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2026 AAHRPP Webinar Series

Managing Conflicts of Interest in a Changing Research Environment

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Robert Frenck, MD Professor of Pediatrics, Infectious Diseases, Cincinnati Children's Hospital Medical Center

Robert Hood, PhD Director of Accreditation and Global Outreach, AAHRPP

Chat Feature

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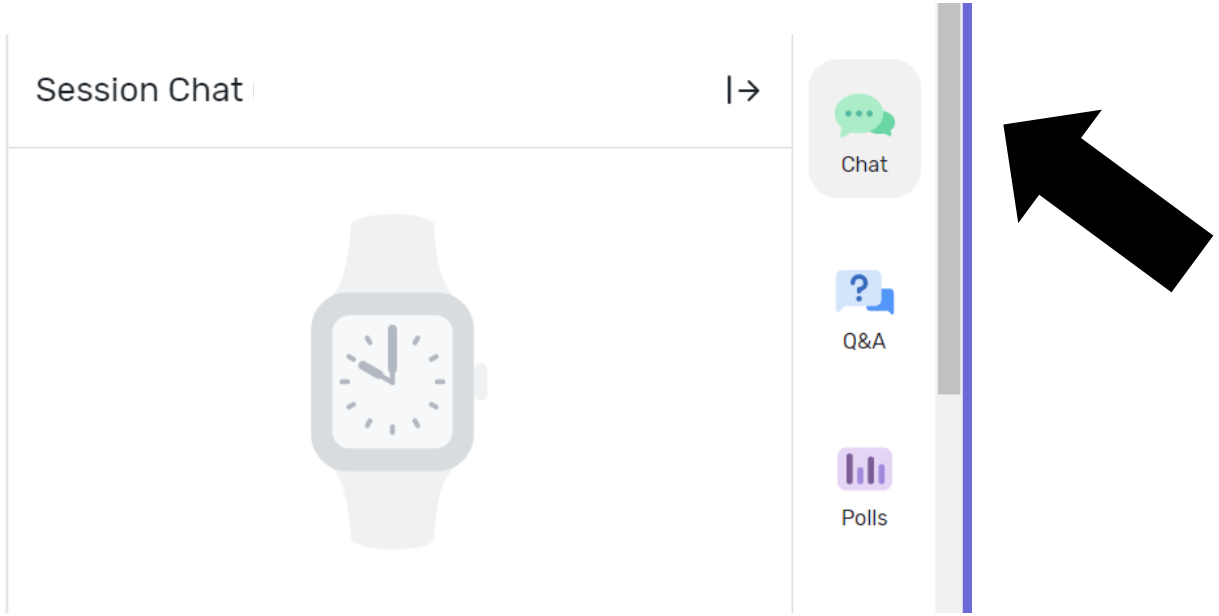

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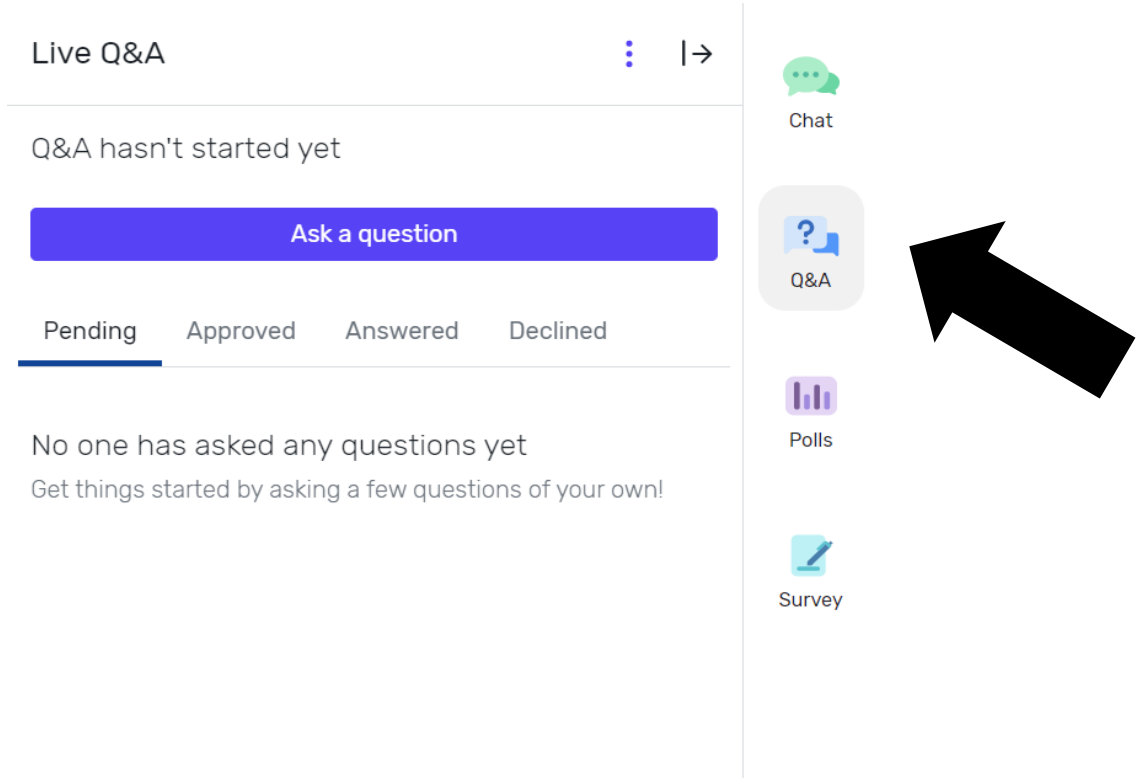
Questions

