A. INTRODUCTION

This policy outlines responsibilities for the approval of University of Colorado Denver |Anschutz Medical Campus applications for extramural funding and program sponsorship.

The university Principal Investigator (PI), administrative unit, and the Office of Grants and Contracts (OGC) are responsible for complying with and enforcing the processes outlined in this policy.

This policy is applicable to all extramural requests for program funding and sponsorship including grant applications, contract proposals, or other proposals for research, training, or service support. This policy does not apply to gifts, bequests, and donations generated under the authority of the CU Foundation. This policy is applicable to non-monetary agreements which meet the definition of Sponsored Projects as outlined herein.

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C. POLICY STATEMENT

1. All requests for extramural support must include the institutional authorizing signature. This signature authority has been delegated to the Director of OGC by the Chancellor.

2. Sponsored projects, including non-monetary agreements generated by faculty members of university, will be managed by the university. Awards should be directed to the university as the principal institution. Faculty will not divert university awards to other institutions (e.g., CU Foundation, University Physicians, Inc.) for management. All sponsored projects will be subject to applicable university direct cost and Facilities and Administrative (“F&A”) cost policies.

3. If an activity provides for collaborative work at another institution, a subcontract or subaward will be established subject to required approvals with that institution. The subcontracted portion of the award will be subject to applicable award regulations.

4. The primary objective of OGC is to provide administrative support to the extramurally funded projects of the university. It shall also provide administrative review and institutional signature for all agreements meeting the definition of a sponsored project involving extramural funds and non-monetary agreements.

D. DEFINITIONS

1. Application Package is a completed application (scientific presentation, budget, and any necessary administrative paperwork) plus all necessary internal approval forms, i.e., Human Subject Review Committee forms, Animal Care Facility clearances, etc. The terms “application” and “proposal” may be used interchangeably throughout this policy.

2. Approval of Application for Grant or Contract (“Routing Form”) is a form accompanying the completed application or proposal through the chain of university approval. Signatures on the routing form indicate the University's willingness for the proposed project to be undertaken within the terms specified in the proposal and on the approval form. The form is for internal use only and is not to be sent to the sponsor.

3. Consideration of Non-Monetary Research Agreements (“Non-Monetary Form”) is used for projects which involve more than the transfer of material, but do not include financial support from a sponsor. See, Non-Monetary Award definition, D.6., below. The Non-Monetary form is used in lieu of the Routing Form and the form must accompany the non-monetary agreement through the chain of university approval. Signatures on the form indicate the University's willingness for the
proposed project to be undertaken within the terms specified in the contract and Non-Monetary Form. The form is for internal use only and is not to be sent to the sponsor. See, Exhibit C.

4. Extramural Support is funding for research, training, or public service projects provided by federal or private sources outside the University. See definition of Sponsored Project, D.8.

5. Master Agreements are industry sponsored agreements negotiated between the university and a sponsor and include the terms and conditions which will govern future work between the parties. Master agreements generally do not include a scope of work and do not identify an individual (i.e., Principal Investigator) to lead the project. Specific work to be conducted under a Master Agreement is established through the issuance of an attachment to the Master Agreement, e.g., a “task order”, “or “work order”, which includes the scope of work and the amount of compensation to be paid.

6. Non-Monetary Agreements are considered Sponsored Projects, as defined in this policy, but do not include financial support from the external agency or entity sponsoring the agreement. Instead, the sponsor may support the project by providing other goods such as materials, supplies, and/or equipment.

7. Proposal is a document in which a prospective PI describes a plan for a research, training or another project and requests financial support. The terms “application” and “proposal” may be used interchangeably throughout this policy.

8. Sponsored Projects are research, instructional, or public service activities that are related to the mission of the university and sponsored by external agencies or entities. If an award meets at least one of the following criteria, it is likely a Sponsored Project. However, the existence of any one of the criteria may not be determinative.

   a. The award is a grant or contract from a governmental entity, unless exempted under OMB Circular A-21.
   b. The proposal responds to a Request for Application (RFA), Request for Proposal (RFP), or other formal solicitation, and the project is initiated by notice of award. Certain RFPs issued by private charitable foundations may not qualify as a Sponsored Project.
   c. The award includes terms that bind the university to a list of scholarly or scientific inquiry.
   d. The Statement of Work specifies programmatic objectives mutually agreed upon by the university and the sponsor, which are to be accomplished within a specific period of time or within a detailed budget framework.
   e. The sponsor is entitled to receive the following types of deliverables: a detailed technical report of research results, milestone reports, or a required report of allowable expenditures. Certain reporting requirements of private
charitable foundations that are stewardship- or accountability-oriented may not qualify as Sponsored Projects.

