CHAPTER FOUR: Proposal Review, Approval, and Submission

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4.1 Review and Approval Responsibilities

Proposals must be reviewed and have the appropriate approvals prior to submission to an external funding agency. The review process includes review by the department chair/unit head, the respective dean or designee and potential review and approval by University compliance offices/committees such as the Human Subjects Protection Program/Institutional Review Board (IRB) and Animal Use/Institutional Animal Care and Use Committee (IACUC). Review and approval by the Office of Sponsored Programs Administration, Grants Division (SPA), Clinical Contracts Division (CCD), or Office of Industry Engagement (OIE) is the final step in the process prior to proposal submission. [NOTE: This process will change upon implementation of the University’s new Integrated Research Information System (iRIS).]

4.2 Institutional Cover Sheet - Proposal Clearance Form (PCF)/Multi-Institutional Research Application (MIRA)

All proposals submitted to external funding agencies must list the “University of Louisville Research Foundation, Inc.” as the award recipient unless the submission is required to be from the University. At least five (5) business days prior to submission to the Sponsor, the proposal must be submitted to SPA, OIE, or the CCD (dependent upon the Sponsor and project type) for final review and approval. A completed and signed Proposal Clearance Form (PCF) or Multi-Institutional Research Application (MIRA) must accompany proposal submission to SPA/OIE/CCD. The PCF/MIRA enables review of administrative, policy, and fiscal issues related to the proposal. The PCF/MIRA consists of a series of informational items and questions to assist the Principal Investigator/Project Director (PI/PD) and University reviewers in assessing potential risks and obligations should the proposal be funded. In addition to the signatures of the PI/PD and co-Investigators, signatures of the department chair/unit head and respective dean or designee are typically required.

The MIRA or PCF Clinical Attachment is utilized for all clinical trials and sponsored research requiring approval of the Biomedical IRB and any other project/study that uses hospital facilities (for example, Jewish Hospital & St. Mary’s Healthcare Services, Norton Healthcare, or University of Louisville Hospital) or resources to conduct the research. The information on the
PCF/MIRA is shared with the respective hospital/study site and is used by the respective hospital/study site to grant approval for the research study to be conducted at their facility.

When University personnel from more than one academic department are participating in a proposed project, all appropriate department chairs/unit heads and deans must provide approval (by signing the PCF/MIRA) prior to submission of the proposal to SPA/OIE/CCD for institutional approval.

If an award is received for which no proposal was submitted, a PCF/MIRA must be completed, signed, and submitted to SPA/OIE/CCD prior to award establishment in PeopleSoft.

**Related Guidance**

PCF Instructions

MIRA Instructions

A Guide to Which EVPRI Offices Handle Which Projects

### 4.3 Other Pre-Submission Approvals and Requirements

PIs/PDs are required to conduct research and manage the financial and regulatory aspects of sponsored projects in compliance with University policy, Federal and state law and Sponsor requirements. PIs/PDs must ensure that they and members of their research team(s) meet all compliance requirements, including any necessary disclosure(s) and training requirements.

Several areas of regulatory compliance may need to be considered when submitting proposals to an external funding agency. Examples include:

1) **Conflict of Interest (COI);**

2) **Human Subjects Protection;**

3) **Animal Subjects Protection;**

4) **Biosafety and Radiation Safety;**

5) **Export and Secure Research Control.**

See [Chapter Nine](#) of the Research Handbook for additional information on these and other research regulations.

If a proposed project requires UofL participants to interact with or handle human subjects, animals, or agents impacting environmental health and safety (e.g., recombinant DNA; pathogenic organisms; human blood, tissues, cell lines, or other potentially infectious materials
[OPIM]), a proposal must be submitted to the appropriate committee(s) for internal review and approval prior to activation of an award. External Sponsors have different policies regarding the status of regulatory approvals at the time of proposal submission; while most will accept “pending review” or “pending approval,” some require full regulatory approval prior to submission. PIs/PDs should review the regulatory requirements of Sponsors when developing proposals for external funding.

Documentation of institutional approval (e.g., an approval letter) for actions “pending” at the time of proposal must be provided to SPA/OIE/CCD prior to activation of an award (chartfield establishment). In limited situations SPA/OIE/CCD may establish a chartfield prior to regulatory approval. As an example, for clinical trials, a chartfield may be established for site initiation visits and other limited startup activities prior to receiving final Institutional Review Board (IRB) approval [NOTE: no human subjects may be consented/enrolled into the trial until the IRB has granted formal approval].

4.4 Proposal Review

All applications and proposals for external funding must be reviewed and approved by SPA, CCD, or OIE for consistency with Sponsor and Federal guidelines and University policies prior to submission. SPA/CCD/OIE also review the budget for accuracy and proper format, ensure the correct application of fringe benefit and Facilities and Administrative Cost (aka F&A or indirect cost) rates, and verify University cost-sharing commitments.

Draft copies of all documents, including the draft budget may be submitted to SPA/CCD/OIE for preliminary review and comment. This is particularly helpful for complex proposals, such as those with multi-year budgets, subagreements, and/or cost sharing commitments. It should be noted that preliminary review and comment does not constitute official approval for submission.

SPA/CCD/OIE must receive the following items for review prior to granting approval for proposal submission:

1) Completed and signed PCF and PCF Clinical Attachment (if applicable);

2) Proposal, including abstract, budget, budget justification, and Sponsor forms. A final copy of the proposal for SPA/CCD/OIE files should be submitted at the time of proposal review (if electronic) or within two weeks following submission;

3) For proposals involving subrecipients, completed Subrecipient Commitment Form, budget, budget justification, and scope of work;

4) Indication of regulatory approval status (e.g., IRB, IACUC, DEHS);

5) Confirmation that all participants on the project, regardless of role, have completed the Conflict of Interest Attestation and Disclosure Form; and
6) Approval in writing of all committed University cost sharing or matching obligations.

4.5 Signature Authority

Only specific designees within SPA, CCD, and OIE have been granted signature authority by the President of the University. Under no circumstance is a PI/PD to sign a proposal to an external funding agency on behalf of the University and/or University of Louisville Research Foundation, Inc. without the prior approval of an Authorized Institutional Official.

4.6 Unfunded Proposals

Upon receipt of notification that a proposal will not be funded, the PI/PD should inform SPA/CCD/OIE as appropriate. SPA/CCD/OIE retains copies of unfunded proposals for one year following notification that the proposal will not be funded.

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