

May 24, 2017

INTERNATIONAL RESEARCH AND SERVICE PROJECTS: RISK MANAGEMENT PROCEDURES*

This memorandum outlines Columbia University's risk management procedures (the "Procedures") for international research and service projects ("Projects"). The University supports and encourages international research and service, but recognizes that the Projects involve special risks that should be considered and addressed.

The Procedures are not designed to second guess the scholarship of a Project or to hinder the grant application process. At the same time, they provide a mechanism for the University to inquire as to what risks should be considered and how they should be managed. In addition, the Procedures will assist the University in the development of a data base of information relating to Projects and to better provide the investigators at the University with international research expertise.

I. Committees

The University will form a standing committee, the International Research Committee (the "IR Committee"), whose members will be appointed by the Executive Vice President for Research (the "EVPR") in consultation with the Office of the Provost.

The IR Committee will consist of two Officers of Instruction and/or Officers of Research and one representative of each of the Office of the General Counsel ("OGC"), the Office of Sponsored Projects Administration ("SPA"), the Human Research Protection Office Institutional Review Boards ("IRB"), the Finance Division, the Office of the Provost, and the Office of Research Compliance and Training ("RCT"). The IR Committee will carry out the Procedures and will report to the EVPR and the Provost periodically upon request.

In addition, and as needed, the EVPR may appoint an International Research Advisory Committee (the "IR Advisory Committee"). The IR Advisory Committee will consist of Officers of Instruction, Officers of Research and senior administrators who have had experience working on Projects. The IR Advisory Committee will advise on policies relating to Projects.

The EVPR will appoint a Chair or Co-Chairs of both the IR Advisory Committee and the IR Committee.

* These Procedures were originally issued on March 12, 2007; revised versions were issued on June 14, 2007, Nov. 28, 2011, March 19, 2013, January 5, 2016, and May 24, 2017.

II. Procedures

A. Criteria

Generally, only those Projects that meet one or more of the following criteria (the “Criteria”) will be reviewed. The Criteria are the following:

1. The direct costs of the Project exceed \$1 million per year, of which at least 50% will be expended outside the United States (either directly or through one or more subcontracts).
2. The Project involves ongoing University operations in a non-U.S. country, such as the establishment of an office, leasing of space or an on-the-ground University presence for more than a nominal period.
3. The Project is located in, funded by, or involves travel to or collaboration with persons in a country on the Treasury Department’s Office of Foreign Assets Control list of sanctioned countries, or involves any transactions, whether compensated or uncompensated, with any restricted parties (i.e., individuals or entities on a U.S. Government restricted party list).
4. The Project involves (or has involved at any stage, including during the pre-proposal stage) the payment, promise to pay or authorization to pay money or “anything of value” to any of the following entities (or to any officers, employees or representatives of any of the following): a government, or a department, agency or instrumentality of a government; a political party or candidate for political office; a public international organization (such as the United Nations or World Bank); or any other person or organization at the request of any governmental official.
5. The Project involves the use of high risk materials (e.g., radioactive materials or certain biologic materials).

In the event that a Columbia regulatory office (e.g., the IRB or SPA) or an academic unit or department, identifies a Project that does not meet the Criteria, but may nonetheless present significant or novel risks to the University or the Project team, such office or academic unit may, in its discretion, refer such Project to the IR Committee for guidance.

B. Pre-Award

N.B. It is intended that the steps set forth below not delay the review and submission of any grant application and, if necessary, will be completed after an application has been submitted.

1. Step One: Notification to Research Administration

a. Initial Notification

In order to provide the maximum time for pre-application review of a sponsored project proposal (or a renewal thereof) (a “Proposal”), the Principal Investigator (“PI”) or Departmental Administrator responsible for the Proposal will notify the appropriate Project Officer in SPA of his/her intent to apply for sponsorship of a Project. The Project Officer will ask the PI or Departmental Administrator the questions set forth in the Criteria Questionnaire. The Criteria Questionnaire is attached as Annex A and will be posted on the SPA and RCT websites.

For those Projects that are not externally sponsored, such as departmentally funded projects, the PI or Department Administrator will notify RCT of his/her intent to initiate the Project and provide the Criteria Questionnaire.

b. Proposal Review

If a SPA Project Officer, upon review of any Proposal, ascertains that the project involves international research, he/she will contact the PI or Departmental Administrator responsible for the Proposal and ask the questions set forth in the Criteria Questionnaire.

If an IRB staff member, upon review of any human subject research protocol, ascertains that the protocol meets Criteria 3 above, he/she will refer the protocol to RCT for follow-up and IR Committee review.

c. Gifts

If the Project is to be funded by a gift, the initial notification to RCT will be coordinated through the Office of Alumni Development.

2. Step Two: International Research Questionnaire

If a SPA Project Officer or an IRB or RCT staff member determines that the Project meets one or more of the Criteria, he/she will contact the PI or Departmental Administrator to obtain answers to the questions set forth in the International Research Questionnaire. A sample Questionnaire is attached as Annex B and will be posted on the SPA and RCT website[s].