To ask questions about the topic for the presenters, please use the “Q&A” icon:



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Upcoming Webinars

Ask... AAHRPP®

Save the following dates for the 2026 "Ask AAHRPP" webinar series:

- **August 11, 2026**, 3:00 pm ET: Responding to the Draft Site Visit Report
- **October 13, 2026**, 3:00 pm ET: Understanding the Council on Accreditation Review
- **Tuesday, December 8**, 2026, 3:00pm ET: Responding to Council Review and Maintaining Accreditation

Visit Webinars (aahrpp.org) for more information and registration links

Upcoming Webinars

Save the following date for the remaining 2026 "HRPP Innovations" webinar:

November 10, 2026: 1:00 pm – 2:30 pm ET

Cybersecurity and Research Data Protection: What Every HRPP Should Know

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Presenter Introductions

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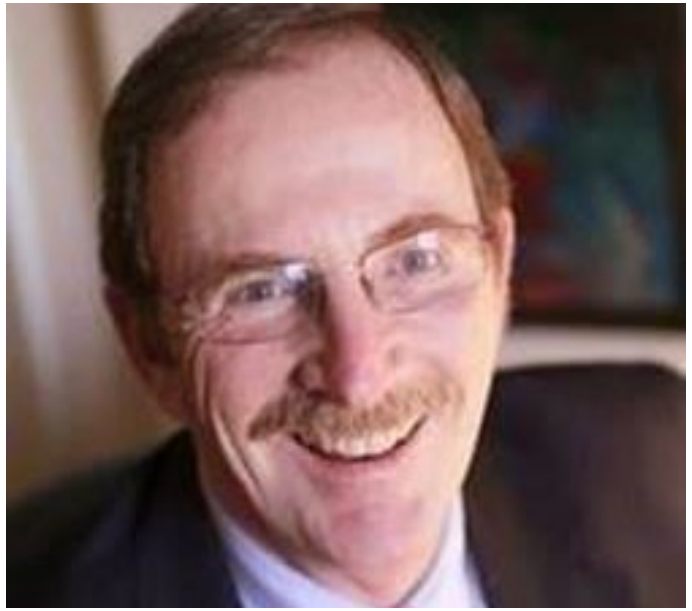
Sujatha Sridhar, MBBS, MCE

UT Health Science Center at Houston



Robert Frenck, MD

Cincinnati Children's Hospital Medical Center

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Robert Hood, PhD

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Disclosure Statement

I have relevant personal/professional/financial relationship(s) with respect to this educational activity with AAHRPP (site visitors and staff):

Sujatha Sridhar, MBBS, MCE Associate Vice President, Research Compliance, The University of Texas Health Science Center at Houston

Robert Frenck, MD Professor of Pediatrics, Infectious Diseases, Cincinnati Children's Hospital Medical Center

Robert Hood, PhD Director of Accreditation and Global Outreach, AAHRPP

Conflicts of Interest – Ethical Frameworks

Helsinki

- Explicit, operational requirements – must disclose any potential conflicts of interest:
- Address in protocol design
- Disclose to participants
- Disclose when disseminating results (publication)

