2023-2024
Student & Faculty Handbook

Tulane University reserves the right to change any of its rules, courses, regulations and charges without notice and to make such changes applicable to students already registered as well as to new students. Although we make every effort to verify the accuracy of the information in this booklet, errors may still be present.

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TULANE UNIVERSITY INTERDISCIPLINARY BIOINNOVATION PHD PROGRAM
Student and Faculty Handbook

A. PROGRAM OVERVIEW

Graduate education in the sciences and engineering rarely offers the training and experiences that fully prepare graduates to enter directly into non-academic research and leadership positions. The Interdisciplinary PhD Program in Bioinnovation at Tulane University challenges this paradigm by cultivating in its students the ability to develop clinically relevant biomedical technologies that have the potential to evolve into marketable products. Participating fellows benefit from and expand upon an environment of translational research at Tulane that spans the School of Science & Engineering (SSE), School of Medicine (SOM) and School of Public Health and Tropical Medicine (SPHTM). Simultaneous collaborations with the Business and Law Schools, industry partners and the FDA provide fellows with a strong foundation in entrepreneurship and regulation. This program was initiated in 2012 and currently is supported by an NIH T32 training grant (T32 EB027632-01).

Training within this program emphasizes *Bioinnovation*, which we define as the development and progression to the marketplace of clinically relevant biomedical technologies and devices. This includes:

1. An integrated research project that centers on the development of novel technologies for the delivery of biologically active substances for use in:
    - regenerative medicine,
    - biosensors or
    - advanced therapeutic biomaterials.
2. A core curriculum consisting of courses in:
    - quantitative fundamentals,
    - biological systems,
    - modeling and transport phenomena and
    - entrepreneurship.
3. An internship at the FDA to:
    - develop an understanding of regulatory, ethical, and practical issues important for the translation of research from the laboratory to the clinical setting,
    - establish non-academic research collaborations and
    - gain insight into research environments outside of academia.
4. An entrepreneurship component through:
    - partnership with Tulane's Institute for Entrepreneurship and the New Orleans Bioinnovation Center (NOBIC),
    - participation in a Bioinnovation colloquium series and
    - collaboration in teams with colleagues from the Schools of Business and Law to take part in business competitions. Teams may be awarded Competitive Incentive Funds to support advanced mentorship, prototype and technology development and patent application preparation.

Our fellows will graduate with a superior grasp of the interrelationship between fundamental and applied research and its application and viability in the medical environment and

marketplace. This will uniquely position them for leading careers at the interface of academia and industry.

B. Program Objectives

The overarching goal of this Bioinnovation program is to provide a rigorous interdisciplinary graduate education in Bioinnovation focused on accelerating the research and design process. Our three primary objectives are:

1. **Program Objective 1 (Research):** Bioinnovation students conduct doctoral research on translational biomedical projects that emphasize transport processes. Each project is developed with the goal of creating new biomedical technologies and devices. This research is inherently interdisciplinary, establishing direct links with students and mentors from across the SSE, SOM and SPHTM as well as industry and government agencies (e.g., FDA).

2. **Program Objective 2 (Education):** Our fellows follow a curriculum that emphasizes science and engineering principles, biological fundamentals, and design. Courses in Business and Law and activities associated with Tulane's Business Model Competition provide a parallel focus on entrepreneurship with exposure to professional opportunities in non-academic environments. The required FDA internship gives trainees an understanding of the national and international regulatory environment while enhancing their research resources.

3. **Program Objective 3 (Community):** Our fellows, faculty and associates comprise a Bioinnovation community that emphasizes interdisciplinary research interactions. This sense of community is further enhanced by the core curriculum, Bioinnovation colloquium, the coordinated FDA internship and collaboration in entrepreneurship activities. This environment fosters the advancement of transformational research projects, curricula, student mentorship and outreach that inspires others to participate in our Bioinnovation program.

