

Proposal Development, Processing and Submission: Procedures

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Responsible College Officer
Director, Grants & Contracts

Responsible Office
Grants & Contracts

Procedure Statement

These procedures contain information for Principal Investigators (PIs), Department Administrators and Weill Medical College of Cornell University (WMC) research support administrators on the preparation and submission of research proposals.

The information presented in this document is specifically directed toward the preparation of grant applications to the National Institutes of Health (NIH). Instructions may be different for other granting agencies so the applicable sponsor guidelines should always be carefully followed.

Reason for Procedure

PIs must officially submit all applications for research support, whether to federal or state agencies, to private foundations, or to industry sponsors, to Grants and Contracts for WMC review and approval before they are submitted to the sponsors. If awarded, the grant is formally made to WMC, which has the responsibility for its fiscal management. For this reason, it is required that every application be reviewed and approved prior to submission by appropriate institutional official(s), who must confirm that it is consistent with WMC and agency policies and practices.

Who Should Know These Procedures

- Dean
- Senior Administration – Vice Provosts, Associate Deans
- Director, Department Chair, Division Head
- Faculty

- Departmental/Divisional Administrators
- Finance Personnel – Research Accounting, Accounting Services
- Grants & Contracts Personnel
- Research Compliance Personnel
- Research Integrity Personnel
- All Employees
- Information Technology Personnel
- Human Resources Personnel
- Students

Contacts

Subject	Contact	Phone	Email
Policy questions	Amy Zier	(212) 821-0949	aaz2001@med.cornell.edu
Institutional research compliance issues	Barbara Pifel	(212) 821-0722	blp2001@med.cornell.edu

Applicable WMC Policies and Procedures

- *Time and Effort: Policy*
- *Time and Effort: Procedures*
- *Charging of Direct Costs to Sponsored Projects: Policy*
- *Subaward Execution and Approval: Procedures*
- *Agreement with Industrial Sponsors of Research: Procedures*
- *Other Support: Procedures*
- *IACUC Protocol Review Procedures*
- *Institutional Review Board Policies and Procedures for Research Involving Human Subjects*
- *Cost Sharing: Procedures*
- *WMC Academic Staff Handbook*

Applicable Federal Regulations

NIH Grants Policy Statement

NIH PHS 398 Application Guidelines

OMB Circular A-21

Pre-Proposal Support

The Grants & Contracts Office at WMC is responsible for assisting PIs and Department Administrators in the proposal development and submission processes for all grants and contracts. Specifically, this office has primary responsibility for the following items:

- Assisting PIs in identifying funding opportunities

- Maintaining records of proposal submissions and awards in COEUS system
- Assisting with the implementation of electronic grant processing systems
- Acting as a liaison with granting agencies and industries
- Identifying and communicating required training courses for PI to be eligible to receive award
- Providing proposal forms and application materials (online resources)
- Ensuring that the applicant is eligible to be a Principal Investigator

The Institute for Clinical Research (ICR) at WMC is responsible for assisting PIs and Department Administrators in the proposal development and submission processes for all clinical trials. To determine if an application or contract should be sent to the Grants and Contracts Office or the ICR, review the abstract or scope of work against the College's definitions of "basic" research, "clinical research", and "clinical trial", which are summarized below.

Send to Grants and Contracts Office:

- "Basic" research: systematic, intensive; to increase knowledge or understanding; systematic application of knowledge to the production; material of human origin, tissues, specimens, and cognitive phenomena
- "Clinical" research: patient-oriented research; epidemiologic and behavioral studies; outcomes research; with human subjects; directly interacts with human subjects; mechanisms of human disease; does not meet definition of "Clinical Trial"

Send to ICR:

- "Clinical Trial" research: biomedical or behavioral; study of human subjects; safe, efficacious, and effective; experimental drug, treatment, device, or intervention; Phase I, Phase II, Phase III, Phase IV

More information on clinical trial submission at WMC is located at http://www.med.cornell.edu/research/cli_tri/.

Preparation of Research Proposal

Eligibility to Serve as a Principal Investigator

All members of the WMC faculty, as defined in the WMC Academic Staff Handbook, are eligible to serve as PIs or program directors on grants, contracts or industrial agreements. This includes faculty members holding appointments as Instructor, Assistant Professor, Associate Professor, Professor, Dean and/or President. A single faculty member must be designated Principal Investigator on each grant, contract or industrial agreement. "Co-Principal Investigator" is not an acceptable designation since a single individual must ultimately be responsible for an individual project.

