

## **RCOI REVIEW PROCESS FOR PROJECTS INVOLVING HUMAN SUBJECTS (MODIFIED FROM AAMC GUIDANCE)**

The following will serve as an outline for the consideration of the Research Conflict of Interest (RCOI) aspects of a project involving human subjects. The assigned Subcommittee would consider each of the following criteria, and the report to the RCOI Committee would reflect the assessment of each criterion. These review criteria may be provided to the investigator in advance to help them provide additional materials and prepare for the Subcommittee meeting.

1. Description of the Research
2. Description of External Interests- is there a Significant Financial Interest (SFI) based on federal and institutional policy definitions?
3. Does a specific Financial Conflict of Interest (FCOI) exist? Consider the extent to which the SFI is directly and substantially linked to the research- i.e. degree to which the research may be affected by the conflicted interest
4. Extent to which the conflicted interest is amenable to effective oversight and management.
5. Should the investigator be allowed to conduct or participate in the study in light of their FCOI? Key decision factors may include:
  - a. Nature of the research- early vs late phase research, low vs high risk research
  - b. Specific institutional resources
  - c. Access to certain patient populations (of interest for the study)
  - d. Combination of skills, qualifications, expertise- the extent to which the investigator is qualified to perform a research study with potential important public benefit
6. Risk-Benefit Analysis related to FCOI- to what extent could the FCOI increase risk to human subjects that cannot be managed?
  - a. Risks to subjects related to FCOI- Is there risk to safety of human subjects and community? Is there increased risk of failure to adhere to inclusion/exclusion criteria of the protocol? Is there danger of overstating the potential benefits of assay/product/results while soliciting consent?
  - b. Risks to data integrity- Is there risk to data integrity?
  - c. Risks to an appearance of COI- Is there risk of an appearance or perception of a conflict of interest?
  - d. Risks to the individual investigator and the university- How does the investigator's role at the university affect the COI review? (ex. administrative, teaching, procurement, etc.)
  - e. Benefits to medicine and science- What are benefits if the study is allowed? Could outcome of study benefit the public?
  - f. Can the risks related to the FCOI be mitigated effectively by modifying the research protocol?