Emory Institutional Conflict of Interest in Human Subject Research
Applicable to Human Subject Research

Institutional Financial Interests
- Equity in a private company from a technology license
- Cash gift greater than $500k to a department/unit
- Royalties/licensing fees on the study technology that exceed $100k

Referral to Conflict of Interest Review Office
- with VP Research Admin determine:
  - whether the relationship exists; and
  - whether it can directly and significantly affect research

PI submits Compelling Circumstances for review of ICOI Review Committee (2 Emory COI Reviewers, 1 External Reviewer)

Management Plan
Disclosure to public and enrollees (required)
Other examples of management tools:
- External IRB
- Independent Monitoring
- Plan of divestiture
- Limiting procedure and analysis at Emory University
- Second opinion for recruitment

Personal Financial Interests of Institutional Leader
(review of IRB protocols/issues for the Department)
- Equity in a privately-held company
- Consulting fees greater than $100k
- Fiduciary Role
- Royalties greater than $100k

Recuse from review and Assign another Institutional Leader

Institutional Leader must divest SFI if recusal is not possible

Appeal sent to Provost & VP Research Administration

(Advisory opinion)

All management plans involving human subject research – individual or institutional – must be reviewed by the IRB; the IRB may add additional safeguards to protect human subject volunteers.