

Start-up Guide for Employee Inventors & Entrepreneurs



LAB THE UNIVERSITY OF ALABAMA AT BIRMINGHAM





Known for its innovative and interdisciplinary approach to education at both the graduate and undergraduate levels, the University of Alabama at Birmingham is an internationally-renowned research university and academic medical center. As Alabama's largest single employer, with some 28,000 employees, UAB had an economic impact in FY2022 exceeding \$12 billion within the state and generated \$371.5 million in state and local taxes.

Our research faculty rank among the nation's best-funded and are noted for exceptional mentoring and training, from undergraduate researchers to post-doctoral fellows. UAB research investigates, reveals and applies knowledge that changes the lives of individuals and the future of communities.

UAB research was supported by nearly \$715 million in sponsored research funds in FY2022, and is conducted by faculty, fellows and students in 10 schools, 24 university-wide research centers, UAB hospitals, clinics and field sites.

Learn more at www.uab.edu.





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WHY START A COMPANY?

THINGS TO CONSIDER BEFORE TURNING YOUR IDEA INTO REALITY



Starting a company to commercialize an invention as an academic researcher can be a life-changing endeavor. The process brings together a breadth of experiences, from the allure of potential societal impact and financial returns, to challenges working within a university culture with federal, state, and local regulatory considerations.

While there are many motivations for starting a company, the primary reason from a commercial standpoint centers on making profits by selling products or services. Anyone seeking to commercialize an idea must identify a market need that their product fills.

Academic entrepreneurs are often "technology-driven" while investors are "market-driven." These differences create a dichotomy between academic and corporate cultures, as the former focuses on cutting-edge technologies while the latter focuses on how technologies meet market needs.

Whether you are a new or serial entrepreneur, the UAB entrepreneurial community is committed to helping you navigate the process.



UAB START-UP ENTITIES & INSTITUTIONAL REVIEW

UAB and The UAB Research Foundation (UABRF) have a special and vested interest in UAB Start-Up Entities that license intellectual property from the university.

A UAB Start-up Entity is a business that:

- Has a current UAB employee, student or immediate family member of a current UAB employee in the role of officer, owner, partner, board of director member, or holder of an ownership interest in the business; and
- Either:
 - Uses or commercializes or plans to use or commercialize a technology which was or is being developed by one or more current or future UAB employees or students who are/were UAB employees or students at the time that the technology is/was developed; or
 - Uses or commercializes or plans to use or commercialize a technology which was developed by one or more current UAB employees or students prior to, or outside of, their UAB employment/student experience.

To support a successful, efficient and productive interaction with the university, UAB Start-up Entities that wish to conduct business with UAB or use UAB resources* are subject to review and approval by the Entrepreneurial Oversight Committee (EOC). The EOC consists of senior University leadership.

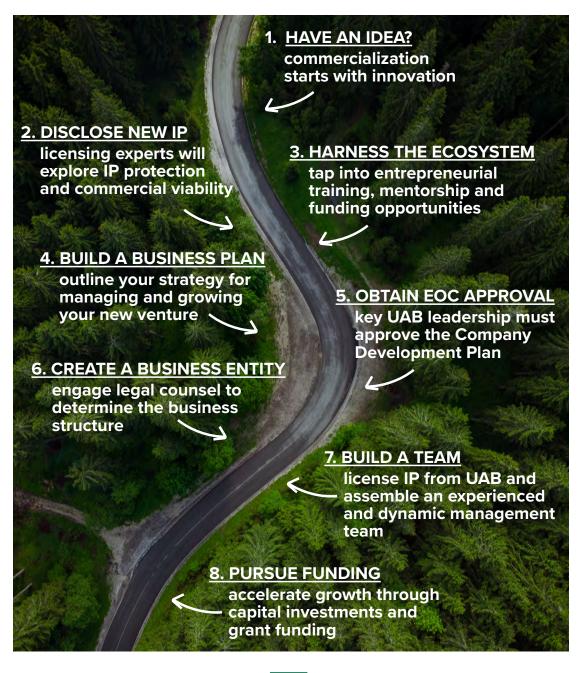
The Entrepreneurial Development Committee (EDC) reports to the EOC and supports UAB Start-up Entities through the EOC approval process by working with the Start-up Entity to create a Company Development Plan. The Company Development Plan includes an analysis of any proposed use of UAB facilities and resources, addresses state ethics concerns and confirms compliance with applicable UAB policies, including conflict of commitment and interest requirements.

*UAB resources are defined as space, equipment, people and intellectual property. See pages 14-17 for more information.



THE ROAD MAP TO COMMERCIALIZATION

NAVIGATING UAB COMMERCIALIZATION RESOURCES





KEY CONSIDERATIONS

EXPLORE THE STAGES OF COMMERCIALIZING AN IDEA AND THE RESOURCES AVAILABLE AT UAB



DISCUSS EARLY & OFTEN

As a UAB inventor, you should consult with your department or division chair to discuss and vet your intentions to ensure alignment with UAB's Faculty Handbook, External Activity Reporting and Conflict of Interest and Commitment policies.

Also, contact the Bill L. Harbert Institute for Innovation and Entrepreneurship (HIIE) early in the process. These discussions will cover the nature of your invention, how to protect the intellectual property and your interest in developing and commercializing the IP through a start-up entity.