If a Departmental Administrator or PI determines that the Project meets one or more of the Criteria, he/she will complete the Questionnaire and provide it to SPA.

3. Step Three: Review of International Research Questionnaire by IR Committee

SPA will provide International Research Questionnaires to the IR Committee. All Projects will be reviewed by the IR Committee unless the Associate Vice President for Sponsored Projects Administration and the Associate Vice President for Research Compliance and Training determine on the basis of the International Research Questionnaire that such review is not necessary. If it is not necessary, the SPA Project Officer will notify the PI or Departmental Administrator.

In reviewing the Questionnaire, the IR Committee will consider the questions set forth in Annex C. Any risk management issues noted by the IR Committee will be discussed with the PI or Departmental Administrator. After its review, the IR Committee will either notify the PI or Departmental Administrator that no further review is needed or work with the PI to resolve any questions.

If any issue needs further discussion, it will be referred to the appropriate senior administrator for review. All issues will be addressed and resolved with the PI as expeditiously as possible.

C. Post-Award Steps

1. Step One: Financial and Legal Review

After an award is received, the Project will be reviewed for financial, legal and operational risks by the IR Committee or an ad hoc working group comprised of representatives of the Finance Division and the OGC and such other persons as deemed appropriate by the Chair or Co-Chairs of the IR Committee (“Post Award Committee”). Annex D identifies key issues that should be addressed as part of this review.

2. Step Two: Finalization of Structure and Procedures

- a. If appropriate, the Finance Division will work with the PI and the PI’s school to establish a set of financial controls and an ongoing monitoring plan for the Project.
- b. The OGC will work with the PI and the PI’s school to establish the appropriate structure for the Project and a plan for mitigation of legal risks, as needed.
- c. The final structure and procedures will be approved by the Post Award Committee and, if so determined by the Post Award Committee, an appropriate senior administrator.

3. Change in Circumstances

If there is any change in the terms of a Project that would result in it meeting one of the Criteria described in Section A above, or if the risk profile of the Project materially changes, the PI must promptly notify the IR Committee of such occurrence. Such notification should be provided to the applicable Project Officer, who will forward it to the IR Committee.

4. Monitoring

For projects identified by the IR Committee, the PI, Project leader, or relevant business unit shall provide an annual update to the IR Committee regarding the Project's status and any changes or new needs with respect to the structures and procedures initially established for the Project.

PI Name:

Project Title:

ANNEX A

CRITERIA QUESTIONNAIRE

- 1) Will the direct costs of the project exceed \$1 million per year and will at least 50% of such costs be expended outside the United States (either directly or through one or more subcontracts)?
- 2) Will the project involve ongoing University operations in a non-U.S. country, such as the establishment of an office, leasing of space or an on-the-ground presence for more than a minimal period?
 - a) If yes, for what period of time?
- 3) Will the project be located in, funded by, or involve travel to or collaboration with a country, or persons in a country, on the Treasury Department's Office of Foreign Assets Control list of sanctioned countries? If YES, what country?

Will the project involve any transactions, whether compensated or uncompensated, with any restricted parties (i.e., individuals or entities on a U.S. Government restricted party list)? If YES, please identify the party in question.

The list of sanctioned countries is available at <http://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx>. The lists of restricted parties are available at <https://www.bis.doc.gov/index.php/policy-guidance/lists-of-parties-of-concern>. (For assistance with screening, please contact SPA.)

- 4) Will the project involve (or has it involved at any stage, including during the pre-proposal stage) the payment, promise to pay or authorization to pay money or "anything of value" to any of the following entities (or to any officers, employees, or representatives of any of the following):
 - a) a government, or a department, agency or instrumentality of a government,
 - b) a political party or candidate for political office,
 - c) a public international organization (such as the United Nations or World Bank), or
 - d) any other person or organization at the request of any government official?

This Criterion applies to subcontracts, subawards, and other contracts with any entities or persons identified above. This Criterion also applies to payments to any person who will in turn offer, promise or make a payment to any entity or persons identified in clauses (a) – (d). An "instrumentality" of a government includes state-owned or state-controlled entities, which can include (as examples) universities, banks, and energy and transportation companies.

"Anything of value" includes cash, fees, travel expenses, gifts, educational or executive training expenses, promises of future employment, reimbursements and other services or items of

any value. “Anything of value” does not, however, include the conveyance of Columbia’s results to the sponsor under the project agreement.

- 5) Will the project involve the use of high risk materials (e.g., radioactive materials or certain biologic pathogens)?