Belmont

- Implied, not mentioned specifically
- Beneficence – researcher's fiduciary role vs divided loyalty
- Respect for persons – informational condition of autonomy
- Justice – related to recruitment

Beneficence

- Requires systematic assessment of risks based on sound science
- Financial/career stake introduces a competing interest the investigator has no standing to bring in
- Conflict is structural, not outcome-based, regardless of whether there is an impact on study design
- Identifying and managing conflicts helps reduce concerns about whether the science is influenced by external factors, reduce doubts about the integrity of the study results

Respect for Persons

- Voluntariness requires participants to understand risks
- In general, research involves an information asymmetry – because of technical specialized knowledge required for research, participants depend researcher to make an informed assessment of risks
- When researchers are conflicted, participants may be exposed to risks based on investigator's conflicting interest (money, career, equity), not based on sound science, and not treated purely as a partner in generating knowledge
  - Incentive to minimize risks, not disclose all risks

Justice

- Fair distribution of research burdens
- Structural problem – potentially skew recruitment toward convenient/profitable populations rather than those most scientifically/clinically appropriate
- Concerns about justice included in FD&C 21 U.S.C. 355(z) and 520(g)(9)(A) "Diversity Action Plan for Clinical Studies"
  - Scientific basis - Increase generalizability of results across intended patient populations, improve understanding of the disease
    - Rejects conflicting interests such as an impact on study timelines, challenges recruiting
  - Requires sponsors to provide goals, rationale for the enrollment goals, and a plan for how the sponsor will meet the goals; waivers allowed
  - FDA Draft Guidance (2024) – statute requires FDA to promulgate rules
    - "Support more equitable and timely access to medical discovers and innovations" and increase generalizability

AAHRPP Evaluation Instrument

Element I.6.A	The organization has and follows written policies and procedures to ensure that research is conducted so that financial conflicts of interest are identified, managed, and minimized or eliminated.
ELEMENT I.6.B.	The organization has and follows written policies and procedures to identify, manage, and minimize or eliminate individual financial conflicts of interest of Researchers and research staff that could influence the conduct of the research or the integrity of the Human Research Protection Program. The organization works with the Institutional Review Board or Ethics Committee in ensuring that financial conflicts of interest are managed and minimized or eliminated, when appropriate.

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Outcome

Financial conflicts of interest are identified, managed, and minimized or eliminated to maintain **protection of research participants,** ensure the **integrity of the research**, and ensure the **credibility of the HRPP.**

Management plans are monitored and enforced and when necessary, non-compliance is addressed with sanctions or administrative actions.

Financial conflicts of interest are reported to regulatory agencies as required.

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Organizational Conflicts of Interest
Element I.6.A.

Organizational Conflict of Interest

- Organizational financial conflict of interest include:
  - Licensing, technology transfer, patents.
  - Investments of the organization.
  - Gifts to the organization when the donor has an interest in the research.
  - Financial interests of senior administrators.
  - Other financial interests.
- Policies and procedures describe the process that the organization uses to identify, evaluate and manage organizational financial conflict of interest.
- Policies and procedure include examples of management strategies.

Case Study 1

- Dr. Smith, a faculty researcher at an academic medical center, invents a new implantable medical device designed to improve outcomes for patients undergoing heart surgery. Under the institution's intellectual property policy, the **university medical center owns the patent for the device**.
- The AMC stands to benefit financially if the device is successfully approved and commercialized through licensing agreements or partnerships.
- Dr. Smith proposes that the medical center conduct a clinical trial to evaluate the safety and effectiveness of the device. The study would involve medical center patients, researchers, and institutional resources.

Case Study 1

Dr. Smith, a faculty researcher at an academic medical center, invents a new implantable medical device designed to improve outcomes for patients undergoing heart surgery. Under the institution's intellectual property policy, the **university medical center owns the patent for the device**.

What type of conflict of interest may exist?

A. No conflict exists because Dr. Smith is the inventor and has the most expertise with the device.
B. A potential organizational conflict exists because the medical center has a financial interest in the success of the device it is studying.
C. A conflict exists only if the device does not perform as expected.
D. There is no conflict as long as the is being done under an Investigational Device Exemption approved by the FDA.