C. Tulane University

Tulane University is a comprehensive Carnegie Research-Extensive (Research-I) institution with a long history of excellence in graduate education and research. Tulane is the only institution in the US that has the combined resources of a School of Medicine, a School of Public Health and Tropical Medicine, a National Primate Research Center with a Level 3 Biosafety Laboratory, and an integrated School of Science & Engineering where health is the number one unifying research theme. As a result of Tulane's Integrative Bioscience Initiative, the university recently renovated the J. Bennett Johnston Health and Environmental Research Building to contain open labs that facilitate communication and collaboration between researchers and provide resources for integrative translational research. This facility houses interdisciplinary research clusters in Regenerative Medicine and Stem Cell Biology, Cancer, Bioinformatics, Biomedical Engineering, Infectious Diseases, Pulmonary Biology, and Health Disparities Research. In conjunction with Tulane's Institute for Entrepreneurship and NOBIC, this provides an excellent environment for interdisciplinary translational research. Tulane's Bioinnovation PhD Program has the resources to move projects quickly through the Bioinnovation process of theoretical conceptualization,

design and simulation, benchtop analysis and animal testing.

D. The New Orleans BioDistrict

Bioinnovation fellows benefit from and contribute to the resurgence of biosciences that has occurred in post-Katrina New Orleans. Termed "BioDistrict New Orleans," this economic strategy articulates a vision for encouraging the bioscience industry to locate within the defined BioDistrict area near Tulane University. A major component of this directive is the opening of a new academic teaching hospital, a new VA Hospital, a new Cancer Research Facility and NOBIC whose expanding employment opportunities provide an anchor for a vibrant urban community in the region's core area.

E. Bioinnovation Graduate Fellows

Doctoral students in this training program will graduate with a PhD in Bioinnovation and, upon approval, a certificate in their field of concentration. This is an academic degree that prepares students for careers as leaders at the interface of academia and industry.

E.1 Application and Admissions

Applications for admission are due by January 15 for the following Fall semester. Applicants must hold a bachelor's degree in the sciences or engineering to be admitted and are required to submit prior academic transcripts and three recommendations. All applicants must take the Graduate Record Exam (GRE). Only the general test is required. Only U.S. citizens and permanent residents are eligible for admittance. Information about the program, and a link to application and recommendation forms may be found at: https://Bioinnovation.tulane.edu.

E.2 Tuition and Expenses

Bioinnovation fellows receive a tuition scholarship to cover the cost of full-time graduate tuition, valued at $63,814 for the 2023-24 academic year. This award is based on merit alone, and no service is required as a condition for receiving it. The continuation of the scholarship in subsequent academic years depends upon academic performance in the graduate program.

Students who have completed their coursework requirements must register for SCEN 7020: Bioinnovation Research to maintain continuous registration. Tuition equal to one 3-credit hour course and part time fees are assessed for this registration. Living expenses for the single student are approximately $12,000. Graduate student housing is available in Tulane University apartments on a limited basis, though most students rent apartments near the university.

E.3 Financial Support

Every first-year graduate student in the Bioinnovation Program is offered a fellowship that provides a stipend amount of $33,000 to be disbursed in biweekly installments during the calendar year. Bioinnovation fellows are eligible to renew this fellowship for a second year if first-year progress is satisfactory. With continued satisfactory progress fellows will receive a stipend of $26,500 from Tulane University for the third academic year. Continued financial support for Bioinnovation fellows beyond the third academic year is based on academic and research merit and will be provided by their research mentor.

All Tulane graduate students are assessed fees each semester based on whether they are enrolled full-time (FT; ≥ 9 credit hours) or part-time (PT). In 2023-24 these include:

- academic support services fee - $400 FT; $44.50/credit hour PT
- student activity fee - $120 FT; $80 PT
- health center fee - $373 FT; PT optional
- Reily recreational center fee - $223 FT; PT optional

For a graduate student's first two years in the Bioinnovation Program, academic support services and health center fees are paid by the training grant. Bioinnovation fellows are still responsible for student activity and Reilly recreational center fees.

Tulane students are required to have medical insurance. Graduate students who do not have medical insurance coverage are responsible for enrolling in a plan at their own expense. If they choose to enroll in the Tulane University-sponsored student medical insurance plan, they receive a 50% supplement each semester to help defray the cost of the plan. This is provided by the Bioinnovation Program for the first three years and by subsequent funding sources through their research mentor starting in the fourth year. Currently, the cost of the Tulane plan is $1651 per semester for individual coverage.