PROTECT IP

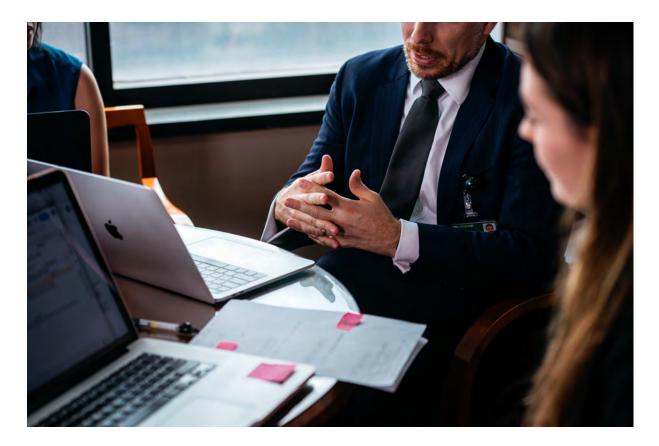
It is very important to take measures to protect your invention before it becomes publicly known or available, such as through a publication or presentation. Once your invention has been publicly known, it is not possible to obtain foreign patent protection and a patent application to protect it in the United States must be filed within the first year after publication.

The IP disclosure process is described on pages 9-10 of this guide.



KEY CONSIDERATIONS

EXPLORE THE STAGES OF COMMERCIALIZING AN IDEA AND THE RESOURCES AVAILABLE AT UAB



BUILD A TEAM

Entrepreneurs must identify personnel who complement their expertise. Specifically, UAB entrepreneurs will need to identify an appropriately-qualified CEO who can negotiate a license from UABRF. Building a scientific advisory team and a Board of Directors that can help bring in resources and connections are important for start-up success.

Best practices for UAB start-up teams are covered on pages 11-13 of this guide.



PROTECT INTELLECTUAL PROPERTY

PROTECT YOUR INVENTION BEFORE IT BECOMES PUBLIC



Intellectual Property (IP) refers to a category of intangible property rights comprised primarily of patents, copyrights and trademarks.

A patent is a grant from the government that gives the exclusive right to make, use and sell an invention for a period of 20 years. Patents for designs are given a 14-year period of protection.

A copyright is an intangible property right granted by the U.S. government to the author or originator of certain expressions of ideas. Works created today are automatically given copyright protection for the life of the author plus 70 years.

A trademark protects names, terms and symbols that are used to identify the source of goods and/or services on the market.



PROTECT INTELLECTUAL PROPERTY

THE GREATEST OPPORTUNITY FOR COMMERCIALIZATION & PUBLIC GOOD

DISCLOSURE OF INVENTIONS

As a condition of UAB employment, faculty and staff are obligated to disclose all inventions to the UABRF, an entity housed within the Harbert Institute for Innovation and Entrepreneurship (HIIE).

Employees must disclose inventions by submitting an Intellectual Property Disclosure at www.uab.edu/innovation/. It is expected that this be done before making any form of public disclosure. Public disclosure is not limited to manuscripts and publications; conference presentations, posters and even correspondence with an outside entity or discussion with a colleague can be deemed a public disclosure.

HIIE ASSESSMENT

Once an invention is disclosed, HIIE Licensing Associates conduct a preliminary evaluation of the IP, considering factors such as patentability, public benefit, commercial potential and patent rights of outside parties. If an invention is deemed commercially viable, the HIIE will market the invention to assess commercial interest and seek licensees or start-up interest.

PROTECTING IP

If the HIIE decides to pursue patent protection, licensing associates will authorize and coordinate the process, engage a patent firm to draft the application and begin working with the employee on commercialization efforts.

In the case of patent-eligible technology, the completed patent application is submitted to the United States Patent and Trademark Office (USPTO) and/or other appropriate jurisdictions where protection is sought. At the time of patent application filing, legal documents confirming the assignment of the patent from the inventor to UABRF will be required. Issuance of a patent by the USPTO commonly takes 3-5 years from application submission. During this time, HIIE licensing associates coordinate with outside patent counsel and the inventors and respond to official communications from the USPTO to determine the scope of eventual patent rights.

IP AT UAB: DETERMINING OWNERSHIP

PATENTS

UAB employees are expected to comply with the university's Patent Policy, Board of Trustees of the University of Alabama Rule 509, which requires invention disclosure. If the invention resulted from unrelated work outside the university, UAB may decide that it does not have a right of ownership.

COPYRIGHTS

UAB employees are expected to comply with the university's Copyright Policy. Ownership of the copyright in the work depends on the conditions and funding of the particular work.



BUILDING A TEAM

BEST PRACTICES FOR SUCCESS

Assembling a cohesive team is an important early step in launching a UAB Start-up Entity. Determining who will take part and establishing expectations concerning roles in, and commitments to, the UAB Start-up Entity can be among the most difficult aspects of creating a new business. If the inventor is the main driver for forming the start-up, then he or she must consider personal goals, the needs of his/her family, and professional commitments. The inventor is generally the key to transitioning the technology from the lab to the business. Even if the inventor is not driving the process, he/she will still likely be involved in the start-up entity in some capacity.



Investors are usually interested in UAB Start-up Entities with strong management teams; they may be less likely to fund even the best ideas if the right team isn't in place. Seek a management team with significant domain expertise, sales, management, fundraising and marketing experience.

