

# Baylor University

## Introduction to Conflicts of Interest and Commitment

# Agenda

1. Introduction and History
2. Definitions
3. Baylor Resources

# Introduction and History

# Introduction

## Approach

- Provide background for COI-related regulation and enforcement
- Discuss how COI programs are developed and maintained
- Review key people and processes impacting COI administration

## Goals

- Provide a foundational understanding of the regulatory and enforcement environment in which COI programs operate
- Understand common structures, people, and processes relevant to COI administration

# COI Background

## History

- 1980: Bayh-Dole Act
- 1995: HHS Financial Conflict of Interest (FCOI) regulations promulgated; NSF issues FCOI policy mirroring HHS regulations
- 1998: early 2000s: Series of high-profile cases raised questions about conflict of interest in research
- 2010: Physician Payments Sunshine Act (Sect 6002 of Affordable Care Act)
- 2012: Revised HHS FCOI regulations effective, NSF retains previous policy
- 2013: Sunshine Act implemented by Final Rule
- 2018: Foreign Influence investigations by NIH begin
- 2019: NIH issues reminder on NIH policy on Other Support related to FCOI and foreign components
- 2019-2020: Series of enforcement actions resulting from foreign influence investigations conducted by the DOJ, including scientists being fired by institutions and arrested for fraudulent activities
- 2020: NSF award terms and conditions revised to establish post-award disclosure requirements for previously undisclosed Current and Pending (Other Support) and in-kind contributions
- 2021: JCORE report and NSPM-33 issued
- 2021: COGR Principles of COC released
- 2022: DOJ announced end of the China Initiative
- 2022: Guidance on NSPM-33 implementation issued

# Definitions

# Defining Conflicts

## Conflict of Interest

- Situation in which an individual, or a member of the individual's immediate family, has a significant financial interest, or financial relationship that could directly and significantly affect the design, conduct, reporting, or funding of research.

## Conflict of Commitment

- Situation in which an individual accepts or incurs conflicting obligations between or among multiple employers or other entities. Many organizational policies define conflicts of commitment as conflicting commitments of time and effort, including obligations to dedicate time in excess of organizational or research agency policies or commitments.

<https://www.whitehouse.gov/wp-content/uploads/2022/01/010422-NSPM-33-Implementation-Guidance.pdf>

# Various Conflicting Areas

Individual Financial Conflict of Interest

Conflicts of Commitment (COC)

Institutional Conflict of Interest

Research

Gifts and Entertainment

Vendor Relationships and Procurement

Institutional Decision Makers: Board, Executive Leadership, etc.

Intellectual Property and Technology Transfer

Philanthropy, Major Gifts and Donor Relationships

Foreign Interests, Activities and Relationships



# Conflict Types

## Conflict of Interest (COI)

- Financial interests that may create or give the appearance of creating bias or affecting decision-making

## Research Financial Conflict of Interest (RFCOI)

- When an individual's personal financial interests could directly and significantly affect the design, conduct, or reporting of research.

## Institutional Conflict of Interest (ICOI)

- When the financial interests of an institution or an institutional official, acting within his or her authority on behalf of the institution, could affect or appear to affect the research, education, clinical care, business transactions, or other activities of the institution

## Conflict of Commitment (COC)

- When an individual's commitment of time and effort to outside activities is inconsistent with the individual's commitment to the institution and/or the institution's interests

# Conflict of Interest

Financial interests that may create or give the appearance of creating bias or affecting decision-making. Examples include, but are not limited to:

## Outside Employment

- Part-time/full-time employment outside of Baylor

## Outside Teaching

- Teaching at a competing institution
- Lab work/research outside of Baylor

## Consulting

- Consulting for a drug/device company
- Any paid consulting or legal work

# Research FCOI

- Financial COI in research is governed by federal regulations, federal agency policies, and other research sponsor requirements.
  - Public Health Service (PHS) regulations: 42 CFR Part 50 Subpart F
  - Federal Drug Administration (FDA): 21 CFR Part 54
  - National Science Foundation (NSF): NSF-20-1 Proposal & Award Policies & Procedures Guide
  - Department of Defense (DOD): FY20 General Application Instructions (version 20190530)
  - Department of Energy (DOE): FY21 Department of Energy Interim Conflict of Interest Policy
  - National Security Presidential Memorandum – 33 (NSPM-33): FY21
- PHS regulations dominate the regulatory landscape and outline responsibilities for both institutions and investigators.