F. Education and Training

The Bioinnovation PhD Program fosters a community of fellows with shared research interests who together participate in common required courses, a Bioinnovation colloquium, a summer-long FDA internship and an entrepreneurship thread that brings them together with students in the Schools of Business and Law. This chapter outlines the requirements all fellows must fulfill to graduate with a PhD from this program.

F.1 Bioinnovation Research Projects

As with all PhD programs, the identification of an appropriate research project is a *sine qua non* of a successful educational experience. This is particularly true with the Bioinnovation Program, which focuses on providing our students with a rich science and engineering foundation that emphasizes translation. The following framework is followed:

F.1.a Laboratory Rotations

During their first year, trainees complete three 8-week rotations in laboratories in the following areas:

- Imaging and Diagnostics,
- Regenerative Medicine,
- Microphysiological Systems, and
- Theragnostics.

For the initial rotation, each fellow is assigned to a laboratory by the Bioinnovation Program based upon his/her background and expressed interests. Placement in laboratories for subsequent rotations is determined by the fellow under the guidance of the Bioinnovation Program and laboratory mentors. Fellows must contact future laboratory mentors at least two weeks in advance to discuss a viable research plan.

To ensure productive use of their time within a given laboratory, students must complete a *Rotation Portfolio*. The following documentation should be included; however, these guidelines may be adapted after consultation with a rotation mentor:

1. a 1- to 2-page essay describing the laboratory research motivation and goals,

2. an annotated bibliography (5 to 10 papers) with a:
    - paragraph-length description of the goals and results of each study and
    - copy of the first page of each article, and

3. a well-documented lab notebook that includes such information as:
    - goal/motivation of an experiment,
    - procedures/step-by-step protocols,
    - accidental or intentional deviations from established protocols,
    - equipment used, and
    - experimental observations.

The *Rotation Portfolio* must be submitted to the Bioinnovation program manager one week after the end-date of a given rotation for review and approval. Fellows are also expected to formally present their research at the conclusion of each rotation during regular Bioinnovation group meetings.

F.1.b Research Pre-Proposal

By the end of the summer of their first year (September 1), Bioinnovation trainees must submit a letter of intent (*i.e.*, the "Research Pre-Proposal") to the program management for approval by the Executive Organizing Committee (EOC).

The Research Pre-Proposal should comply with the following instructions:

- Research Motivation and Goals: Describe the physiologic condition or disease state that your research is targeting (*e.g.*, What are the known biological mechanisms, causal factors and symptoms of the disease? What is the associated morbidity and mortality?). Explicitly state the goals of your research project and describe your current strategy to address these goals.
- Translation: A primary goal of the Bioinnovation Program is to support the development of practical solutions that address a particular clinical problem or unmet need and have a higher potential of translating from the research laboratory to the medical arena. It is important to keep this in mind as you design and carry out your PhD research. In this section, you should discuss the translational and commercialization potential of your proposed PhD project.
- Collaboration: As a member of the Bioinnovation team, it is important that you establish lasting and meaningful collaborations with other researchers while you work through your dissertation project. This sharing of resources and perspectives is a necessary component of your traineeship that will serve to advance the translational potential and depth of your research. It is important for you to carefully consider now who these individuals might be and to bring them into your research project as early as possible. For the pre-proposal, identify your advisor and co-mentors / collaborators and indicate how their insight will contribute to your research project.

F.1.c Qualifying Exam

Upon meeting the course requirements (and no earlier than the semester in which the normal course requirements for the PhD are to be completed), Bioinnovation fellows should undertake the Qualifying Exam. Normally this should occur in May or June of the second year of graduate study. A student who fails to take the test within a reasonable length of time will be advised by the department not to continue graduate study.

In order to take the Qualifying Exam, the prospective PhD candidate must submit a petition to the Bioinnovation Program Manager by March 15. The petition should include:

- A copy of the candidate's transcript. Petitions will only be guaranteed for acceptance if the candidate demonstrates that they will have completed course requirements at the time of the exam and that they have a cumulative GPA of at least 3.5 in these courses.

- A document (no more than 1 page long) that describes the student's PhD research area. This document should also list three relevant graduate courses that the student has completed and explain how the sub-disciplines related to these courses have prepared the student to begin independent advanced study in their PhD research area. The Executive Organizing Committee (EOC) will review each petition. Upon acceptance of the petition, the EOC will notify the student and faculty advisor that they may proceed and schedule the exam.