CHOOSING YOUR ROLE

If a UAB employee wishes to be involved with a UAB Start-up Entity, prior approval must be obtained before any external activity can be undertaken. Appropriate roles for UAB employees in a UAB Start-up Entity are scientific or technical roles (chief scientific officer, chief technical officer, scientific advisor/ consultant). In general, approval will not be provided if an employee plans to undertake a managerial role such as a chief executive officer, president, vice president, chief financial officer, chief operating officer or principal officer of a UAB Start-up Entity. However, in limited and rare circumstances and with the advance written approval of the applicable chair and dean (for faculty) or supervisor (for staff) and of the UAB Entrepreneurial Oversight Committee, the holding of managerial roles may be permitted in a UAB Start-up Entity for short periods of time. Such permissions would be based on such factors such as: (1) the extent to which UAB resources may have been or will be used for the entity; (2) the employee's experience in developing start-up ventures; (3) where the employee is in their academic career; and (4) the stage of the entity's development.

It is important for employees who wish to seek such approval and serve in such managerial capacities to note it is likely that in the evolution of a UAB Start-up Entity, they may need to transition to a less than a full-time faculty or staff appointment at UAB. It is an employee's primary responsibility to fulfill all of the responsibilities associated with their position at the University.



BUILDING A TEAM

UAB POLICY ON CONFLICT OF COMMITMENT

INVOLVEMENT IN A NEW VENTURE AS A UAB FACULTY MEMBER

UAB employees owe their primary professional allegiance to UAB. Their primary commitment of time and intellectual energies should be to the education, research and scholarship program of the university. All university employees are required to obtain approval from their department chairs and dean for any external activity, including a UAB Start-Up Entity. Employees must request approval every 12 months (if the external activity is ongoing), and each time material changes occur in the nature of the activity, time committed or remuneration received.

As set forth in HR Policy 128, full- time faculty are limited to twenty (20) typical working days per year and no more than five (5) per quarter for all approved external activities, Full-time faculty exceeding this 20-day limit per year are expected to use nights and weekends, vacation, university or personal holidays. Faculty with nine (9) month appointments may use designated time off.

There is not a bright-line test for determining whether, overall, a faculty member is or is not making his or her commitment of time primarily to UAB. Determining whether you have fulfilled your "primary obligations and commitments" to UAB should be the result of a constructive process worked out between faculty and chair.

INVOLVING OTHER UAB EMPLOYEES

It is important to discuss the opportunity fully when asking non-faculty UAB employees to participate in a company. UAB employees who are not faculty members must also obtain approval through the External Activity process and may not perform non-UAB work during their regular UAB work hours.

INVOLVING FOREIGN NATIONALS

UAB hosts a variety of international students, scholars and faculty. Individuals studying or working at UAB who are foreign nationals may have certain restrictions for employment and other activities based on the nature and type of their visa. For example, an individual's visa status may only permit his/her employment or enrollment at UAB. Such restrictions will impact his/her availability to participate in the company's activities if they exceed the scope of activities permitted by the visa.

Furthermore, visas obtained by UAB for individuals to work or study at UAB are not transferable to an outside company. Outside companies should consult with independent legal counsel for assistance.







INCORPORATING INDIVIDUALS FROM UAB IN YOUR COMPANY

INVOLVING STUDENTS AND POSTDOCS

UAB recognizes that graduate student, post-doctoral student and trainee involvement in outside companies may offer educational benefits to these students. A UAB Start-up Entity which has been approved by the Entrepreneurial Oversight Committee may employ graduate students, post-doctoral students and trainees while they are studying/conducting research at UAB if (a) the employment benefits the student's education/ research in his/her academic field of study; (b) the employment does not interfere with the student's ability to complete or publish the student's dissertation or other academic manuscripts; and (c) the student's department manages the relationship between the faculty member and the student to avoid conflicts that may interfere with the student's education/research and ensures that the student's Individual Development Plan (see below) is adhered to.

If a student is being taught and/or supervised by a faculty member who has an ownership or financial interest in the company, prior to the student's employment, the student, the faculty member, the chair of the student's department and the Graduate School Dean will create and approve an Individual Development Plan (IDP) that delineates appropriate engagement with the company. This fully approved IDP for the student shall be attached to the faculty member's management plan addressing the responsibilities to UAB.

In addition to being evaluated on the elements of his/her own management plan, the faculty member will also be evaluated upon his/her management of the student in accordance with the student's IDP (www.uab.edu/idp).

The faculty member must also (a) ensure that the student's obligations to the company do not interfere with his/her academic obligations and (b) evaluate the student's academic work in a manner that is completely independent of the student's performance for the company.





POLICIES CONCERNING THE USE OF UNIVERSITY RESOURCES BY EXTERNAL ENTITIES

University resources are defined as space, equipment, people and intellectual property. As a public institution, UAB is heavily subsidized by state and federal tax dollars and tasked with the performance of academic and medical research. A start-up entity's use or access to the university's research infrastructure is governed by UAB policies and guidelines concerning such use by external entities. In cases of complex requests, the EDC will work with the dean and department chair associated with the start-up company to develop a plan that outlines appropriate use and allocation of university resources and that is in compliance with applicable UAB policies.

COMPANY ACCESS TO UAB SPACE, SERVICES & EQUIPMENT

The use of UAB resources by external entities requires disclosure to, and prior approval by, appropriate departmental and school authorities. The charges for use of the resource must be set at an amount equal to all direct and overhead costs associated with providing the resource and making use of it. Use of UAB resources are governed by a contract between UAB and the external entity, and the UAB Associate Vice President for Financial Affairs must approve the charge structure. External entities must not use UAB expendable resources unless the full cost for replacement is included in the agreement budget. Likewise, UAB services related to a nonexpendable resource must be captured in the budget included in the agreement.

