



## **Campus Administrative Policy**

**Policy Title: Faculty Entrepreneurial Activity & SBIR/STTR Collaboration**

**Policy Number:** 6008      **Functional Area:** Research

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**Supersedes:** N/A (New Policy)

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**Reviewing Office:** Office of University Counsel

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**Applies to:** CU Anschutz  
CU Denver

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### **A. Introduction**

The University of Colorado Denver | Anschutz Medical Campus (the “University”) encourages its employees (“University Employee(s)”) to interact with business and industry, public and private organizations, and government agencies in ways that support the University’s mission,

including the formation of start-up companies based on discoveries made as a University Employee. However, University Employees must balance all teaching, research, outreach, and other activities with their entrepreneurship endeavors. Specifically, University Employees shall not compromise their employment activities or leverage their positions within the University for their own financial and/or personal benefit, whether such benefit is real or perceived. The University is bound by certain federal and state laws, rules, and regulations related to use of government funds, government-funded space, and conflicts of interest. The purpose of this policy is to ensure University Employees are aware of their obligations when forming a University Employee Owned Company. The goal of this policy is to provide clear guidance to faculty so that they can be successful in these endeavors.

## **B. Definitions**

1. Immediate Family Member means the spouse/domestic partner, ex/former spouse/domestic partner, parents/in-laws, and dependent child/children of a faculty member or a CU Denver | Anschutz employee.
2. SBC PI refers to a Principal Investigator (PI) at a small business concern on a SBIR or STTR award.
3. Samples and/or Data means any biological specimen (i.e., blood, tissue, urine, etc.) taken from a participant in a research study or clinical setting, or lawfully obtained via a legally approved transfer, such as under a Material Transfer Agreement or as properly obtained from an affiliate hospital or clinic. “Data” refers to any characteristics or information, usually numerical, that are collected through observation in furtherance of research.
4. Small Business Concern (SBC) is a business that is independently owned and operated and not dominant in its field of operation; has its principal place of business in the United States and is organized for profit; is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; has, including its affiliates, not more than 500 employees; and meets

other regulatory requirements established by the Small Business Administration at 13 Code of Federal Regulations (CFR) Part 121.

5. Small Business Innovation Research (SBIR) Program is a three-phase federal assistance program administered by multiple federal awarding agencies and authorized by the Small Business Innovation Development Act of 1982 (P.L. 97-219), and reauthorizing legislation (P.L. 99-443, P.L. 102-564, and P.L. 112-81).
6. Small Business Technology Transfer (STTR) Program is a three-phase federal assistance program administered by multiple federal awarding agencies and authorized by the Small Business Reauthorization Act of 1997 (P.L. 105-135), and reauthorizing legislation, P.L. 107-50, P.L. 112-81 (SBIR/STTR Reauthorization Act of 2011), and as reauthorized and extended under Public Law 114-328, Section 1834.
7. Sponsored Project means any externally-funded activities in which a formal written agreement, i.e., a grant, contract, or cooperative agreement, is entered into by the University and the funding agency, foundation, or other third-party entity, including industry funders or sponsors.
8. University refers to the University of Colorado Denver | Anschutz Medical Campus, and University of Colorado Denver South Denver location.
9. University Employee means any University faculty (including volunteer or adjunct faculty), University Staff, or University Classified employee as defined by University Human Resources policy, regardless of FTE status.
10. University Employee Owned Company means an SBC owned in whole or in part by a University Employee or their Immediate Family Member or controlled by a University Employee or their Immediate Family Member including for- and non-profits and which reasonably appears to relate to the individual's University responsibilities.
11. University PI refers to a University employee or faculty appointee designated as a PI on a SBIR or STTR sub award made to the University.

### **C. Policy Statement**

1. **Attachment A** to this policy outlines the obligations a University Employee must follow when seeking to establish a University Employee Owned Company (“UEOC”) while continuing to be employed by the University.
2. **Attachment B** to this policy outlines the additional obligations that the University Employee must follow if the UEOC applies for or receives federal Government funds for various scientific research and development projects through the Small Business Innovation Research (“SBIR”) and the Small Business Technology Transfer (“STTR”) programs.