Each student should work with his/her faculty advisor to create a Qualifying Exam Committee (QEC) in keeping with the minimum requirements of Tulane's Office of Graduate & Postdoctoral Studies (http://tulane.edu/ogps/upload/Policy_Minimum-PhD-Degree-Requirements-Updated-9-3-2013.pdf). The QEC is chaired by the faculty advisor and must have at least 4 members who collectively meet the following criteria*:

- at least 3 must be faculty members, 2 of whom must belong to Tulane's faculty,
- 1 member must be affiliated with the School of Science and Engineering,
- 1 member must be affiliated with the School of Medicine,
- 1 member must be qualified to assess business feasibility, and
- 1 member must be part of the Bioinnovation EOC.

It is acceptable for a single Committee member to satisfy several of these requirements. The final composition of the QEC must be approved by the Bioinnovation Program Director. The QEC is expected to meet periodically at the request of the Committee Chair or graduate student to ensure that all members remain informed of the student's progress. The student is responsible for scheduling each Committee meeting.

*These same requirements apply to Prospectus and Dissertation Committees.

The Qualifying Exam consists of one research proposition selected by the student from a list of options generated by the QEC. The proposition will consist of an original translational research problem and should reflect ideas or theories derived by the student from advanced courses, seminars, literature and research experience. The topic must not directly relate to research ideas generated by the faculty advisor or the student's dissertation topic. The preparation and defense

of this proposition is intended to broaden the student's background conceptually and methodologically. The scope of the proposal will be that of a 2 to 3 year research project outlining specific experimental plans designed to address the central scientific question identified by the student.

The mechanics of the submission of the proposal and its defense are as follows: The student's advisor indicates the general readiness of the student and works with fellow QEC members to compile a list of potential Qualifying Exam research questions. Three weeks before the date of the Qualifying Examination, the student's advisor gives the student the list of research questions. At this time, the student may contact any member of the QEC to discuss expectations regarding the scope of both the written proposal and the oral examination. The student will then prepare the proposal based on the QEC's recommendations. The student will have two weeks to write the proposal and an additional week to prepare for the oral defense.

The proposal should conform to the NIH–NRSA–F32-style (https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/fellowship-forms-d.pdf, pages F61-F63). It should not exceed 7 pages, excluding references, and must include the following:

- Specific Aims (limited to1 page – including a hypothesis),
- Research Strategy (limited to 6 pages) which should include
- Background and significance (impact),
- Innovation, and
- Experimental Approach (methods, predicted results, potential experimentation or interpretation problems, alternative approaches, statistical methods), and
- References.

In addition, the student should prepare a 1-page commercialization addendum that analyzes the proposed product relative to competitive designs, addressing such issues as IP landscape, regulatory pathway, market positioning, scalability and sustainability.

The proposal must represent the student's own work, but the student should use multiple sources of information (*e.g.*, original publications and faculty members outside of the QEC). QEC members should receive copies of the proposition at least one week prior to the scheduled date of the oral exam. The written proposal and oral defense will be judged on the basis of the student's knowledge of the field, originality of the approach proposed for the experiments, impact of the results and conclusions to be drawn from the experiments, and the ability of the student to critically evaluate his/her proposed research methods and expected results. During the oral exam, the student will also be questioned on any other area of the core curriculum at the discretion of the QEC.

All faculty members affiliated with the Bioinnovation PhD Program are invited to attend the Qualifying Exam and may ask the student questions. Only QEC members vote on the student's successful completion. It is expected that the decision to "pass" a student should be by unanimous vote. The student will be informed of the results of the exam by June 30, with the following possible outcomes: pass (and possible recommendations); conditional pass (with specific requirements); or fail. If the exam is failed, it may be retaken once. A student who fails the exam twice will not be admitted to PhD candidacy.

