Research Misconduct Rules Revamped: ORI Essentials for Emory

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Research Compliance and Regulatory Affairs

Research Administration

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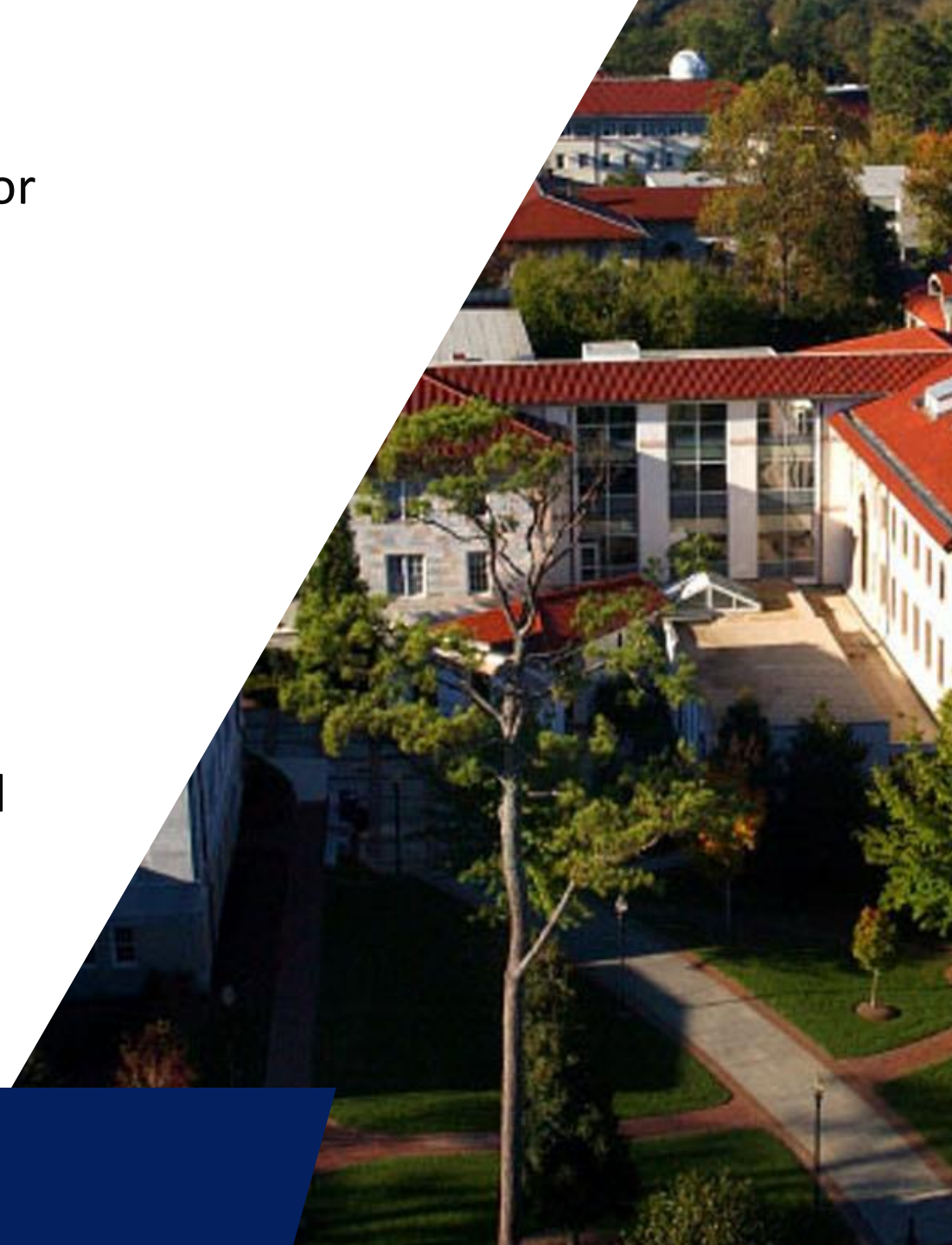
Key Highlights

