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# Clinical and Diagnostic Sciences Biotechnology Regulatory Affairs Program 2018-2019



## STUDENT HANDBOOK

### **UAB SCHOOL OF HEALTH PROFESSIONS**

# DEPARTMENT OF CLINICAL AND DIAGNOSTIC SCIENCES BIOTECHNOLOGY REGULATORY AFFAIRS PROGRAM 2018-2019 ACADEMIC HANDBOOK

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#### **INTRODUCTION**

#### **DEAN'S WELCOME MESSAGE**

Welcome to the University of Alabama at Birmingham School of Health Professions (SHP), one of the nation's leaders in the health care industry.

We are home to one of the largest health professions schools in the nation with more than 25 programs at the baccalaureate, master's, and doctoral levels with over 2,000 undergraduate and graduate students enrolled. The School of Health Professions is part of UAB's thriving academic health center. As one of our students, you will have the opportunity to work side-by-side with world-renowned researchers and faculty, utilize advanced technologies and experience cutting-edge approaches to clinical treatment.

We understand that healthcare needs are constantly changing. That is why we continue to add innovative programs such as Biotechnology, Genetic Counseling, our one-of-a-kind Low Vision Rehabilitation graduate certificate, Healthcare Quality and Safety, Ph.D. in Rehabilitation Science, and a Master's in Biomedical and Health Sciences, which can be completed within eleven months. Our newest programs are Healthcare Simulation and Clinical Pathologist Assistant, and we have many other well-established curriculums.

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

All of our programs with rankings preside among the nation's top 25 of the *U.S. News and World Report*. We continue to be rated at the top of the list in research funding from the National Institutes of Health, and SHP is the only school in the country to house both an NIH-funded Nutrition and Obesity Research Center and an NIH Diabetes Research and Training Center.

Graduating from SHP means you will have acquired an esteemed degree, enjoy choosing among a host of job options in healthcare, an industry that continues to grow rapidly, and be well-prepared to make a difference in your field.

Our alumni give advice to current students that is worth repeating: 'be a sponge, 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 field and watching you become the professional we know you can be.

Harold P. Jones, PhD Dean, UAB School of Health Professions

#### OVERVIEW OF THE SCHOOL OF HEALTH PROFESSIONS

A leader in federally funded research, the UAB School of Health Professions (SHP), is the largest academic institution of its type in the United States and currently boasts nationally ranked programs. What began in the 1950's as a collection of courses 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 the consistently nationally ranked program in Nutrition Sciences.

Dr. Harold Jones became the school's dean in 2001. Through his visionary leadership and guidance, the school is experiencing unparalleled success. Up until that time, the SHRP's programs were housed in various locations throughout the UAB campus. However, in the spring of 2002, many of the classrooms, laboratories and faculty offices moved to the newly completed School of Health Professions Building (SHPB). This was the first building dedicated to housing health related programs since their original grouping more than 30 years prior.

Today, the school is the School of Health Professions, and is comprised of more than 25 programs – at the 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

#### OFFICE FOR STUDENT RECRUITMENT, ENGAGEMENT AND SUCCESS (OSRES)

The SHP Office for Student Recruitment, Engagement and Success (OSRES) supports UAB's mission and values with a focus on achievement, collaboration and diversity. It furthers the School of Health Professions' mission to be a leader shaping the future of healthcare by recruiting the best and brightest to SHP; developing students to impact the campus and communities; and graduating tomorrow's healthcare leaders. Guided by these commitments, the OSRES provides support to all students through a number of programs including the following:

- Academic Coaching
- Tutoring and Supplemental Instruction
- Campus Resource Referral
- Management of school-wide Scholarships in SHP

The OSRES also coordinates the School of Health Professions Student Affairs Committee (SAC.) SAC is responsible for student activities, services, programs, organizations, policies and procedures consistent with the university's non-academic conduct policies. Subcommittees of SAC include the following:

