



Managing Cases of Research Misconduct

The Office of Research Integrity
(ORI) Experience

Chris B. Pascal, J.D., Director ORI

Managing Cases of Misconduct

- ORI jurisdiction is based on statutory and regulatory authority: 42 USC 289b and 42 CFR Part 93
- ORI jurisdiction is generally limited to research misconduct that is funded by the Public Health Service (PHS) or applications for grants or contracts from the PHS
- In addition, ORI may occasionally pursue misconduct cases through the HHS debarment authority even though the research is not funded by PHS, e.g., an investigator from a private foundation or a foreign institution commits serious and repetitive misconduct and then wants to apply for a PHS grant

Managing Cases of Misconduct (cont)

- The Public Health Service also provides funding overseas and occasionally makes findings of misconduct against foreign investigators
- These individuals would also be subject to administrative actions such as debarment, correction of the literature, and public notice of the misconduct finding

Managing Cases (cont)

- Most cases of misconduct are reported to ORI by the research institution that receives an allegation of misconduct from a scientist who works in a lab or department and suspects misconduct based on his or her knowledge of the research
- Then the allegation should go to the institutional official who handles misconduct cases, generally referred to as the research integrity officer (RIO)

Managing Cases (cont)

- The RIO then should conduct an inquiry (a preliminary investigation)
- If the inquiry finds sufficient evidence of misconduct, the institution should conduct a full investigation that looks at all the evidence, examines the research data in detail, and reaches conclusions about whether misconduct occurred or not

Managing Cases (cont)

- When the institution completes its investigation, it reports to ORI
- The institution prepares a thorough written report that addresses whether misconduct occurred and if so what administrative actions should be taken against the accused individual (the respondent)

Managing Cases (cont)

- When ORI receives the institution's investigation report, it typically does a thorough oversight review of the report
- This could include an analysis of all the data, digital images, tables and graphs, and all other relevant evidence
- ORI will also determine whether abstracts, journal articles or other representations are fabricated, falsified, or otherwise incorrect

Managing Cases (cont)

- If corrections or retractions are needed, ORI will contact the appropriate journals and provide information about the misconduct so that the literature can be corrected
- Over the years, ORI has developed a very good relationship with the journals in removing incorrect or falsified information from the literature

Managing Cases (cont)

- When ORI agrees with the institution that misconduct occurred, it will generally take administrative actions against the respondent
- For serious misconduct, a typical action may be a 3 year debarment from receiving public funds, an exclusion from advisory service to PHS, and an agreement to retract or correct false or incorrect journal articles

Managing Cases (cont)

- Research institutions have broad authority to take actions against individuals that commit misconduct
- They may fire an individual, place restrictions on the scientist, suspend privileges, block the investigator from submitting grant applications, and require withdrawal or correction of journal articles
- Institutions can generally carry out these actions whether or not the ORI makes misconduct findings

Managing Cases (cont)

- When ORI makes a finding of misconduct, it will announce the finding publicly on our website, newsletter, and the Federal Register, and directly inform the institution involved
- If restrictions are placed on the respondent, e.g., debarment for 3 years, ORI will request that the relevant institution and funding agency, usually NIH, enforce those restrictions

Managing Cases (cont)

- When misconduct is not found, ORI maintains the confidentiality of the accused individual indefinitely
- This is done for reasons of fairness and legality (the Federal Privacy Act) and to ensure that the scientific community has confidence in the misconduct process

Managing Cases (cont)

- In conclusion, responding to misconduct cases requires professional and dedicated staff, a robust regulatory and legal framework, and a commitment to pursue wrong-doing
- It is also essential that the institution establish policies and procedures that give the complainant (whistleblower) and the respondent (the accused individual) a fair opportunity to protect their interests
- ORI also provides the respondent an opportunity to defend him or her self through the HHS Departmental Appeals Board which provides a trial type hearing with witnesses and evidence