Memorial Sloan Kettering Cancer Center

Sponsor – Investigator Relationships and Responsibilities: *Conflict of Interest*

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Clinical Research Study Management and Compliance

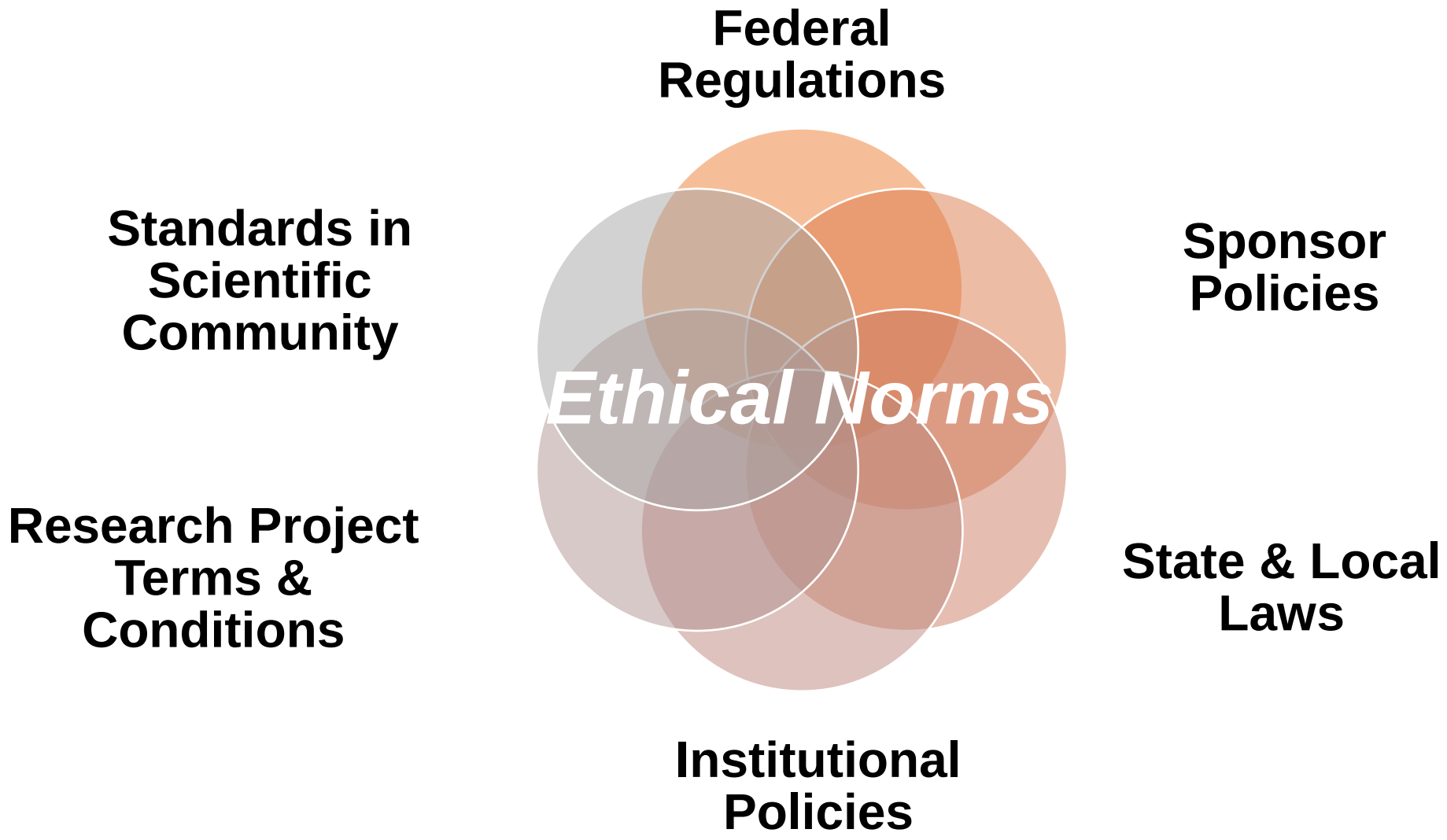
Objectives

1. Define conflict of interest (COI) in research
2. Highlight key ethical principles and regulatory requirements relating to COI
3. Outline COI-related roles and responsibilities of investigators involved in clinical research
4. Describe the processes of identifying, reviewing, and managing COIs
5. Discuss examples of COIs in clinical research