f. The award requires separate accounting procedures and detailed financial reports.

g. The sponsor requires the return of unexpended funds or only reimburses for incurred costs (expenditure-driven).

h. The award provides for compliance audits by or on behalf of the sponsor, which may or may not include a financial audit.

i. The award is for a project requiring compliance oversight including, but not limited to: human subjects, animal use, biohazards, or bio-safety.

j. The award terms include publication or data restrictions or monitoring.

k. The sponsor requests intellectual property rights or controls the disposition of capital equipment.

l. The award is by a sponsor who has licensing rights to inventions from the same lab/researcher benefiting from the award.

m. The sponsor designates a sponsor employee (agent) as project technical monitor (as opposed to designating a contact person to improve communications).

n. The award is for a sub-award project under a federal award.

o. The award requires a matching or cost sharing commitment on the part of the university.

p. The award generates program income to a federal award.

q. The award from the sponsor is for membership fees to centers and affiliate programs. The university may receive membership fees for its centers and affiliate programs, as characterized by any one of the following examples:

1) The member agreement imparts “Center Member” status to the sponsor.

2) The member receives the right to exert any type of control over the operation of the institute, center, or program.

3) The member receives special or discounted access to laboratories or other university facilities for its use.

4) The member receives patent, licensing rights, or other intellectual property rights provisions benefiting the sponsor.

E. **PROCEDURES**

Grants and Contracts processes a large number of grant and contract proposals on behalf of university faculty. In order to track the commitments and risks associated with each proposal, OGC has developed a number of specific administrative processes and procedures to provide an overall review of these activities. To facilitate the review process, the Routing Form, Exhibit A (see also, Instructions for Approval of Application for Grant or Contract, Exhibit B), shall be completed and routed with each application package, proposal, contract, or any other form of request for extramural funding, except for Non-Monetary Agreements. The Non-Monetary Form, Exhibit C, shall be completed for and routed with all Non-Monetary Agreements.

Additional forms that are required in specific situations include the following:

- Clinical Trials Required Form Effort Commitment and Certification Form 4-1d
• Facilities and Administrative Costs Variance Request Form 4-4a
• Proposal Checklist for Direct Charging of Facilities and Form 4-7a
• Administrative Costs
• Request for Account Prior to the Beginning Date of a New Project Form 4-10a
• Request for Intellectual Property Variance Form 4-1b

The routing requirement does not apply to Master Agreements as defined herein (that is, Master Agreements that do not include a scope of work or a PI to perform the work). Once the specific terms of the scope of work and compensation have been finalized, the scope of work and compensation to be paid shall be attached to the Master Agreement by a Task Order or Project Agreement and the application shall be routed as outlined above. The signatures required for processing a Routing Form, along with associated responsibilities, are as follows:

1. The PI is responsible for the technical content and quality of the proposed project. The PI assures that the project and other professional activities are compatible; that no individuals on the project will have commitments in excess of 100 percent effort; and, by signing the routing form, accepts responsibility for the proper technical and financial conduct of the project as indicated in the certification statement on the routing form.

2. Department Chair indicates that the proposed project is appropriate to the department's mission; that staff and budget commitments are in accordance with the departmental Programs and space availability; and the Chair accepts responsibility for technical and financial conduct of the project.

   The Department Chair signature also indicates that the prospective PI is a full-time faculty or academic staff member who possesses the stature, judgment, and technical competence necessary for the direction of the proposed project.

   Additionally, the signature of the Department Chair on the routing form indicates that the PI has not been given notice of termination of faculty appointment; has not tendered a resignation of faculty appointment; and that there are no circumstances known to the chair that would jeopardize the performance of a grant obligation by the principal investigator. (Note: This signature may be an approved designee or other individual in an acting capacity. When the chair or designee is unavailable, the requirement for this signature may be waived by the dean.)

3. Dean or Administrator indicates approval of the academic content of the application; that space and personnel are available with which to pursue the project; and that the project is appropriate to and coordinated with the school or units, programs, and policies. The signature verifies regulatory compliance, such as approval of human subjects and/or animal care protocols; resolution of biosafety issues; and it indicates acceptance of responsibility for financial and technical conduct of the project. (This signature may be a designee or other individual in an acting capacity.)

4. Grants and Contracts indicates that University and sponsor policies have been met
and that the application is complete. Specifically, Grants and Contracts signature indicates:

a. All approvals have been obtained;
b. The budget is in order and any unusual requirements or commitments have been brought to the attention of university administration; and
c. Proper coordination with and notification to the Board of Regents has been made.