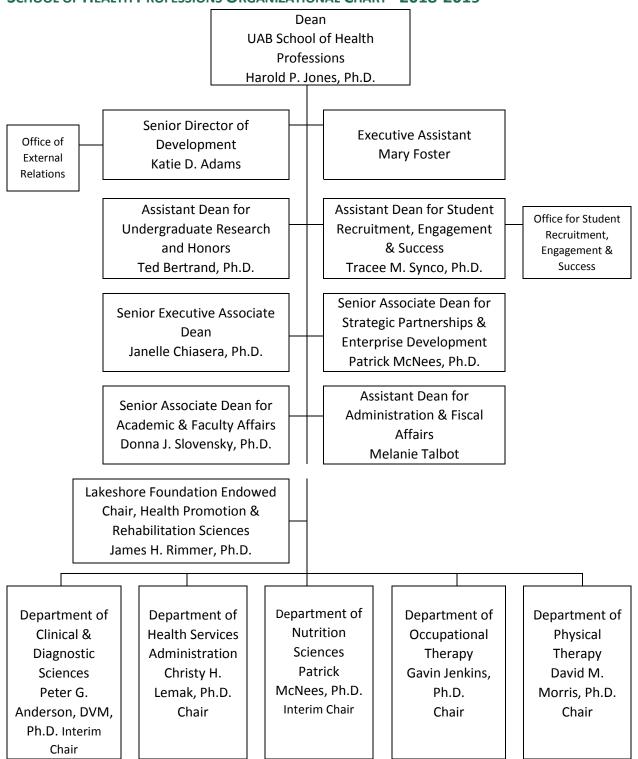
- Homecoming
- Orientation
- Student Activities
- Non Academic Misconduct/ Breaches in Professional Behaviors

Additionally, the OSRES team recognizes that with classes and labs, internships, and studying, students have particularly demanding schedules. In response, we bring resources to you and serve as liaison between SHP and university departments across student services.

The team at OSRES is here to support students. We have an open-door policy and encourage students to connect. Students should feel free to drop-by, no appointment needed; call, email or schedule a meeting. We are here to help students in the School of Health Professions make the most of their UAB experience.

**OSRES** - Location: SHPB 230 Telephone: 205-934-4195 or 205-934-4194 Email: shp@uab.edu

#### SCHOOL OF HEALTH PROFESSIONS ORGANIZATIONAL CHART - 2018-2019



#### 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 HONOR CODE (UAB)**

The University of Alabama at Birmingham expects all members of its academic community to function according to the highest ethical and professional standards. Students, faculty, and the administration of the institution must be involved to ensure this quality of academic conduct. Academic misconduct undermines the purpose of education. Such behavior is a serious violation of the trust that must exist among faculty and students for a university to nurture intellectual growth and development. Academic misconduct can generally be defined as all acts of dishonesty in an academic or related matter. Academic dishonesty includes, but is not limited to, the following categories of behavior:

ABETTING is helping another student commit an act of academic dishonesty. Allowing someone to copy your quiz answers or use your work as their own are examples of abetting.

CHEATING is the unauthorized use or attempted use of unauthorized materials, information, study aids, the work of others, or computer-related information.

PLAGIARISM means claiming as your own the ideas, words, data, computer programs, creative compositions, artwork, etc., done by someone else. Examples include improper citation of referenced works, the use of commercially available scholarly papers, failure to cite sources, or copying another person's ideas.

FABRICATION means presenting falsified data, citations, or quotations as genuine.

MISREPRESENTATION is falsification, alteration, or the misstatement of the contents of documents, academic work, or other materials related to academic matters, including work substantially done for one class as work done for another without receiving prior approval from the instructor.

Violations of the UAB Academic Honor Code are punishable by a range of penalties, from receiving a failing grade on an assignment, to an F in the course, to dismissal. Any course grade of F for academic misconduct supersedes any other grade or notation for that class. Withdrawal from a course while a possible violation of the Academic Honor Code is under review will not preclude the assignment of a course grade that appropriately reflects the student's performance prior to withdrawal if the violation is substantiated.

For more information go to: www.uab.edu/students/one-stop/policies/academic-honor-code

#### **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: <a href="mailto:askit@uab.edu">askit@uab.edu</a> Website: <a href="https://uabprod.service-now.com/ess">https://uabprod.service-now.com/ess</a> portal/home.do

#### **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 has 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 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**

SHP students are required by policy, to undergo a background check using the school's approved vendor, CastleBranch <a href="www.castlebranch.com">www.castlebranch.com</a>, at the time of program admission, and again, prior to placement in a clinical rotation. 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 <a href="www.uab.edu">www.uab.edu</a> 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 <a href="https://www.uab.edu/blazerexpress/">www.uab.edu/blazerexpress/</a>.

#### **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, 35233

Hours: M - F 9:00 a.m. - 5:00 pm.; Sat 7:00 a.m. - 6:30 p.m.; Sun -- Closed

Telephone: (205) 996-2665 Website: <a href="http://uab.bncollege.com">http://uab.bncollege.com</a>

#### **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 <a href="https://www.uab.edu/onecard">www.uab.edu/onecard</a>.

#### **CAMPUS MAP**

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

#### **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 <a href="https://www.uab.edu/elearning/canvas">www.uab.edu/elearning/canvas</a>. Students should monitor their course sites routinely for communication from faculty and manage course assignments.