MSK Supports Innovation & Industry Engagement

- Advancements in treatment and public health can only happen through scientific discovery
- MSK researchers develop novel concepts and treatments in furtherance of our mission
- In order to translate innovative research into treatments that can be made available to patients everywhere, researchers and research institutions work with industry partners who have the necessary resources and expertise to commercialize these products
- MSK physicians and researchers are experts, and are permitted to advise and consult with industry in order to provide critical expertise and guidance needed to further research and development efforts *(in the absence of unmanageable conflicts of interest or commitment)*
- We must balance this engagement with ensuring the integrity and objectivity of MSK's mission-driven clinical care, research, and educational activities

Regulatory Framework to Consider



Defining Conflict of Interest

Conflict of Interest

A conflict of interest arises when an individual's personal interests influence his/her judgment or objectivity related to professional obligations and responsibilities

Conflict of Interest in Research

A conflict of interest arises when an individual's personal interests influence the objectivity of the design, conduct, or reporting of research

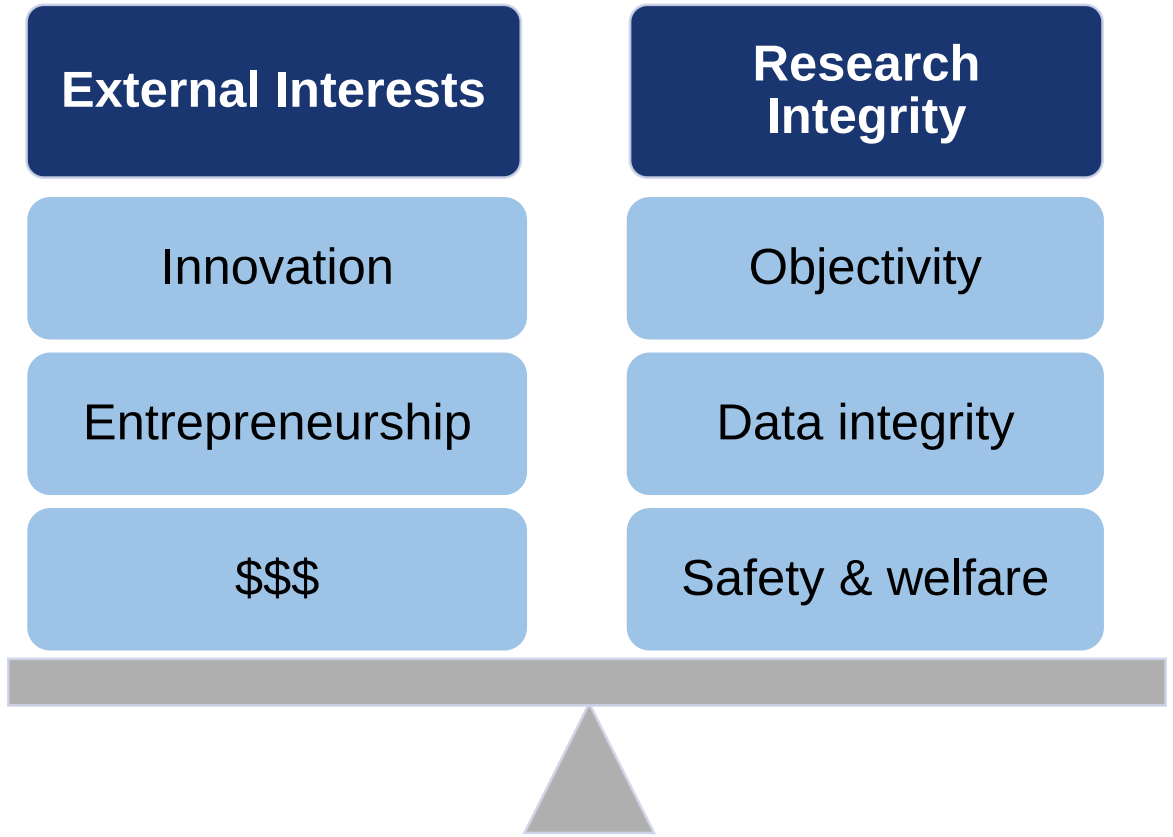
Perception is a significant factor when considering COIs.

