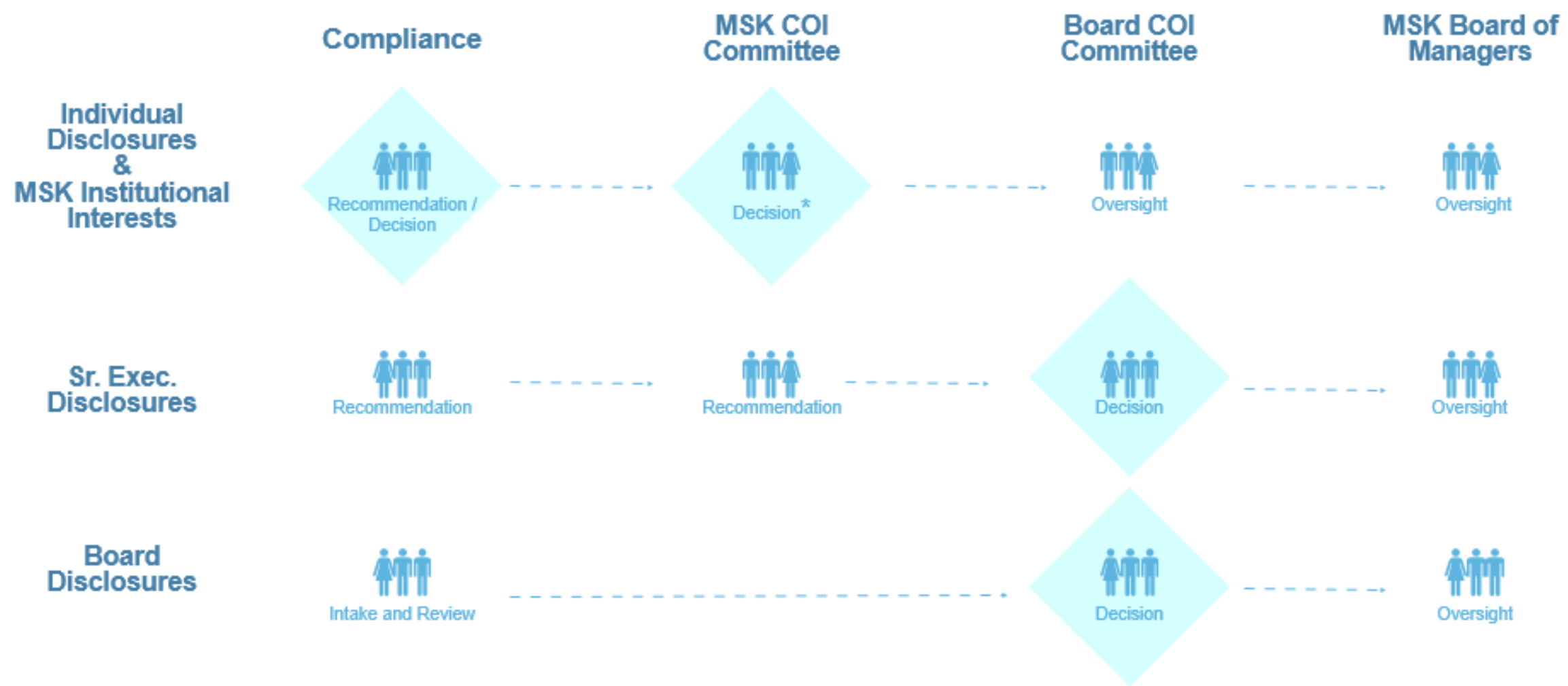


# High-Level COI Governance Structure & Process



\*In consultation with clinical, scientific, and/or administrative leadership as needed.

# From COIC COI Charter

## Delegation

As permitted by MSK's [\*Conflict of Interest and Commitment Policy\*](#), the COIC may delegate certain matters and decisions to designees, including the COIC Chairs, designated reviewers of the COIC, and the Compliance COI Office. Reviews and dispositions may occur by delegates on behalf of the COIC per criteria and procedures agreed upon by the COIC, and dispositions resulting from such actions will be reported to the COIC on a regular basis.