# Institutional Conflict of Interest

Definition: When the financial interests of an institution or an institutional official, acting within his or her authority on behalf of the institution, could affect, or appear to affect, the research, education, business transactions, or other activities of the institution.



**Financial  
interests held by  
high-level  
institution  
leadership**



**Major gifts to the  
institution,  
department, or  
individual PIs**



**Intellectual  
property rights  
held by the  
institution**



**Institutionally-  
held equity and  
investments**



**Strategic  
relationships  
between the  
institution and  
third parties**

# Conflict of Commitment

Federally regulated conflict of commitment policies are not yet active, but recent activity suggests they are forthcoming in 2023.

## COC Component

- Outside Activities/Time Away
- Employment outside of Baylor
- Foreign Relationships and Activities

## Example COC Activities

Teaching/Speaking Engagements

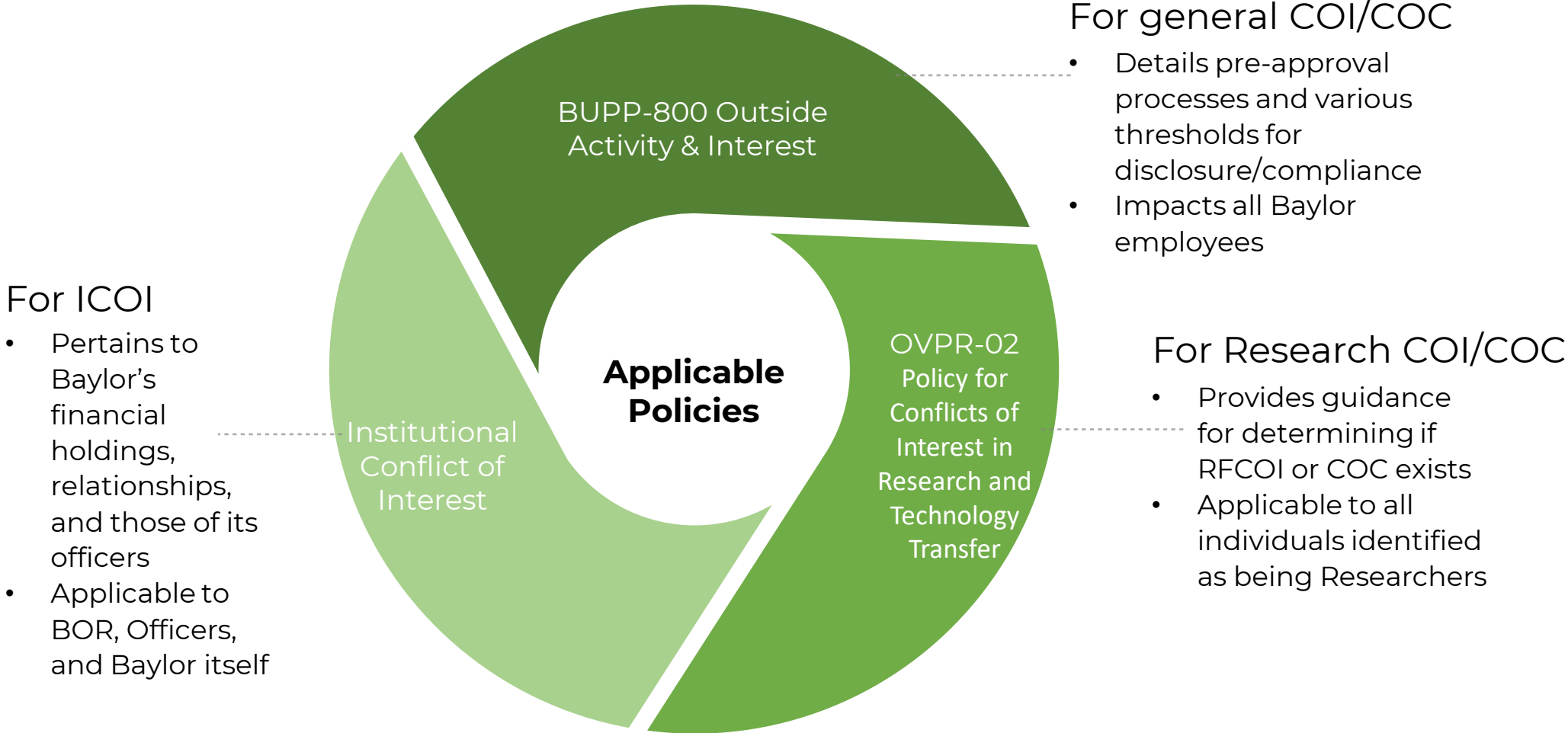
Scientific Advisory Boards

Consulting

Data Safety Monitoring Boards

# Baylor Resources

# Baylor Policies

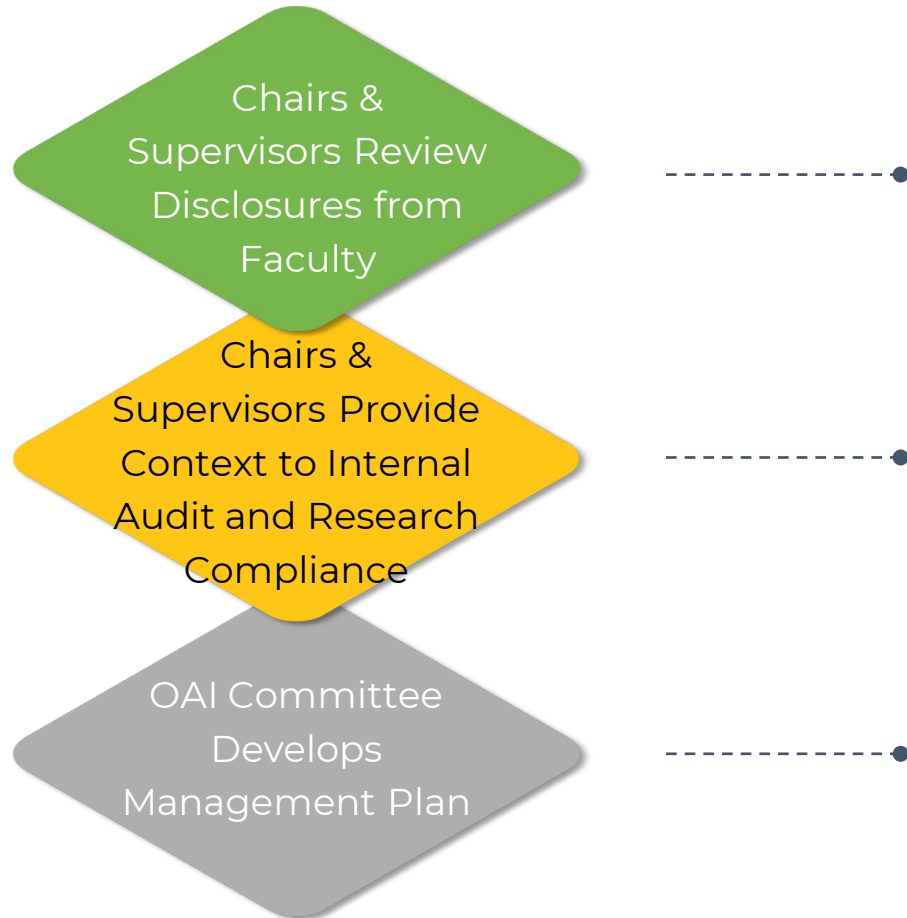


# What to Expect: Disclosers



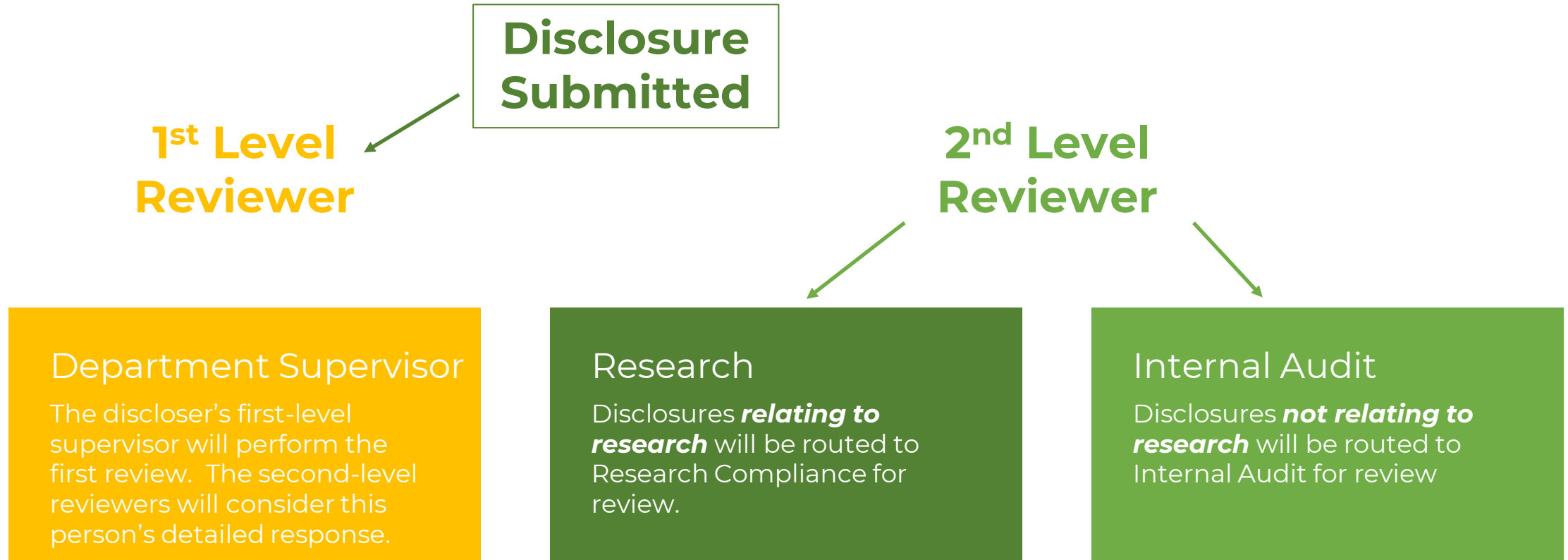


# What to Expect: Reviewers



- Chairs and supervisors will review disclosures that exceed thresholds (usually \$5,000 or more than one day) and pre-approval requests.
- We will provide additional training and resources for Chairs and supervisors to support disclosure review.
- The Chair's or supervisor's review will be provided to Internal Audit or Research Compliance.
- Internal Audit or Research Compliance will determine whether the disclosure constitutes a conflict that should be managed.
- The OAI Committee reviews recommendations on conflicts that should be managed.
- The Chair or Dean will be involved in determining appropriate management strategies.

# BUPP-800 and OVPR-02 Reviewer Responsibilities



# High-Level Reviewer Checklist

Activities that affects the design, conduct, or reporting of research

Activities that may appear to produce a public perception of a conflict

Activities that could be affected by the discloser's research projects

Activities with entities that do business with Baylor

Contracts between the discloser and the sponsor of the discloser's research

Outside activities that include involvement of the discloser's students or graduate assistants

Family members who are employed by the discloser's research sponsor

Family members who are attending or employed by Baylor

\*Reviewers will have the option to attend additional training. Dates to be announced.

# Thank you!

## Questions?

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**CARA**