COMPANY PROJECT

A start-up entity may wish for UAB researchers to conduct a project for the company. This is accomplished through an agreement that is negotiated, reviewed and processed through the UAB Office of Sponsored Programs. Projects should be appropriate for the university setting. For example, routine tests and work that are readily available through commercial entities are generally not appropriate to be conducted at UAB. UAB is required by federal regulation, state law and UAB policies to own any intellectual property developed by its employees and students. However, a research agreement negotiated with UAB allows the sponsoring company to negotiate a license to use any IP developed by UAB while performing the research project.

IRB, IACUC & OTHER REGULATED SERVICES

UAB's human subject research and protection, animal care and use, and health and safety programs are for the benefit of research activities involving UAB employees and researchers acting in their UAB capacity. These programs are subject to complex federal and state regulations and the responsibilities and risks associated with conducting human subject and animal research are significant. Under no circumstances may external entities or individuals, such as an employee start-up entity or a physician's private practice, use the services of UAB's research administrative offices under the pretext of UAB research activity unless UAB is engaged in a particular project through a sub-agreement with the company and/or there is a specific agreement in writing between the company and UAB.



UAB POLICIES ON CONFLICT OF COMMITMENT & CONFLICT OF INTEREST*

***EFFECTIVE JANUARY 2021**

FINANCIAL CONFLICT OF INTEREST (FCOI)

All UAB employees are required to fulfill their institutional responsibilities based on sound professional judgement unimpaired by their personal relationships or financial interests. Once identified, the University reviews and undertakes appropriate action to manage actual, potential or perceived conflicts of interests between an employee's institutional responsibilities and their personal relationships and/or financial interests. Accordingly, disclosure and transparency are crucial to successful management of conflicts of interest.

Some UAB employees (all full time faculty, employees who are investigators for purposes of undertaking research, and all institutional officials) are expected to file annual disclosures of financial interests that are held by them, their spouse and/or dependents that relate to their institutional responsibilities. In addition, if any new financial interests are acquired in the period between annual disclosures, employees are required to disclose the new financial interest within thirty (30) days of acquiring or discovering it.

The University has various processes and groups that are charged with reviewing conflicts of interest that might affect an employee's institutional responsibilities. Those that relate to extramurally-funded research and all research involving human subjects, regardless of funding source, are primarily reviewed by the Conflict of Interest Review Board (CIRB). Management of identified financial conflicts of interest requires the development and implementation of management plans which are designed to manage, reduce or eliminate the financial conflict of interest so the research may be undertaken.

A Significant Financial Interest (SFI) is defined as a financial interest consisting of one or more of the following interests of the Investigator (or those of his/her spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

- Publicly traded entity: If the value of any remuneration received from the entity in the 12 months preceding the disclosure the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$ 5,000. This includes: salary, any payment for services not otherwise identified as salary, consulting fees, honoraria, paid authorship, equity interest (e. g., stock, stock option, or other ownership interest).
- Non-publicly traded entity: If the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator holds any equity interest.
- Intellectual property rights and interests upon receipt of income related to such rights and interests, including patents and copyrights.
- Reimbursed or sponsored travel.



UAB POLICIES ON INSTITUTIONAL CONFLICTS OF INTEREST



INSTITUTIONAL CONFLICT OF INTEREST (ICOI)

The role of the UAB Institutional Conflict of Interest Committee for Research (ICOI Committee for Research) is to review proposals to conduct human subjects clinical trial research at UAB in which it has been identified that either the institution or an institutional official has a financial interest that may influence or be perceived to influence the design, conduct, or reporting of such human subjects clinical trials research (an "institutional conflict of interest"). The ICOI Committee is appointed by the university president and consists of seven members, three of whom are independent, having no financial relationship with UAB and not being influenced by interests of UAB.

All other proposals to conduct research (other than human subjects clinical research) in which an "institutional conflict of interest" exists are reviewed, managed and monitored by the Conflict of Interest Review Board (CIRB). Conflicts of interest can and do exist outside of research, and per the UAB COI policy, are to be managed by deans and department chairs.



ALABAMA ETHICS LAW



ALABAMA ETHICS LAW

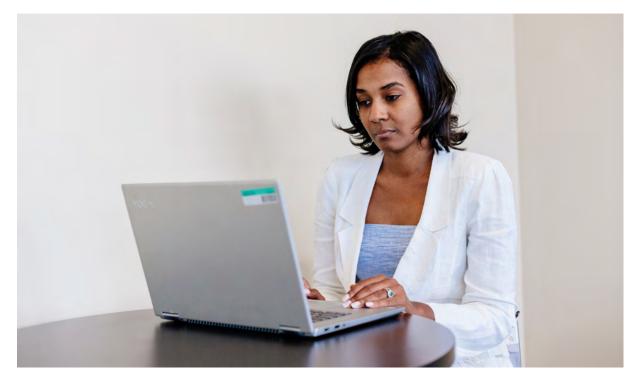
The Alabama Ethics Law applies to public officials and public employees, including full and part-time UAB employees. Generally, the Alabama Ethics Law requires UAB employees to avoid conflicts of interest and refrain from using public property for personal gain. Unless the business is conducting work at UAB through a negotiated agreement, a UAB employee may not use or cause to be used UAB equipment, facilities, time, materials, human labor, or other UAB property under his/her discretion or control for the private benefit or business benefit of the employee except as otherwise provided by law or pursuant to a lawful employment agreement. Likewise, a UAB employee may not use his/her position with UAB to obtain personal gain for himself/herself, a family member or any business with which the employee is associated. The Alabama Ethics Laws prevents UAB employees, or members of their households, or any businesses associated with these officials and employees, from entering into contracts for which UAB will provide payment unless the contract has been awarded through a competitive-bidding process.

