Background

- Began in 2010
- 10 criteria for review
- Focuses on several areas of risk
  - Grant management
  - Institutional risk
  - Other risk areas (jurisdictional issues, indemnification clauses, etc.)
- Review conducted by the Office of the Vice Provost for Research and the Office of the Vice Provost for International Affairs
  - Sponsored Programs, Office of the General Counsel, and other offices are consulted as needed
1. The project has an aggregate budget of more than $10 million for U.S.-based projects, or is an international program whose annual budget is greater than:
   - FAS, HMS - $5.0 million
   - HBS - $3.8 million
   - HSPH - $3.0 million
   - HLS - $1.5 million
   - HKS - $1.3 million
   - HGSE, HSDM, GSD, HDS, SEAS, RIAS - $1.0 million

2. The project involves the public use of Harvard University's name and/or trademark. Projects which use the name of a Harvard School or other subsidiary unit of the University do not need Provost’s Review, but do require approval of the School Dean. Further information can be found at The Office of the Provost website.

3. The project supports the establishment of any new international site. For this purpose, "new international site" refers to: (1) real estate, including offices and research space, outside the U.S. that is leased for Harvard use for a period of six months or longer; or (2) a project outside the U.S. to which two or more Harvard faculty members, employees, staff members of an affiliated entity, independent contractors, post-doctoral fellows, or students are assigned and placed for a period of six months or longer; or (3) a project that involves significant work in, or the posting of a Harvard faculty member, employee, staff member of an affiliated entity, an independent contractor, post-doctoral fellow, or student to, countries or regions identified as 'High Risk' by Harvard’s Global Support Services.

4. The project is international and involves human subjects research that requires IRB expedited or full review. NOTE: If a proposal meets this criterion and no other criterion, it can be reviewed at the time of award rather than at the time of submission.

5. The project involves, or is allied with, the direct provision of medical or clinical services.
6. A majority of funds in the project (over 50%) will not be expended at Harvard but will be expended through vendors or subcontractors other than Harvard, or a majority of project activities will be conducted by persons who are not Harvard staff. Exception: Projects in which more than 50% of funds are expended at Harvard-affiliated hospitals (list here, under “HMS affiliates”) do not require provostial review.

7. The project has a substantial risk of violating Harvard's anti-discrimination policy.

8. The sponsor or project may present a serious reputational risk for the University or may otherwise attract significant adverse publicity to the University.

9. The project involves activities for which there is inadequate or uncertain program, financial and/or managerial infrastructure, which may be a special concern in projects that take place outside the United States.

10. The project involves a scope, scale, or type of work that is beyond the University's teaching and research mission or is especially unusual or complex.
Risk Area: Grant Management

- Large-scale projects
  - Availability of the infrastructure to manage the grant
- Projects with multiple sub-awardees
  - Receiving institution’s ability to perform the work
  - Sub-recipient monitoring
Risk Area: Institutional Risk

- Projects involving clinical care
  - Guidance: Provision of Clinical and Medical Services During Clinical Research

- International projects
  - International Travel Policies
    - Harvard College International Travel Policy
    - Graduate & Professional Student International Travel Policy
  - Cultural or Political Sensitivities
    - Study team’s experience in the region
    - Special populations of interest

- Reputational risk
  - Conflict of interest
  - Nature of the study or population involved

- Projects outside the teaching or research mission of the University
  - Advocacy work
  - Consulting projects
    - Service or Consulting Agreements Involving Faculty Contracted Through Harvard Policy
Other Risk Areas

- Financial risks
  - Indemnification clause
- Jurisdictional issues
  - Licenses or permits needed to conduct the work at the proposed location
- Publication approval
- Export Control
  - Specially Designated Nationals (SDN) List
QUESTIONS?