Proposal Submission Process (Module 5.00)

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While preparing a proposal for submission to OGC, the following regulatory and safety issues need to be considered and addressed as required.

- Facilities Usage at UCD|AMC
- Completion of Conflict of Interest (COI) disclosure through the Office of Regulatory Compliance
- Animal Subjects
- Human Subjects
- Radiation and Safety
- Biosafety
Facilities Usage at UCD

Is adequate space available to perform the proposed project?

• If no facilities are available for the project or program, the Planning Office must be consulted for additional space or new space. For more information see the Office of Institutional Planning.

• If facilities are available for the project, be prepared to identify the primary location as “on” or “off” campus (see Fiscal Policy 4-4).

Familiarity with all fiscal policies is critical to ensure compliance. List of University of Colorado Denver | Anschutz Policies and Guidelines

• Fiscal Policy 2-4, Use of Facilities and Equipment by Outside Parties or for Private Gain, Fiscal Policy 3-11

• Use of Campus Facilities, Space and Services by External Entities, and/or Fiscal Policy 3-12

• Real Estate Management-Space Acquisition and Use may become applicable in certain circumstances.
Disclosure of Financial Interests

UCD is committed to:

- Maintaining the integrity and truthfulness of its research and scholarship through the responsible and ethical conduct of its faculty, staff and students
- And has instituted policies and procedures for the disclosure of potential conflicts of interest and for handling any perceived conflicts that are disclosed.

A financial conflict of interest is not inherently wrong as long as it is disclosed to the institution and is managed, reduced, or eliminated.

The CU Administrative Policy Statement, Conflict of Interest Policy refers to situations in which outside relationships or activities conflict (such as professional consulting for a fee) or have the appearance of conflicting, with an employee’s commitment to his/her University duties or responsibilities.

Acceptable when:
- They comply with University policy
- Promote professional development of faculty and student employees, and enrich the individual's contributions to the institution, to their profession and to the community

For Example, Consulting relationships may serve to create conduits for the exchange of information and technologies that enhance the University environment and permit faculty to test the soundness of their ideas. Separate policies may apply to faculty; for example, in the School of Medicine, faculty are subject to separate guidelines and required to direct all outside professional activities through University Physicians, Incorporated (UPI).”
Disclosure of Financial Interests

Any UCD|AMC faculty or staff engaging in employment or financial activities outside of UCD|AMC should be familiar with current UCD|AMC policy regarding conflict of interest and the appropriate disclosure rules.

*Contact the Office of Regulatory Compliance for additional information."

OGC requires disclosure of financial interests for each new proposal received. Faculty are to keep their chair and dean or supervisors fully apprised of situations that are or could be potentially perceived as being a conflict of interest.
Animal Subjects

If animals will be used for the project, the PI is responsible for contacting the Animal Care and Use Committee (IACUC) office for the necessary forms and approval procedures.

- During the proposal review “routing” process, OGC will ensure:
  - Date of committee approval and protocol number is completed on the routing form in order to approve the proposal.
  - Approval to use animals is obtained prior to submission of all non-governmental proposals.*

*Some federal sponsors like the Public Health Service (PHS) may accept approvals after the grant application submission. Be sure to review sponsor guidelines as needed for more information on what is or is not required.

You may also contact OGC should you need assistance.
If human subjects are proposed in a research project, UC Denver must review and approve the research protocol before human subject research can be conducted. This includes continuing review and approval.

• The PI must obtain approval for human subjects research protocols and is responsible to work with the Institutional Review Board (IRB)
  - Colorado Multiple Institution Review Board (COMIRB)
  - Western Institutional Review Board (WIRB)

• IRB approval must be obtained before a sponsored project involving human subjects can be established in the UCD|AMC financial system. Lack of an approved protocol will delay award setup.

• Many sponsors accept proposals with a “pending” human subject protection protocol. Federal agencies often utilize a “Just-in-Time” procedure which postpones the requirement to submit an approved protocol until after the peer review process and just prior to the funding.
If using radioactive materials

- Approval is required from the Committee on Ionizing Radiation (CIR).
- The PI is responsible for contacting this office to complete the necessary forms and procedures.
If the project involves the use of biohazards
  ➢ Infectious agents
  ➢ Infectious genetic material
  ➢ Human gene therapy
  ➢ Recombinant DNA or RNA
  ➢ Select Agents

PI must complete the appropriate documentation & submit it to the Biosafety Officer, Health and Safety Division.

Subject to institutional review and approval by:
  ➢ Environmental Health and Safety Committee
  ➢ Infectious Agents Committee and/or
  ➢ Institutional Biosafety Committee.
Proposal Review and Approval

OGC is responsible for all research, instructional, or public service activities that are related to the mission of the UCD|AMC and sponsored by external agencies or entities.

All extramural requests for program funding and sponsorship, including grant applications and contract proposals must obtain institutional authorization prior to being submitted to the sponsor.

- Route all documentation to OGC per campus guidelines

Gifts, bequests, and donations should be submitted to the CU Foundation rather than OGC.
Involves the process of completing and submitting proposal applications for internal approvals:

• Approval of Application for Grant or Contract (Routing Form)
• Contract proposal (or any other form of request for extramural funding)
• The required signatures for processing the routing forms:
  ➢ Principal Investigator
  ➢ Department Chair, Dean or Administrator
  ➢ Office of Grants and Contracts Official

Other signatures obtained only when applicable include Technology Transfer, Resident Counsel (legal review), the Vice Chancellor, and/or the Chancellor.
Proposal Routing – What to Route

The PI is responsible to obtain all appropriate or special signature approvals in the routing process.