F.1.d Prospectus

Once all coursework is complete and the qualifying exam has been passed, within the third year of study, Bioinnovation PhD fellows must submit and defend their prospectus to their Prospectus Committee.* This written document maps out an overall doctoral research plan; it may be modified, with Dissertation Committee* approval, as their research project progresses. The prospectus should be formatted as follows:

1. Abstract (1-2 paragraphs)

2. Specific Aims (SAs; 1 page):
   - State concisely the goals of the proposed research and summarize expected outcomes, including the impact that the results of the proposed research will exert on the research fields involved.
   - Explain potential technological innovations and commercial applications.

3. Background and Motivation (2-4 pages):
   - Include motivations and key references.

4. Research Project Description (8-12 pages):

a) Significance:
   - Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
   - Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
   - Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.
   - Explain the project's potential to lead to a marketable product, process or service.

b) Innovation:
   - Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
   - Describe any novel concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
   - Explain any refinements, improvements, or new applications of concepts, approaches or methodologies, instrumentation, or interventions.

c) Approach:
   - Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project.
   - Explain why the proposed approach was chosen over other strategies.
   - Provide a data management plan.
   - Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.

5. Timeline (1 page):
    - Provide a tentative sequence or timetable for the project.
    - Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.

6. References

Notes:

- Cite published experimental details and include preliminary data.
- The prospectus may address *Significance*, *Innovation* and *Approach* for each Specific Aim individually or for all Specific Aims collectively.

Students must submit and present their prospectus to the Prospectus Committee,* and a final draft must be provided to the Bioinnovation Program Manager. Upon completion of these requirements, students are eligible to submit and defend their PhD dissertation.

**Formation of the Prospectus and Dissertation Committees should follow the same guidelines as for the Qualifying Exam Committee (QEC); however, the individual members of each may differ.*

F.1.e Optional Collaborative Research with Non-Academic Partners

In order to foster long-term research collaborations among trainees, researchers in a non-academic environment and Tulane faculty members, we encourage the development of research dissertation projects that create links with non-academic labs.

- The trainee will be required to identify a research project in concert with his/her Tulane faculty advisors and a PhD research staff member at a non-academic institution.

- An application (co-signed by the non-academic research mentor) must be approved by the Bioinnovation EOC, which will consider the scientific merit of the project as well as its impact on the Bioinnovation fellow's time-to-degree. The non-academic research mentor will be a member of the dissertation committee.

- Trainees may receive Competitive Incentive Funds to facilitate this collaboration.

The following have agreed to participate in this optional research cooperation, although students are not limited to these institutions:

- FDA Office of Science and Engineering Laboratories (OSEL): OSEL is the laboratory of the Center for Devices and Radiological Health (CDRH) that performs product testing; develops reliable standardized test methods for CDRH and industry use; performs anticipatory and forward-thinking scientific investigations on emerging technologies, and contributes laboratory data to national and international standards used in CDRH decision making.

- Institute for Human and Machine Cognition (IHMC): IHMC is a not-for-profit research institute in Pensacola, FL that collaborates extensively with industry and government to develop science and technology aimed at leveraging and extending human capabilities.

- Tissue Growth Technologies (TGT): TGT is an industrial partner in Minnetonka, MN that develops bioreactors to deliver computer controlled mechanical stimulation intended to mimic the *in vivo* mechanical environment in order to condition and engineer developing tissues; reveal fundamental mechanisms of cell function; direct stem cell fate, and/or provide an *in vitro* test- bed for drug development. TGT will be an excellent industrial liaison with fellows conducting research in dissertation projects related to Regenerative Medicine.

F.2 Bioinnovation Curriculum

A high-quality fundamental science and engineering education is the foundation from which translational research must be based. We provide this foundation through a rigorous science and engineering curriculum that teaches key scientific principles and approaches that are critical to the development of biological delivery technologies. This includes courses in (1) quantitative fundamentals, (2) biological systems and (3) modeling and transport phenomena. Students also complete courses through Tulane's Schools of Business and Law to develop an understanding of intellectual property considerations, market analysis and business model development.

Bioinnovation graduate students also attend a required colloquium series during their tenure in the Program. Seminars focus on issues relevant to translational research, including research ethics, responsible conduct in research, entrepreneurship, intellectual property and regulation. This lecture series helps to bring industry/government issues to the attention of the Bioinnovation community.

