent/Legal Guardian   **Date**
(required only if student is under 19)

Attachment 4:

<div align="center">

UAB School of Health Professions

Consent to Criminal Background Check and Release of Results

</div>

For and in consideration of my participation in clinical education experiences, I understand that I will be required to submit to a criminal background check as a prerequisite to my assignment to a clinical site. I hereby consent to have a criminal background check and consent to the release the results to the Office of Academic and Faculty Affairs, my Program Director, and the subsequent release of the results to the clinical site to which I am assigned.

I understand that any clinical site to which I am assigned has the right to require additional background check as a condition of my placement. I hereby consent to any facility-required background check and consent to the release of the results of the check to my Program Director.

_____   _____
Student's Signature   **Date**

_____   _____
Signature of Parent/Legal Guardian   **Date**
(required only if student is under 19)

EMERGENCY PLAN - SHPB

The current SHPB Emergency Plan can be accessed at https://www.uab.edu/shp/home/emergency-plan.

FINAL COURSE GRADE APPEAL PROCESS

www.uab.edu/shp/home/images/PDF/grievance_procedures.pdf

PLAGIARISM

www.uab.edu/shp/home/images/PDF/Plagiarism_Policy.pdf

Please note that all papers submitted for grading in any SHP program may be reviewed using the online plagiarism monitoring software, Turnitin.com. All documents submitted to Turnitin.com are added to their database of papers used to screen future assignments for plagiarism.

UAB POLICIES

CLASSROOM BEHAVIORS

ATTENDANCE / ABSENCE (UNDERGRADUATE)

http://catalog.uab.edu/undergraduate/progresstowardadegree/#enrollmenttext

HEALTH

BLOOD AND BODY FLUID EXPOSURE

https://www.uab.edu/employee-health/employees/needle-sticks-exposures

IMMUNIZATIONS

https://secure2.compliancebridge.com/uab/portal/getdoc.php?file=322

SUBSTANCE USE/ABUSE

ALCOHOLIC BEVERAGES, USE AND CONSUMPTION

https://secure2.compliancebridge.com/uab/portal/getdoc.php?file=373

DRUG FREE CAMPUS (GENERAL POLICY)

https://secure2.compliancebridge.com/uab/portal/getdoc.php?file=416

NON-SMOKING

https://secure2.compliancebridge.com/uab/portal/getdoc.php?file=392

TECHNOLOGY GUIDELINES

COMPUTER AND NETWORK RESOURCES (ACCEPTABLE USE)

https://secure2.compliancebridge.com/uab/portal/getdoc.php?file=300

COMPUTER SOFTWARE COPYING AND USE

https://secure2.compliancebridge.com/uab/portal/getdoc.php?file=153

INCLUSIVENESS

EQUAL OPPORTUNITY AND DISCRIMINATORY HARASSMENT

https://secure2.compliancebridge.com/uab/portal/getdoc.php?file=98

RESEARCH AND SCHOLARLY ACTIVITIES

ACADEMIC INTEGRITY CODE

https://www.uab.edu/one-stop/policies/academic-integrity-code

ETHICAL STANDARDS IN RESEARCH AND OTHER SCHOLARLY ACTIVITIES

https://secure2.compliancebridge.com/uab/portal/getdoc.php?file=398

PATENT (INTELLECTUAL PROPERTY)

https://secure2.compliancebridge.com/uab/portal/getdoc.php?file=397

CAMPUS SAFETY

FIREARMS, AMMUNITION, AND OTHER DANGEROUS WEAPONS

https://secure2.compliancebridge.com/uab/portal/getdoc.php?file=330

Note: Additional university policies may be located by searching the UAB Policies and Procedures Library available online at www.uab.edu/policies/Pages/default.aspx*.*

SECTION 3 – PROGRAM POLICIES

WELCOME

Welcome to the Biotechnology Regulatory Affairs Certificate Program. This handbook has been compiled to provide you with information to help you as you progress through your program. Where appropriate, the contact for more detailed information on various subjects has been included. If, however, you desire or need further explanation of any matter, or other types of information, please contact your faculty advisor or program director. The UAB web pages, or links, are included for some of the sections of this handbook, and you are encouraged to review the links for information you may need. The UAB and School of Health Professions (SHP) pages have search engines to allow you to input keywords and find information. Also, the campus directory and calendars are located on the main UAB page: www.uab.edu. Students should regularly refer to the web site for their specific program for updates.