Case Study 1

Dr. Smith, a faculty researcher at an academic medical center, invents a new implantable medical device designed to improve outcomes for patients undergoing heart surgery. Under the institution's intellectual property policy, the **university medical center owns the patent for the device**.

How should the AMC manage this situation?

A. There is no situation - Dr. Smith needs to conduct this trial as they developed the device have the expertise.
B. Review the AMC's ownership interest, assess the conflict, and create a management plan.
C. Keep the patent ownership confidential to prevent concerns among participants.
D. Prevent any research on the device at the institution.

Case Study 1

Dr. Smith, a faculty researcher at an academic medical center, invents a new implantable medical device designed to improve outcomes for patients undergoing heart surgery. Under the institution's intellectual property policy, the **university medical center owns the patent for the device**.

Which of the following are appropriate strategies for managing this organizational conflict of interest if trial is done at the AMC?

A. Ensure non conflicted investigators are responsible for enrollment, consent discussion and assessment of adverse events.
B. Disclose the medical center's ownership of the patent and the potential financial interests associated with the device in consent forms.
C. Require review by an Institutional Review Board external to the AMC.
D. Establish independent Data and Safety Monitoring Board.
E. All of the above.

Case Study 2

- Dr. Smith developed an AI model that predicts whether a patient has early pancreatic cancer from digital pathology images. She founded a startup company to commercialize the technology and owns company stock. Her organization also holds equity in the company.
- Dr. Smith proposes a human subjects research study enrolling 500 patients to evaluate the AI model. She will serve as the Principal Investigator, oversee data analysis, and report the study results. The company will fund the study and use the findings to support regulatory approval and future commercialization.

Case Study 2

Dr. Smith, Smith developed an AI model that predicts whether a patient has early pancreatic cancer from digital pathology images. Dr. Smith proposes a human subjects research study enrolling 500 patients to evaluate the AI model. She will serve as the Principal Investigator, oversee data analysis, and report the study results.

Which of the following concerns should be addressed before the research is approved?

A. Financial conflicts of interest
B. Research objectivity and independent oversight
C. Bias in AI training and evaluation
D. Transparency with research participants
E. All of the above

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Researcher and Research Staff Conflicts of Interest

Element I.6.B.

Financial Conflict of Interest

- A financial conflict of interest of a researcher or research staff (defined as anyone involved in the design, conduct, or reporting of research) can be broadly defined as an interest that competes with the researcher's or research staff's obligation to protect the rights and welfare of research participants, preserve the integrity of the research, or uphold the credibility of the HRPP.
- Policy and procedures should be consistent but may vary to meet unique requirements of a particular law, regulations, or code when an organization must follow multiple laws, regulations, or codes.

Policy and procedures:

- Disclosure
- Evaluation
- Management
- Monitoring
- Enforcement
- Reporting
- Education

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Disclosure

- Disclosure threshold can vary, depending on funding or regulatory oversight, so long as the organization has the ability to track different disclosure requirements.
- Disclosure
  - At least annually
  - Update new significant financial interests promptly following of acquisition or discovery.
- Review disclosures consistently and document determinations.

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Significant Financial Interest – US Public Health Service (PHS)

- Remuneration or equity interest over $5000 from publicly traded entity in the past 12 months.
- Renumeration over $5000 or any equity interest from non-publicly traded entity last the past 12 months.
- Intellectual property rights (e.g., patents, copyrights) upon receipt of related income.
- Reimbursed or sponsored travel.

Renumeration includes salary e.g., consulting fees, honoraria, paid authorship.
Equity interest e.g., stock, stock option, or other ownership interest.
Intellectual property rights and interest e.g., patents, copyrights.

Financial Interest – US National Science Foundation (NSF)

Financial interests of the researcher or research staff, or their immediate family means:

- Ownership interest, stock options, or other financial interest related to the research unless it:
- Does not exceed $10,000 when aggregated for the immediate family.
- Is publicly traded on a stock exchange.
- Compensation related to the research unless it does not exceed $10,000 in the past year when aggregated for the immediate family.
- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.