The Bioinnovation curriculum was designed to balance breadth and depth while maintaining a time-to-degree of five years. Tulane requires *48-credits* of coursework:

- 9 didactic courses are required (*27-credits*) + the Bioinnovation Colloquium:
  - courses are distributed into 4 curricular threads (outlined in table below)
  - students must take at least 1 course in each thread in their first year
  - bold entries are highly recommended
  - students may petition the program manager for approval to substitute with an equivalent graduate-level class
  - **SCEN 6000** may not be substituted and must be taken in the first year.
- *6-credits* from FDA summer internship (SCEN 7010: Bioinnovation Internship)
- *15-credits* from independent study (SCEN 7020: Bioinnovation Research)
  - students are not eligible to receive SCEN 7020 credit until completing all didactic courses

Thread 1 – Data Science: Each student will develop a foundation in statistics and analysis of biological and engineering data that is the cornerstone of the theoretical, computational, and experimental analyses of biomedical systems (2 courses required).

- BIOS 6030: Introductory Biostatistics
- BIOS 6030: Introductory Biostatistics
- BIOS 6040 Intermediate Biostatistics
- BIOS 7080: Design of Experiments
- CMPS-6140 Intro Artificial Intelligence
- CMPS 6160 Intro to Data Science
- CMPS 6240 Intro to Machine Learning
- FINE 6020 Analysis for Financial Management
- GBCH 7250 Biomed Stat and Data Analysis
- GBCH 7330 Advanced Bioinformatics
- MATH 6080 Intro to Statistical Inference
- MATH 7310/7320: Applied Math I/II

Thread 2 – Biological Systems: Each student will develop experience in experimental and theoretical analyses of biosystems (2 courses required)

- BMEN 6030/5 Anat & Physio for Eng w Lab
- BMEN 6070/5 Quant Physiology with Lab
- BMEN-6400 Biomaterials and Tissue Eng
- BMSP 7770: Systems Biology
- CELL 6710: Molecular Biology of Cancer
- GEHS 6600 Principles of Toxicology
- MIIM 7500 Graduate Microbiology
- MIIM 7600 Medical Immunology

Thread 3 – Modeling and Transport Phenomena: Each student will develop knowledge of modeling and simulation methods and biological delivery processes (2 courses required).

- BIOS 6310: Intro to Methods in Data Science
- BMEN 6060 Biomedical Acoustics
- BMEN 6820 Math Analysis Bio Systems
- BMEN 6830 Intro Biomed Imaging
- BMEN-6600 Comput Model Biomed Sys
- BMEN-6660 Microphysiological Systems
- BMEN-6840 Medical Imaging Physics
- CELL 6050: Foundations of Pharmacology
- CENG 6710 Biochemical Engineering
- CENG 6870 Biomolecular and Cellular Eng

Thread 4 – Community and Entrepreneurship: Each student will build a foundation in business plan development and intellectual property. In this process they will work with students of Law and Business **(3 courses + Colloquium + FDA Internship required)**.

- ACCN-6050 Accounting Meas, Report and Control (3)
- BMEN 6080 Tech Invent & Commercial
- CPST 6320 Business Intelligence
- FINE 7140 Venture Cap & Private Equity
- INTD 6010: Responsible Conduct of Research (0 credits)
- MGMT-7170 Healthcare Policy & Reform (3)
- MGSC-6090 Ops and Supply Chain Mgmt (3)
- MKTG 6020 Marketing
- MKTG 7250: Social Media and Marketing
- MKTG-6020 Marketing
- SCEN 6000 Entrepreneurship in Bioscience: A New Way of Inventing
- SCEN 7020: Bioinnovation Research
- SPHL 6070 Health Systems Policy and Management

Other courses may be permitted with prior approval. One independent study option is an online course GPSO 7175: Health and Medical Terminology, which teaches students proper medical and scientific terminology usage within the context of human anatomy, physiology and pathology. Contact the program manager for registration information.