- **Definitions:** Clearer, more standardized definitions for intent (intentionally, knowingly, recklessly) and plagiarism (excluding self-plagiarism).
- **Timelines:** Extended inquiry (90 days) and investigation (180 days) periods to better manage complex cases.
- **Procedures:** Stricter requirements for evidence sequestration, detailed inventory, and robust documentation for the "institutional record".
- **Transparency:** Focus on clear, accessible policies and promoting an ethical research environment.
- **Leadership Role:** Increased emphasis on leaders modeling ethical behavior, ensuring accountability, and supporting oversight



Training Focus

- **Policy Implementation:** Understanding and updating institutional policies to align with the new Part 93 regulations.
- **Procedural Adjustments:** Training on new timelines, documentation, and handling of the institutional record.
- **Ethical Culture:** Fostering an environment that encourages reporting and promotes responsible conduct of research (RCR).
- **Stakeholder Training:** Ensuring all levels (students, PIs, coordinators, IRB) understand new definitions and responsibilities.
- **Practical Application:** Using tools such as RCRA infographics and Brainier trainings

Know your RIO (Team)

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Changes to Research Misconduct Regulatory Requirements

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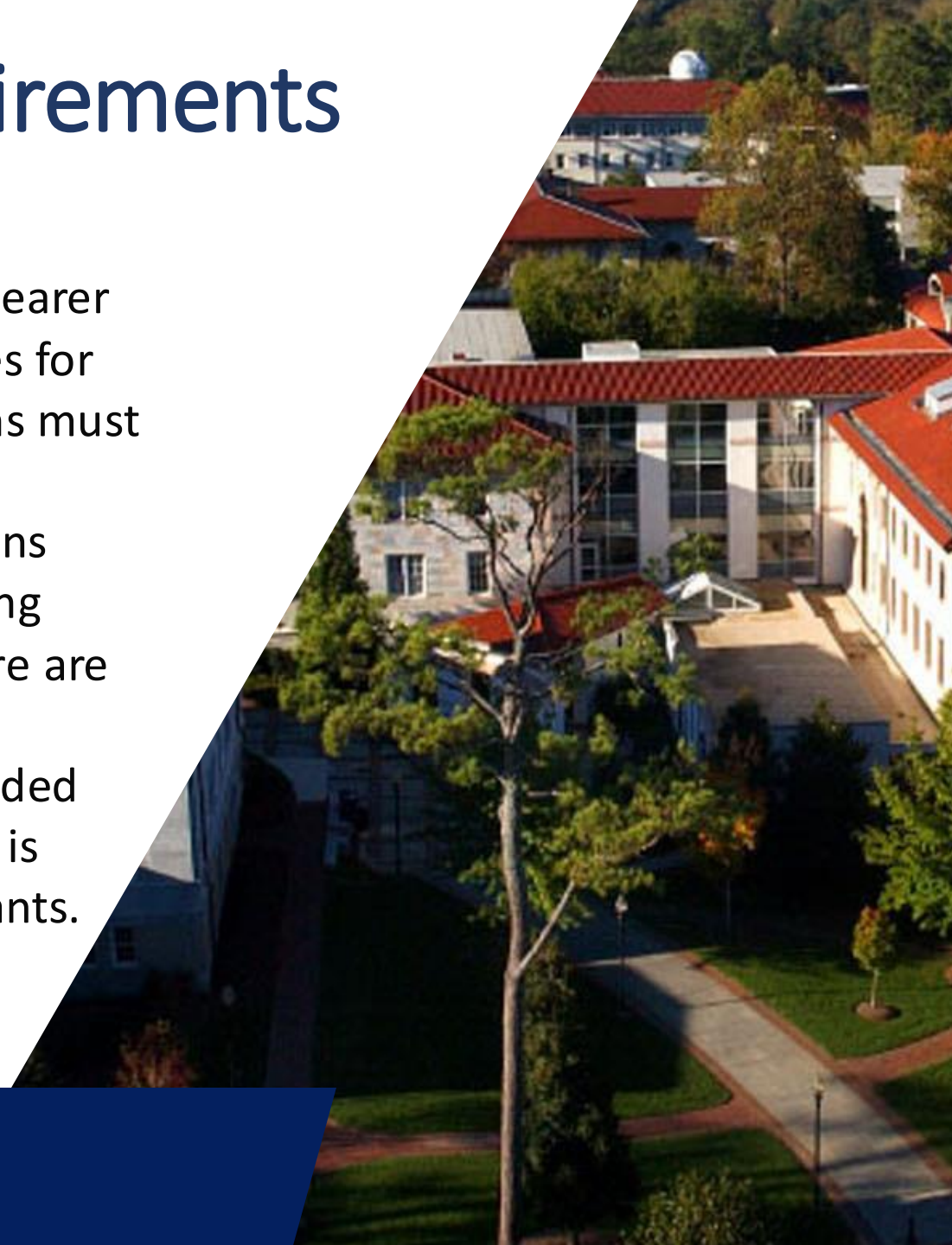
Highlights of Regulatory Requirements