### **D. Commitment to Time**

1. All Officers of the University, in addition to the requirements set forth in this Policy, are required to follow Administrative Policy Statement 4013: Disclosure of Interests and APS 5012: Conflicts of Interest and Commitment in Research and Teaching.
2. The Conflicts of Interest (“COI”) Office is responsible for collecting conflict of interest disclosures in accordance with the CU Denver | Anschutz COI and Commitment Policies and Procedure document. The COI Office will also coordinate with all interested parties to ensure that an appropriate management plan is drafted and agreed upon by all interested parties if the conflict is one that can be managed. It is also responsible for centralized document storage of COI management plans.
3. It is the responsibility of the dean of the University Employee’s school or college, the University Employee’s direct supervisor, and the University Employee to ensure management plans are adhered to and, in coordination with the COI Office, ensure management plans are routinely updated to reflect any significant changes. It is the responsibility of the COI Office in collaboration with the University Employee, to ensure that management plans are developed, approved, and filed with the COI Office.
4. The anticipated commitment of time must be initially disclosed by the University Employee to the University Employee’s direct

supervisor when a UEOC is formed and declared to the University as part of the initial COI disclosure. All University Employees must report any existing UEOC to the COI office within 12 months of the effective date of this Policy.

5. It is the responsibility of the University Employee's direct supervisor to review and oversee the disclosed anticipated commitment allocation to determine if it is feasible for the University Employee to also be able to fulfil their employment obligations to the University, based on their percentage of employment. Time commitments to a UEOC must be disclosed by the University Employee to his/her direct supervisor along with the COI disclosure form which shall be updated should the originally disclosed commitment change. For tenured and tenure track faculty subject to the 1/6 rule, they must receive approval from their Dean, whose approval is then also provided to the COI Office.
6. Effort for the UEOC which is anticipated to be more than 4 hours per week, 1 day per month, or 12 days per year requires notification to the University Employee's applicable department Head or Dean above the direct supervisor and will be documented in the COI management plan acknowledging the disclosed time allocation is acceptable prior to University Employee's effort being committed to the UEOC. Any University Employee who desires to commit time to a UEOC above the limits set forth in this Policy may be required to reduce their employment percentage with the University accordingly.
7. University Employees who desire to provide any type of services (not including Sponsored Projects) to a company in which they have an equity interest, must document their effort via a consulting agreement. If the University Employee is subject to a Member Practice Agreement<sup>1</sup>, they must have the consulting agreement reviewed and approved through CU Medicine.
8. In no event shall a Sponsored Project agreement be entered into directly between a UEOC and a third party if the University is an

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<sup>1</sup> University faculty members with an appointment over 0.5 FTE in the School of Medicine are required to sign a Member Practice Agreement assigning service income to CU Medicine. This requirement applies for faculty even if they are not providing clinical services (i.e., hold a PhD).

eligible recipient of the funding and able to provide the necessary services, as further detailed in Attachment A. Any deviation from this requirement must be approved by the Dean of the school or college of the University Employee proposing the arrangement. This requirement applies regardless of FTE percentage and funding source. In the event the UEOC is a direct recipient of grant funding via an SBIR or STTR grant, the UEOC must enter into a contract with the University for the work to be performed at the University.

## Notes

1. Dates of official enactment and amendments:  
October 1, 2020: Adopted/Approved by the CU Denver and CU Anschutz Chancellor
2. History:  
October 1, 2020: New Policy.
3. Initial Policy Effective Date: October 1, 2020
4. Cross References/Appendix:
  - Application and Proposal Approval Process for Sponsored Projects
  - Procedures for Evaluating Conflicts of Interest and Commitment
  - *Regent Policy 3B: Conflict of Interest – University Staff*
  - *Regent Policy 13.E: Fiscal Misconduct*
  - *Administrative Policy Statement 1012: Sponsored Research Policies*
  - *Administrative Policy Statement 2027: Code of Conduct*
  - *Administrative Policy Statement 4013: Disclosure of Interests*
  - *Administrative Policy Statement 5012: Conflicts of Interest and Commitment in Research and Teaching*
  - *Campus Policy 3035: Facilities Use by Employees and Students*
  - *Campus Policy 3036: Facilities Use by External Entities*
  - *Campus Policy 1005: Faculty Compensation – CU Anschutz*
  - *Campus Policy 1006: Faculty Compensation – CU Denver*