# Reviews – Structure, Roles & Responsibilities

## Compliance COI Team

- ⚙ Gathering of information
- ⚙ Analysis
- ⚙ Recommendations
- ⚙ Decisions for routine cases based on established criteria

## Committee Chairs & Designated Reviewers

- ⚙ Recommendations and decisions for complex or unusual cases
- ⚙ Institutional COI decisions for basic science and preclinical research

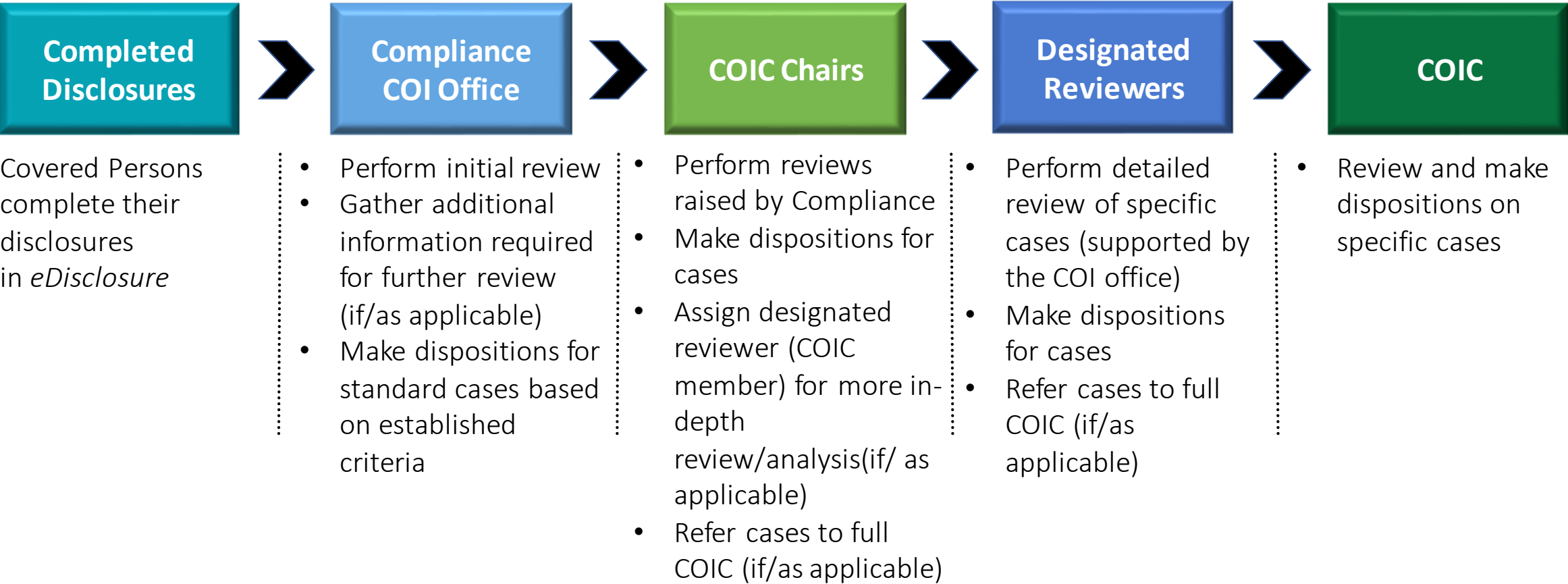
## Committee

- ⚙ Decisions for complex or unusual cases
- ⚙ Compelling circumstances decisions (individual and institutional) related to clinical research

# Scope of Reviews and General Process

- 1. **Annual Disclosures** – full assessment of an individual’s whole portfolio of outside financial interests and activities
- 2. **Transactional Reviews** – assessment of all FIs in the context of any new research (e.g., each protocol, grant, Clinical Trial Agreement (CTA)) and/or new transactions or business decisions (e.g., selection of new vendor, internal reviews)
- 3. **Reviews related to new / updated disclosures** – ongoing assessments as updated disclosures (new FIs) are disclosed