#### **COUNSELING SERVICES**

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

#### 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. The UAB student conduct code may be accessed online: <a href="http://www.uab.edu/students/sarc/services/student-conduct-code">http://www.uab.edu/students/sarc/services/student-conduct-code</a>

#### **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 or (205) 934-4248 (TDD) Fax: (205) 934-8170

Email: dss@uab.edu Website: www.uab.edu/students/disability/

#### **DRUG SCREENING**

By policy, SHP students 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 clinical rotation. 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. The Office for Student Recruitment, Engagement and Success (OSRES) manages the procedures and compliance for the school. If you have questions, contact them at (205) 934-4194 or shp@uab.edu or visit room 230 in the School of Health Professions Building. For more information visit: <a href="http://www.uab.edu/shp/home/about-shp/student-services">http://www.uab.edu/shp/home/about-shp/student-services</a>

#### **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: 934-3535; 934-HELP (4357); or 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 www.uab.edu/balert

#### DIVERSITY, EQUITY AND INCLUSION (DEI)

The mission of DEI is to "... champion equity and inclusion and, in particular, to advocate for inclusive excellence and equity so that UAB students, faculty, staff, community partners and friends can flourish and excel." Inspired by "... what we value, what we learn from research and what we teach and share with the world." DEI's goal is "... to inspire our people to take a courageous step to inspire equity and inclusive excellence throughout our state, nation and world, every day." Dr. Paulette Patterson Dilworth is the Vice President responsible for the activities of this office. Information: <a href="http://www.uab.edu/dei/">http://www.uab.edu/dei/</a>

#### **FERPA**

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 <a href="FERPA@uab.edu">FERPA@uab.edu</a>, or contact the SHP Office for Student Recruitment, Engagement and Success.

#### **FINANCIAL AID**

Located at 1700 University Blvd., Lister Hill Library, Room G20. Hours of Operation are from 8:00 am to 5:00 pm Monday thru Friday. Phone: (205) 934-8223; Fax: (205) 975-6168. Additional information can be located on the website www.uab.edu/students/paying-for-UAB.

#### **FOOD SERVICES**

Dining facilities available on campus, closest to the SHP buildings include:

- Commons on the Green located on the Campus Green, south of 9th Avenue and the Campus Recreation Center
- Einstein's Bagels located at the plaza entrance to the Learning Resource Center. Hours vary per semester.

Vending machines are located in the basement of the Learning Resource Center and on the 6<sup>th</sup> floor of the Webb Building. Additional information about meal plans and campus dining facilities is available at <a href="https://www.uab.edu/dining">www.uab.edu/dining</a>.

#### **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 <a href="https://www.uab.edu/graduate/">www.uab.edu/graduate/</a>.

#### **GRADUATION**

All students must complete an application for degree six months prior to graduating. For more information and important deadlines please go to <a href="www.uab.edu/commencement/degree-applications">www.uab.edu/commencement/degree-applications</a>. SHP holds a special commencement ceremony for graduates in the professional masters programs in the spring and fall semesters. The SHP ceremonies are scheduled on the Friday afternoon prior to the university commencement ceremonies being held the next morning on Saturday. The University holds commencement every semester. Check the commencement website for the most current information: <a href="http://www.uab.edu/commencement/">http://www.uab.edu/commencement/</a>

#### STUDENT HEALTH AND WELLNESS

The University provides prevention, counseling, and treatment services to students through the UAB Student Health and Wellness located at 1714 9<sup>th</sup> Avenue South. The clinic is open from 8:00 a.m. – 5:00

p.m. Monday – Friday, but is closed between noon and 1:00 p.m. daily. Detailed information about services and operating practices is located on the SHS website at <a href="https://www.uab.edu/studenthealth">www.uab.edu/studenthealth</a>. Appointments may be scheduled by calling 205-934-3581.

#### **MEDICAL CLEARANCE**

SHP students are required to receive medical clearance at the time of program admission. UAB Student Health and Wellness utilizes a secure web-based process for the storage of required documents accessed through BlazerNET. More information is available at the Student Health and Wellness website: <a href="https://www.uab.edu/students/health/medical-clearance/immunizations">www.uab.edu/students/health/medical-clearance/immunizations</a>.

#### **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 <a href="www.uab.edu/learningsystem">www.uab.edu/learningsystem</a>. Compliance with the training requirement is monitored monthly. Students who have not completed the training are reported to the Office for Student Recruitment, Engagement, and Success for follow-up with the appropriate program director.