## ATTACHMENT A

### **Requirements for Current University Employees who wish to establish, or have established, an UEOC.**

- 1) University Employee Start-Up Companies. A University Employee must notify the University of existing UEOCs and their intent to create a UEOC through the COI office. The University Employee must:
  - a) Notify the applicable Department Head/Chair, Dean of the University Employee's school or college (if applicable), or the Chancellor or their designee of any UEOC or any UEOC they intend to form, prior to establishment.
  - b) Work with the University COI Office to establish a baseline conflict of interest management plan based on the initial 3 year goals of the proposed company.
- 2) Investment in a UEOC.
  - a) Any personal investment by a University Employee in a UEOC must be declared per COI disclosure requirements;
  - b) Any Chair, Department Head or Dean who wants to invest in a company founded by a University Employee must discuss their desire to invest in a UEOC with their applicable Dean, or Chancellor or their designee, and secure appropriate approvals from said Dean or Chancellor prior to investing.
  - c) Any Department that desires to invest in a UEOC must obtain prior approval from the Dean of the applicable School or College or the Chancellor, as applicable.
- 3) Externally Funded Projects.
  - a) Any project funded by the Federal Government or an industry sponsor where the University is an eligible recipient and able to provide the necessary services must be applied for by the University and routed through the Office of Grants and Contracts or the Clinical Research Administration Office. A UEOC cannot receive these funds directly. Please keep in

mind that other requirements may apply when a UECO receives other funding from the Federal Government or other external sponsor.

4) Samples and / or Data.

- a) Samples and/or Data collected or currently stored at the University are generally owned and/or controlled by the University except as limited by contract or data sharing requirements. Further, the University does not sell or make exclusively available Samples or Data to commercial entities, including start-up companies and UEOCs, unless the commercial entity enters into a collaborative research and/or commercialization relationship with the University.
- b) Transfer of Samples and/or Data to a UEOC requires the University Employee to conduct an inventory of the Samples and/or Data concerned as well as copies of applicable study participant consent forms or Material Transfer Agreements (“MTAs”). The Office of Regulatory Compliance will review all applicable documentation to determine the current restrictions on the use of said Samples and/or Data.
- c) Restrictions and /or limitations as to the use of such Samples and/or Data will be detailed in an MTA executed between the UEOC and University prior to transfer of any Samples and/or Data.
- d) Prior written approval of the Department Head and Dean, as appropriate, is required before such an MTA transferring Samples and/or Data as described in this Policy can be executed.

5) Research and fee-for-service contracting back to the University (excluding SBIR and STTR awards, which are outlined in Attachment B). All research or fee for service activities provided by the University for an UEOC must be contracted and budgeted at fair market value as determined by the Executive Vice Chancellor for Administration and Finance and Chief Financial Officer for UEOCs involving CU Anschutz Campus University Employees for activities taking place at the CU Anschutz Campus, and the Senior Vice Chancellor for



Administration and Finance and Chief Financial Officer for UEOCs involved CU Denver University Employees and activities taking place at the CU Denver Campus. These approvals will be coordinated by the office of Grants and Contracts in processing these contracts. Any research or fee for service activities performed by the UEOC related to the University Employee's activities at the University must be contracted to the University unless approved by the appropriate Dean.

