

KEY CONCEPTS IN CLINICAL EPIDEMIOLOGY

Research Integrity definitions and challenges

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Abstract

Research integrity is guided by a set of principles to ensure research reliability and rigor. It serves as a pillar to uphold society's trust in science and foster scientific progress. However, over the past 2 decades, a surge in research integrity concerns, including fraudulent research, reproducibility challenges, and questionable practices, has raised critical questions about the reliability of scientific outputs, particularly in biomedical research. In the biomedical sciences, any breaches in research integrity could potentially lead to a domino effect impacting patient care, medical interventions, and the broader implementation of healthcare policies. Addressing these breaches requires measures such as rigorous research methods, transparent reporting, and changing the research culture. Institutional support through clear guidelines, robust training, and mentorship is crucial to fostering a culture of research integrity. However, structural and institutional factors, including research incentives and recognition systems, play an important role in research behavior. Therefore, promoting research integrity demands a collective effort from all stakeholders to maintain public trust in the scientific community and ensure the reliability of science. Here we discuss some definitions and principles, the implications for biomedical sciences, and propose actionable steps to foster research integrity. © 2024 The Author(s). Published by Elsevier Inc. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

Keyword: Research integrity; Reproducibility; Misconduct; Responsible conduct of research; Questionable research practices; Biomedical sciences

1. Background

In 2023 alone, more than 10,000 papers have been retracted [1], marking a significant escalation in the retraction rate, even when accounting for the growth in publications. This surge in retractions highlights a concerning trend indicative of detrimental scientific practices [2]. Over the past 2 decades, an alarming number of research integrity concerns have been identified and reported, raising critical questions about the reliability of research outputs. The violations include fraudulent research, reproducibility issues, questionable research practices, and other practices involving the research enterprise. Inevitably, such practices

undermine public trust in science and its institutions, with particularly significant implications for biomedical research.

The foundation of scientific knowledge and discoveries relies on the collective body of research developed by others. Thus, it is essential to safeguard the trustworthiness and integrity of scientific findings.

2. Definitions and principles

Research integrity, as a dynamic and broad construct, can be described as the conduct of the research process ethically, with honesty, robustness, and transparency when proposing, conducting, evaluating, and reporting research findings. It involves the compliance with rules, regulations, and guidelines, as well as widely accepted professional codes and norms [3]. The core principles of research integrity include rigor, honesty, transparency, respect, and accountability (Fig 1) [4–6]. Research integrity reflects on individual researchers and the whole research community, including institutions, funding agencies, regulatory bodies,

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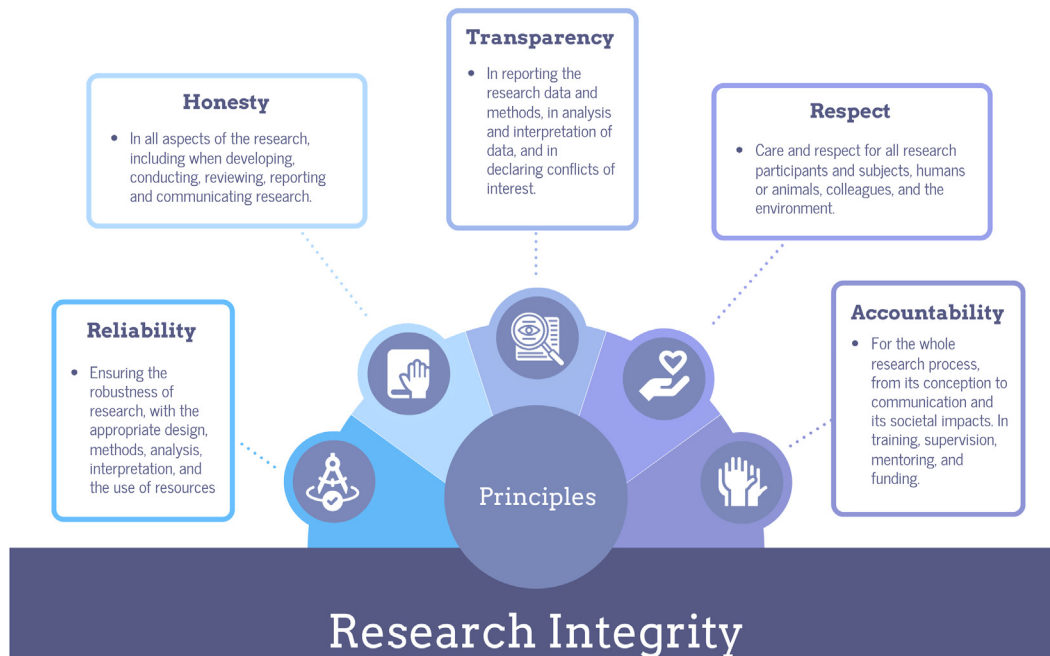


Figure 1. Graphical representation of research integrity principles. (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

and scientific journals. Research integrity is guided by principles and virtues, and it is included in the broader concept of responsible conduct of research (RCR). RCR serves as a practical framework that translates the overarching principles of research integrity and ethics into actionable guidelines, promoting ethical behavior and decision-making in the day-to-day activities of researchers [7].