A violation of the Alabama Ethics Laws may result in a criminal conviction for a public employee or official. Penalties include terms of imprisonment lasting up to twenty (20) years and fines of up to \$30,000.



UNIVERSITY WEB LINKS

LINKS TO FREQUENTLY-USED RESOURCES & POLICIES



CONFLICT OF INTEREST AND CONFLICT OF COMMITMENT POLICIES* *EFFECTIVE JANUARY 2021

- <u>Conflicts of Commitment</u>
- Procedure for Identifying and Managing Investigator and Institutional Conflicts of Interest
- <u>Required UAB COI Course</u>

EXTERNAL ACTIVITY LINKS

- External & Internal Activities Policy Faculty Handbook
- Employment & Other External Activities
- External Activities (Office of Compliance and Risk Assurance)

INTELLECTUAL PROPERTY LINKS

- Ownership of Intellectual Property Faculty Handbook (Patent Policy)
- Disclose Intellectual Property
- <u>Revenue Distribution Agreement</u>



UAB COMMERCIALIZATION RESOURCES

ON-CAMPUS PROGRAMS AVAILABLE TO EMPLOYEE INNOVATORS

CENTER FOR CLINICAL & TRANSLATIONAL SCIENCE INNOVATION PANELS

The Center for Clinical and Translational Science (CCTS) partners with research teams to accelerate the translation of scientific discoveries to improve health. In addition to a broad portfolio of training activities, the CCTS supports Innovation Panels (iPanels), a discussion forum for investigators seeking to advance experimental insights to commercial applications. iPanels connect teams to disciplinary experts, business leaders, health innovators, members of the institution's technology development team, and research administration representatives to address the freedom to operate, commercial potential, funding opportunities and strategies to advance research application and commercialization.

Visit www.uab.edu/ccts.

HARBERT INSTITUTE FOR INNOVATION AND ENTREPRENEURSHIP

The Bill L. Harbert Institute for Innovation and Entrepreneurship (HIIE) fosters an entrepreneurial ecosystem at UAB and provides the infrastructure for students, staff, and faculty to commercialize innovation on campus, within the community, and beyond. Through partnerships with UAB schools, colleges, programs, and the local business community, the HIIE works to increase innovation and entrepreneurial opportunities for students, faculty, staff, and businesses to launch sustainable startups with new or disruptive technologies.

Visit www.uab.edu/innovation for more information.

UAB I-CORPS & RESEARCH COMMERCIALIZATION

I-Corps is an accelerator program created by the National Science Foundation to develop early ventures and discoveries and accelerate them towards successful commercial ventures. I-Corps @ UAB provides the infrastructure, resources, advice, networking opportunities, training, and funding for motivated entrepreneurs to develop effective solutions to customer problems. The five-week I-Corps@ NCATS Short Course is offered regionally several times a year. Participants attend two face-to-face sessions (the kick-off and finale), and will conduct customer discovery during the three weeks in between, checking in virtually during "office hours." Participants learn how to:

- Determine the commercial viability of an innovation;
- Develop a successful business case for securing funding;
- Grow a network of innovation partners, mentors, and potential collaborators; and
- Develop greater self-confidence and a new way of thinking about how to value the impact of research.

Visit www.uab.edu/icorps for more information.



LICENSE & OPTION AGREEMENTS

NEGOTIATING INTELLECTUAL PROPERTY AGREEMENTS WITH UAB

LICENSING

UABRF is the contracting agency of UAB for intellectual property. A UAB employee and start-up company can expect the following during the licensing process:

- UAB will not license to an individual; only to an existing company or a start-up company. A start-up company must be able to demonstrate that it has the resources to adequately develop/commercialize the intellectual property it wishes to license.
- Under a license agreement, UABRF will generally require the start-up company to agree to provisions that are consistent with licenses to non-inventor associated companies (taking into consideration the unique circumstances of each technology and transaction).
- The start-up company should find an appropriate non-UAB affiliated individual to negotiate the terms of a license agreement. This can be another person working for the start-up company, who does not have a conflict with UAB or it could be someone, such as an attorney, hired specifically to represent the start-up company in the negotiations.
- All start-up companies will be treated similarly as any other university licensee. If a start-up company fails to meet the diligence provisions, make financial payments or otherwise meet its obligations under a license agreement, the company risks losing the license.

TYPICAL AGREEMENTS

UABRF can grant rights to access and use intellectual property made at UAB and owned by UABRF through various agreements. The most common of these agreements are:

- Option Agreement: an agreement whereby an outside party takes a right to exercise an option to license a UABRFowned intellectual property in a prescribed amount of time and under certain conditions set forth in the Option Agreement.
- Non-Exclusive License Agreement: an agreement whereby an outside party has a right to utilize UABRF-owned intellectual property on a certain basis but does not have the right to exclude others from using such intellectual property.
- Exclusive License Agreement: an agreement whereby an outside party has a right to utilize UABRF-owned intellectual property and to exclude others from using such IP in an enumerated Field of Use and Territory which are both set forth in the Agreement.