F.3 FDA Internship

A hallmark of this Bioinnovation program is the FDA internship, which equips our students with the necessary experiences to understand the practical and regulatory considerations that are required for the successful development of biomedical technologies and devices. It also provides

the opportunity to develop strong collaborations with researchers in industry or government. In this process, Bioinnovation fellows expand their understanding of non-academic career paths that are available after they have completed their PhD. This summer internship consists of two main components:

1. *Introduction to Regulation*: Students shadow FDA employees conducting surveillance of medical devices. In collaboration with the Division of Postmarket Surveillance, students learn how FDA collects, analyzes and enforces medical device adverse event reportability (21 CFR Part 803, 806). They have the opportunity to be directly engaged in post-market issues management forums and to participate in teams involved with ongoing post-market issues. These teams problem solve to determine what actions the FDA needs to take to resolve issues. (*e.g.*, pacemaker lead breakage failures or electrosurgical unit ground electrode burns). Bioinnovation interns may serve on these teams, allowing them to experience directly how their scientific work plugs in to the rest of the agency. This provides trainees with a meaningful experience in the FDA's regulatory environment.

2. *Introduction to FDA Research:* With approval from their FDA director, trainees may conduct initial research investigations in the Office of Science and Engineering Laboratories (OSEL) and in the Office of Surveillance and Biometrics (OSB). This research focuses on mechanistic understanding of new technologies and issues that affect the safety and efficacy of medical devices. This aspect of the initial internship experience serves the purposes of:
    - introducing the trainee to the extraordinary tools and facilities that are available at the FDA White Oak campus in Silver Spring, MD;
    - providing a mentorship experience to the trainees by PhD researchers who are pursuing careers in a non-academic scientific environment and
    - initiating research projects that may extend throughout (and potentially beyond) the completion of the student's PhD research.

First year students must send the FDA a description of research interests (*via* the Program Manager) during their second semester of study, and a suitable project will be identified.

F.4 Responsible Conduct of Research (RCR) Training

All participants in the Bioinnovation PhD Program must complete RCR Training.

F.4.a Required Course

Tulane, through its subscription with Collaborative Institutional Training Initiative ("CITI training"), offers web-based training in the following areas:

- Responsible Conduct in Research (RCR)
- Responsible Conduct in Use of Human Subjects in Research
- Laboratory Animal Welfare
- Good Clinical Practices ("GCP")

We require all T32 fellows to complete successfully the RCR seven-module course, and to forward a certificate of completion to our program administrator.

Certification of RCR training via CITI training is valid for a period of three years. Each fellow must take CITI's refresher course prior to the expiration of the three years in order to maintain his or her RCR training certification.

F.4.b Additional Training

In addition, the Office of Research Compliance coordinates a seminar series led by faculty members covering RCR topics. Training seminar topics include:

- societal impacts of research
- conflict of interest - personal, professional, and financial
- policies regarding human subjects in research
- research misconduct and policies for handling misconduct
- responsible authorship and publication
- data acquisition management, sharing, and ownership
- enhancing reproducibility through rigor and transparency: NIH expectations
- enhancing reproducibility through rigor and transparency: sex as a biological variable

Bioinnovation fellows are encouraged to attend this seminar series, which is specifically designed to satisfy the NIH's RCR requirements. Participants may register for the course and upon attendance at the 8 sessions will receive a "satisfactory" on their transcripts.

A Note on International Collaboration: While this graduate program does not include international collaboration, the experiences afforded our Bioinnovation fellows will position them well in the global marketplace. In particular, through their experiences at the FDA they understand US government regulation and enforcement. While this training is centered on the US, the mission of the FDA extends beyond our borders. For example, one aspect of the FDA Mission is to "Participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements." So, while the specific goal of the Bioinnovation Program is not directed to international studies, our students benefit from developing an intuitive understanding of the global impact of FDA policies and regulatory processes.

F.5 Bioinnovation Entrepreneurship

Bioinnovation students must complete courses offered by Tulane's Freeman School of Business, through the Levy-Rosenblum Institute for Entrepreneurship. As outlined in the curriculum table, each student takes at least three classes in the entrepreneurship thread, including *MGMT 6240 Practice of Management - New Venture Planning*. This course links to Tulane's Business Model Competition (TBMC), which focuses on ventures that adhere to the principles of conscious capitalism.

Bioinnovation fellows participate in local and national entrepreneurship events and business competitions, including New Orleans Entrepreneur Week, NOBIC's Innovation Louisiana, the NIH StartUp Challenges and Tulane's Novel Tech Challenge. Starting in their second year trainees are encouraged to compete in Tulane's Business Model Competition (TBMC). This spring semester event draws teams from across the US and feeds directly into the International Business Model Competition in Provo, UT. Bioinnovation fellows compete in teams with peers in business and

law and NOBIC mentors. This provides trainees with experience in interdisciplinary business collaboration while teaching them to address issues related to business planning and technology commercialization.