In a conceptual framework defining research behavior on a continuum [7], RCR is at one extreme, representing the ideal behavior the scientific community should strive to achieve. At the opposite end lies research fraud or misconduct, commonly referring to fabrication, falsification, and plagiarism. Cases of misconduct usually involve intentional or grossly negligent acts [8], and major cases trigger important debates on research integrity, often focused on motivations and personal behavior.

However, research integrity is much more than research misconduct and obvious violations of the integrity of science. The scientific process is not always idyllic and immune to imperfections. Instances of flawed, uninterpretable, and sloppy results outnumber cases of misconduct. Yet, their cumulative impact can be more detrimental to science [9,10]. Everyday ethical lapses can include excessively manipulating data under the guise of "cleaning," gaming science metrics, biased reporting, sloppy data management, or bad mentorship. These practices exemplify the questionable or detrimental research

practices (QRP) that occupy the middle ground along the continuum.

3. Implications for biomedical sciences

Although exposing the underbelly of science can also have consequences [11], we must be able to openly and fairly discuss the consequences of poor scientific quality. The consequences of research misbehavior can include the waste of resources [12] and reputational damage to individuals and institutions. However, for biomedical sciences, the implications of poor or fraudulent research extend beyond wet or dry laboratory settings to consequences for public health and medical practice. Clinical and epidemiological research is essential for understanding illnesses, creating new medicines, and improving care for patients. Consequently, any research integrity violations might cause a cascading effect on patient care, medical interventions, and the overall applications of healthcare policy. For instance, flawed methodology and selective reporting of results from a clinical study can influence clinical practice guidelines and impact patient outcomes, potentially affecting patient safety and well-being. A study assessing data from submitted clinical trials found that 44% contained at least one instance of flawed data, and 26% of the trials seemed to be completely fake [13]. These results

were only possible because the author had access to anonymized individual participant data. Whether the flawed data and/or seemingly fake data changed the study remains unanswered [14]. The case of flawed trials can be even more alarming, as they might be included in systematic reviews and meta-analyses [15], which often inform clinical practice guideline recommendations and health policies. Several other articles could exemplify how studies involving research misbehavior can be detrimental to biomedical sciences, for example, when patients were enrolled in fraudulent trials [16] or how unreliable data delayed an effective treatment during pandemics [17].

Research integrity cases often capture media attention [18,19] and transcend academic murals, undermining public trust in science. The dissemination of such cases amplifies the impact, potentially leading to skepticism and hesitation in adopting public health guidance. For instance, in the COVID-19 pandemic, the willingness to vaccinate was affected by a low public trust in vaccination and its development, leading to delay in immunization efforts [20]. This highlights the broader societal consequences of misconduct and questionable research practices and emphasizes the importance of the scientific community upholding the highest standards in the research process.

4. Research integrity into practice

There are several practices to foster the integrity. A robust methodology and transparent, honest, and impartial reporting are the core of a reliable scientific output. It is essential to promote a responsible conduct and communication of scientific findings. A set of measures can help curbing research misbehavior while improving research quality [5]. These measures include: (1) use of rigorous research methods, statistics, and data management; (2) research registration and adherence to the protocol; (3) control of bias and disclosure of conflicts of interest; (4) use of reporting guidelines and checklists; (5) make data, code, and materials available openly; (6) attribute authorship with responsibility and accountability; (7) publication of preprints; and (8) reward responsible and reproducible practices. Measures for improving research reproducibility and integrity often overlap. However, we cannot ignore intentional acts, and for that, it is important to have training on research integrity and RCR, clear guidelines, and a professional environment with a strong research integrity culture.

Research integrity is a multifactorial concept. While individual choices will ultimately be determinant in the ethical deliberation, the broader structural and institutional factors shape the environment in which these choices are made. Poor integrity culture or climate, hostile working environment, detrimental competition, pressure to publish, poor mentoring and oversight, and the dysfunctional award system of science are some of the factors that have been associated with scientific misbehavior.

For effective behavior change, the research environment must be changed, where all stakeholders play a role. Research-performing organizations (eg, universities) are key in this process [21]. The current organizational environment rewards and incentivizes quantity over quality while also failing to provide proper training and mentoring [22]. Institutions can support researchers by creating clear guidelines on research integrity. The guidelines and other interventions should not be static; they should be tailored for each scientific field and career stage [23]. Institutions should also provide strong training on specific methodological topics (eg, statistics, study designs, research data management, and the Findable, Accessible, Interoperable, Reusable principles [24]) and research integrity. Research integrity training raises awareness about RCR and research misbehavior and facilitates a more open discussion about these topics within the institution. Responsible supervision and mentorship are equally important to foster research integrity [25]. While a supervision role is often task-oriented, mentorship is more about caring holistically for the students' long-term development. Trained mentors should be role models, as integrity is effectively learned through practice. However, there are several cases of misconduct and QRPs where a lack of or inadequate supervision was identified [26–28], or even cases where QRPs were encouraged or initiated by supervisors [29]. Funders' role in fostering research integrity is also of great relevance. They must not only adopt and develop similar practices themselves, such as the guidelines and policies, but also take a step to enforce, guide, and ensure changes in research organizations that receive their funding.