TYPICAL TERMS & CONDITIONS

HIIE staff negotiate intellectual property licenses and the UAB Office of Counsel reviews all such contracts. Typical licensing agreements require some or all of the following terms based on the comparable market rates for specific innovations:

- Intellectual property protection expense reimbursement;
- A one-time licensing fee;
- Royalties on sales;
- Sublicensing rights, royalties and terms;
- And where appropriate and satisfactory to both parties, equity in the start-up entity.





WHEN SHOULD I CONTACT MY DEPARTMENT CHAIR AND DEAN TO DISCUSS PROPOSED START-UP-RELATED ACTIVITIES?

As soon as possible. Their early involvement is critical to helping you succeed, particularly as they will need to approve of the activity and manage your conflicts of interest and commitment.

HOW MANY DAYS MAY I DEDICATE TO START-UP-RELATED ACTIVITIES?

It depends. Employment and other activities outside of UAB are regulated by HR Policy 128. External activities are allowed as long as they do not interfere with other institutional responsibilities as an employee, they are compatible with the interests of UAB as a public academic institution and they do not violate state law and policy related to use of UAB resources or facilities. Per HR Policy 128, employees may pursue external activities on nights and weekends, University and personal holidays and vacation and may reasonably rearrange work schedules to release no more than twenty (20) typical working days per year and recommend no more than five (5) days be rearranged per quarter. Additional information is available in UAB Enterprise Conflict of Interest and Conflict of Commitment Policy and the "External Activities" section of the UAB Faculty Handbook.

AS A UAB EMPLOYEE, WHAT ROLE MAY I TAKE IN THE NEW COMPANY?

Generally, the licensing of technology to a company requires the assistance and support of the inventor(s) both before and after the execution of the license. The vision, passion and expertise of the inventor are often necessary in launching and sustaining an early stage technology company. However, full-time employee roles and responsibilities at UAB are incompatible with the significant managerial responsibilities associated with a start-up business. Managerial roles at these types of businesses, such as president, CEO, CFO or COO, should be filled by professionals who possess the appropriate expertise and business acumen. An inventor may participate through consultant or advisory roles (e.g., chief scientific officer, chief technology officer) by following UAB's External Activities approval process.

Employee inventors wishing to be involved in an early-stage technology company should work with the HIIE to complete a Company Development Plan and submit a UAB External Activities form as early as possible. Only in rare circumstances will an employee be approved to fill a managerial business role and remain a UAB employee. The supervisors of the employee will need to make a compelling case to the Entrepreneurial Oversight Committee for this default position to not apply.

ARE THERE DISCLOSURE REQUIREMENTS IF I ACQUIRE A NEW FINANCIAL INTEREST?

There will likely be additional disclosure requirements after acquiring a new financial interest. Your requirement to disclose will depend on a number of factors including but not limited to: the type/nature of your financial interest; whether or not your UAB research is related to the entity's interests; and the types of sponsored research in which you are involved. The disclosure requirements are based on Conflict of Interest Conflict of Commitment policies. Contact the CIRB for additional guidance.





HOW DO I ADDRESS MY POTENTIAL CONFLICT OF INTEREST IN RESEARCH?

The UAB Conflict of Interest Review Board makes determinations of conflict of interest as it relates to research. The dean and department chair make other conflict of interest determinations related to personnel, procurement and finances, or use of UAB resources. Each potential conflict of interest is unique, therefore the CIRB considers multiple factors when determining whether or not additional safeguards are required to protect the objectivity of the research. Some factors the CIRB considers include but are not limited to: the study design, the status of the entity and the nature of the Investigator's financial interest. Contact the CIRB for additional guidance.

WHAT IF I'M NOT READY TO LICENSE UAB TECHNOLOGY THAT WILL BE THE BASIS OF MY START-UP COMPANY?

A variety of agreements are available to serve the particular needs of the company at different stages of its growth. Initially an Option Agreement to utilize IP may be sufficient. This type of short-term agreement negotiated between the Start-up Entity and UABRF provides for an exclusive negotiation period in exchange for limited financial consideration to UAB. This allows the start-up to perform any necessary due diligence around the IP and business opportunity, refine its commercialization plan and negotiate the license without being concerned that another party will also be negotiating with UAB. An Evaluation License provides the company with the ability to conduct more in-depth due diligence, including evaluating how the technology works in the company's hands or performing proof of concept experiments to confirm the viability of the company's plans. HIIE licensing staff can explain the different licensing arrangements to help determine the best fit for company based on its current circumstances.

WHAT HAPPENS IF MY COMPANY DEVELOPS IP?

It is anticipated that, during its research and development activities, a company will develop new IP that is distinct from the in-licensed UAB IP. If the new IP is generated independently by the company without UAB resources or UAB employees, the company will usually own the IP. If UAB funds, facilities or employees were involved in generating the IP, UAB is likely to have at least a joint ownership position in the IP. Similarly, if no UAB resources are used but company employees and UAB employees are co-inventors or co-authors, IP ownership may be shared in the resulting invention.

MAY I INVOLVE STUDENTS IN THE START-UP?

