

Duke University has implemented multiple programs and initiatives to support a culture of rigor, reproducibility, and responsible conduct of research. These programs are intended to support research integrity across all disciplines and at all levels. The [Duke Office of Scientific Integrity \(DOSI\)](#) is a key element in advancing this culture of scientific integrity. DOSI is composed of five areas of focus:

1. **Conflict of Interest:** Review, management and reporting of financial conflicts of interest.
2. **Misconduct in Research:** Review and management of research misconduct defined as falsification, fabrication, plagiarism, and questionable research practices.
3. **Institutional Research Incident Response Committee:** Resolution of issues that could hinder research progress or create an institutional risk
4. **Advancing Scientific Integrity Services and Training:** education, tools/resources, and outreach in improving research integrity and data management practices to support Duke's collective commitment to maintaining and improving a culture of scientific integrity.
5. **Clinical Quality Management Program:** standardized, prospective quality assurance and quality control measures in clinical research

As part of our continuous improvement efforts, we evaluated Duke's current policy governing research misconduct which dates back to January 2007. We identified several areas that would benefit from revision and further clarification, such as removal of practices that unnecessarily go beyond regulatory requirements or aligning the process with how it is implemented in routine practice. Further, our current policy does not conform to the PHS Office of Research Integrity's recommended template for policies and procedures for responding to allegations of research misconduct. Thus, we propose replacing the current policy (appendix P, pages 32 - 40), with the attached revised draft, which closely follows PHS regulations (42 CFR 50 and 93). Given the significant change in formatting, a summary of changes is provided below rather than a tracked version.

- Scope of policy now expressly includes researchers other than faculty;
- Research misconduct involving students that are **NOT** federally funded **MAY** be referred to applicable school or college at the discretion of the Deciding Official;
- Research misconduct involving staff that are **NOT** federally funded **MAY** be referred for administrative review per the staff handbook at the discretion of the Deciding Official;
- The definition of research misconduct is now limited to falsification, fabrication, and plagiarism. This policy removes other types of misconduct (i.e. serious deviations from accepted practice) and examples of what is/is not misconduct were removed as they are not applicable under federal regulations;
- The assessment of allegation stage no longer has a specified time frame (had been within 1 week);
- There is no longer an appeal for the Complainant at any stage (per the PHS Office of Research Integrity, "it is the responsibility of the investigative body, not the complainant, to ensure that the allegation is thoroughly and competently investigated to resolution.");
- The Standing committee will have no fewer than 3 committee members (this was the practice but it is now formalized in the policy);

- The Provost/Chancellor may now appoint a member directly to the standing committee for a specific inquiry process if needed for timeliness, but that member will not be involved in any later inquiry processes unless appointed in the usual way;
- Formal manner and time frame for Respondent to object to appointed members of committees (e.g. perceived conflict of interest, etc.) to reflect current practice;
- Allowance throughout inquiry or investigation process for Dean(s) to determine appropriateness or need for administrative leave, salary continuation, or hold on APT process;
- Factual findings from investigation committee are now conclusive and binding for other University purposes;
- The complainant will be advised of the deciding official's findings rather than those of the investigation committee (i.e. when the review process is complete);
- University's obligations to third parties, e.g. sponsors, clarified to include all sponsors and new NIH notification requirements ([NOT-OD-19-020](#));
- 6 year statute of limitations on the review of allegations added (consistent with PHS regulations);
- Record retention requirements specified to be 7 years per PHS standards, rather than "permanent"