BIOTECHNOLOGY REGULATORY AFFAIRS MISSION STATEMENT

As the biotechnology industry grows and life science companies mature, there is an increasing demand for a workforce trained in regulatory affairs. Our program offers an opportunity to learn from faculty that are subject matter experts with real-world experience. Currently, there are thousands of ongoing clinical trials of new drugs, with many of them soon to be approved and ready for full-scale production, resulting in an all-time high demand for individuals with regulatory training.

The Biotechnology Regulatory Affairs certificate program is designed to provide students with targeted training and education in:

- The philosophies and roles of the domestic and international regulatory agencies that oversee drug, biologic, device, and diagnostics development,

- The laws that govern the development, manufacturing and commercial distribution of drugs, biologics and medical devices,

- The analysis of how emerging developments and trends are reshaping drug development and medical device regulation,

- The biological processes and laboratory techniques utilized for the discovery, development and evaluation of therapeutic drugs,

- Major concepts under which clinical trials are designed and run,

- The roles of the U.S. Food and Drug Administration (FDA), Institutional Review Boards, the Code of Federal Regulations and ethical principles,

- The complexities of clinical trial initiation and the issues of site and data management.

ABOUT THE GRADUATE CERTIFICATE PROGRAM

The Biotechnology Regulatory Affairs Graduate Certificate program curriculum is designed to help you ensure that your company's therapeutics, biologics, diagnostics or medical device products progress successfully through the development, manufacturing and marketing processes. As the biotechnology, industry grows and life science companies mature, there is an increasing demand for a workforce trained in regulatory affairs.

Our faculty create a culture of innovation and collaboration that embraces social responsibility and entrepreneurial principles. UAB faculty are teachers, scholars, researchers, clinicians and entrepreneurs, who earn the highest honours in their fields, lead professional societies and provide exceptional mentoring and training.

FACULTY AND STAFF

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cqsheele@uab.edu

The Department of Clinical & Diagnostic Sciences has a centralized staff team that supports all CDS programs. For student questions, please contact the CDS Receptionist:

SHPB 430

(205)975-4CDS (4237)

ASKCDS@uab.edu

CURRICULUM

Curriculum Courses for BTR:

Classes offered each semester		
BTR 605	Biotechnology Regulatory & Quality Systems*	3
BTR 615	Applications of Biological Processes in Drug Development	3
BTR 620	Food and Drug Law	3
BTR 640	Clinical Development of Drugs, Biologics, Diagnostics, and Medical Devices	3
BTR 690	Clinical Trial Implementation	3

BTR 605 is offered during the Fall semester only. All remaining courses are offered during the Fall, Summer and Spring semesters.

EXPECTED STUDENT BEHAVIOR

Students are expected to demonstrate interest and ability for professional education, as well as mature professional behavior. Acceptable behavior includes, but is not limited to, the following:
1. Integrity in all program assignments.
    - refrain from giving or receiving unauthorized aid in examinations or other assigned work
    - treat knowledge concerning patients and official documents as confidential (comply with HIPAA)
    - refrain from plagiarism and falsification of student laboratory results, patient reports, official documents, classroom assignments and attendance records
2. Dependability in program assignments.
    - arrive for class (didactic and internship) on time
    - attend all scheduled classes
    - remain in the area of assignment until dismissed (by the instructor or supervisor)
    - inform appropriate individuals as soon as possible when absence/tardiness is unavoidable (see Attendance policies)
    - carry out assignments as scheduled and complete them on time
    - record and/or report data in an accurate and orderly fashion
    - make up course work and assignments missed during excused absence
3. Responsibility for own actions in didactic and clinical courses.
    - accept constructive criticism and use it to improve performance

- refrain from personal habits that distract or disrupt the classroom and/or clinical environment (e.g., excessive talking, profanity, chewing gum or tobacco, eating and drinking)
- maintain neat, clean personal appearance complying with existing dress codes
- comply with established safety standards
- refrain from any behavior or action that jeopardizes the welfare of the patient, fellow students and faculty
- keep the work area clean and orderly
- refrain from activities which potentially damage equipment, supplies, and/or private and public property

4. Stability
   - refrain from the use of alcoholic beverages or illegal drugs at required school activities and during all courses
   - adjust to changes such as work-flow and procedures without sacrificing accuracy and reliability in clinical assignments

Students are also expected to report violations of "Expected Student Behaviors", or any other instances of unethical conduct in any case to the faculty or other appropriate authorities.