- 6) Use of Facilities. The UEOC must demonstrate functioning space in which research, development, and/or fee-for-service activities can and will take place. University facilities cannot be the location for the research, development, and/or fee-for-service activities of the UEOC unless this work is conducted under a University-UEOC subcontract or fee for services agreement at fair market rates. A University Employee cannot use the University or its address as the registered agent or for the purpose of receiving mail/packages.
- 7) Departmental Review and Approval. Proposals to conduct research at the University involving a UEOC must be reviewed and approved by the appropriate Department Chair, or designated representative, and the Department fiscal administrator, to ensure that the proposed project has scientific or mission-related merit, constitutes a good use of University space, is appropriately managed from a fiscal standpoint, and that the project will not compromise the University Employee's academic responsibilities.
- 8) UEOC Employment.
  - a) The appropriate Department Chair or Dean must provide prior approval if any University Employees or postdoctoral researchers desire to hold a management or officer position, a position as a member of the Board of Directors or of the Scientific Advisory Board, or undertake any responsibilities with a UEOC. Any involvement described in this paragraph 7(a), if approved, must be managed with a COI management plan.
  - b) No University Employee, including any faculty member or University staff member, may utilize their position at the

University to influence or participate on behalf of a UEOC in making business decisions or negotiating agreements between the UEOC and the University.

- c) University Employees may not require nor allow their graduate students or postdoctoral researchers to be employed by the UEOC without special institutional approval. Graduate students or postdoctoral researchers who wish to be employed by the UEOC must get prior written approval from the Vice Chancellor for Research. Additionally, undergraduate students and graduate students may not perform work for either the University or the UEOC when the University Employee has a financial interest in the UEOC and the University Employee is the student's mentor.

## ATTACHMENT B

### **Additional Requirements for UEOC that Apply for or Receive SBIR or STTR Funding from the Federal Government:**

1. PI Designation. The SBC PI and the University PI (“Subcontractor PI”) must be different individuals. If the SBC PI and University PI are immediate family members, then if the conflict can be managed, a COI management plan must be approved by the Office of Regulatory Compliance.
2. Required Subcontract or Fee For Service Agreement. All work performed for, or in connection with, any SBC using University facilities, equipment, materials, employees, students, and/or other resources must be performed under a fully negotiated and executed agreement at negotiated fair market rates between the University and the SBC. The PI must work with the Office of Grants and Contracts on the agreement between the SBC and University. Such agreement must be in place before work on the University side can begin for the Sponsored Project and/or program.
3. Scope of Work. The SBC’s scope of work must represent a significant portion of the research and/or development activities for the entire award. For any project involving an SBC, there must be a clear distinction between the work done by the SBC and the work performed by the University.
4. Limitations on Subcontracts to the University. A University Employee who has an ownership interest in a SBC, regardless of the monetary value, must be managed in accordance with University COI policy. The PI must have a management plan approved by the Office of Regulatory Compliance before the subcontract will be executed. Existence of a COI plan will be confirmed by OGC.
5. SBC Requirements. The SBC must have evidence of functioning space in which research and/or development activities can and will take place. University facilities must not be the location for the immediate research and development activities of the SBC unless this work is

conducted under a University-SBC subcontract or fee for service agreement, as appropriate.

6. Employment Limitations. No University student, staff member, visiting researcher or visiting scientist may perform work (either scientific or administrative) related to the University's portion of a SBC's SBIR or STTR award and concurrently serve as an employee or intern of that SBC. This limitation does not apply to faculty members, subject to applicable grant terms and conditions and regulations.
7. Prior Approval. Any University Employees or postdoctoral researchers that hold a management or officer position, a position as a member of the Board of Directors or of the Scientific Advisory Board, or undertake any responsibilities with a SBC must be managed with a COI management plan.
8. Misuse of Position. No University employee, including any faculty member or University staff member, may utilize their position at the University to influence or participate on behalf of a SBC in making business decisions or negotiating agreements between the SBC and the University.
9. Departmental Review and Approval. Proposals to conduct research at the University under a SBIR or STTR subaward must be reviewed and approved by the appropriate Department Chair, or designated representative, and the Department fiscal administrator, to ensure that the proposed project has scientific or mission-related merit, constitutes a good use of University space, is appropriately managed from a fiscal standpoint, and that the project will not compromise the University Employee's academic responsibilities.
10. Student and Postdoctoral Researcher Protections. University Employees may not require or allow their graduate students or postdoctoral researchers to serve as the SBC PI without special institutional approval. Graduate students or postdoctoral researchers who wish to serve as the SBC PI must get written approval from the Vice Chancellor for Research. Additionally, undergraduate students and graduate students may not perform work for either the University or the SBC under an SBIR or STTR award when the University Employee has a

financial interest in the SBC and the University Employee is the student's mentor.