- **Formalized Assessment:** Institutions must now have a formal process for an initial assessment of all allegations to determine if they meet the definition of research misconduct, are within PHS jurisdiction, and are credible enough to warrant a full inquiry.
- **Streamlined Inquiry Process:** An inquiry committee is no longer a requirement; a single institutional official, such as the Research Integrity Officer (RIO), can now conduct the inquiry.
- **Expanded Inquiry Reports:** Inquiry reports must include more detail, such as an inventory of sequestered research records, transcripts of interviews, scientific analyses, and the procedural history.

Highlights of Regulatory Requirements contd.

- **Clarified Definitions and Timelines:** The rule provides clearer definitions for key terms and extends allowable timelines for procedural steps, which leaders involved in investigations must understand.
- **Confidentiality and Non-Retaliation:** The rule strengthens protections for respondents and whistleblowers regarding confidentiality and retaliation, which leaders must ensure are enforced within their teams and departments.
- **Multi-Institutional Coordination:** New guidance is provided for handling cases that span multiple institutions, which is especially relevant for leaders on large, collaborative grants.



Final Rule- ORI Research Misconduct Regulations

Let's Compare

2005	2025
Full Committee needed for Inquiry and Investigation	Committee only neded at Investigation
Honest error determined at Investigation	Honest error determined at Inquiry
No need to document assessment	Assessment documentation is now required (already in place at Emory)

Final Rule- ORI Research Misconduct Regulations

Let's Compare

2005	2025
No requirement to share transcripts	Interview transcripts required (can be redacted)
Critical definitions missing	Regulation provides critical definitions (recklessness)
Some process unclear- required ORI consultation	Answers on subsequent data and data corrections

Final Rule- ORI Research Misconduct Regulations

Let's Compare

2005

60 days for Inquiry/120 for Investigation

No clear process when more than one institution is involved

Reporting template, interviews, record-keeping requirements not defined

2025

90 days for Inquiry/180 for Investigation

If more than one institution is involved, Emory RIO will determine lead institution process

Emory currently uses:

- Similar templates,
- Court-transcriptionist for interviews
- Keeps detailed records

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Key Definitions

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Key Definitions

- Research Misconduct
  - Fabrication, Falsification and Plagiarism
- Respondent
- Complainant
- Assessment
- Inquiry and Investigation

Changes to Emory Research Misconduct Policy

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Highlights of Policy Changes

- Change to Inquiry Process
- Administrative Official will become the School Representative (SR).
- At Emory, we will continue to have the SR sign off on cases when we decide not to move to Inquiry.
- DSO will continue to identify members for Inquiry and Investigation
- Designated Official to give final determination, not school or Dean
- Sequestration will take place on all cases.

Highlights of Policy Changes contd.

New Definitions:

- “Intentionally” is “to act with the aim of carrying out the act.”
- “Knowingly” is “to act with awareness of the act.”
- “Recklessly” is “to act recklessly means to propose, perform, or review research, or report research results, with indifference to a known risk of fabrication, falsification, or plagiarism.”

Multiple Institution Process

- Need for lead institution: Emory RIO to determine next steps on a per case basis