#### 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 <a href="https://www.uab.edu/research/administration/offices/OSP/Pages/Training.aspx">www.uab.edu/research/administration/offices/OSP/Pages/Training.aspx</a>.

#### **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 <a href="https://www.uab.edu/women/resources/campus-lactation-centers">www.uab.edu/women/resources/campus-lactation-centers</a>.

#### LIBRARIES AND LEARNING RESOURCE CENTER

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

#### **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. Web: <a href="http://www.uab.edu/lrc/">http://www.uab.edu/lrc/</a>

Located: 1714 9<sup>th</sup> Avenue S. Phone: (205) 934-5146 Email: <a href="mailto:shplrc@uab.edu">shplrc@uab.edu</a>
Hours: Monday – Thursday 7:00 am – 8 pm; Friday 7 am – 5:30 pm; closed weekends

#### **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 Phone: (205) 934-2230

Website: www.uab.edu/lister/

#### 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 13<sup>th</sup> Street South Website: <u>www.mhsl.uab.edu</u> Phone: (205) 934-6364 (Reference) (205) 934-4338 (User Services)

#### **ONESTOP STUDENT SERVICES**

If you have questions or need assistance with an academic or administrative process, the UAB OneStop is where to go! Advisers will help you solve your problem or do the legwork for you if another UAB resource is needed. OneStop is located in the Hill Student Center 1400 University Blvd. You may contact the OneStop 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 8<sup>th</sup> 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) (<a href="www.aha.org">www.aha.org</a>) 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 Grievance Procedures for Violations of Academic Standards). 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 <a href="https://www.uab.edu/campusrecreation">www.uab.edu/campusrecreation</a>.

#### SCHOLARSHIPS: BLAZER SCHOLARSHIP MANAGEMENT AND RESOURCE TOOL (B-SMART)

The OSRES manages the School of Health Professions' scholarship offerings and will send reminders to students when applications are open. Visit B Smart and start an application to automatically be considered for scholarship opportunities in SHP.

OSRES manages the following:

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. 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.

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.

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.

Matthew F. McNulty Jr. Health Services Emergency Loan – Students enrolled in any SHP program may apply for this low interest loan to address emergencies. Loan amounts are variable based on need.

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

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

You must visit B-SMART <a href="http://www.uab.edu/students/paying-for-college/">http://www.uab.edu/students/paying-for-college/</a> to apply. Many programs in SHP also have scholarships available to currently enrolled students. 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: <a href="https://twitter.com/uab-shp">https://twitter.com/uab-shp</a>

• Facebook: www.facebook.com/UABSHP

YouTube: <u>www.youtube.com/uabshp</u>

• Vimeo: <a href="http://vimeo.com/uabshp">http://vimeo.com/uabshp</a>

• LinkedIn: www.linkedin.com/groups?gid=3596638

• Website: <a href="www.uab.edu/shp">www.uab.edu/shp</a>

The School's Academic Affairs Committee published the following guidelines:

The Academic Affairs Committee proposes the following for social networking vehicles. Online communities like provide opportunities to share and explore interests that enrich the higher education learning experience. However, use them with discretion. UAB social media users are expected to act with honesty, integrity, and respect for others.

Professional Use - Only UAB employees authorized by their departments may use social networking Web sites to conduct University business. The authorized employee/position will serve as the point of contact for the web site. In keeping with University policy<sup>1</sup>, the authorized employee may post on a social network profile: the University's name, school, department, and/or unit information, a University email address or University telephone number for contact purposes, or post official department information, resources, calendars, and events. The employee should use care that any personal opinions or opposition to the University either by direct statement or perception not be published. General Use - The following guidelines are strongly suggested:

- 1. Use networking sites legally and appropriately. Consider your personal obligation as a citizen of the university. Use proper conduct in your posts regarding the university and your colleagues/fellow students.
- 2. Consider the use of a student, staff or faculty member to monitor any departmental social pages. All parties need to understand the guidelines presented.
- 3. Remember, you cannot ensure who does and does not have access to your information. Any text or photo placed online is available to anyone in the world even if you limit access to your site.
- 4. Information that you post online may continue to stay on the World Wide Web even after you erase or delete that information from your profiles or blog. Do not post anything that could reflect negatively on you, your family, your friends, and the university.
- 5. Do not post any confidential or sensitive information online.
- 6. By agreeing to the terms of use, online communities have your permission to republish your content worldwide and share information with advertisers, third parties, law enforcement, and others.
- 7. You are legally responsible for your posts on the social networking sites. Be discreet, respectful, and as accurate/factual as you can be in any comments or content you posted online.
- 8. Potential employers, admissions officers, and scholarship committees often search social networking sites to screen candidates. Your profile will be a part of how others know you.