11. Award Terms and Conditions. If the terms and conditions of a SBIR or STTR award are more restrictive than the University's policies, the award terms and conditions take precedence.
12. Intellectual Property. If an SBC applicant for a SBIR or STTR award might require a license from the University for Intellectual Property prior to commencing research under the SBIR or STTR award, the University requires that the SBC contact CU Innovations to inquire about the availability of such rights in advance of execution of the SBIR or STTR subcontract with the SBC.
13. University Employment Restrictions. Due to federal requirements relating to PI effort on SBIR funded grants, no University faculty may hold a greater than 0.49 FTE appointment at the University and concurrently serve as an SBIR PI. In order to be an SBIR PI, a University Employee must have an appointment below 50% and cannot receive benefits at the University.

Should any violation or potential violation of this Policy arise or be discovered at any time, it is the obligation of the University Employee who discovered or becomes aware of such violation or potential violation to immediately notify the Office of Regulatory Compliance and Finance Office so that appropriate remedial action, if necessary, can be taken. This Policy is applicable to all University Employees who participate in an SBIR or STTR collaboration.

## ATTACHMENT C: Federal Requirements

### Obligations under SBIR and STTR programs:

1. The SBIR and STTR programs have regulations concerning financial conflicts of interest between award recipients and collaborators (subcontractors), in addition to effort allocation between the University and the SBC. Participation in these programs involving the University and a SBC can create a conflict of interest for University Employees, particularly if a University Employee has an equity interest in, works for, or has another form of relationship with the SBC.
2. Only an eligible SBC may submit an application for funding through the SBIR and STTR programs. The University may collaborate as a subcontractor or as a service provider with a SBC and receive funds through a sub award agreement or fee for service agreement with the SBC.
3. SBIR and STTR programs have different eligibility and participation requirements. Please reference each federal agency for their guidance <https://sbir.nih.gov/policy> (for NIH), <https://www.nsf.gov/pubs/2018/nsf18550/nsf18550.htm> (for NSF), and <https://www.acq.osd.mil/osbp/sbir/about/governing-laws-directives.shtml> (for DOD) for federal conditions associated with receipt and administration of these grants.
4. In general, SBIR program requirements of participating federal awarding agencies include (and is subject to change by the granting agency):
  - a. The proposal must be submitted by an eligible SBC.
  - b. The primary employment (more than 50%) of the Principal Investigator (PI) must be with the SBC at the time of award and for the duration of the project. Primary employment with a SBC precludes full-time employment at another organization, including an academic appointment of 50% or more. Therefore, employees of the University with a .50 FTE or greater may not serve as the PI of a SBIR grant. The only mechanism by which a University Employee may serve as the PI of a SBIR grant is to take

- an unpaid leave of absence from the University or reduce their University appointment to less than 50%.
- c. For projects with multiple PIs, at least one must meet the primary employment requirement. Deviations from this requirement may occur only with written approval from the federal awarding agency.
  - d. During Phase I, a minimum of two-thirds of total effort must be performed by the SBC.
  - e. During Phase II, a minimum of one-half of total effort must be performed by the SBC.
  - f. Collaboration with a research institution is optional.
5. In general, STTR program requirements of participating federal awarding agencies include (and is subject to change by the granting agency):
- a. The proposal must be submitted by an eligible SBC.
  - b. Primary employment for the PI is not stipulated under the STTR program; therefore, the PI may be primarily employed by either the SBC or the University at the time of award and for the duration of the project period. The PI's primary employment means the organization where the PI spends more than one half of their time. This precludes full-time employment with both the University and an SBC at the same time.
  - c. The PI must commit at least 10% of effort to the project. Combined with University activities, effort may not exceed 100%, which may require reduction in University appointment.
  - d. SBCs are required to partner with research universities or other non-profit research institutions which have a formal collaborative and contractual relationship with the SBC.
  - e. In both Phase I and Phase II, at least 40% of the work must be performed by the SBC and at least 30% of the work must be performed by the partnering research institution.