New Case Review Processes

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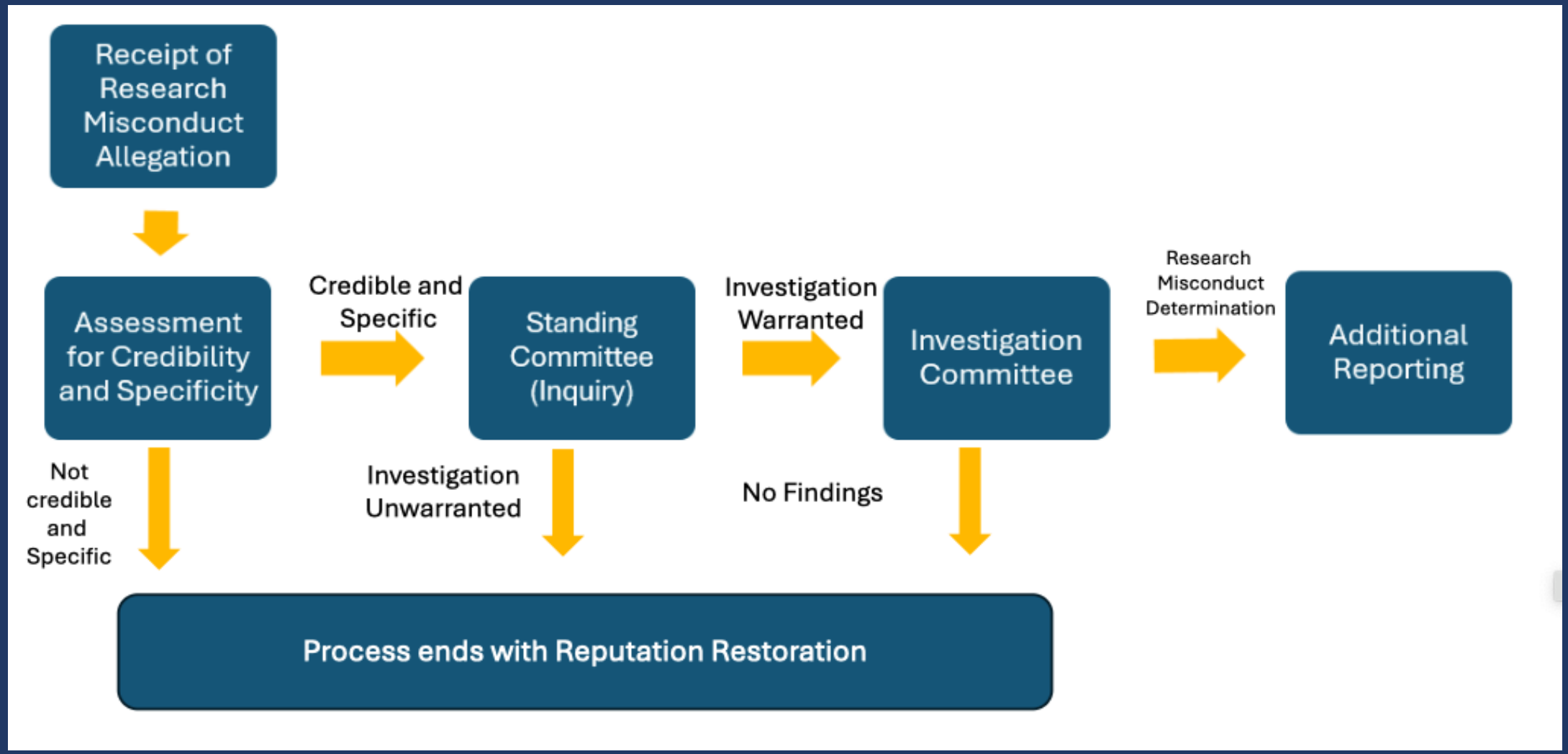
Changes to RM Allegation Review Process



Inquiry

- New regs- don’t require an Inquiry Committee- RIO decision to move to Investigation
- Starting Jan 1, 2026:
  - School/SR will create a standing committee to review RM inquiry cases
  - Members will review information with SR and RIO to determine need for investigation
  - Different members for each school

Investigation

- Same in-depth review of case with external expert review to help with decision
- At Investigation
  - Faculty members from the Inquiry Committee can serve at the Investigation
  - At Investigation, three members are required to conduct proceedings.

