

Alignment of a Medical Society and a Journal to Address Academic Misconduct

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Background

- Research Integrity is Paramount: Accuracy in science, Public trust, Patient care
- Large increase in the number of research allegations regarding published articles, and allegations are now far more visible.
 - Some web sties estimate 5,500 papers retracted in 2022 vs 119 in 2002
- Due to the volume of allegations processes are being re-considered.
 - Often the prevue of editor in Chief
 - Processes need to be efficient, transparent, and fair.



Evolution of Processes

- Become evident that processes in place within Journals:
 - Needed to be refreshed
 - Easily overwhelmed due to lack of recourses and time
 - Editors felt isolated and often ill-equipped to assess allegations
- Momentum to address the issue
 - Appearance that time to decision was very slow
 - Editors were relucent to take action, including retraction
 - Reflection on journal
 - Reflection on their work (or that or previous editors)



Evolution of Processes

- Each Journals guidelines needed to be examined
 - Allegations have become more complex
 - New technology has been used (images, repeated numbers)
 - Allegations have become more public and instantaneous
 - Reputations have been challenged publicly
 - Often research is not under the preview of one "institution"
 - Research is multi-center, multi-national and investigators move
- Allegation are not proof of misconduct
 - Careers can be damaged



Evolution of Processes

- Some Journals, like *Fertility and Sterility*, are associated with a medical society The American Society for Reproductive Medicine (ASRM)
 - Allegations can affect the reputation of a medical society
 - Action (or inaction) reflect on a medical society
 - Reputational risk
 - Legal risk
 - The society has a family of journals (need to harmonize)



The Approach of Fertility and Sterility and ASRM

- Recognized the need for:
 - Expanded expertise
 - Enhance the rigor of review of allegation
 - Harmonization of processes to ensure fairness
 - Give the EIC some cover
 - Need for consensus building
 - Minimizing the power (or inaction) of one person
 - Decrease the time to address allegation
 - Standardize portal of entry and acknowledgment of receipt (and list of action)
 - Address complex issue of collaborative research
 - Research is multi-center, multi-national and investigators change affiliations



The Approach of Fertility and Sterility and ASRM

- Formation of *Research Integrity Committee*
 - Committee consists of 6 10 members (started 12/22)
 - Chair (co-chairs)
 - Biostatisticians
 - Study methodologists
 - Clinical expertise
 - Legal and ethics considerations
 - As hoc member appointed by publisher
 - EIC is ad hoc to the committee
 - Direct Administrative support
 - Regular meetings



- Formed January 2023
- Received more than 25 allegations
 - Implausible enrollment/dropout/retention
 - Discrepancy between abstract or trail registration and published paper

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- Methodological or data reporting error
- Repeating numbers within or among papers
- Misrepresentation of data in conclusions
- Duplicate publication or plagiarism
- 10 retractions
- 2 statement of concern
- 2 errata
- 3 cases declined to investigate
- Many still pending



- Lessons learned
 - Difficult in finding volunteers with expertise
 - Training committee members to understand guidelines (COPE)
 - Objective allegations regarding data are easier (incorrect data, plagiarism, timelines)
 - Subjective allegation are challenging
 - Repetitive numbers within or in multiple manuscripts
 - Claims of feasibility
 - Level of evidence needed to "take action" is subjective
 - "Impact" of deliberations when data "is not" available
 - How to resolve disagreements (within and external to the committee)



- Points of discussion
 - Is there a statue of limitation for review?
 - When do we expect that data should be available?
 - When was the expectation of a change to digital data?
 - Do not feel it is a privacy issue (or HIPPA)
 - We request other proof of study (consent, IRB, logs, clinic records)
 - How much time is allotted for response after contacting investigators or institution?
 - Do we contact co-investigators?
 - Institutions do not always cooperate
 - Does decision need to be unanimous?
 - Are meeting abstracts reviewed?



- Moving forward and unresolved issues
 - Steps are in place to reduce research misconduct at submission stage:
 - Request data, attestations, methods review
 - Number of RCTS has deminished
 - Refresh COPE guidelines
 - Timelines, involvement of institution, clarity regarding spectrum of action
 - What are the consequences of suspecting misconduct at submission?
 - How can journals share information to minimize submission elsewhere
 - What is the optimal use of a Statement of Concern
 - At allegation? Creditable allegation? As an outcome?
 - Correct balance of objectively, due process, confidentiality, efficiency



- Moving forward and unresolved issues
 - Understand why "your' journal may be susceptible to accepting papers with misconduct
 - Better education regarding ethics of publication globally
 - serial publication, last minute change in data or authorship
 - Disclosure of monetary incentive for publication
 - What is the role of the publisher?
 - Greater resources are need to address the problem (whose resources?)
 - Need modern techniques to keep pace with technology
 - Al, translation, images
- This is a large undertaking, but scientific integrity is paramount!





THANK YOU

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