5. Other (signatures obtained only when applicable)

a. Legal Counsel indicates the legality of the terms of the award document (grant, contract or other) and/or legality of proposed activities or commitments expressed or implied in the proposal.
b. Vice Chancellor indicates that Central Administration resources are available and that the project is consistent with university programs, plans and policies.
c. Chancellor indicates approval of any deviations from normal policies and procedures. The Chancellor’s signature is also an attestation that the university is willing to undertake the project on the basis of the proposed budget and the conditions detailed in the proposal or contract and on the routing form.

Notes

1. Dates of official enactment and amendments:
   May 1, 2009: Adopted by Vice Chancellor for Research
   April 1, 2011: Updated
   February 11, 2019: Formatting Updated

2. History:
   February 11, 2019: Modified to reflect a Campus-wide effort to recast and revitalize Campus policy sites into a standardized and more coherent set of chaptered policy statements organized around the several operational divisions of the university. Article links, University branding, and formatting updated by the Provost’s office.

3. Initial Policy Effective Date: April 1, 2011

4. Cross References/Appendix: N/A
1. PROJECT TITLE:

2a. PROPOSED PERIOD From __________ To __________

2b. TOTAL PROJECT PERIOD From __________ To __________

3. [ ] New

   [ ] Continuation – Competing

   [ ] Continuation – Non-Competing

   [ ] Current Project No.

   [ ] Award No.

4. [ ] Research Program

   [ ] Fellowship/Traineeship

   [ ] Facilities Request

   [ ] Instructional Program

   [ ] Career Development Award

   [ ] Service Program

5. FACILITIES: Is adequate space available to conduct the project? Yes [ ] No [ ]

Where will the majority (50% or more) of UC Denver effort be performed?

- [ ] Biomedical Research Building (on-campus)
- [ ] Anschutz Out-Patient Pavilion (off-campus)
- [ ] Location given is a [ ] On-Campus Site [ ] Off-Campus Site

6. LAB ANIMALS:

   [ ] Yes [ ] No

   If yes: Protocol Number: ____________________________

   Approval/Reapproval Date: __________________________

7. HUMAN SUBJECTS (HS): Yes [ ] No [ ]

   If yes: Protocol Number: ____________________________

   Approval/Reapproval Date: __________________________

8a. RADIATION SAFETY:

   [ ] Yes [ ] No

   If yes: Auth. Number: ____________________________

   Approval/Reapproval Date: __________________________

   [ ] Ionizing Radiation generating equipment [ ] Other:

   [ ] Radioactive Materials

8b. BIOSAFETY:

   [ ] Yes [ ] No

   If yes: Auth. Number: ____________________________

   Approval/Reapproval Date: __________________________

   [ ] Recombinant DNA [ ] Infectious Agents [ ] Select Agents [ ] Other

9. COST SHARING: Does this proposal contribute any UCD resources (i.e. costs that will not be paid or reimbursed by the sponsor)? Yes [ ] No [ ]

   If yes: a. Is cost sharing required by this sponsor? Yes [ ] No [ ]

   b. Is cost sharing included in the proposed budget? Yes [ ] No [ ]

   c. Is cost sharing mentioned in the proposal narrative? Yes [ ] No [ ]

10. DISCLOSURE OF FINANCIAL INTERESTS: The PI is responsible for ensuring that all individuals performing work under the proposed project have a current Conflict of Interest Disclosure on file with the UCD COI office. Agreed [ ]

   PRINCIPAL INVESTIGATOR: My signature certifies that: 1) I acknowledge and accept responsibility for the technical content and quality of the proposed project; 2) I assure that the project and other professional activities are compatible; 3) I assure that no individuals on the project will have commitments in excess of 100% effort; 4) I accept responsibility for the proper technical and financial conduct of the project; 5) I assure that the information contained on this form and attached application/proposal is true, accurate and complete to the best of my knowledge; 6) I acknowledge and accept responsibility for compliance with award terms and conditions and University policies and procedures, particularly for the technical conduct of the work, submission of technical reports, regulatory compliance, and financial management if an award is made; 7) I assure that arrangements have been made to fund any cost sharing requirements if an award is made; 8) Any items requiring special consideration by the Dean, Chancellor’s Office, Planning Office, etc. have been disclosed; 9) I assure that if a joint appointment with the Veterans Administration exists, a memorandum of understanding has been executed between the UCD and the VA, full disclosure has been made to the NIH or other sponsors as required, and my time and effort will not be double billed for the same effort; 10) I understand that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil or administrative penalties; 11) If an award is made, I am responsible for compliance with award terms and conditions and University policies and procedures, particularly for the technical conduct of the work, submission of technical reports, regulatory compliance, and financial management; and 12) I understand that all individuals performing work under the proposed project must have a Conflict of Interest Disclosure on file the Office of Regulatory Compliance.