- *Note: The NIH has begun to allow the designation of Co-Principal Investigator, however this is only on specific pilot projects and is not a widespread practice. Consult with Grants and Contracts Office if you are involved in one of these pilot projects.*

Senior Research Associates may serve as PIs on research grant applications, provided this is specifically approved by the applicable Department Chairperson(s). This approval confirms that the Senior Research Associate's skills and competencies are such that he/she can carry out the responsibilities of a PI in the area of the application.

With approval of the relevant Department Chairperson(s), trainees may apply for fellowships or other awards appropriate to their level of experience and competence.

Agency Instructions

In preparing grant applications, it is essential that the instructions of the granting agencies be followed rigorously. The following is a list of important areas for consideration when preparing a grant application:

- **Animal and Human Subjects:** If the research involves the use of animals and/or human subjects, the NIH requires for all new, revised, or competing continuation applications, that the protocol approval status be pending at time of submission. Therefore, the investigator should indicate a pending status of the protocol on his/her application. If the application is reviewed and determined by the NIH to be in a fundable range, the protocol and grant should be submitted to the appropriate IACUC and/or IRB Committee for review and approval. The verification of approval documentation from the IACUC and/or IRB Committee for both the protocol and the grant (and any other requested information) are submitted through the NIH “Just-in-Time” (JIT) mechanism. *Note: It is advisable for faculty who are proposing to use unusual species or unusually large numbers of animals to consult with the RARC staff prior to preparing an application, so that efforts to resolve any difficulties can be initiated in a timely manner.*
- **Other Support:** Information requested in PHS grant or contract applications related to “Other Support” must be complete, accurate, and reliable. The NIH Guide for Grants and Contracts implies that failure to provide complete and accurate information could be construed as an attempt to mislead PHS agency advisory groups and staff in their review and award responsibilities. Final “Other Support” information must be documented, submitted, and approved during the JIT procedures. Please see *Other Support: Procedures* for detailed information.
- **Human Subjects – Minority Populations:** Plans for recruitment of underrepresented minorities into Institutional National Research Service Award (NRSA) programs must be included in all applications. If women or minorities are excluded or are inadequately represented in clinical research, particularly in proposed population-based studies, a clear, compelling rationale for exclusion or inadequate representation should be provided. The composition of the proposed study population must be described in terms of gender and racial/ethnic group, together with a rationale for its choice. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study.
- **Subawards:** Further information is available on the processes and responsibilities for initiating and finalizing subawards in the WMC procedural document *Subaward Execution and Approval: Procedures*.
- **Responsible Conduct of Research:** As of July 1, 1990, applications for NIH Institutional Training Grants must include specific plans for instructing students (fellows) in the responsible conduct of research.
- **Data Sharing:** All investigator-initiated applications with direct costs greater than \$500,000 in any single year will be expected to address data sharing in their applications. An outline of this course is to be included in all NIH applications and is available on the Grants & Contracts website at http://www.med.cornell.edu/research/gra_con/nih_fed_cit.html.
- **Model Organisms:** All applications where the development of model organisms is anticipated are to include a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, or state appropriate reasons why such sharing is restricted or not possible. Sample plans can be found on the Grants & Contracts website. Unlike the data sharing requirement above, this requirement is for all applications.
- **Biosafety:** If recombinant DNA or transgenic animals are used, the research must be reviewed and approved by the Institutional Biosafety Committee (IBC).

- **Safety:** NIH and WMC environmental and radiation safety rules and regulations must be followed. A “Research Safety Checklist” must accompany all research applications, contract proposals, or industry agreements. This enables the Office of Life Safety Services to monitor potential biological, chemical and physical hazards so as to ensure a safe work environment and maintain compliance with local, state, and federal laws and regulations.
- **Equipment:** When funds are requested from a PHS grant or contract to purchase equipment, PHS policy requires that the institution conduct a survey of existing equipment to ensure that the equipment requested is not available within the institution for use by the investigator. A WMC Equipment Survey Form is completed by the PI to confirm that he/she has conducted a search (includes checking with the WMC Finance and Accounting department) to locate like equipment to use for the research project and to determine no such equipment is available for use. This form is submitted to and reviewed by the Grants & Contracts Office during the application process.
- **Clinical Trials:** Clinical trial research must be registered on the NIH website www.clinicaltrials.gov.
- **Application Formatting:** If outdated PHS application forms are used, the NIH will return the application without review. The NIH will also return applications that exceed the page limits specified in the PHS 398 instructions or supplemental instructions. If the print on the application is too faint or small for legibility after copying, the application may be returned without review by some agencies. Note that the instructions for preparing NIH grant applications contain very precise rules with respect to type size (different for Page 1 and remainder of application), number of letters per inch, and number of lines per inch. If these rules are not adhered to rigorously, the application may be returned without review.

