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MEMORANDUM

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DATE: March 1, 2018

TO: Board of Trustees of The Ohio State University
Timothy P. Smucker, Chair, Audit and Compliance Committee

COPY TO: Gates Garrity-Rokous
Emily Schriver

FROM: Mark Barnes
Minal M. Caron

SUBJECT: Executive Summary: Review of OSU Research Misconduct Policy and Past Cases

In February 2017, the Board of Trustees of The Ohio State University (“OSU”), through OSU’s Office of Legal Affairs, engaged our firm to conduct an independent review of OSU’s research integrity practices with a specific focus on the following questions:

1. What are best practices for reviewing allegations of research misconduct?
2. Is OSU’s research misconduct policy, *University Policy and Procedures Concerning Research Misconduct* (the “Policy”), consistent with legal requirements and best practices?
3. Did OSU follow its policies and legal requirements in addressing past research misconduct allegations concerning the work of Carlo Croce, M.D. and his laboratory (the “Past Allegations”)?

Our review involved an assessment of applicable OSU policies, including the following, against applicable regulations and best practices: (1) the Policy; (2) OSU’s *Research Data Policy*; and (3) *Rule 3335-5-04: Hearing procedures for complaints against faculty members*. Additionally, we reviewed the files relating to the Past Allegations: specifically, several allegations of research misconduct, along with a few other ancillary matters in which concerns were raised relating to various research issues that did not rise to the level of a cognizable allegation of research misconduct (e.g., disputes about authorship, and alleged misuse of grant funds unrelated to fabrication, falsification, or plagiarism of data). In identifying best practices and developing our findings and recommendations, we worked with two outside experts in research integrity who had been engaged by OSU to assist with this review. Our review also involved a separate significant research misconduct investigation in the College of Pharmacy; while the university’s investigation is not yet final, we reviewed the final investigation report of the College’s Investigation Committee, and we understand that the investigation will be concluded shortly.

Our findings may be summarized as follows:

- The Policy, as implemented by OSU’s Office of Research Compliance (“ORC”), is consistent with federal regulations relating to research misconduct. Specifically, through our review of applicable policies, the Past Allegation files and interviews with OSU personnel, we confirmed that Jennifer Yucel, Ph.D., Research Compliance Administrator and Research Integrity Officer (“RIO”), is an experienced, nationally respected RIO who has conducted the relevant research misconduct proceedings consistent with the Policy and 42 C.F.R. Part 93 (“Part 93”). We identified a few areas in which explicit policies could be adopted to codify various best practices that are used by ORC when addressing allegations of research misconduct but are not explicitly addressed in the Policy. For example, we confirmed that OSU typically sequesters evidence before or when OSU notifies a respondent in a research misconduct proceeding of an allegation, inquiry or investigation, but the Policy does not in present form specifically reference this sequestration.
- The Policy, as implemented by ORC, adopts many best practices and is fully consistent with research misconduct policies and practices we have reviewed and on which we have advised multiple American academic institutions. Our report details suggestions for enhancements to the Policy that reflect additional established or emerging best practices for institutional reviews of research misconduct allegations. These enhancements include (a) placing on the RIO express responsibility for adjudicating conflict of interest issues in research misconduct proceedings, (b) establishing a standing faculty committee on research misconduct, (c) for biomedical research, adopting the uniform authorship standards of the International Committee of Medical Journal Editors, to clarify the attribution of authorship and data integrity responsibilities of OSU researchers and (d) routinely referring to authorities at other institutions any allegations of research misconduct relating to research carried out primarily at those other institutions.
- Based on our interviews and review of files, we believe that the determinations made by OSU with respect to all Past Allegations complied with applicable law and with relevant institutional policies and reached reasoned and supportable conclusions.
 - We confirmed that several of these allegations did not involve any cognizable allegation of research misconduct, as defined under the Policy and Part 93.
 - For approximately half of the remaining allegations, OSU concluded that they related most directly to persons who conducted the relevant research at institutions other than OSU, and, therefore, that OSU was not the proper party to evaluate such allegations. Our review of the underlying matter files confirms that this was an appropriate conclusion in each instance and consistent with the conclusions that peer institutions would likely have reached in similar circumstances. We have suggested, however, that as a best-in-class process enhancement, OSU should adopt a policy of referring allegations relating to research carried out primarily at another institution to that other institution for fact-finding and resolution.
 - OSU carried out preliminary assessments of the remaining allegations of research misconduct. All institutional decisions rendered in resolving each of the Past Allegations were defensible and reasonable.
 - Each of the corrective actions that OSU pursued in connection with the Past Allegations fell within the range of acceptable practice.

- We identified, with the significant benefit of hindsight, several improvements for OSU's consideration. These include:
 - The OSU officials responsible for adjudicating the Past Allegations exercised their discretion appropriately and reasonably. At the same time, for certain of the Past Allegations, we believe that the institutional process could have benefitted from improved and proactive identification and remediation of a perceived conflict of interest. Specifically, while we found no instance of any compromise of judgment, and although discretionary decisions were based on appropriate reasoning, the institution's process could be improved to identify and avoid risks of perceived conflicts of interest.
 - When a co-author cannot produce the original data supporting a particular figure or image in a publication during an institutional investigation, a best-in-class practice is for the institution to evaluate whether this suggests broader data retention or research integrity problems in the paper, project or laboratory. We believe OSU's investigative process could be refined for this reason to broaden, in appropriate cases, the scope of review of an inquiry or investigation.
- As noted, we also reviewed the final investigation report relating to a research misconduct investigation conducted in the College of Pharmacy. The final investigation report reflects a detailed and appropriate investigation of the allegations in question.
- OSU has also provided us a draft action plan, the *Research Integrity Plan*, through which the university seeks to continue to implement best-in-class policies and practices relating to research integrity, including but not limited to some of the process enhancements described in this executive summary. These proposed additional practices also include consideration of faculty performance relating to research integrity policies and practices as part of faculty hiring and advancement decisions. The plan demonstrates OSU's substantial commitment to continue to develop a system that, we believe, if implemented successfully will render OSU a national leader among large universities in developing policies and practices designed to foster an institution-wide culture of research integrity.