The *appearance* of a COI …

The *potential* for lack of objectivity

Why Do We Care About COI in Research?

The risk that an individual's external interests may bias or compromise
– or have the appearance of biasing or compromising –
an individual's judgment, objectivity, or decision-making in research



The impact - even potential or perceived impact - of external interests on research integrity needs to be assessed

Key Ethical Principles

- Research is intended to further knowledge and advance the public good
- There is an expectation, particularly with federally-funded research, that the design, conduct, and reporting of research is performed in an ethically sound, objective, and unbiased manner, important for many reasons:
  - ✓ Public health and safety
  - ✓ Current and future direction of research
  - ✓ Current and future direction of resources for research

Key Ethical Principles

While research practices vary by discipline, certain ethical principles and standards apply across-the-board:

- **HONESTY** — conveying information truthfully
- **ACCURACY** — reporting findings precisely and taking care to avoid errors
- **EFFICIENCY**— using resources wisely and avoiding waste
- **OBJECTIVITY** — letting the facts speak for themselves and avoiding improper bias

** Source: Steneck, Nicholas H. (2007). Introduction to the Responsible Conduct of Research.*

Impetus and Environment for Focus on COI Regulations

"Biomedical and behavioral research and the resulting interactions among government, research institutions, and the private sector have become increasingly complex."

~ 42 CFR Part 50 Federal Register Notice Summary

"Top Cancer Researcher Fails to Disclose Corporate Financial Ties in Major Research Journals"
~ New York Times, September 2018

"Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing"
~ JAMA, May 2017

"Baylor College of Medicine Faces NIH Sanctions Over Financial Conflicts"
~ Chronicle of Higher Education, January 2010

"29 Percent Of Cancer Studies Report Conflict Of Interest"
~ Science Daily, May 2009

"Grassley Intensifies Probe Into NIH & Stanford"
~ Pharmalot, August 2008

"Drugmakers and College Labs - Too Cozy?"
~ Business Week, June 2008

"Top Psychiatrist Failed to Report Drug Income"
~ The New York Times, October 2008

Key Roles & Responsibilities

Investigators

- Meet any and all disclosure requirements
- Comply with terms of COI management plans (if applicable)

Institutions

- Implement and enforce COI policies
- Collect and review disclosures
- Manage, reduce, or eliminate COIs
- Report COIs to external entities (if applicable)

Research Sponsors*

- Collect research study-specific disclosures (where applicable)
- Submit financial disclosure forms

** And/or applicants / sponsors of FDA marketing applications*

Varying Disclosure Requirements

Your Home Institution

- Typically broad disclosure requirements – any financial interests or outside activities

Research Sponsors*

- Typically specific thresholds for disclosure of specific financial interests and relationships

Journals/Conferences

- Varies, but most common is disclosure of any financial interests broadly relevant to the work

** And/or applicants / sponsors of FDA marketing applications*

Main Types of Financial Interests & Relationships

Professional Services

- Consulting, speaking, advisory board service, etc.

Fiduciary Role

- Board of Directors position, Executive position (CSO, CEO, etc.)

  Note: *Such roles require prior COI Committee approval (e.g., before accepting role; before incorporating new company)*

Ownership / Equity

- Stock, stock options, partnership shares, etc.

Intellectual Property

- Patents, royalty payments, licensing fees, etc.

Other

- Sponsored/reimbursed travel
- Research support

COI Review & Determination Process

Review

Disclosures are reviewed for potential *overlap with* or *impact on objectivity of* an individual responsibilities

- Research
- Patient care
- Education
- Business decisions

Disposition

Determinations are made

- No conflict
- Conflict of interest – manageable
- Conflict of interest – *not* manageable and must be eliminated