Possibly, under certain conditions. An Individual Development Plan must be a) developed in collaboration with the student's mentor and b) approved by the Graduate School, prior to start of the work. It is the responsibility of the graduate student's faculty mentor to comply with the IDP, for amending the plan and seeking additional approval as the situation dictates (uab.edu/idp).



BEST PRACTICES FOR LAUNCHING A START-UP

Consult HIIE to protect/disclose possible intellectual property Discu<mark>ss and ve</mark>t idea with department chair and dean

Working with the HIIE, complete the Company Development Plan template If the anticipated company personnel includes foreign nationals, postdocs or graduate students; see special guidance po<mark>ssibilities</mark> by scheduling a CCTS iPanel & participating in the I-Corps program

Explore business

Build a management team, including preliminary conversations with independent legal counsel

Seek External Activities approval for the anticipated startup activity Work with the HIIE, obtain Entrepreneurial Development Committee and Entrepreneurial Oversight Committee approval

Contact HIIE to establish licensing agreement if licensing IP from UABRF

Post EOC approval, register/form company per the rules of the state of incorporation



UAB RESOURCE CHART

SUBJECT AREA	OFFICE	CONTACT
Connecting to the start-up ecosystem	Bill L. Harbert Institute for Innovation and Entrepreneurship	Licensing Associates
Patent application License UABRF IP	Bill L. Harbert Institute for Innovation and Entrepreneurship	Licensing Associates
Company sponsored research	Office of Sponsored Programs	Associate Director of Industry Sponsored Research
Financial disclosure requirements related to research Prepare for upcoming Conflict of Interest Oversight Committee review	Conflict of Interest Review Board	Office of the CIRB
Approval of start-up External Activity of faculty/staff/employees	School and Department	Dean and Department Chair





The UAB Entrepreneurial Development Committee aims to build and refine this guide with feedback from the entrepreneurial community. The following members of the EDC invite stakeholders to share thoughts, suggestions and comments by emailing innovation@uab.edu:

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APPENDIX: SBIR/STTR FUNDING

UAB is committed to improving society through processes and products. Our campus abounds with innovations that can potentially benefit the public through development and commercialization. UAB scientists are the source of a wealth of innovative ideas and may choose to form and operate a new company based on new ideas. The inventor provides the technical expertise and vision to guide a company's initial research and development and his/her continued role in a company is based on their expertise and interests. However, as the company matures and additional investment is needed, the founder's role will likely change. In established companies, the founder generally offers consulting services and may serve as an unpaid member of the board of directors or on the scientific advisory board. UAB has a long history of entrepreneurial activity and the university is supportive of its entrepreneurs. It is also an institution of public trust and strives to balance innovation and entrepreneurial activities with transactional transparency. This short guide is intended to lead new entrepreneurs to success and help avoid common pitfalls.

SBIR/STTR GUIDANCE

A number of federal agencies receive mandated set- aside funding to support research and development activities under the Small Business Innovation Research program (SBIR) and the Small Business Technology Transfer program (STTR). Public, US-based, small business concerns (SBC) (< 500 employees) are eligible to apply for these grants and contracts with the goal of stimulation of technical innovation and private sector commercialization of technology developed through federally-supported research and development. These funds can only be awarded to small business concerns as defined by federal regulations.

In some instances, the SBC applicant desires UAB faculty and/or other employees to participate in the research to advance the company's development aims, facilitate the transfer of technology and improve the well-being and productivity of society. UAB employees also provide valuable experience and knowledge. In other cases, UAB faculty, students, and staff want to start companies and view SBIR and STTR grants as a good way to fund further research of intellectual property that they developed at UAB, which is not the intent of these programs.

While SBIR and STTR activities are encouraged, they may also give rise to conflict of interest and conflict of commitment issues, and should be discussed with division directors, department chairs, and deans. The Office of Compliance and Risk Assurance, the Office of Counsel, the Office of the Vice President for Research and the HIIE work collaboratively to balance support for entrepreneurial activities with compliance requirements. The following Guidelines and Frequently Asked Questions are intended to assist members of the UAB research community in addressing and, if possible, resolving, the potential issues that may arise when they want to participate in SBIR- or STTR-funded research.



APPENDIX: FEDERAL SBIR/STTR GUIDELINES

FEDERAL SBIR/STTR PROGRAM GUIDELINES

Only small business concerns (SBC) may apply for SBIR and STTR grants. A SBC must be an independently operated, for-profit, American-owned business with 500 or fewer employees. UAB is not an SBC and is not eligible to be a direct recipient of SBIR or STTR but does meet the criteria to serve as a Research Institution (RI) for such grants. The involvement of UAB occurs via a subcontract from the SBC to UAB. When there is involvement of UAB as the RI, there is a Principal Investigator (PI) for the SBC and a separate PI for UAB.

SBIR:

- The SBIR PI must be employed more than 50% by the SBC. The SBC should be the PI's primary employer, and thus, full-time UAB employees are not eligible to serve in this role.
- SBIR SBC applicants may choose to collaborate with an RI but are not required to. If the SBC chooses to sub-contract with UAB or multiple RIs, the SBC must do 67% of the research during Phase 1 and 50% during Phase II.
- Research conducted by the SBC must be conducted in research facilities it either owns or controls. A company whose research facilities consist only of a mailing address or business office does not meet these eligibility requirements.
- The company must also demonstrate possession and use of a basic accounting system for Phase I
 awards and a system that is sophisticated enough to calculate "cost plus fixed fee" (CPFF) for Phase II
 awards. The company's time-keeping system must be able to capture total work effort and effort
 breakdown. A company whose research facilities consist of only a mailing address or a business office
 does not meet these eligibility requirements.