#### **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. There are two tuition rates: Alabama resident (in-state) and Non-resident (out-of-state). Currently, non-resident students who register for online course sections pay resident tuition. Non-resident tuition is charged for on-site courses such as: clinical practicums, independent study courses, and project courses.

SHP programs have specific fees attached to programs, courses or laboratories. These fees are addressed in the program section of this handbook. Current standard tuition and fees for the School are posted at <a href="https://www.uab.edu/shp/home/admissions-tuition/tuition">www.uab.edu/shp/home/admissions-tuition/tuition</a>.

Payment deadlines for each semester are published on the official academic calendar and on the UAB website at <a href="www.uab.edu/whentopay/">www.uab.edu/whentopay/</a>. 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 <a href="https://www.uab.edu/emergency/preparedness">www.uab.edu/emergency/preparedness</a>. Other information sources include:

Webpage: <u>www.uab.edu/emergency</u>	B-ALERT system: <u>www.uab.edu/balert</u>
<ul> <li>Hotline: (205)- 934-2165</li> </ul>	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 handbook for additional information.

Check the Academic Calendar for deadlines: <a href="https://www.uab.edu/students/academics/acade

#### Section 2 – SHP and UAB Policies

#### **SCHOOL OF HEALTH PROFESSIONS POLICIES**

#### **BACKGROUND CHECK AND DRUG SCREEN**

www.uab.edu/shp/home/images/PDF/SHP Background and Drug Screen Policy05 2012.pdf

#### **GRIEVANCE PROCEDURES FOR VIOLATIONS OF ACADEMIC STANDARDS**

www.uab.edu/shp/home/images/PDF/grievance procedures.pdf

#### **IMPAIRMENT AND SUBSTANCE ABUSE**

www.uab.edu/shp/home/images/PDF/shp%20substance%20abuse%20policy.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**

#### AIDS AND HIV INFECTION

www.uab.edu/policies/content/Pages/UAB-HS-POL-0000252.aspx

#### **BODY FLUID EXPOSURE**

www.uab.edu/humanresources/home/employeehealth/reportingexposures

#### **IMMUNIZATIONS**

www.uab.edu/policies/content/Pages/UAB-AD-POL-0000086.aspx

#### **SUBSTANCE USE/ABUSE**

#### **ALCOHOLIC BEVERAGES, USE AND CONSUMPTION**

www.uab.edu/policies/content/Pages/UAB-AD-POL-0000071.aspx

#### DRUG FREE CAMPUS (GENERAL POLICY)

www.uab.edu/policies/content/Pages/UAB--POL-0000046.aspx

Drug-free Campus Policy for Students (Attachments)

Attachment A -www.uab.edu/policies/content/Pages/UAB--GDL-0000632.aspx

Attachment B - www.uab.edu/policies/content/Pages/UAB--GDL-0000626.aspx

Attachment B.1 - www.uab.edu/policies/content/Pages/UAB-AD-GDL-0000627.aspx

Attachment C - www.uab.edu/policies/content/Pages/UAB--GDL-0000628.aspx

#### **NONSMOKING**

www.uab.edu/policies/content/Pages/UAB-HS-POL-0000110.aspx

#### **TECHNOLOGY GUIDELINES**

**COMPUTER AND NETWORK RESOURCES (ACCEPTABLE USE)** 

www.uab.edu/policies/content/Pages/UAB-IT-POL-0000004.aspx

#### **COMPUTER SOFTWARE COPYING AND USE**

www.uab.edu/policies/content/Pages/UAB-IT-POL-0000028.aspx

#### **INCLUSIVENESS**

**EQUAL OPPORTUNITY AND DISCRIMINATORY HARASSMENT** 

www.uab.edu/policies/content/Pages/UAB-BT-POL-0000052.aspx

#### **RESEARCH AND SCHOLARLY ACTIVITIES**

ETHICAL STANDARDS IN RESEARCH AND OTHER SCHOLARLY ACTIVITIES

www.uab.edu/policies/content/Pages/UAB-RA-POL-0000263.aspx

#### PATENT (INTELLECTUAL PROPERTY)

www.uab.edu/policies/content/Pages/UAB-RA-POL-0000115.aspx

FIREARMS, AMMUNITION, AND OTHER DANGEROUS WEAPONS

www.uab.edu/policies/content/Pages/UAB-HR-POL-0000257.aspx

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 – DEPARTMENTAL POLICIES

#### DEPARTMENT OF CLINICAL AND DIAGNOSTIC SCIENCES (CDS)

#### Welcome

The Department of Clinical and Diagnostic Sciences is comprised of academic programs essential to today's healthcare system. Our programs provide training for future health care professionals in a variety of disciplines ranging from the diagnosis of illness and disease, the administration of advanced treatment therapies, and the performance of vital roles in surgical suites and in outpatient and inpatient healthcare settings. Graduates of our programs are well poised for a wide variety of job opportunities due to the outstanding education received at UAB.