PI Name:

Project Title:

ANNEX B

INTERNATIONAL RESEARCH QUESTIONNAIRE

1. Which non-U.S. countries do you expect to involve in your project?
2. How long is the proposed grant period?
3. What is the annual dollar amount of the grant and the source of funding? Are any “local” funds to be used in the conduct of the project?
4. What activities do you expect to be involved in?
5. Do you expect to have Columbia employees or students located in a non-U.S. country? If so, (a) what will they be doing, and (b) how long will each be located in the non-U.S. country?
6. Will you have a local collaborator (either in the form of a local sponsor or subcontractee)? If so, what will they be doing? Will they be compensated? If so, how do you plan to compensate them?
7. Do you plan to (a) hire local employees in the project, (b) open local bank accounts or (c) enter into leases or other contracts for goods and services?
8. Will the project involve human subjects or recipients of services? If so, how will they be used or what services will be provided? Are there any vulnerable populations impacted? Please provide the status of the IRB protocol (e.g., approved, submitted but not yet approved, or not yet submitted) and IRB Protocol Number (if available).
9. Please describe any arrangements or understandings (written, oral, etc.), with any person involving the payment, promise to pay, or authorization to pay money or “anything of value” to any of the following entities (or to any officers, employees, or representatives of any of the following):
 - a) a government or a department, agency or instrumentality of a government,
 - b) a political party or candidate for political office, or
 - c) a public international organization (such as the United Nations or World Bank), or
 - d) any other person or organization at the request of any government official?

This question applies to subcontracts, subawards, and other contracts with any entities or persons identified above and also applies to payments to any person who will in

turn offer, promise or make a payment to any entity or persons identified in clauses (a)–(d). Agreements to reimburse expenses are included in this question.

10. Have you had any previous projects in the non-U.S. country in which your proposed project will be located? If so, what was the nature of the project and were there any problems that arose?
11. Are you aware of any other Columbia projects in the non-U.S. country in which your proposed project will be located? If so, please identify.
12. What are the principal risks relating to the project that should be addressed?

ANNEX C

QUESTIONS FOR THE IR COMMITTEE

1. What local laws or customs should Columbia be concerned about?
2. What are the specific principal risks associated with the project?
3. What moral or ethical issues are involved in the conduct of the project?
4. Have the unique costs of the project been factored into the budget (e.g., costs of local regulatory compliance, special insurance needs, physical security costs, etc.)?
5. What oversight mechanisms should be in place? If the project has sub-recipients, what compliance and monitoring processes should be established? Who will bear the cost of monitoring and compliance, particularly in projects that have sub-recipients?
6. Has appropriate local approval been obtained to carry out the project?
7. What impact would termination of the project be likely to have on people or programs in the non-U.S. country?

ANNEX D

POST-AWARD REVIEW

A. Financial Risks

1. Incurrence of unfunded obligations: are there any expected gaps in funding that will require future fundraising or Columbia contributions? What happens if Project is over budget? Moral obligation? Is there an anticipated need for an ongoing Columbia presence after the project is completed?
2. Tax liability to foreign jurisdiction: what revenues are subject to tax? Import duties? VAT taxes? Exemptions? Permanent establishment? Withholding?
3. Payments: escrows; cost reimbursements; invoicing; money transfers; payroll; withholding pending audit; carry forwards; bank accounts; currency.
4. Inappropriate uses / payees of funds.
5. Impact on federal or other domestic research funding.
6. Will there be any gaps in insurance coverage?
7. Inflation/currency exchange issues.

B. Operational Risks

1. Specific scope: What are Columbia's responsibilities and success criteria?
2. Governance: does Columbia retain control? If not, how are minority rights protected?
3. How will the project be staffed and managed? What are the reporting lines? Who will have responsibility of the ongoing programmatic review?
4. Day to day operational issues: employees; banking arrangements; insurance; security.
5. Assets: ownership? Lease? Whose liability?
6. Termination rights. Does Columbia have the right to suspend the project or terminate early? What are the foreseeable risks to the local community and/or political ramifications of an early termination?

7. Changing conditions in the host country.
8. Role of students.
9. If the project receives U.S. governmental funding, how will subrecipients and other local resources comply with applicable regulations? What training is needed?

C. Legal Risks

1. Applicability of non-U.S. laws. Who has reviewed project to assure local regulatory compliance? Who will be responsible for ongoing regulatory compliance?
2. Legal status in host country.
3. Liability exposure (e.g., for local injuries/torts, breach of local contract or local employee claims)? What is optimum operational structure in host country?
4. Government reporting obligations (both U.S. and non U.S.).
5. Export Controls / Trade Sanctions and other U.S. laws governing international research.
6. Compliance with Columbia's policy on anti-corruption, including compliance with Foreign Corrupt Practices Act and other applicable laws.
7. Intellectual Property rights: publication rights; allocation of benefits; commercialization; administration.
8. Breaches: remedies; dispute resolution; jurisdictional issues; governing law.
9. Use of CU name; control over publicity.
10. Human Subjects research: Columbia IRB approval; local IRB or equivalent approval; compensation; informed consent.
11. Issues relating to service recipients: nature of services (i.e., medical, social, psychological); physical risks to recipients; replacement providers.
12. Employment and personnel issues: Columbia and host country employees; what benefits will local staff receive? Who will have signing authority?
13. Hostile environment; student or employee arrest or kidnapping.