- Facilities
- Human subjects
- Lab animals
- Hazardous materials
- Bio-safety agents

At time of submission to OGC, the proposal should be complete administratively and scientifically for the final review and signature unless arrangements have been made for OGC to complete a preview.

The PI may be required to sign other documents either by OGC or the sponsor.

Any required approval by UCD|AMC or the institutional official are to be signed by the OGC’s authorized official for UCD|AMC.
Proposal Routing – What to Route

• Any document or documentation that is submitted to a sponsor or that is considered an attachment to a proposal.
• All such documents should be included in the package of information routed to OGC.
• Route a copy of any special project guidelines to assist OGC in the review process.
Grant applications should be routed with sufficient lead-time. Consider what needs to be achieved and the steps in the process to reach that goal.

- To complete the routing, allocate time to:
  - Secure the department and Dean signatures
  - Obtain OGC’s review and comment on the application
    
    This includes allowing OGC time to identify any problems and for the PI or designee to submit any corrections that need to be made to the routing or application in order to obtain institutional endorsement.
  
  - Obtain Institutional Endorsement

- A good rule of thumb for minimum lead-time on grant applications is to have the application submitted to the Dean’s office 5-7 working days prior to the sponsor’s application submission deadline.
Proposal Routing - Contract Review

Contract proposals typically take more time to review and approve compared to grant applications.

- Often require the negotiation of contract language.
- A Contract Specialist will work with the PI or designee to negotiate the terms and conditions of the contract with the sponsor as appropriate.

Contract proposals should be submitted with **INCREASED** lead time

- Follow the lead time recommendations for Grant Proposals
- Add an additional 2-3 days if your proposal include the need for contract review

Expect the **minimum** lead-time on Contract applications to be **8-10 working days** prior to the sponsor’s application submission deadline.
Document Transfer to OGC

Begin the routing process as early as possible.

When to Route
Route new proposals and continuing proposals that deal with new monies:

- Funds that have not already been awarded to UCD|AMC
- Any new or additional award monies require the completion of an Approval of Application for Grant or Contract (Routing Form).

When Not to Route
Actions that need OGC approval but do not require routing:

- Award notices for proposals that have already been routed
- Executed agreements that have already been routed
- Requests or authorizations for additional time
- Requests for carry forward of monies already awarded
What is the Purpose of Routing?

Routing provides internal approval to OGC of:

- Institutional
- Regulatory
- Safety information
- Written documentation of approval

PI’s should review the certifications contained in the routing materials before signing the routing form and any other institutional or proposal documentation.
What is the Purpose of Routing?

PI provides UCD|AMC with the assurance and certification:

• The routing and corresponding proposal is accurate and complete.

• If awarded, PI is aware that he/she is 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.

• Arrangements have been made for funding any cost sharing requirements.

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What is the Purpose of Routing?

• Disclosures have been made of any items requiring special consideration by the Dean, Chancellor’s Office, Planning Office or Resident Architect.

• If a Research Program or Career Development Award, Disclosure of Financial Interests to Sponsored Research has been completed.

• If there is a joint appointment with the Veterans Administration, a Memorandum of Understanding has been executed between UCD|AMC & VA
  – Full disclosure has been made to the NIH or other sponsors as required; and the PI’s time and effort will not be double billed for the same effort.
If Clinical Trial research, PI also certifies:

- Faculty and staff should have a proportionate amount of their compensation charged to the clinical trial directly or billed to the clinical trial through UPI for related faculty services.

- Clinical trial data collection and analysis expenditures are billed appropriately to the clinical trial and not to medical insurance carriers.

- Patient care billed to a third party commercial or governmental insurance plan is in accordance with the third party commercial or governmental insurance plan requirements.

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If Clinical Trial research, PI also certifies:

- Associated income must be deposited into the UCD|AMC financial system through OGC and/or the OGC lock box mechanism.

- PI understands that a residual balance of equal to or greater than $25,000 at the conclusion of the clinical trial is to be reported through the “Disclosure of Financial Interests Related to Sponsored Research” form (Fiscal Policy 4-9)
  - Reported through annual reporting of conflict of interest to the chair/unit director
  - Reported as required under COMIRB policy.

- It is the PI’s responsibility to apply the accounting practices (allowability, allocability, and reasonableness) for costs associated with the agreement.

  *Costs that are allocable to a particular agreement may not be shifted to other sponsored agreements, to other government or commercial health insurance payers or to the patient.*
OGC Review and Approval

OGC reviews proposals for the following:

- Does the proposal have the appropriate internal approvals?
- Does it meet all sponsor guidelines?
- Is the budget appropriate?
  
  *For example, does the budget calculate correctly?*
- Is the proposal in compliance with University policies and procedures?
  
  - PI eligibility
  - Terms and condition
Routing benefits the PI because it:

- Helps the PI present the best proposal to the sponsor.
- Reduces surprises. The division/department, school and University are all on board with proposal commitments.
- May reduce negotiations between OGC and sponsor.
- May reduce time or administrative efforts handling Post-Award issues after the award is received. 
  
  *Sponsor approvals, cost transfers, etc.*

- Improves relations with sponsors and may improve future funding opportunities.