#### **About the Department**

Comprised of multiple academic programs, the Department of Clinical & Diagnostic Sciences provides training for tomorrow's health care professionals from physician assistants and genetic counselors to nuclear medicine technologists. Students receive hands-on training from renowned faculty while using the tools to prepare them for a career in health care.

#### **CDS Professional Development Program**

Professional success after graduation requires many skills beyond the discipline specific technical skills that each student will master during their program. The CDS Professional Development Program is designed to provide students with a strong foundation in a variety of non-technical skills such as interpersonal communication and team based care. The program also provides practical instruction in areas such as professional networking and interviewing to enable students to be successful job candidates upon graduation. Each student will be provided with detailed information about the Professional Development Program activities and assignments.

#### **Accreditation Information**

The accrediting agencies for programs offered by the Department include:

Program	Accreditation
Physician Assistant Studies	Accreditation Review Committee for Physician Assistant, Inc. (ARC-PA)
(PAS)	http://www.arc-pa.org/
Nuclear Medicine Technology	Joint Review Committee for Nuclear Medicine Technology (JRCNMT)
(NMT)	http://jrcnmt.org/
Clinical Laboratory Sciences	National Accrediting Agency for Clinical Laboratory Sciences (NAACLS)
(CLS)	http://www.naacls.org/
Genetic Counseling	Accreditation Council for Genetic Counseling (ACGC)
(GC)	http://www.gceducation.org

#### **CDS POLICIES**

#### **ACADEMIC PROGRESS**

Academic Progress Review is implemented to promote, assist, and maintain student performance. The main purpose is to provide feedback to students regarding their performance and to identify areas of strength and/or weakness in performance or behavior.

Generally speaking, program faculty, and/or the program director, may academically counsel students on a semester-by-semester basis to assess progress in the curriculum and to provide students counseling regarding deficiencies as needed. These meetings may be documented and the student may be required to sign the documentation of the academic progress sessions with associated notes placed in the student's file.

In cases regarding deficiencies, suggestions and/or action plans may be developed in conjunction with the student so as to provide a plan for reversing the deficiencies by a specified timeframe. Such suggestions and/or action plans will be documented and signed (by both faculty and the student) and will be placed in the student's file. If a student does not comply with the suggestions and/or action plan and/or does not meet the deadlines as specified, the student may be dismissed from the program.

#### **ATTENDANCE AND EXCUSED ABSENCES**

#### **CDS Attendance Policy**

Attendance is mandatory for all classes, lectures, labs, program-related seminars, clinical practice, internships, etc.

Absences are either excused or unexcused and both require timely notification to the course instructor. Students who are absent during clinical practice or an internship must notify both the program clinical practice coordinator/internship coordinator and the clinical practice instructor/clinical internship instructor as soon as possible. Time missed during clinical practice or the internship must be made up and this may result in a delay in graduation.

Below is a list of excused absences recognized by the Department of Clinical and Diagnostic Sciences and UAB:

- Absences due to jury or military duty, provided that official documentation has 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 absence schedule occurs, students are responsible for providing their instructors with advance 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.
- Absences due to religious observations provided that students give faculty written notice prior to the drop/add deadline of the term.

In instances resulting in unavoidable absence(s), a student is expected to inform the program office and the associated course instructor in advance of the planned absence. For unforeseen events (car accident or breakdown, injury), the student is expected to notify the program and course instructor at the earliest possible time.

Make-up of missed class information or assignments is the student's responsibility. Make-up of class activities and projects is at the discretion of the course faculty – refer to individual course syllabi for more detailed attendance policies pertaining to the course.

\*NOTE: The program cannot guarantee that all work missed for an excused absence can be made up. Some activities (including laboratories) due to their complex, time intensive, and/or cost intensive nature will not be able to be made up. Similarly, when students arrive to laboratories late they risk missing important information/directions that may adversely affect their grade. Instructors are not obligated to repeat directions for students when they are tardy.