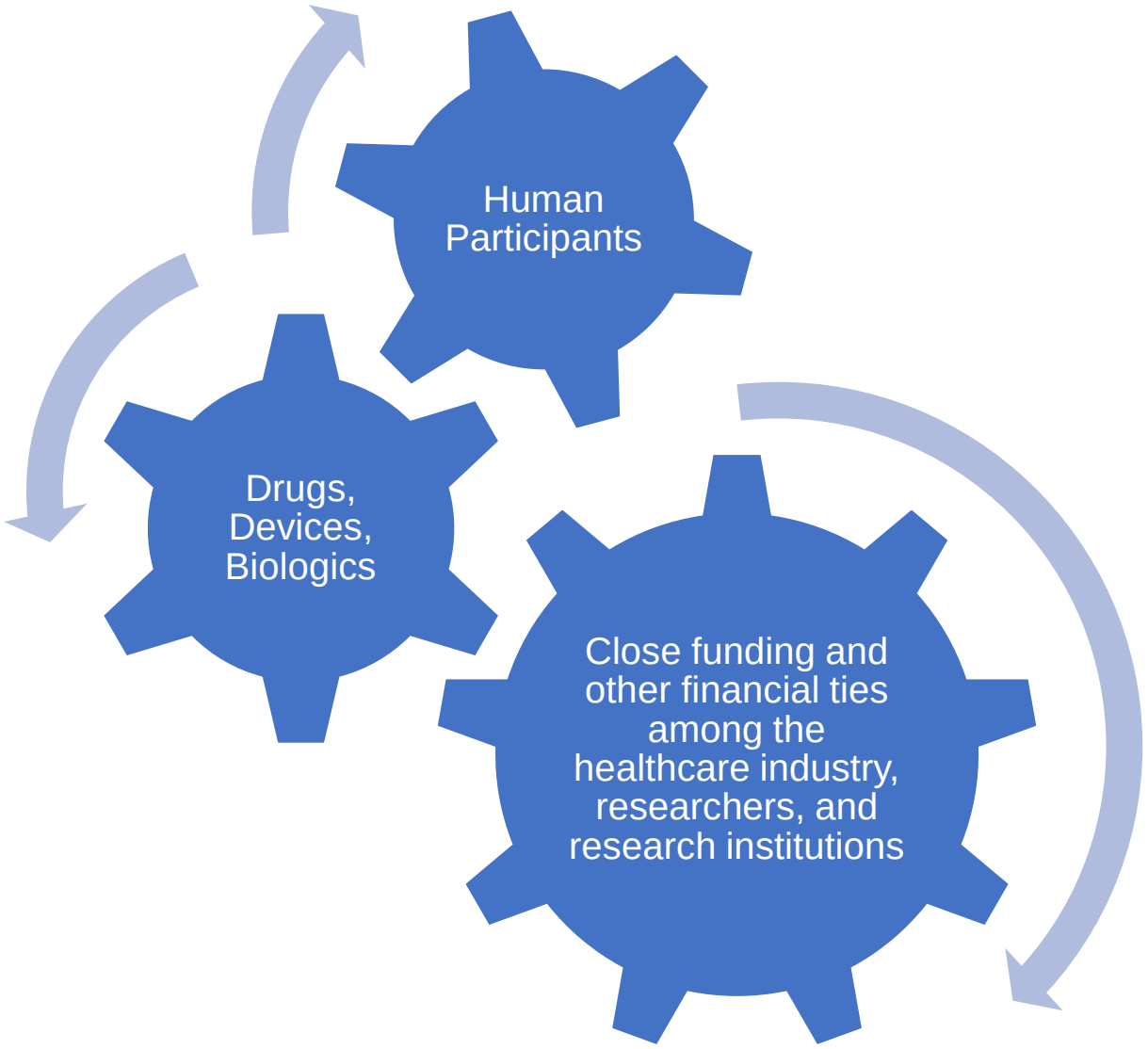
COI Management

Management strategies are designed to *promote transparency* and *mitigate risk of bias*

COI Review Considerations

- Not all financial interests and relationships present COIs
- External interests and activities are reviewed to determine whether or not they have the potential to impact or bias the integrity and/or objectivity of an MSK activity (or present the perception thereof)
  - *For example, does a financial interest relate to and have the potential to impact the objectivity of the design, conduct, or reporting of an MSK research study, and/or impact the rights and welfare of human participants in the research study?*
- The nature and magnitude of the external interest/relationship, the nature of the MSK activity, and the role of the individual in the MSK activity are all taken into consideration when making a COI determination

Special Considerations for Clinical Research



Adequate protection of the rights and welfare of human research participants is paramount.

What actions can be utilized to minimize risks to participants?

