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 sites 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 resources 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 reluctant to take action, including retraction
    • Reflection on journal
    • Reflection on their work (or that of 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
ASRM Research Integrity Committee

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

• 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)
ASRM Research Integrity 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?
ASRM Research Integrity Committee

• 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 diminished
  • 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
ASRM Research Integrity Committee

• 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
    • AI, translation, images

• This is a large undertaking, but scientific integrity is paramount!
THANK YOU