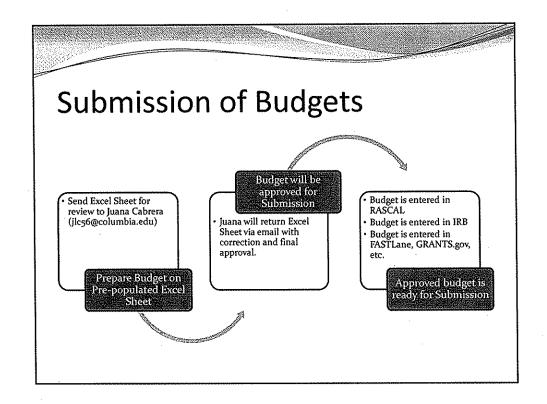
Anthropology Departmental Proposal Process

- Submission of Budgets
- Submission in RASCAL
- Submission in RASCAL/IRB
- Submission to Outside Funding Agencies through FASTLANE, Grants.gov, etc.

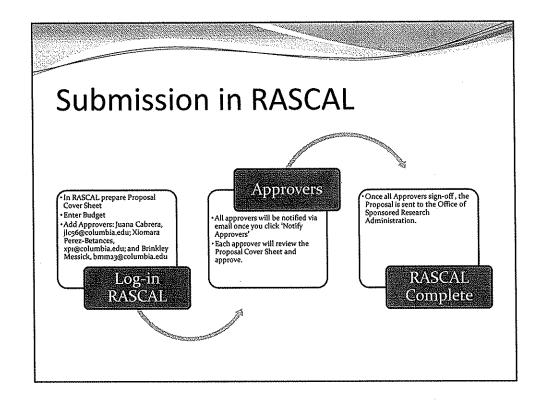
(NSF, NEH, NIH, Wenner-Gren, SSRC, Ford, etc.)



Purpose of Budgets

Preparation of a budget is an important part of the proposal preparation process. The budget should be accurate, realistic and reasonable in light of the work proposed. The requested amount should not be so small as to preclude successful completion of the stated goals nor so large that the sponsor will not seriously consider funding the proposal.

Research expenses are divided into direct costs, which are specific line items in a budget such as salaries and fringe benefits, equipment and travel, and indirect costs (also called Facilities and Administrative (F&A) costs), which are other costs that are less readily allocable to specific individual projects, such as the administrative support and the operation and maintenance of facilities. Indirect costs are paid as a fraction of direct costs, with the fraction negotiated by the University and the sponsor.



What is RASCAL?

RASCAL is web-based application developed to simplify the University's research compliance and research administration processes. It is designed to help researchers and administrators manage ongoing research projects and related compliance activities here at Columbia.

Who Can Use RASCAL?

Any Columbia University Employee who has a $\underline{\text{Columbia UNI}}$ (University Network ID) may use RASCAL.

What Can You Do With RASCAL?

Currently RASCAL serves as the electronic system for: Submission of Human Subjects Protocols to the University's <u>Institutional Review Board</u>

Submission of Animal Care Protocols to the University's <u>Institutional Animal Care and</u> Use Committee

Submission of Hazardous Materials appendices to the University's <u>Safety Officers</u> Submission of HIPAA forms to the <u>HIPAA Compliance Office</u>

Training and Certification for <u>Environmental Health and Safety</u> and <u>Other Compliance</u> Requirements

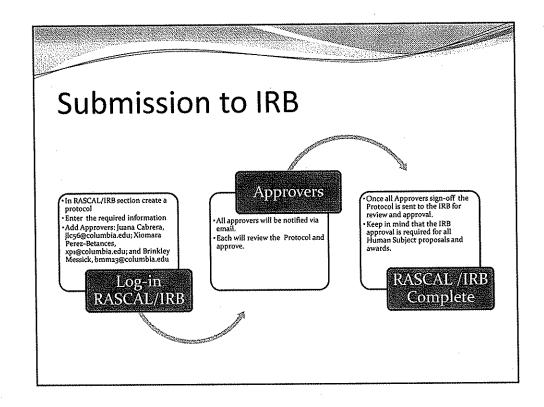
Declaration and review of Conflicts of Interest

Submission of Grants coversheets for Sponsored Projects and Clinical Trials

If you have a <u>Columbia UNI</u> you will be able to <u>create protocols</u>, <u>create appendices</u>, fill <u>out a conflict of interest disclosure</u>, <u>access available training and associated certification tests</u>, <u>and create HIPAA forms</u>. If you need special administrative access you should access the administration section of Rascal to find out more about requesting additional access.

Website: https://www.rascal.columbia.edu/

Website: http://sponsoredprojectshandbook.columbia.edu/content/rascal



What is the Institutional Review Board (IRB) Office?

The IRB Office is responsible for the protection of the rights and welfare of individuals (subjects, participants) who participate (actively and/or inactively) in research.

All research conducted by individuals affiliated with Columbia University (faculty, staff, and students) MUST obtain Columbia University IRB approval prior to conducting any human subjects research.