Financial Interest – US FDA

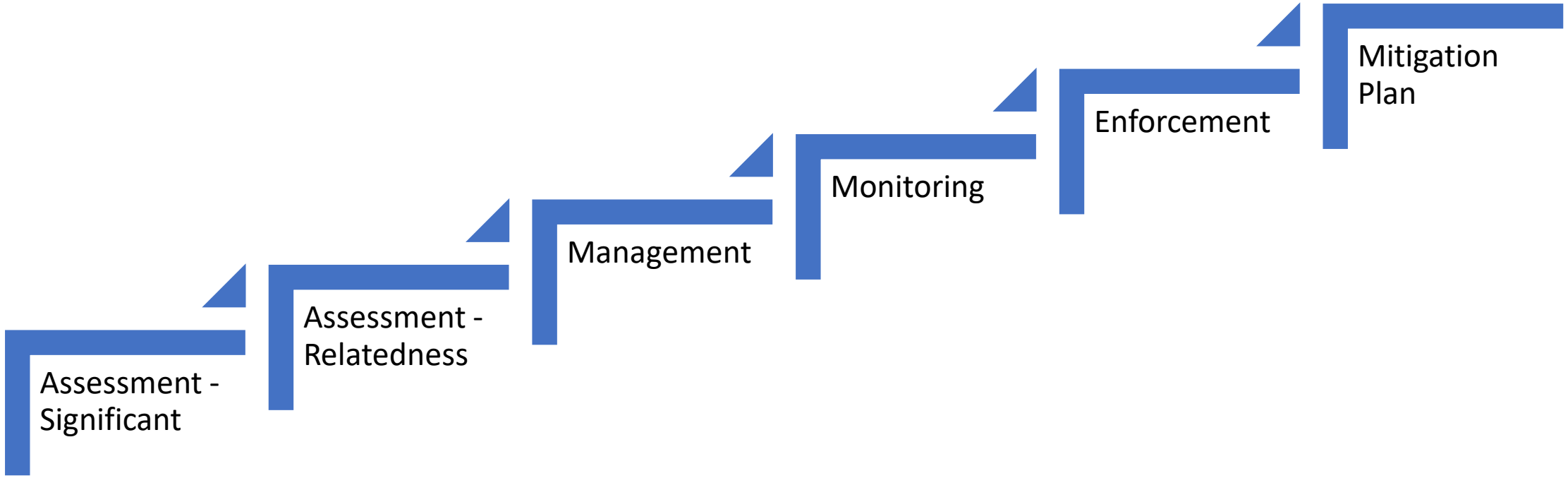
- Financial interests of the researcher or research staff, or their immediate family means
- Ownership interest, stock options, or other financial interest related to the research unless it meets four tests:
  - Does not exceed $50,000 when aggregated for the immediate family.
  - Publicly traded on a stock exchange.
  - No arrangement has been entered into where the value of the ownership interests will be affected by the outcome of the research.
  - Does not exceed 5% interest in any one single entity when aggregated for the immediate family.
- Compensation related to the research unless it meets two tests:
  - Does not exceed $25,000 in the past year when aggregated for the immediate family.
  - No arrangement has been entered into where the amount of compensation will be affected by the outcome of the research.
  - Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.

https://www.fda.gov/media/85293/download

Education

- The process to educate researchers and research staff about disclosures and responsibilities related to financial conflict of interest.
- Education is required of each individual initially and at least every four years.
- Education is required immediately when:
  - Financial conflict of interest policies are revised in a manner that changes researcher requirements.
  - A researcher is new to the organization.
  - A researcher is noncompliant with financial conflict of interest policies and procedures.

Evaluate and Manage



Management plan strategies

- Disapprove research at institution
- Eliminate conflict
  - Conflicted individual does not participate in research
  - Conflicted individual divests financial interest
- Manage conflict
  - Non conflicted Principal Investigator
  - Non conflicted individuals for enrollment
  - Non conflicted individuals for eligibility assessment
  - Measures to promote objectivity (blinding, randomization, objective end points)
  - Disclosure – publications, consent forms
  - Independent data and safety monitoring
  - Non conflicted individuals for assessment for AEs
- Other strategies..

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Communication with IRB/EC

- The process to inform the IRB/EC of the results of COI process evaluation, including any management plan.
- The process that allows the IRB/EC to have the final authority to decide whether the interest and its management, if any, allows the research to be approved.