   Principal Investigator: ____________________________ Date: ____________________________

11. BUDGETARY ITEMS - If #7 (Human Subjects) is yes, answer the following:

   a. Will this project involve work with HS to be done at UCH, TCH, or any other non-UCD facilities? Yes [ ] No [ ]

   b. Are all research-related patient care costs included in the budget, including any applicable non-UCD facility charges incurred as direct costs? Yes [ ] No [ ]

   If no, explain why under comments or on a separate page attached to this form.

12. CLINICAL TRIAL: Answer the following questions if the project is a clinical trial:

   a. Project sponsor is: [ ] US Govt. agency [ ] agency of U.S. state, country or municipality; [ ] foreign government; [ ] private company

   b. Project hypothesis developed by the PI? Yes [ ] No [ ]

   c. Protocol designed by university personnel? Yes [ ] No [ ]

   d. Who initiated the project? Sponsor [ ] PI

   e. Stage of drug development for trial: [ ] Preclinical testing [ ] Phase I [ ] Phase II [ ] Phase III [ ] Phase IV [ ] New Drug App. has been filed [ ] Device [ ] Other

13. SUMMARY OF PROPOSED BUDGET

   DIRECT COSTS

   Personnel
   - Salaries and Wages
   $ ____________________________

   - Fringe Benefits
   $ ____________________________

   Consultant Costs
   $ ____________________________

   Equipment (over $5,000)
   $ ____________________________

   Supplies
   $ ____________________________

   Travel
   $ ____________________________

   Hospital Patient Care Costs
   $ ____________________________

   Subrecipient(s): How many? ____________________________

   Trainee Costs
   - Stipends
   $ ____________________________

   - Tuition and Fees
   $ ____________________________

   Other Expenses
   - Center for Laboratory Animal Care (at SOM)
   $ ____________________________

   - IRB Review of Industry Sponsored Protocols
   $ ____________________________

   - Rent
   $ ____________________________

   - Tuition Remission & Related Fringe Benefits
   $ ____________________________

   TOTAL DIRECT COSTS
   $ ____________________________

   FACILITIES AND ADMINISTRATIVE COSTS (F&A)

   % F&A ____________________________

   Costs Subject to F&A $ ____________________________

   TOTAL DIRECT AND F&A COSTS
   $ ____________________________

   APPROVALS (To be obtained by PI/Administrator)

   Department Chair or Director
   Date

   Dean
   Date

   Grants and Contracts
   Date

   Instructions (http://www.ucdhsc.edu/admin/policies/G&C/fp4-05a.doc)
Consideration of Non-monetary Research Agreements (that are more than material transfer agreements)

To be submitted to Grants and Contracts in place of Form 4-5a, the Routing Form.

<table>
<thead>
<tr>
<th>PRINCIPAL INVESTIGATOR(s)</th>
<th>PHONE</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPOSOR</td>
<td>CONTACT PERSON</td>
</tr>
<tr>
<td>SCHOOL</td>
<td>DEPARTMENT</td>
</tr>
<tr>
<td>TITLE</td>
<td></td>
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</tbody>
</table>

Contact between the University and the Sponsor, which resulted in this Agreement was initiated by:

- [ ] Sponsor
- [ ] Principal Investigator or other University personnel
- [ ] Other (please explain): ________________________________

Scope of Project (Summary):

Dates of Project:


List benefits to Principal Investigator and Institution (check and attach additional information*):

- [ ] TANGIBLE
- [ ] INTANGIBLE
  - Outside of scope of funded agreements
  - Advance scientific knowledge
  - Compassionate use

List costs to Institution (check and identify dollar amounts, plus attach additional information*):

- [ ] TANGIBLE
  - Personnel $ __________
  - Equipment $ __________
  - Space $ __________
- [ ] INTANGIBLE
  - Invention Ownership/management
  - Publication delay
  - Confidential Information time

Source of Funds/Support for costs* (Identify sources of funding [include speed type])

If patient billing is identified, please identify why it is acceptable to bill considering Medicare and other third party payers position on research related costs.

What association does the Investigator(s) have with this sponsor other than this unfunded agreement?

- [ ] Consultant
- [ ] Significant Payments (> $10K)
- [ ] Equity
- [ ] Ownership
- [ ] Other, explain: ________________________________

Does the scope of work for using this material overlap with the scope of work of any of your other funded research? No [ ] Yes [ ] If yes, explain: ________________________________

Principal Investigator's Signature: ________________________________ Date: _____________

Department Chair's Signature: ________________________________ Date: _____________

Evaluation Criteria:

- [ ] Compassionate Use
- [ ] New knowledge/programmatic benefits exceed economic benefits of agreement
- [ ] Will lead to future funded agreements
- [ ] Other, please explain: ________________________________