For All Applications

After identifying a potential funding source and writing a proposal, ALL applications (grants or contracts) must be routed to the Grants & Contracts Office, or the Institute for Clinical Research if a clinical trial. PIs are ultimately responsible for adherence to the agency instructions in preparing grant or contract applications. It may at times be possible to obtain exceptions to such rules, but they must be requested and approved in advance of submission of the application. The investigator should remember that rules vary widely for different agencies and foundations. The Grants & Contracts and ICR staff will review all applications for compliance with these requirements. It is important that the PI include a copy of the agency guidelines with the application to Grants & Contracts or ICR. In order for the staff to conduct a comprehensive review, it is essential that Grants & Contracts or ICR receive the completed applications **no later than seven (7) working days prior to the agency deadline** for submission.

Research Proposal Budget Considerations

Budget Preparation

PIs are primarily responsible for developing the budget for their grant applications, and the Department Administrator is responsible for providing help as needed on preparation of budgets.

In preparing budgets for grant applications, faculty salary must be included at a level commensurate with the effort devoted to the project, unless prohibited by granting agency regulations. If the appropriate salary is not included, this must be approved in writing by the Department Chairperson. The amount requested should be based upon the faculty member’s Job Category and Institutional Base Salary (IBS), which can be defined as the annual compensation that WMC pays for an employee’s appointment, whether that employee’s time is spent on research, clinical care, teaching, administration, or other activities. *Further information is contained in WMC [Time and Effort: Policy and Time and Effort](#).*

Procedures documents, along with the Training and Certification Program of Faculty and Administrators which is available online. It should be noted that Fringe Benefits are provided based upon Institutional Base Salary, and a proportional share of the Fringe Benefits should be budgeted on the grant application. The NIH has established a “cap” indicating the maximum salary that can be used in calculating budgets (contact the Grants & Contracts Office for current figures).

- *Note: A faculty member's total effort, which consists of all research activity as well as any departmental teaching and/or administrative duties, must not exceed 100%.*

PIs are also primarily responsible for verifying that all budget items are in accordance with OMB Circular A-21. Specifically it is important to note which items can be charged directly to sponsored projects. For example, administrative, clerical and secretarial costs cannot generally be charged as direct costs on grants from the NIH and should normally be treated as facilities and administrative costs (indirect costs). Further guidance is provided on this topic in WMC's *Charging of Direct Costs to Sponsored Projects: Policy* document.

Other important factors to include or consider when developing the budget include:

- The appropriate facilities and administrative rate (and request for reduction, if applicable)
- The current fringe benefit rates
- Identifying issues related to any potential program income
- Requesting matching funds or identifying in-kind contributions

In preparing budgets for multi-year awards, the PI and/or Department Administrator should use estimates provided by the Accounting Department through the FRS system and the various RASP departments for annual changes in salaries, fringe benefit rates, institutional and other services (e.g., animal housing, radioactive waste disposal, etc.). It should be remembered that these are only estimates and should not be regarded as reflecting definitive institutional plans or commitments. Significant changes in these rates may occur as a result of changes in government regulations or other external factors over which the institution has no control. PIs should also be aware that institutes of the NIH and other granting agencies may apply “across-the-board” reductions to non-competing continuations and have established limits on the annual increases which will be allowed on the budgets of multi-year awards. This is just one of the factors that could cause the budget of a multi-year award to change from year to year. Due to potential for changes in an award's budget, RASP requires and will request PIs and/or Department Administrators to submit a budget (including subaward budgets if applicable) for each NGA at time of award. If there are any inconsistencies between the budget and the official NGA, the PI and/or Department Administrator must be sure the budget submitted to Grants & Contracts or ICR at time of award has been revised to match the NGA. Grant & Contracts or ICR will then forward the budget and other applicable documents to Research Accounting.

Any application for over one million dollars requires approval by the Board of Overseers. Any application for over five (5) million dollars requires approval by the University Board of Trustees.