However, it is important to reemphasize that the interventions will not be effective if the research incentives and priorities do not change. Exclusive focus on quantitative metrics shifts the research priority to rapid studies, which are often sloppy and have poor methodologies. Additionally, metrics such as the journal impact factor have little or inconsistent association with research quality [30–32]. The recognition and rewards systems also have implications for funders, which still seem to encourage a culture of competitiveness instead of a culture of research integrity by, for instance, employing the same metrics and prioritizing novelty over replication studies [33].

There are several international initiatives developed to shape the way research is conducted, disseminated, and assessed, prioritizing fairness, transparency, and integrity. The Francisco Declaration on Research Assessment (DORA; see [sfdora.org](https://www.sfdora.org)) provides a series of 18 recommendations to change the way researchers and scientific outputs are evaluated. More than 20,000 individuals and institutions have signed the declaration and will commit to a fairer and more transparent method of assessment. The Coalition for Advancing Research Assessment (CoARA), initiated by the European Commission, is a related effort to change the research assessment landscape. CoARA signatories must create and post an action plan. Signatories commit

to start reviewing their criteria within a year of signing the agreement and to share and report their approaches within 5 years. Other initiatives propose employing a holistic approach for assessment; for example, the Hong Kong Principles [34] propose rewarding RCR practices, open science, transparent reporting, and other scholarly contributions.

5. Conclusion

When discussing strategies to foster research integrity, it is important to emphasize, again, that all stakeholders have significant roles in promoting the quality and trustworthiness of research. A coordinated effort is essential to maintain both the scientific community and the public trust in researchers and their organizations. Research integrity thrives when research institutes cultivate a culture of awareness rather than resorting to witch-hunting tactics. It requires a safe and respectful space where individuals can freely engage in discussions regarding integrity-related issues and collectively learn from their mistakes. It's essential to acknowledge that mistakes are inevitable, but the crucial aspect lies in the willingness to learn from them, adhering to the principle that "mistakes are expected, respected, inspected, and corrected." Regular and open discussions about research integrity set moral compasses, and in an ideal world, research integrity is part of researchers' DNA.

CRedit authorship contribution statement

Anna Catharina V. Armond: Writing – review & editing, Writing – original draft, Conceptualization. **Kelly D. Cobey:** Writing – review & editing, Conceptualization. **David Moher:** Writing – review & editing, Conceptualization.

Data availability

No data was used for the research described in the article.

Declaration of competing interest

D.M. is a member of the editorial board for the Journal of Clinical Epidemiology. K.D.C. is co-chair of the San Francisco Declaration on Research Assessment (DORA). A.C.V.A. has no competing interest to declare.

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Further reading

- [1] Steneck NH. Fostering integrity in research: Definitions, current knowledge, and future directions. *Sci Eng Ethics* 2006;12(1):53–74.

In this paper, Steneck provides clear definitions, present the current state of knowledge on research integrity, and offer valuable insights into future directions for promoting ethical conduct in scientific endeavors. This paper serves as a valuable resource for researchers, institutions, and policymakers aiming to enhance research integrity practices.

- [2] Hatch A, Curry S. Changing how we evaluate research is difficult, but not impossible. *eLife* 2020;9:e58654.

The framework for driving institutional change was developed at a meeting convened by the San Francisco Declaration on Research Assessment group and the Howard Hughes Medical Institute. The framework consists of four broad goals to consider when discussing research(er) assessment: (1) understanding the obstacles to changes in the way research is assessed; (2) experimenting with different approaches to research assessment; (3) creating a shared vision when revising existing research assessment policies and practices; and (4) communicating that vision on campus and beyond. This framework aims to address challenges in the assessment of research and promote a more comprehensive and inclusive approach to evaluating scholarly work.

- [3] de Vries R, Anderson MS, Martinson BC. Normal Misbehavior: Scientists Talk about the Ethics of Research. *J Empir Res Hum Res Ethics* 2006;1(1):43–50.

In this paper, the authors assess researchers' perceptions of detrimental behaviors. They identified that less clear and more common practices associated with everyday problems in the research and work environment can pose problems for the enterprise of science. The authors explore the concept of "normal misbehavior" within the scientific community, shedding light on the nuanced ethical dilemmas faced by researchers.

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The paper discusses the significant increase in 2023. The paper explores the implications of this unprecedented number of retractions across various fields, highlighting the challenges and consequences associated with such a high volume of retractions.