#### **ATTENDANCE INFRACTIONS**

For each unexcused absence, there will be a 1% overall grade reduction for that course or lab per absence. Two tardies will equal one unexcused absence. A tardy is considered being more than 10 minutes late to class. Faculty may choose to include attendance and timeliness in grading criteria and may implement a more restrictive attendance policy. The attendance policy for each course will be described in all course syllabi. The Department of Clinical and Diagnostic Sciences also reserves the right to institute an attendance policy for official program/department activities.

#### **CONSENSUAL ROMANTIC RELATIONSHIPS**

http://www.uab.edu/policies/content/Pages/UAB-HR-POL-0000254.aspx

#### **DATA PROTECTION AND SECURITY**

http://www.uab.edu/policies/content/Pages/UAB-IT-POL-0000038.aspx

#### **DRESS CODE**

Guidelines for professional attire require consideration for patients, visitors, and coworkers, as well as personal safety. Therefore, CDS students are expected to promote a professional image by following these guidelines.

#### **Clothing:**

- Clothing should be clean, neat, in good repair, and appropriate for the profession.
- Casual or athletic wear, such as sweat suits or warm-up pants, are not acceptable.
- Shorts are not acceptable.
- Skirt length shall be no shorter than two inches above the top of the knee and may not be tight fitting.
- Undergarments shall be worn and shall not be visible, even when in stretching or bending positions.
- Shoes shall be appropriate for the work environment and compliant with professional attire. Flip flops are not appropriate.
- Caps or head coverings are not acceptable unless they are for religious purposes or are part of a uniform.
- Sunshades (or hand-tinted, non-prescription glasses) shall not be worn unless they are required for medical purposes.
- Identification badges shall be worn at all times.

#### **Grooming:**

#### Piercings

- Facial and/or body adornments are not permitted other than in the ear lobe.
- No more than two pairs of earrings may be worn. Earrings will be no longer than one inch in diameter or length.

#### Hair

- Hair should be clean and neat.
- Hair may not be dyed unnatural colors and/or have patterns.
- Hair ornaments should be moderate and in good taste.
- Hair should be well-groomed, closely trimmed beards, sideburns, and mustaches are allowed.

#### Daily Hygiene

• Daily hygiene must include clean teeth, hair, clothes, and body, including use of deodorant.

In addition to these basic guidelines, students are expected to follow any additional provisions of a facilities dress code while in clinical practice.

#### **Dress Code Infractions:**

Failure to comply with the above dress code requirements will result in removal from program activities until requirements are met. Students will be counted as absent (unexcused) and will receive a grade of zero for any missed work during that time with no opportunity to make-up the missed work.

\*Note- The above Dress Code is a minimum standard set forth by the Department of Clinical and Diagnostic Sciences. Each program and/or course within CDS has the liberty to set forth and enforce a stricter dress code. Similarly, clinics also have their own dress codes that must be followed precisely.

#### FOOD AND DRINK IN THE CLASSROOM

Food or drinks in laboratories is prohibited. Food and drink in classrooms is allowed at the discretion of faculty.

#### **GRADING POLICY**

In each CDS course, the instructor will announce the grading criteria and publish it in the course syllabus. The following policy relating to the "I" (incomplete) grade or deferred credit supplements the School of Health Professions' policy.

#### **INCOMPLETE & DEFERRED CREDIT POLICY**

The awarding of an "I" (incomplete) grade is not done lightly. An "I" will be given only when an emergency or unexpected event prohibits the student from meeting course objectives in a timely manner. A student receiving a grade of "I" (incomplete) must arrange with the instructor to complete the course requirements as soon as possible, and in order to progress within the program the student must arrange to complete the requirements prior to the final day of registration for the next term. A grade of "I" not changed by the instructor by the beginning of the next regular term will automatically convert to an "F."

#### **INFECTION CONTROL**

Because students are working with patients having low immunities, the clinical supervisor reserves the right to send any student to UAB Student Health Services if the need arises. The clinical supervisor will call UAB Student Health and Wellness and request that the student be sent off duty if he/she has an infection of any kind. The student must then acquire a doctor's written permission to return to clinical education. Students are required to adhere to the policy of the clinical affiliate for working with patients with local infections or infectious diseases. Students are required to inquire about this policy at the beginning of rotation through a clinical affiliate.

#### **LIABILITY INSURANCE**

Liability insurance is provided by the University for all students registered for clinical education courses. The coverage protects students in any assigned clinical site to which they are assigned as a student.