Matching Funds or Cost Sharing

Some grants, contracts or industrial agreements require commitment of matching funds (cost sharing) or other special institutional resources. Such applications require prior approval by the Executive Vice Dean for Research of the Medical College or his/her designee. A letter summarizing the nature of the application and detailing the commitments required from the institution should be submitted to the office of Grants & Contracts within a reasonable time frame so that the Institution has a significant amount of time to evaluate the request. Following review by Grants & Contracts the request will be submitted, together with a recommendation, to the Executive Vice Dean for Research or the Executive Vice Dean's designee for his/her consideration. The PI will be notified in writing of the Executive Vice Dean's decision. For more information on Cost Sharing at WMC, please see the *Cost Sharing: Policy and Cost Sharing: Procedures* documents.

Training Grants

All applications for training grants that include support for graduate students must receive prior approval from the Dean of the Weill Cornell Graduate School of Medical Sciences (GSMS). Faculty planning to submit such applications should send a letter of intent to the Grants & Contracts Office within a reasonable time frame before the due date for receipt of applications, describing the nature of the planned proposal and its financial implications regarding student stipends, fringe benefits, tuition, etc. The letter of intent will be forwarded to the Dean of the GSMS for his/her review and approval. The faculty member will be notified, in writing, of the Dean's decision.

Submission of Research Proposal

Initiating an Application

To obtain approval for submission of an application, it is necessary to fill out a WMC *Research Application Routing Form (Routing Form)*, financial disclosure forms, and additional applicable forms, which are obtainable from the Office of Research and Sponsored Programs (RASP) or at http://med.cornell.edu/research/for_pol/grant_con.html. The *Routing Form* must be signed by the PI, his/her Department Chairperson (or chairpersons if employees from departments other than the PI's department are represented on the budget) and Division Chief (where applicable). The signatures indicate that the PI, Department Chairperson and Division Chief have read, approved and take responsibility for the contents of the application.

The Department Chairperson's signature indicates that the work, in his/her opinion, is scientifically meritorious, that he/she is willing to have the research performed in his/her department, and that all necessary resources are available to conduct the research should an award be made. If commitment of institutional resources, other than those under the direct control of the Department Chairperson, is necessary for the project, then pre-approval of the application by the Executive Vice Dean for Research of the Medical College or his/her designee is required. Applicants are urged to consult with the staff of the RASP, Grants & Contracts or ICR offices during the process of preparing applications as stated above, especially with regard to budgetary considerations and other applicable institutional and granting agency policies.

Grant Submission

After the Department Chairperson has reviewed and approved the grant proposal, the PI must then forward it to Grants & Contracts or ICR. A complete, original grant application, along with a signed *Routing Form* and other applicable internal documents, must be received by Grants & Contracts or ICR no less than **7 working days prior to the external agency's deadline (electronic or hard copy)**. There is no guarantee that applications will be processed if they are received less than 7 working days before the agency deadline. If an extension is needed, a request justifying the need for extra time must be submitted to Grants & Contracts or ICR.

All paperwork should be submitted to the Grants & Contracts Office in one of the following ways:

- Leave paperwork in the Grants & Contracts pick-up box, Room A-128 (1300 York Avenue). Mail is delivered to the Grants & Contracts Office twice a day, at 10 am and 3 pm.
- Deliver directly to our office between the hours of 9 am and 5 pm. The office is located at 425 East 61st Street, 2nd Floor, Room 223.
- Submit all documents electronically to Grants & Contracts

The procedures for clinical trial submission at WMC are located on the ICR website at http://www.med.cornell.edu/research/cli_tri/.

The following is the minimum information needed when submitting an application to Grants & Contracts or ICR and to NIH:

For Submission to G&C or ICR

- Routing Form
- Other internal forms as directed on routing form
- Financial Disclosure Forms for WMC key personnel and key personnel from all subgrantee institutions.
- RFA or PA if applicable (Note: The RFA/PA may indicate supplemental instructions. Submit any additional documents as requested in the RFA/PA. For program projects grants, center grants, career grants, consult the NIH guidelines for any specific instructions.)
- Scope of Work
- Research Billing Analysis Form, if applicable.