Reports

- Reports need to be shared with the Respondents with the attachments, including transcripts
- Info can be redacted if needed
- Inquiry Report signed by standing committee members, RIO, SR
- Investigation Report signed by Investigation Committee members, RIO and DO

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Research Ethics & RCR

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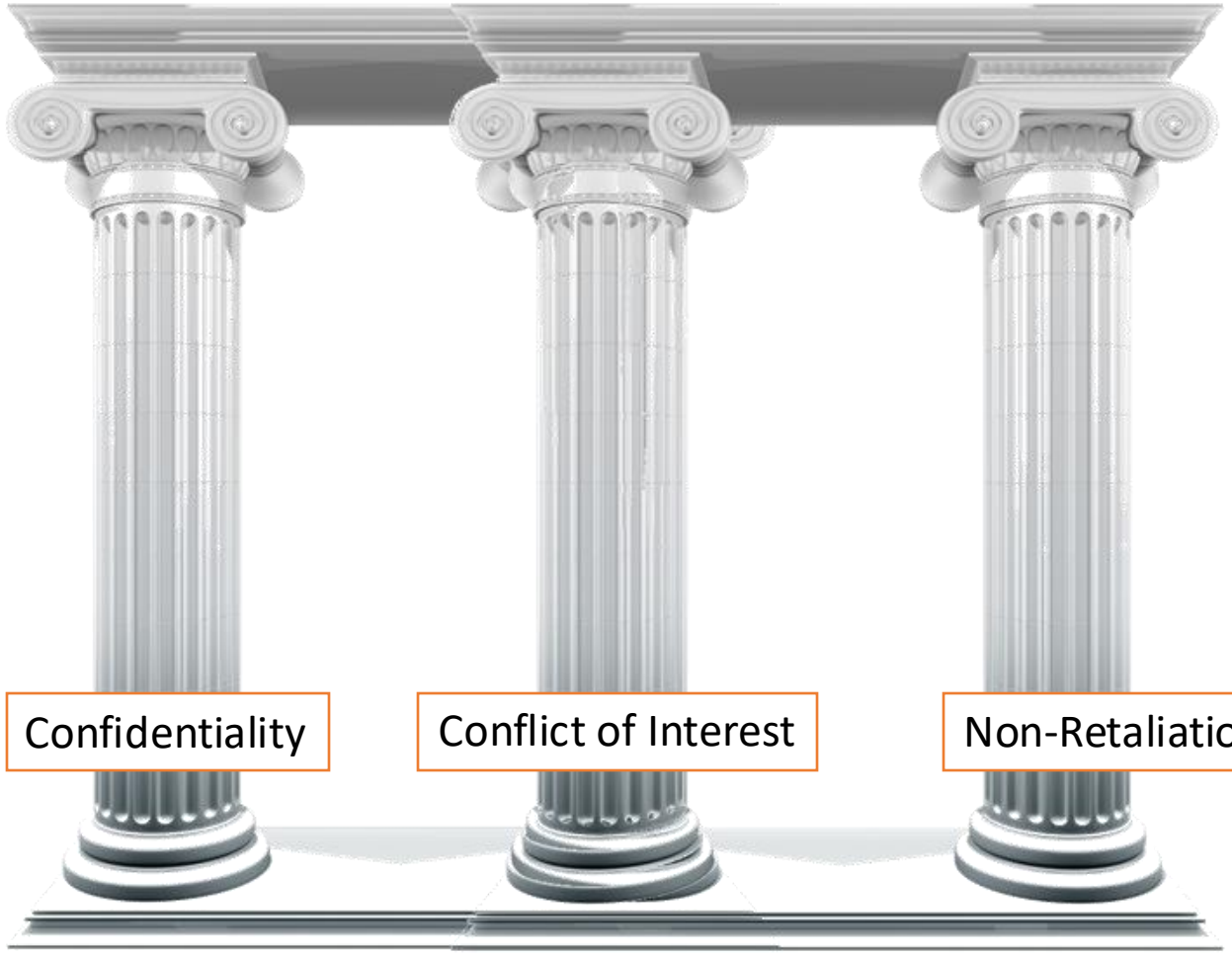
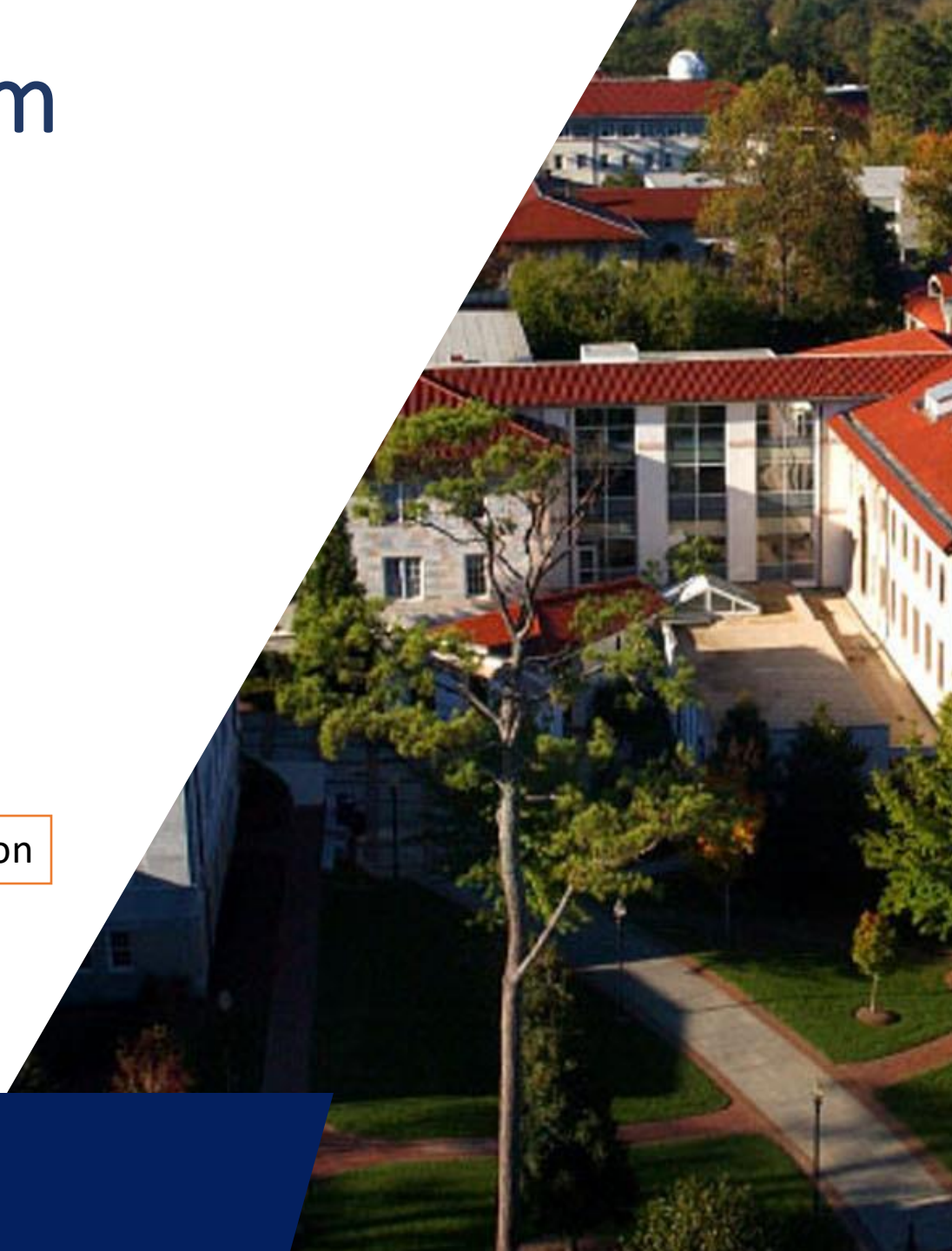
Research Ethics & RCR Program

Responsible Conduct of Research Program (RCR)

- Critical to understand the importance of maintaining research integrity in any research project at Emory
- RCR training covers several important ethical areas such as COI/COC prevention/mitigation; authorship dispute prevention; appropriate mentor/mentee relationship; among many others.
- Required by NIH, NSF, NIFA and other federal supporting agencies. Required for all Laney Graduate Students

Research Ethics & RCR Program





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New RCRA Resources

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New Resources

New Policy 7.8- to be published

New Infographic: https://rcra.emory.edu/_includes/documents/sections/research-misconduct/2005-vs-2025-42-cfr-part-93.pdf

Modified Infographic: https://rcra.emory.edu/_includes/documents/sections/research-misconduct/rm-prevention-basics-to-know.pdf

Training in Brainier: search in Brainier for “Preventing Research Misconduct”.

New Resources

Our website (not new but above-info added):
https://rcra.emory.edu/research-misconduct/research-misconduct-2024.html

iThenticate: program to detect possible plagiarism. For Faculty members.

DSO Guidance (previously AO Guidance)

New SOPs, Templates and other resources to align with new regulations

Questions?