

# Start-up Companies and Conflicts of Interest

## Columbia's Conflict of Interest Policy

### What is a Financial Conflict of Interest (COI) in Research?

A financial conflict of interest exists where a researcher's outside financial interests or activities could improperly affect, or give the appearance of affecting, the researcher's activities at Columbia.

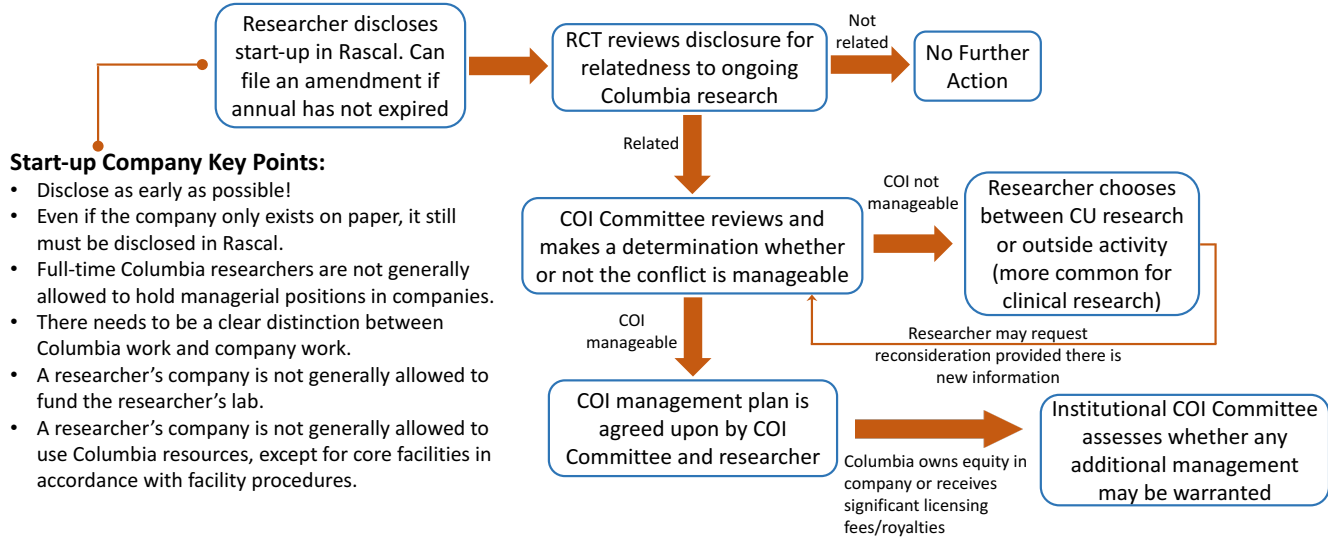
### What are the Objectives of Columbia's COI Policy?

- Promote responsible relationships with industry
- Protect the credibility and objectivity of Columbia research
- Protect participants in human research studies
- Protect Columbia researchers from allegations of bias or appearance of bias resulting from outside financial interests that may relate to Columbia research
- Comply with federal regulations and funder requirements

### Key COI Policy Provisions:

- "Transparency is paramount."
  - Disclosure of financial interests that relate to any Columbia research is required in publications, presentations and reports of the related research.
  - Researchers must also disclose financial interests related to research in a Financial Interest Report – an on-line form filed at least annually in Rascal.
- A researcher with a significant financial conflict of interest is not ordinarily allowed to participate in research related to the conflict. However, in any particular case, an exception may be warranted as determined by the Conflict of Interest Committee.
- The Conflict of Interest Committee reviews potential conflicts and determines how to manage them.
  - Faculty committee appointed by the Executive Vice President for Research with input from schools
  - Two subcommittees – Morningside and CUMC – plus Institutional Conflict of Interest Committee
  - Generally meet monthly
  - Case-by-case review, assessing risks and benefits
- The research assigned to students, post-doctoral fellows, trainees and other subordinates should further the University's mission to advance knowledge and learning at the highest levels. Conflicted principal investigators may not assign students or trainees to research projects where the principal investigator has a significant financial interest without prior approval by the Conflict of Interest Committee.

## COI Review Process at Columbia



### Start-up Company Key Points:

- Disclose as early as possible!
- Even if the company only exists on paper, it still must be disclosed in Rascal.
- Full-time Columbia researchers are not generally allowed to hold managerial positions in companies.
- There needs to be a clear distinction between Columbia work and company work.
- A researcher's company is not generally allowed to fund the researcher's lab.
- A researcher's company is not generally allowed to use Columbia resources, except for core facilities in accordance with facility procedures.

## Examples of COI Management Strategies:

Every situation is different, but similar cases are treated similarly. The COI Committee considers management plans based on the facts of each case, and with the input of the conflicted investigator. **Not every case is manageable.**

### Disclosure

- Notify students/trainees of financial interest
- Advise members that department chair or other applicable person is available to address any concerns
- Publications/presentations
- Consent forms

### Review/Oversight

- Chair or division chief
- Biostatistician
- Columbia faculty committee
- External faculty committee

### Modify Research Design and/or Roles to Minimize Risk of Bias

- Blinding
- Adding biostatistician
- Limit conflicted person's involvement with data analysis or interpretation

### Institutional COI

- Disclosure in publications and presentations
- Disclosure in consent forms
- External IRB Review

### Resources:

- Office of Research Compliance and Training - <https://researchcompliance.columbia.edu>
- RCT Website on COI - <https://research.columbia.edu/content/conflict-interest-and-research>
- COI consultations available, email [aps2180@columbia.edu](mailto:aps2180@columbia.edu) or [research-compliance@columbia.edu](mailto:research-compliance@columbia.edu)