## Review Process Flow



# General Framework for Dispositions

Interest	Related to MSK Responsibilities	Exception to Policy Req'd	Related Research – Compelling Circumstances Req'd	Disposition	Notes
Fiduciary Role – Executive Officer	☑	☑	☑	If permitted, management plan with transition timeline	Regardless of related research, may need management plan if leadership role or institutional committee role
Fiduciary Role – Board of Directors	☑		☑	If consistent with MSK’s mission and approved, and if CC approved, COI management plan	Regardless of related research, may need management plan if leadership role or institutional committee role
Equity > \$25K in Public Entity	☑		☑	If CC approved, COI management plan	If no related research, no institutional committee service, or directly related purchasing role, no management plan needed
Any Equity (even if \$0) in Private Entity					
Compensation > \$25K	☑		☑	If CC approved, COI management plan	If no related research, no institutional committee service, or directly related purchasing role, no management plan needed
Intellectual Property Rights	☑		☑	If CC approved, COI management plan	If no related research or no institutional committee service, no management plan needed
Compensation \$5K - \$25K	☑			Transparency management plan	If no related research, no institutional committee service, or directly related purchasing role, no management plan needed
Equity in Public Entity \$5K - \$25K	☑			Transparency management plan	If no related research, no institutional committee service, or directly related purchasing role, no management plan needed
Compensation/Public Equity < \$5K	☑			No COI or management unless exceptional circumstances	
Travel	☑			No COI or management unless exceptional circumstances	

# Example of Report-out of Reviews Handled Outside of COIC

## Report on Reviews Handled Outside of COIC (TIMEFRAME)

**OBJECTIVE:** Share report of annual and research-related COI reviews and dispositions that occurred outside of the full COIC, including by Compliance COI staff, Designated Reviewers, and/or the COIC Committee Chairs.

**This report includes reviews not referred for full COIC review.  
Please contact Compliance if you have questions or would like to discuss.**

Institutional: Reviews completed outside of COIC for institutional conflicts from 7/9/2020 – 8/12/2020: XX

Research: Reviews completed outside of COIC for transactional research from 7/9/2020 – 8/12/2020: XX

Annual: Reviews completed outside of COIC for the 2020 annual disclosures from 7/9/2020 – 8/12/2020: XX

### Institutional Conflict of Interest Reviews

1. [ENTITY NAME] – Identification and management of [ENTITY NAME] related interests in new sponsored research agreement
  - [PROJECT ID]: sponsored by [ENTITY NAME] ([ENTITY NAME])
  - COIC Chairs reviewed and determined to present an Institutional COI on [DATE]. *To be included in ICOI management plan under [L-ROC] or [C-ROC] oversight [if applicable].*
  - As this research is non-interventional, requirements for compelling circumstances do not apply

### Research-Related Reviews

1. Reviews arising from sponsored research (transactional sponsored projects reviews)  
Compliance performed ~XX reviews (~XX individuals on ~XX projects); of these:
  - X new management plans were issued
    - o [INVESTIGATOR NAME] (COMPANY; PROJECT ID: XXXXX)
  - X projects in new funding year were reviewed and continued under existing/updated management plans
    - o [INVESTIGATOR NAME] (COMPANY; PROJECT: XXXXX)
2. Reviews arising from IRB protocols (transactional IRB protocol reviews)  
Compliance performed ~XX reviews (~XX individuals on ~XX protocols); of these:
  - XX management plans were issued or updated
    - o [INVESTIGATOR NAME] (COMPANY; PROJECT ID: XXXXX)

# Example of Report-out of Reviews Handled Outside of COIC (continued)

## Annual Reviews

Reviews arising from the 2020 Annual Disclosure process, completed outside of COIC, from 7/9/2020 – 8/12/2020: **xx**

Name	Department	Disposition	Determination Made By
[name]	[department]	COI - Management Plan	COIC Chair(s)
[name]	[department]	COI - Management Plan	COIC Chair(s)
[name]	[department]	COI - Management Plan	COIC Chair(s)
[name]	[department]	COI - Management Plan	Designated Reviewer [name]
[name]	[department]	COI - Management Plan	COI Office
[name]	[department]	No Conflict	COI Office
[name]	[department]	No Conflict	COI Office