For Submission to NIH

- WMC Face Page
- Subgrantee signed Face Page, if applicable
- WMC NIH Form Page 2
- WMC NIH Table of Contents
- WMC NIH Modular budget page if applicable
- WMC Budget for year 1 (NIH form page 4) and budget for all the years (NIH form page 5)
- Subgrantee Budget for year 1 (NIH form page 4) and budget for all the years (NIH form page 5)
- WMC Budget Justification with Subgrantee budget justification information included, if applicable
- WMC Introduction to Revised Application if applicable
- WMC Research Plan (A-J)
- Section E or F of research plan that pertains to IACUC or IRB, if applicable
- NIH Biosketches for key personnel from WMC and subgrantee institution
- WMC Resource page
- Subgrantee Resource page, if applicable
- WMC Checklist page
- Subgrantee Checklist page, if applicable
- WMC Targeted Enrollment Table if using human subjects
- Subgrantee Targeted Enrollment Table if using human subjects
- Human Subjects Education Form if using human subjects. List only the WMC personnel that have passed the human subjects education test.
- Certificates of proof of passing the human subjects education test for key personnel from subgrantee institution.
- Appendix
- Letters of Support if applicable (*Do not need to submit to G&C for review*)

Proposal Review

Senior Specialists in the Grants & Contracts Office or ICR, assigned by department, will review and approve applications and supporting documentation to ensure that the submission complies with funding agency guidelines and institutional policies of WMC. Grants & Contracts or ICR will then approve and certify the proposal budget and ensure that budget items are in accordance with OMB Circular A-21 and other cost accounting standards. The Grants & Contracts Office or ICR is primarily responsible for reviewing other important items on the proposal such as: requests for F&A rate reductions or waivers, and determining the appropriateness of the grantor. Prior to submission, all applications for research grants, contracts, awards and industrial agreements must be approved by the Director of Grants & Contracts, who is the Authorized Institutional Official and, depending on the requirements of the granting body, may need to be signed by other appropriate institutional officials.

Once the Institutional Official has signed the proposal on behalf of WMC, it is returned to the PI for submission in hard copy format to the sponsor (where applicable). After submission of the application to the funding agency, the PI must forward a final copy to the Grants & Contracts Office or ICR. This is still WMC's current process of submission for some funding agencies. However, NIH is transitioning to electronic submission of all grant applications by the end of 2007. If the proposal is to be submitted electronically, such as through Grants.gov, then the Grants & Contracts Office or ICR is primarily responsible for its submission.

- *Note: Additional information on the NIH's [Grants.gov](http://www.grants.gov) initiative and WMC's procedures for electronic submission are available on the following link: http://www.med.cornell.edu/research/qra_con/grants_info.html.*

Award Acceptance and Just-In-Time (JIT) Information

The sponsoring agency will notify the PI when the proposal is within a fundable range and require IRB, IACUC and updated Other Support documentation to be submitted as applicable. For NIH applications, if a PI received a request for this additional information, the request is done through the Just-In-Time mechanism. Grants & Contracts or ICR will also send a follow-up communication to the PI regarding any JIT documentation needed. The following documentation, as applicable, will need to be submitted to the sponsoring agency to satisfy the JIT requirement: 1) Other Support information for all key personnel; 2) documentation of IACUC approval for the grant, which is the form IACUC issues to a PI entitled "Verification of protocol approval" and lists the grant number and is signed by the Institutional Official; and 3) the 310 form issued by the IRB to the PI verifying IRB approval of the grant. After the PI has submitted any applicable JIT materials to Grants & Contracts or ICR, the office will review and approve the documentation. The PI is then primarily responsible for the submission of these materials to the sponsor.

Please note that the NIH requires that the grant and protocol be reviewed together and approved. The Institutional letter approving solely the protocol does not fulfill the federal requirement. The documents referenced above in #2 and #3 provide the grant number and are signed by the Institutional Official.

Training Requirement for Award Acceptance

To accomplish compliance with pre- and post-award reporting requirements for Federal research funding, a "Training and Certification Program" has been created and posted on the web. **All PIs and Department / Division Administrators must complete the "Training and Certification Program" and pass the test before WMC will accept any research grants awarded on behalf of the PI.** This training is now available at <http://med.cornell.edu/research> under the Intranet Links portion of the page. PIs and Department Administrators will receive a certificate of completion once they have passed the test. Compliance with this Program is required because it is a legal obligation imposed on WMC by Federal regulations and by the terms and condition of our sponsored projects as a condition of accepting Federal research funding. The Assistant Dean for Research Compliance is responsible for administering the "Training and Certification Program", tracking compliance, and enforcing this policy.