

## **POLICY ON GRANT AND CLINICAL TRIALS SUBMISSION**

### **PURPOSE**

The purpose of this policy is:

1. to meet commitments with, and adhere to standards of operation for, Medical School Administration Grants Office (Grants Office) and Division of Research Development and Administration (DRDA),
2. to acknowledge the current success of departmental research, static resources and increasing responsibilities and deadlines to administer current grants,
3. to administer resources wisely and improve the ratio of submitted versus funded projects (well-thought and planned grants translate to a higher likelihood of funding),
4. to acknowledge the labor intensive process of grant formatting and processing,
5. to demonstrate respect for the time of all involved personnel, including Anesthesiology's research division, Grants Office, DRDA, other departments and collaborators outside of the University.

### Grants:

Deadlines established in this policy are based on time requirements as follows:

Research Administrator (RA) and/or Study Coordinator (SC): twelve (12) business days; an additional three (3) business days is required if another department is involved, for a total of fifteen (15) business days. Additional time may be required due to number of grants being submitted for a single deadline or within a single week.

Medical School Administration Grants Office: two (2) business days, plus some time for required revisions and transit time to DRDA

Division of Research Development and Administration: five (5) business days

Transit to Sponsor: one (1) business day is required for over-night delivery of grant to sponsor.

### Clinical Trials:

Deadlines established in this policy are based on the following lengths of time it takes to dissect pertinent portions of contracts and complete university forms:

Research Administrator: five (5) business days

Medical School Administration Grants Office: three (3) business days, plus some time for required revisions and transit time to DRDA

Division of Research Development and Administration: this is an unknown time frame. The DRDA project representatives are highly trained and skilled personnel who have been charged by the Regents to closely examine contracts to:

1. identify contract language or content that violates University Policy;
2. to protect the University and its agents, including faculty, from liabilities; and

3. to fairly process clinical trials on a first-come, first-served basis.

Other issues that affect the speed at which clinical trials are awarded:

1. DRDA Project Representative work load;
2. Contract Administration work load (DRDA forwards all clinical trials to contract administration for approval prior to final award);
3. negotiations with sponsor regarding contract content and speed at which both parties resolve issues.
4. failure of Principal Investigator to obtain and/or communicate IRB, University Committee on the Use and Care of Animals (UCUCA) or other approvals to Research Administrator;
5. Turn-around time for documents requiring signatures from sponsors, DRDA or PIs and other departmental personnel.

## Grants

Principal Investigators must make an early decision regarding who will compile the grant documents, i.e. either the Research Administrator may complete all grant paperwork, or the research area's Study Coordinator may take this responsibility. In order to ensure all parties ample time to investigate proposal submission guidelines, plan other work responsibilities, and compile the grant, this information must be communicated immediately to Research Administrator and Study Coordinator within the guidelines established below.

If the PI is not able to meet deadlines established herein, or delays progression of the grant submission process by not having information organized and a set plan, the Research Administrator will make the decision regarding the probability of the grant meeting the current deadline on a case-by-case basis and will proceed accordingly. If the decision is made to delay grant submission until the next cycle (the following cycle for NIH grants is four months later), the Research Administrator will ensure the grant is submitted on time, as long as the PI has all information and materials compiled appropriately by the next deadline (23 business days prior to grant submission).

If the research area's **Study Coordinator will be responsible** for completing grant documents (to the letter of the request for proposals), the following deadlines are required:

1. Principal Investigator immediately will notify Research Administrator and Study Coordinator as soon as decision is made to apply for funding, and identify plan for paperwork completion.
2. If only Anesthesiology space and personnel are involved, the grant must be submitted to the Research Administrator ten (10) business days prior to the grant mailing deadline. The Research Administrator will review proposal guidelines, study the administrative components of the grant and edit for accuracy, return documents to Study Coordinator for editing, complete Proposal Approval Form, and obtain all departmental signatures from Principal Investigator, Clinical Department

Administrator, and Research Administrator, prior to forwarding to Medical School Administration.

3. If external departments are involved, either in research space or personnel in any capacity (including consultants), an additional three (3) days is required, for a total thirteen (13) business days prior to grant submission deadline. The Research Administrator will notify involved departments and obtain signatures on the Proposal Approval Form as required.
4. Research Administrator will be available to Study Coordinator to facilitate grant processing and provide direction as needed.

If **Research Administrator will be responsible** for completion of forms, the following deadlines are required:

1. If only Anesthesiology space and personnel are involved, PI must discuss with RA all grant materials twenty (20) business days prior to grant submission deadline. This will allow RA to research proposal guidelines and begin work. The RA will give the final grant to the PI for signature ten (10) business days prior to grant submission deadline.
2. If external departments or entities are involved, either in research space or personnel in any capacity (including consultants), an additional three (3) working days are required, or a total of twenty-three (23) working days prior to grant submission deadline. The Research Administrator will notify involved entities, investigate proposal guidelines, request required materials from external entities, and begin paperwork. The RA will give the final grant to the PI for signature ten (10) business days prior to grant submission deadline and obtain signatures on the Proposal Approval Form as required.
3. Study Coordinator will be available to Research Administrator to facilitate grant processing and provide guidance as needed.

### **Clinical Trials**

Principal Investigators (PI) will submit to Research Administrator (RA) a sponsor's contract, protocol and all supporting documents, including a plan for research personnel whose salaries will be supported by the contract. Research Administrator will complete University Form 7471 (budget) and PAF, obtain necessary signatures from PI, Department Administrator and RA, and submit grant to Medical School Administration. There are many issues that affect the speed at which Division of Research Development and Administration awards these contracts, as outlined in this policy's Purpose. What PIs should do to facilitate speedier processing is:

1. Obtain IRB, UCUCA and other approvals as quickly as possible;
2. return signed documents to Research Administrator as soon as possible;
3. submit all documents to Research Administrator at one time.

Research Policy # 001  
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## **SUMMARY**

Adherence to the policy and deadlines identified herein are required by all research personnel. These timelines will help to maintain Department of Anesthesiology's collegial relationships with Medical School Administration and DRDA, which have developed over many years, and upon which our department missions depend.

**Attachment A: Timeline for Responsibilities.**