GOALS AND OBJECTIVES

The Graduate Certificate Program in Biotechnology Regulatory Affairs is designed to prepare a diverse student body for careers in various fields involving biotechnology, regulatory science, clinical development of pharmaceuticals and medical devices. The curriculum is designed to provide broad training and education in:
- Legal and regulatory issues in biotechnology
- Overview of biological processes and laboratory techniques for discovery, development and evaluation of therapeutic drugs
- Regulations related investigational new drug applications (IND), new drug applications (NDA), good laboratory practices (GLP), good clinical practices (GCP) and current good manufacturing practices (cGMP)

More specifically, graduates of this program are expected to:
1. Demonstrate attributes desirable of Biotechnology Professionals
   a. Dependability
      i. Demonstrate integrity, honesty and conscientiousness in work
      ii. Accept responsibility for own actions
      iii. Organize and complete work on schedule without sacrificing accuracy and reliability
      iv. Follow established policies and procedures

<pre style="white-space:pre-wrap">
                    v. Be punctual when required or assignment
          b. Stability
                    i. Work effectively under conditions of stress and/or change
                   ii. Maintain professional demeanor under adverse conditions
          c. Ability to interact effectively with others
                    i. Influence and contribute to a pleasant work environment
                   ii. Communicate with others in a professional and courteous manner
                  iii. Contribute willingly to the accomplishment of group endeavors
          d. Professionalism
                    i. Maintain a neat, clean, personal appearance complying with existing dress
                        codes
                   ii. Show initiative and interest to improve technical skills and expand knowledge
                  iii. Investigate appropriate sources (literature and personnel) for technical and
                        professional information
                   iv. Maintain confidentiality of patient and laboratory data
</pre>

The objectives below will be addressed within the Biotechnology Regulatory Affairs courses:

1. Biotechnology Regulatory & Quality Systems
   a. Regulations needed to ensure the quality of drugs and biologics
   b. Regulations for manufacturing, packaging, labeling, storing FDA regulated products
   c. Regulations governing good laboratory and manufacturing practices
   d. Regulatory dynamics of foods and their components
   e. FDA administrative procedures for searches, seizure actions, injunctions & criminal prosecutions

2. Drug Discovery
   a. Drug discovery and development process
   b. Methodology used in discovery of new targets for drug intervention

3. Clinical Trials
   a. Basic study design, regulatory requirements and ethical considerations
   b. Informed consent, clinical oversight, institutional review board, Good Clinical Practice (GCP), investigational clinical supplies, data management activities, safety reporting, and monitoring
   c. Different phases of drug and device development

AFFECTIVE EVALUATION

S = Satisfactory; I = Improvement Needed; U = Unsatisfactory; E = Essential Function

Performance of online asynchronous learning	S	I/U	E
A. Provide introduction to Instructor & Students			
B. Participates in weekly discussion posts			
C. Submits assignments prior to the deadline date			
D. Reviews PowerPoint presentations & class lectures			
E. Weekly responses and submitted assignments demonstrate the student has achieved learning objectives			

ESSENTIAL REQUIREMENTS

In order to successfully complete the certificate requirements for the Biotechnology Regulatory Affairs Certificate Program, students must complete the academic requirements. Students must meet the essential requirements in addition to academic requirements. "Essential requirements are those physical abilities, mental abilities, skills, attitudes and behaviors the students must show or perform at each level of their education." The absence of essential requirement would fundamentally alter the program's goals. The essential requirements include categories of observation, movement, communication, intellect, and behavior.

Basic Software/Hardware

Students will need to have access to the following software/hardware:
- Computer
- Speakers
- Internet Connection

Basic Technical Skills

Online courses are not difficult to access or participate in, but do require you to be able to:
- Use a keyboard and mouse
- Save, open, and edit various file types
- Open, send, reply, and attach and open attachments to email messages
- Upload and download files from and to your computer and the Internet
- Navigate the Internet
- Navigate the UAB Canvas course environment
- Software to open pdf files

Internet Connection

A high-speed internet connection with speeds of 1.5 mbps or higher is recommended for online courses to ensure that you can access all of the course materials and resources, particularly large file sizes as with streaming video. However, technologies used in individual courses vary. See the course syllabus for additional technical requirements.