Compelling Circumstances – human subjects

- Skills, qualifications, expertise of the conflicted individual
- Specific institutional resources
- Access to certain patient populations
- Degree to which the significant financial interest and the research are linked
- Safeguards to promote objectivity in the study plan or research project design (*e.g.,* RCT, non-conflicted co-investigators, external lab, objective endpoints)
- Risk-Benefit analysis related to financial interest - to what extent could the conflict increase risk to human subjects that cannot be managed?
- Extent to which the conflicted interest is amenable to effective oversight and management

Monitoring and Enforcement

- Polices and procedures should address:
  - Monitoring of management plans.
  - Mechanisms for enforcement and provision of employee sanctions or other administrative actions to ensure researcher compliance.
  - Examples of sanctions or other administrative actions.
  - Mechanism for retrospective review and a mitigation report if necessary.

Case Study 3

- Dr. Smith, a faculty researcher, provides consulting services for NovaCura Therapeutics, a publicly traded pharmaceutical company developing an investigational cancer drug called OncoLexa.
- During the past 12 months, Dr. Smith received $26,800 from NovaCura Therapeutics in consulting fees and travel reimbursement.
- Dr. Smith now proposes to serve as the Principal Investigator on a NIH funded clinical trial evaluating OncoLexa at the institution.

Case Study 3

Dr. Smith received $ 26,800 from NovaCura Therapeutics. Proposes clinical trial evaluating OncoLexa.

A. The financial relationship does not require disclosure because OncoLexa is a promising drug which may help patients.
B. Assess the financial interests for relatedness and develop a management plan if the conflict is manageable.
C. Dr. Smith is an expert in this field. It is not a conflict if NovoCure seeks his expertise in developing OncoLexa.
D. This study has received federal funding, the IRB and COI office should not place obstacles.

Case Study 3

- Dr. Smith received $ 26,800 from NovaCura Therapeutics. Proposes clinical trial evaluating OncoLexa.

Management plan should include:

A. Requiring disclosure of the financial conflict to the research team.
B. Appointing an independent monitor to oversee aspects of the study.
C. Modifying Dr. Smith's responsibilities for participant recruitment, consent, or data analysis.
D. Requiring periodic review of the management plan by the institution.
E. All the above.

Case Study 4

- Dr. Hill serves as the Principal Investigator on a clinical trial at the institution sponsored by Apexa Technologies, a privately held medical device company evaluating an investigational cardiac monitoring device called CardioSense.
- When the study began two years ago, Dr. Hill had no financial relationship or outside activities with Apexa Technologies.
- The company has now invited Dr. Hill to serve as a consultant, providing feedback based on her clinical and research experience with CardioSense.
- Dr. Hill expects to receive $17,000 in consulting fees over the next 12 months while continuing to serve as Principal Investigator on the study.

Case Study 4

Dr. Hill's research evaluates CardioSense and now is consulting for Apexa Technologies and will be paid $17,000.

What are the appropriate next steps?

A. No action is needed because the consulting relationship began after the study was approved.
B. Dr. Hill should disclose the new financial relationship, and the institution should review it to determine whether it constitutes a Financial Conflict of Interest.
C. Dr. Hill must immediately resign as Principal Investigator.
D. The study should be suspended until the consulting agreement ends.

Case Study 4

Dr. Hill's research evaluates CardioSense and now is consulting for Apexa Technologies and will be paid $17,000.

If the institution determines that an FCOI exists, which management strategies may be appropriate? *(Select all that apply.)*

A. Develop a written FCOI management plan with ongoing institutional oversight.
B. Modify Dr. Hill's research responsibilities, such as limiting involvement in participant recruitment, informed consent, or data analysis.
C. Ensure that there is an independent monitor to oversee the conduct of the study.
D. Require disclosure of the conflict to appropriate members of the research team and, when applicable, in publications or presentations.
E. Suspend trial until Dr. Hill ends the consulting relationship.

Summary

Financial conflicts of interest are identified, managed, and minimized or eliminated to maintain **protection of research participants,** ensure the **integrity of the research**, and ensure the **credibility of the HRPP.**

Management plans are monitored and enforced and when necessary, non-compliance is addressed with sanctions or administrative actions.

The IRB retains authority to decide whether the interest and its management, if any, allows the research to be approved.

Financial conflicts of interest are reported to regulatory agencies as required.

Resources

- AAHRPP Tipsheet - Financial COI for Researchers and Staff
- AAMC FOCI - Tools and Templates (membership required)
- NIH - COI Policy Checklist

Questions?

Thank You!