International Research and the (IRB) Office

International research may be subject to multiple policies and regulations such as

- -Columbia policies
- Federal regulations
 - -Department of Commerce
 - -Department of State
 - -Department of Treasury
 - Grantor regulations
 - -IRB and host country IRB
- -Private funder's requirements
- -Host country regulations
- -International agency policies

Seven Questions to Consider when planning to Conduct International Research

- Who will conduct the research? (Student, Faculty, Sub-contractor, Non-U.S. collaborator or local employee)
- 2. Where will the research take place?
 - Is it in a high-risk country? (OFAC-embargoed countries: Belarus, Burma, Cote D'Ivoire, Cuba, Democratic Republic of Congo, Iran, Iraq, Liberia, Libya, North Korea, Sudan, Syria, Zimbabwe)
 - Guidance on local culture and practices
- 3. Do you need to establish a 'presence' in that country?
 - -leasing space?
 - -establishing an office?
 - -ongoing operations?

Seven Questions to Consider when planning to Conduct International Research (cont'd)

- 4. Will you have a non-U.S. funding source or collaborator? We CAN NOT collaborate with individuals or institutions on the 'Specially Designated Nationals' List (http://www.treas.gov/offices/enforcement/ofac/sdn/)
- 5. Does the project involve heavily regulated or high risk activities (e.g. use of radioactive materials or provision of medical care)?
- 6. How much will the project cost? How will you pay for expenses?
- 7. Will you use special technology or technical information? Any of three regulatory regimes may apply: OFAC sanctions (Treasury), EAR [Export Admin. Regulations] (Commerce), ITAR [International Traffic in Arms Regulations] (State)

Human Subjects/IRB

Rascal is used by investigators to create IRB protocols and informed consent forms and by the IRB to administer the protocol review process. See <u>Additional Approvals - Human Subjects</u>.

Rascal also transfers data from other modules that are needed to obtain IRB approval of a protocol:

- Conflict of Interest
- · Radiation Safety
- · Training Certification
- Hazardous Materials
- Infectious Agents
- · Human Materials
- Recombinant DNA
- Hazardous Chemicals or Toxins
- Radioisotopes

What is human subjects research?

Human Subject research is defined by FEDERAL DEFINITIONS 45 cfr 46.102

"Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge..."

"Human Subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

- Data through intervention or interaction with an individual, or
- Identifiable private information

Examples:

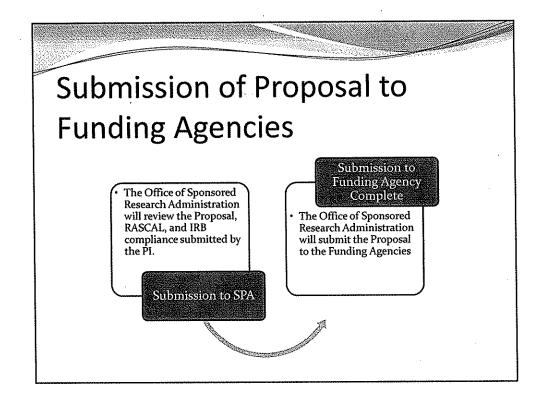
-interviews

- -analysis of existing data
- -surveys, questionnaires
- -observations

- -focus groups
- -records reviews (medical, school)
- -collecting samples (blood, urine, saliva, etc.)

What to do in order to comply?

- -Refer to the Columbia University Institutional Review Board website: www.columbia.edu/cu/irb
- -Complete REQUIRED human subjects training found in RASCAL under the 'Testing Center' tab
- -Complete and submit a human subjects protocol application via RASCAL



Proposal Submission

Proposals are submitted to the sponsor either in paper format or electronically. Each sponsor has its own requirements for how proposals should be submitted; SPA and the CTO can assist PIs and DAs in making sure the correct procedures are followed. All proposals, whether to be submitted in paper format or electronically, must be submitted to SPA five business days before the sponsor's deadline. See <u>Deadlines for Non-Industry Sponsored Research</u>.

See <u>Non-Industry Sponsored Research</u> and <u>Industry Sponsored Clinical Research</u> for the items that are required to be submitted to SPA prior to the submission of a proposal to the sponsor.

Updated: March 1, 2010

Who can be a PI?

In order to maintain academic standards and in recognition of the University's assumption of liabilities under sponsored projects, the University limits the eligibility of persons who can serve as PIs.

A PI normally must have a full-time appointment and must be:

- An Officer of Instruction:
 - -Professor
 - -Associate Professor
 - -Assistant Professor
 - -Instructor
- An Officer of Research:
 - -Senior Research Scientist/Scholar
 - -Research Scientist/Scholar

What are the Internal Deadlines?

The Internal deadline for the submission of your completed proposal to the Office of Sponsored Projects Administration (SPA) is 9:00am FIVE business days prior to the agency's deadline.

If the agency has no deadline SPA requires that you submit your completed proposal FIVE business days for review and submission of your proposal.

You should contact our office as soon as you know you will be applying for a solicited or unsolicited proposal. We in turn will contact the Project Officer in SPA on your behalf.

What does the Office of Research/Sponsored Projects Administration (SPA) do...

- -Proposal review and submission
- -Review of grant awards
- -Review, negotiate and sign contract agreement
- -Serve as Institutional Officials for the Federal Government and have Signatory Authority for all Sponsored Agreements