- What does Internet speed mean?
    - Some online courses use videos. Viewing is only possible if a certain amount of data is transferred to your computer in a timely manner.
    - The speed that the data can be sent to you is called your "Internet speed". YouTube and most other videos are encoded with at least a 256Kbps (kilobits per second) rate/speed.
- Approximate speeds of the common types of Internet Service Providers:
    - Dial-up internet - 56 bps (from phone company)
    - DSL internet - 768 kbps+ (from phone company)
    - Cable internet - 1,000-10,000+ kbps (from cable company)
    - Dial-up connections cannot retrieve the data fast enough causing video to frequently pause to let more data arrive. DSL and Cable connections are more than adequate to watch most online videos.
- How can I determine my current Internet speed?
    - Visit www.bandwidthplace.com.
    - Write down your Download and Upload speeds after you complete the test.
    - This will aid technical support in assisting you with technical issues you may experience.

CANVAS COMPUTER REQUIREMENTS

UAB uses Canvas, a learning management system, to deliver its online courses. The following are some specific requirements needed to access Canvas. Please note: Additional technical requirements may be required for some courses.

What are the basic computer specifications for Canvas?

This is a list of basic computer system requirements to use Canvas. It is always recommended to use the most up-to-date versions and better connections. Canvas will still run with the minimum specifications, but you may experience slower loading times. Find out more about Computer Specifications.

Which browsers does Canvas support?

Because it's built using web standards, Canvas runs on Windows, Mac, Linux, iOS, Android, or any other device with a modern web browser.

Canvas supports the last two versions of every browser release. We highly recommend updating to the newest version of whatever browser you are using as well as the most up-to-date Flash plug-in. Find out more about Supported Browsers.

Required Components
- Flash: Flash is required in several places in Canvas: media recording/streaming and viewing as well as uploading files to a course or an assignment. Other than these features, Flash is not required to use most areas of Canvas. Install Flash Player in Five Easy Steps.

- Java: The Java plug-in is required for screen sharing in Conferences. Please note that some browsers do not support Java. Otherwise, there are no other browser plug-ins used by Canvas. Verify Java and Find Out-of-Date Versions.
- Adobe Reader: Adobe Reader software is the free global standard for reliably viewing, printing, and commenting on PDF documents. It's the only PDF file viewer that can open and interact with all types of PDF content, including forms and multimedia. Go to the Free Reader Download.

DOCUMENTATION OF COURSE COMPLETION

Biotechnology Course Completion Checklist

COURSE	TITLE	CR HRS	GRADE	COMMENT
BTR 605	Biotechnology Regulatory & Quality Systems	3		
BTR 615	Applications of Biological Processes in Drug Development	3		
BTR 620	Food and Drug Law	3		
BTR 640	Clinical Development of Drugs, Biologics, Diagnostics, and Medical Devices	3		
BTR 690	Clinical Trial Implementation	3		

APPLICATION FOR DEGREE AND CERTIFICATE

Application for Degree

Upon successful completion of all program requirements, students will be awarded the Graduate Certificate. All students must apply for their certificate at least 3 months prior to their anticipated graduation date. The application for the certificate are in the online format and may be accessed from the following website: https://www.uab.edu/graduate/students/current-students/completing-your-degree/application-deadlines

Application for Graduate Degree/Certificate

Students planning to graduate in the upcoming term can access the Application for Graduate Degree/Certificate online through BlazerNET by clicking Links/Forms and selecting Apply for Graduate Degree/Certificate. The application must be submitted by the deadline date listed on **our website**; however, check with your department as some programs have earlier deadline dates (e.g. School of Education).

Upon submission of the application for degree/certificate, a fee will be assessed to your student account. This fee covers the verification of your curriculum requirements and your diploma (if earning a graduate degree) and will only be assessed the first time you apply to graduate. The fee for graduate degrees is $50 and the fee for graduate certificates is $20. .

BIOTECHNOLOGY INTERNSHIPS

The program does not offer internships. However, if you are located in the Birmingham area, we can provide you details on how to best locate a volunteer position in regulatory affairs or clinical research.