STTR:

- STTR SBC applicants must collaborate with an RI, subcontracting a minimum of 30% (up to 60%) of the proposed work to the collaborating RI. The RI must be a non-profit college or university, a domestic non-profit research organization or a federally-funded Research and Development Center.
- Between 40% and 70% of the research must be conducted by the SBC in research facilities it either owns or controls. A company whose research facilities consist of only a mailing address or a business office does not meet these eligibility requirements.



APPENDIX: UAB SBIR/ STTR GUIDANCE

UAB SBIR/STTR PROGRAM GUIDANCE

Plans for proposed research to be conducted at UAB under the SBIR or STTR programs must be reviewed and approved by the UAB PI's division director, department chairs or deans before the SBC submits the application to the federal sponsor. The entire proposal (not just the UAB subcontract/portion of the research) must be reviewed and approved by UAB, including the budget. The review will be based on the following criteria:

- The proposed work has scientific merit.
- The work constitutes good use of UAB research facilities.
- The work does not compromise the faculty member's academic responsibilities or the staff member's responsibilities.
- The subcontract is for a unique and specific scope of work distinct from the research funded by other outside entities, and for work that does not overlap with the UAB faculty member's other research efforts.
- Budgets will reflect full cost recovery (direct and indirect) for the portion of the research project to be conducted at UAB, including the UAB PI and other personnel time.

The SBC PI and the UAB PI completing the subaward portion of the research may not be the same individual. The SBIR/STTR policy, instructions and project percentage requirements/effort make clear that establishing a separation of entities and roles is important. Having the same person on both sides of the collaboration blurs the respective parties' roles, responsibilities and commitments. If UAB faculty are committed 100% institutionally to the university, they will not have the effort available to meet the effort requirement of service as the SBC PI for the purposes of SBIR/ STTR. UAB faculty members that want to serve as SBC PIs must be prepared to reduce their time commitment to UAB to less than 100%.

An Allocation of Rights agreement for Project IP must be put in place between the SBC and UAB in order for UAB to issue a Letter of Support to the SBC for the proposal.

If the SBC's proposed project will use UAB-owned background intellectual property, the SBC must contact the HIIE as soon as possible to begin negotiation of an agreement. A background IP agreement must be in place prior to UAB's acceptance of the subaward.

The SBC's portion of the research should be conducted only at the SBC's research facilities, not at UAB or the UAB PI's laboratory.

UAB provides service and support for the UAB side of the research, i.e. letter of intent for collaboration, subcontract execution, etc. but is unable to assist the SBC with the company portion of an SBIR/STTR or other company proposal for research.



APPENDIX: FAQs

I AM A UAB FACULTY MEMBER WITH AN EQUITY INTEREST IN A UAB START-UP ENTITY. I WANT TO APPLY FOR STTR FUNDING AND UAB (SPECIFICALLY MY LAB) WILL BE THE RESEARCH INSTITUTION PARTNER. HOW CAN I MAKE THIS A SMOOTH PROCESS?

- Reach out to your dean, department chair or division director to facilitate proactive consideration of the situation. It is the dean or division director's responsibility to ensure that the conflict of interest and conflict of commitment can be adequately managed and that a COI/COC management plan is instituted and complied with for all parties.
- Ensure that any equity interest in the start-up company has been fully disclosed with the Conflict of Interest Review Board via their electronic filing system. Interest in a start-up entity, even if the value is nothing or unknown, meets the criteria for a Significant Financial Interest (SFI) and must be disclosed and appropriately managed.
- Ensure that there is a designated PI of the SBC (company) portion of the research and that there is a designated PI of the UAB (RI) portion of the research, and that they are not the same person.
- Ensure that the UAB PI submits the 30-Day Notice of Intent to Submit an SBIR/STTR Proposal e- form and that the full proposal and required documents are submitted to the UAB Office of Sponsored Programs at least five (5) business days before you plan to submit the application. Ensure your company has adequate resources to carry out the SBC portion of the research; both technical and administrative. UAB resources may not be used to apply for the STTR or used to perform the SBC portion of the research.

I WOULD LIKE THE RESEARCH ADMINISTRATOR FROM MY DEPARTMENT TO HELP ME PREPARE THE SBIR APPLICATION FOR MY COMPANY. UAB IS THE RI ON THE SBIR PROPOSAL. IS THIS OK?

No. University resources may not be used to perform the SBC's portion of the work, including proposal preparation. The research administrator can provide support for the UAB side of the research collaboration, performing such tasks as preparing the UAB budget, obtaining the Letter of Support from OSP and preparing the subcontract upon award.

CAN STUDENTS WORK FOR THE SBC IN WHICH THEIR UAB SUPERVISOR OR PROFESSOR HAS A FINANCIAL INTEREST WHILE THEY ARE ENROLLED AT UAB?

Possibly. The potential benefits of being involved in a faculty member's outside activities should be weighed against other considerations such as the student's ability to concurrently work and effectively engage in their academic activities. Students should share their particular situation with the dean of Graduate School or the associate dean for postdoctoral affairs who will consult with the Entrepreneurial Development Committee.