#### **Non-Academic Student Conduct**

 $\frac{\text{http://www.uab.edu/2015compliancecertification/IMAGES/SOURCE1F03.PDF?id=415eda97-a4fc-e311-b111-86539cf2d30e}{\text{http://www.uab.edu/2015compliancecertification/IMAGES/SOURCE1F03.PDF?id=415eda97-a4fc-e311-b111-86539cf2d30e}{\text{http://www.uab.edu/2015compliancecertification/IMAGES/SOURCE1F03.PDF?id=415eda97-a4fc-e311-b111-86539cf2d30e}$ 

#### **Non-Resident Tuition Policy**

http://www.uab.edu/shp/cds/images/PDF/Policies/shpnon-residenttuitionpolicy.pdf

#### **PREGNANCY POLICY**

All students are encouraged to inform the program director immediately in writing once pregnancy has been confirmed. If students choose not to inform the program of their pregnancy, the program will not consider them pregnant and cannot exercise options that could protect the fetus.

For students who voluntarily disclose pregnancy the program director will discuss factors to be considered in cases of pregnancy with the student based on acceptable professional guidelines.

A student is offered three alternatives after the consultation with the program director. These are:

- 1. Immediate withdrawal in good standing from the program. Readmission to the program after the pregnancy will be in accordance with the Readmit Policy.
- 2. Continuation in the program after being given specific instruction regarding safety practices, safety monitoring, and specific clinical and laboratory assignments.
- 3. Continuation in the program with additional safety monitoring but without modification of assignments.

The student must be able to progress in her educational experiences, both clinical and academic. If the student cannot, she will be strongly advised to withdraw as in alternative number one. If there are any questions regarding any aspect of the above statements, please call the Program Director.

#### SECTION 4 - PROGRAM INFORMATION

#### **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.

#### **PROGRAM MISSION STATEMENT**

The mission of the Biotechnology program is to provide quality education to prepare a diverse student body for careers in various fields involving biotechnology and its related disciplines. The program is designed to provide students with broad training and education in:

- Scientific principles and knowledge underlying biotechnology, drug discovery and design.
- Scientific principles and knowledge underlying emerging diagnostic technologies associated with biotechnology.
- Basic laboratory techniques in biotechnology.
- Business principles and knowledge underlying the commercialization of science.
- Processes and procedures required to launch a biotechnology company.
- Legal, regulatory and marketing issues in biotechnology.

#### **ABOUT THE PROGRAM**

The Biotechnology Regulatory Affairs Graduate Certificate program curriculum is designed to prepare you to help 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 honors in their fields, lead professional societies and provide exceptional mentoring and training.

#### **FACULTY & STAFF**



**Tino Unlap, PhD**Program Director and Professor

Department of Clinical & Diagnostic Sciences 1716 9th Avenue South, SHPB 443 (205) 934-7382 unlap@uab.edu



**Dina Avery, DHSc, MA, MAEd**Assistant Professor and Regulatory Affairs Specialist

Department of Clinical & Diagnostic Sciences 1716 9th Avenue South, SHPB 471 (205) 934-33-78 dvavery@uab.edu



Joseph Garner, PhD

**Assistant Professor** 

Department of Clinical & Diagnostic Sciences 1716 9th Avenue South, SHPB 451 (205) 934-3882 <a href="mailto:dream.new.graph.edu">drgarner@uab.edu</a>



**Sharney Logan, MPA**Program Coordinator II

Department of Clinical & Diagnostic Sciences 1716 9th Avenue South, SHPB 447 (205) 934-2632 slogan@uab.edu



**Kathy Nugent, PhD**Assistant Professor

Department of Clinical & Diagnostic Sciences 1716 9th Avenue South, SHPB 449 (205) 934-7384 knugent@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

#### **C**URRICULUM

#### **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	

#### **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
- 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 & 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
    - 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

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
- 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			
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.
  - o Write down your Download and Upload speeds after you complete the test.
  - o 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. <u>Find out more about Computer Specifications</u>. 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. <u>Find out more about Supported Browsers</u>.

#### **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. <u>Install Flash Player in Five Easy Steps.</u>
- 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 & 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: http://www.uab.edu/graduate/graduate-school-quicklinks/online-forms

#### 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 are, we can assist you with locating 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

D = Inadequate (undergraduate only)

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.

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

<sup>\*</sup> 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	В
2	С
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: <a href="http://www.uab.edu/graduate/graduate-catalog/72-policies-and-procedures">http://www.uab.edu/graduate/graduate-catalog/72-policies-and-procedures</a>

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 & 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: <a href="http://www.bioalabama.com/about/">http://www.bioalabama.com/about/</a>

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

#### **Regulatory Affairs Professionals Society (RAPS)**

RAPS is a place for great networking, making invaluable connections and building a strong community. More than 16000 colleagues are available to connect with you. Student memberships are available.