GRADES

Final grades and credits for each student are recorded and preserved as a permanent record at UAB. The final grades for academic courses are compiled and proportioned to develop a final course grade. The course instructor will inform the students at the beginning of each term in each course syllabus of the system of proportioning of scores used to develop the course grade. Minimum performance criteria designated by the course instructor must be achieved by the student. These criteria indicate the level of competency of the individual student.

Grades are awarded according to the level of the student's achievement in each course. The grades for academic courses are indicated by letters:

A = Excellent

B = Above Average

C = Average

F = Failure

P = Pass

W = Withdrawal, a notation (Not a Grade) assigned by the Registrar and reflects an administrative action initiated by the student in accordance with UAB regulations.

I* = Incomplete, a temporary notation assigned a student who has not completed course requirements.

N = No Grade Submitted, a temporary notation made by the Registrar if the course instructor does not assign a grade prior to issuing of grade reports or when the course is designated to extend beyond a single term.

X = Absent from Final Exam

* Such a notation is the prerogative of the instructor and is normally assigned only if the student's circumstances are extenuating and if there is reasonable expectation that the course requirements can be satisfactorily completed by the end of the following term. The notation of "I" will convert to an "F" unless an extension is requested specifying the date the student will complete the course requirements.

The student's grade point average is calculated by dividing the total quality points earned by the semester hours attempted. Semester hours attempted is defined as the total semester hours for any course in which the student was registered on a regular basis and receives an A, B, C, D, F, or WF. Quality points are awarded as follows:

Quality Points	Letter Grade
4	A
3	B
2	C
None	D, F, P, NP, F or W

Graduate School Requirements – Good Academic Standing

A student must maintain a grade point average of at least 3.0 (B average) and earn at least as many hours of P grades as the total of NP and WF grades combined to be in good academic standing as defined by the Graduate School.

GRADUATE STUDENT REQUIREMENTS

Information on Graduate School Policies and Procedures may be found online at:
http://www.uab.edu/graduate/graduate-catalog/72-policies-and-procedures

Graduate School policies and procedures are developed to ensure that high standards for graduate study are maintained at UAB. These policies and procedures are the joint responsibility of the Graduate Council and the Graduate School Dean. The Graduate Council, through consultation with the dean, is responsible for developing academic requirements and describing these requirements through appropriate policies. The dean, through consultation with the Graduate Council or the Advisory Committee of the Graduate Council, is responsible for developing procedures that effectively enforce academic requirements and implement policies.

The Graduate Council, through its Advisory Committee, will review academic requirements, policies, procedures, and Graduate School activities annually and recommend appropriate changes. Changes in academic requirements and related policies will require a majority vote of the Graduate Council. A change in composition or responsibility of the Graduate Council will require a two-thirds majority vote of the Graduate Council.

STUDENT ORGANIZATIONS AND ACTIVITIES

Biotechnology Association of Alabama (**BAA)**

BAA is a statewide organization representing Alabama's bio related industries, research scientists, clinicians and business professionals who are working together to foster, develop and support the life sciences in Alabama.

BAA events, programs and member benefits are designed to enhance the progress of the Biotechnology industry and its members. The BAA is the state affiliate in Alabama of the Biotechnology Industry Organization (BIO), the preeminent national association for biotechnology companies.

For more information on the BAA refer to the following link: http://www.bioalabama.com/about/

The Biotechnology Program encourages students to join BAA. The BAA membership application may be found at the link below: http://www.bioalabama.com/membership/

Regulatory Affairs Professionals Society (RAPS)

The Regulatory Affairs Professionals Society (RAPS) is the largest global organization of and for those involved with the regulation of healthcare and related products, including medical devices, pharmaceuticals, biologics and nutritional products. Founded in 1976, RAPS helped establish the regulatory profession and continues to actively support the professional and lead the profession as a neutral, non-lobbying nonprofit organization. RAPS offers education and training, professional standards, publications, research, knowledge sharing, networking, career development opportunities and other valuable resources. To learn more about RAPS student membership, visit https://www.raps.org/join-raps

Society of Clinical Research Associates (SOCRA)

In order to promote quality clinical research, to protect the welfare of research participants, and improve global health, SOCRA's mission is:

- To establish educational programming and provide continuing education for clinical research professionals
- To establish an internationally recognized certification program for clinical research professionals (CCRP®)
- To foster the professional development and peer recognition of clinical research professionals

To learn more about membership, visit https://www.socra.org/membership/applications-and-renewals/apply-for-new-membership/