It should be noted that this model was recently successful in promoting a biotechnology company founded by Prof. John (a member of the EOC) and two of his doctoral students. This group has created the startup company NanoFex that is developing technology to remediate groundwater contaminants. The two students teamed with business and law students and NOBIC interns and successfully competed for a $50k award at the business competition associated with the 3rd annual New Orleans Entrepreneur Week. These funds are intended help to translate their fundamental technology to the marketplace.

F.6 Additional Bioinnovation Community Activities

As mentioned in §F.2, all Bioinnovation graduate students must attend a Bioinnovation colloquium series during their tenure in the program. Fellows also participate in a number of additional Bioinnovation-affiliated activities that foster a sense of community among the program participants across all schools and disciplines. Some examples include:

- *Research-In-Progress/Journal Clubs:* Research project team members regularly meet to demonstrate findings, discuss difficulties and share plans for upcoming experiments for each subproject. These meetings help Bioinnovation fellows to compile and leverage the input from different fields to improve their research approaches. Furthermore, they develop experience for conference presentations and their dissertation defense.

- *Annual Symposium:* All students participate in an annual symposium during Tulane's "Research Days" events. This provides an ideal opportunity to enlighten the academic community and public on the role of interdepartmental research collaborations in advancing biomedical research and design to clinically-relevant technologies and devices.

- *Undergraduate Mentoring:* A fundamental component of the research environment at Tulane University is the incorporation of undergraduates in the research mission of our departments. Within their laboratories, fellows work under the guidance of their faculty advisors to co-mentor undergraduates involved in research projects. Laboratories benefit from the natural camaraderie and mentoring that exists between post-doctoral researchers, PhD, MS and undergraduate students. Through this process Bioinnovation graduate students experience leadership and management roles – simultaneously, undergraduates become engaged in components of our Bioinnovation Program. Undergraduate mentoring is collaborative and provides a broader impact for our Program by educating undergraduate students about advanced research and career opportunities.

G. Program Timeline

Year 01 Fall and Spring Semesters
I. Core Curriculum and Community Building:
Thread 1 – Data Science
Thread 2 – Biological Systems
Thread 3 – Modeling and Transport Phenomena
Thread 4 – Entrepreneurship: SCEN 6000 Bioinnovation Colloquium

II. Lab Rotations: three eight-week research rotations in different scientific focus areas (regenerative medicine, biosensors and advanced therapeutic biomaterials)

III. Match to Research Lab and Project: Research Pre-Proposal

Year 01 Summer
I. 12-week FDA Internship (SCEN 7010)

Years 02 to 05
I. Translational Dissertation Research

II. Complete remaining required coursework + additional research credit (SCEN 7020):
Thread 1 - Quantitative Fundamentals
Thread 2 – Biological Systems
Thread 3 – Modeling and Transport Phenomena
Thread 4 – Entrepreneurship Bioinnovation Colloquium

III. Business Model Competitions in Y02 +

IV. Qualifying Exam by end of Y02

V. Prospectus in Y03

VI. Graduation in Year 05

H. Tulane University Graduation Requirements

Official forms and policies may be found at https://sse.tulane.edu/node/2592. In order to graduate from Tulane University with a PhD, the following documents must have been submitted to the Dean's Office during a student's tenure in the Bioinnovation Program:

- Admission to Candidacy Form,
- Recommendation for Approval of Dissertation Prospectus,
- Application for Degree Form, and
- Oral Defense Approval Form.

After satisfactorily completing and defending their dissertation (formatting instructions are found here: https://sse.tulane.edu/completion-degree-requirements. Students must submit electronic copies to ProQuest and the The Digital Repository of the Tulane Library for official publication.

The following are approximate critical dates to consider prior to graduation:

GRADUATION DATE	MAY PhD	AUG PhD	DEC PhD
Application for Degree Form Deadline	February 1	June 15	October 1
Oral Defense Approval Form and Dissertation Submission Deadline	April 15	August 5	December 5