- Careful study design (e.g., randomized, controlled, blinded studies)
- Disclosure of interests to research team and research participants
- Restricted role for conflicted investigator (cannot be PI, no or distant role relative to subject interaction, data analysis, etc.)
- Independent data review (e.g., objective third-party review of study data (similar to DSMBs))

Common COI Management Strategies

- ✓ Disclosure of interests to staff, lab, and research team members; to research subjects; in presentations & publications
- ✓ Restrictions around certain activities and/or decisions (e.g., prohibition from serving as PI/co-PI or a consenting professional on related clinical trials; limits on executive role in an outside venture; recusal from business or purchasing decisions)
- ✓ Independent individuals/committees to provide objective scientific oversight for complex and/or significant conflicts
- ✓ Independent appointee to serve as resource for fellows, residents, student, and trainees when leader is conflicted

Examples of COIs in Research

- Financial relationship with an entity sponsoring the research, or the entity that manufactures the product being tested in the research (e.g., paid consulting, speaking)
- Fiduciary role in entity sponsoring the research (e.g., service on board of directors)
- Ownership interest in entity sponsoring the research, or manufacturing the product being tested in the research (e.g., stock, stock options
- Intellectual property rights (e.g., patent) for product being evaluated or further developed in the research

Key Take-aways

- ✓ COI requirements exist to establish transparency relative to researchers' external financial interests, and provide assurance that such external financial interests will not bias the researchers' objectivity or impact judgement or decisions relative to human participant safety
- ✓ Complete and accurate disclosure of interests is critical; when in doubt, err on the side of disclosure

Questions

Memorial Sloan Kettering Cancer Center

For Additional Reference

Key Federal Regulatory Requirements *(For Reference)*

Public Health Service (PHS): 42 CFR Part 50 Subpart F

Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought

Applies to research funded by PHS (agencies under PHS include NIH, NCI, CDC, AHRQ)

Food and Drug Administration (FDA): 21 CFR Part 54

Financial Disclosure by Clinical Investigators

Applies to research involving a human drug, biological product, or device

PHS: Specific Disclosure Requirements *(For Reference)*

An external financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children), when combined for the 12 months preceding the disclosure date, from a single entity:

- Compensation and/or other payments for service (e.g., salary, consulting, advisory, and/or lecturing fees, paid authorship, gifts, and honoraria) exceeding $5,000;
- Equity interests (e.g., stock, stock options, or other ownership interests) in a publicly-traded entity for which the value exceeds $5,000;
- Reimbursed or sponsored travel exceeding $5,000;
- Intellectual property rights and interests exceeding $5,000 (e.g., patents, copyrights), upon receipt of income related to such rights and interests; and
- Any equity interests (e.g., stock, stock options, or other ownership interests) in a non-publicly-traded entity.

FDA: Specific Disclosure Requirements *(For Reference)*

Financial interests that must be disclosed by clinical investigator (and those of the Investigator's spouse and dependent children):

- Compensation made to the investigator in which the value of compensation could be affected by study outcome (*e.g., compensation that could be higher for a favorable outcome than for an unfavorable outcome, or compensation to the investigator in the form of an equity interest in the study sponsor or in the form of compensation tied to sales of the product, such as a royalty interest)*
- A proprietary interest in the tested product, such as a patent, trademark, copyright or licensing agreement
- Equity interest in the sponsor of a covered study that exceeds $50,000 in value if a publicly-traded company
- Any equity interest in the sponsor of a covered study if a non-publicly traded company
- Significant payments of other sorts (SPOOS), which are payments that have a cumulative monetary value of $25,000 or more made by the sponsor of a covered study to the investigator or the investigators' institution to support activities of the investigator *exclusive of* the costs of conducting the study

Role of Institutional Review Boards (IRBs) *(For Reference)*

HHS Guidance: *Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection*

- Recommends that IRBs, institutions, and investigators consider whether specific financial relationships create financial interests in research studies that may adversely affect the rights and welfare of subjects.
  - Stems from responsibilities for protecting the rights and welfare of research participants identified in 45 CFR Part 46
  - 45 CFR Part 56 requires that additional information be given to subjects "*when in the IRB's judgment the information would meaningfully add to protection of the rights and welfare of subjects*" – this allows the IRB to require disclosure of financial interests by investigators for the IRB to consider