

# Retraction due to informed consent: An empirical study using the Retraction Watch Database

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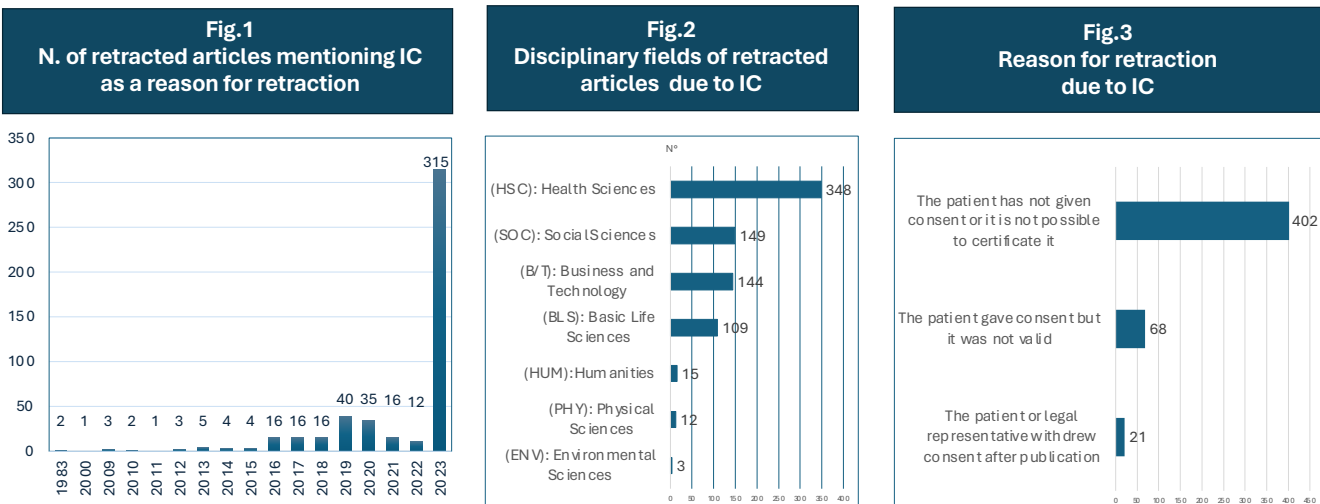
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**Background:** Informed consent (IC) is a cornerstone of contemporary research ethics. Studies without participants' IC violate principles of research ethics and integrity and may lead to serious consequences, including the retraction of associated articles. Our study marks the first quantitative investigation into retractions of scientific articles due to IC issues. Analyzing the frequency and nature of retractions related to IC may shed light on current research malpractices and aid researchers in addressing challenges surrounding valid consent in research.

**Objective.** To explore the interplay between informed consent, article retractions, and breaches of research ethics and integrity.

**Method.** We conducted a systematic search using the Retraction Watch Database.<sup>1</sup> We included all retraction notices published between 1983 and 2023 citing "consent" as a reason. Each note underwent analysis considering: the year of publication and retraction, scientific field, article type, impact factor and/or other bibliometric metadata of publishing journal, authors' nationality, number of post-retraction citations, reasons for retraction specifically related to IC, and other reasons for retraction.

**Primary findings.** A total of **491 articles** met our criteria. The majority were retracted in 2023 (315/491, 64.15%), amid a significant scandal involving "paper mills" (**Fig.1**).<sup>2</sup> Health Sciences (HSC) were most affected (348/491, 70.9%), followed by Social Sciences (SOC) (149/491, 30.35%) and Business/Technology (B/T) (144/491, 29.33%) (**Fig.2**). Analysis of retraction notices revealed three primary reasons for retractions due to IC issues (**Fig.3**): in most cases (402/491, 81.87%), retractions occurred due to either lack of consent or inability to verify it; in other cases (68/491, 13.85%), consent was obtained but later deemed invalid, e.g., due to coercion. Notably, in a few instances (21/491, 4.28%), retractions were not due to ethical breaches but participants' post-publication withdrawal of consent for privacy reasons.



**Secondary findings.** Additionally, our search led to other interesting results. **First**, we found that informed consent stood as the sole reason for retraction in a non-negligible portion of cases (74/491, 15%). In the remaining cases, other contributing factors were prevalent, and included: "Lack of IRB/IACUC Approval" (355/491, 72,3%); "Concerns/Issues About Data" (325/491, 66,19%); "Investigation by Journal/Publisher" (321/491, 65,38%); "Concerns/Issues About Results" (286/491, 58,25%); and "Investigation by Third Party" (284/491, 57,84%). **Secondly**, Research Articles accounted for most of the retractions (336/491, 68,43%), followed by Clinical Studies (87/491, 17,72%) and Case Reports (50/491, 10,18%). **Thirdly**, most of retractions occurred within 1 year of publication (303/491, 61,71%). **Fourthly**, most articles were published in journals with an impact factor between 0 and 5 (349/491, 71%). **Fifthly**, half of the retracted articles (50.51%) received at least one citation post-retraction. **Lastly**, China emerged as the country most associated with retraction related to informed consent issues (326/491, 66,4%), followed by the United States (67/491, 13,65%), United Kingdom and South Korea (16/491, 3,26%). If we measure the number of individual authors involved, after China (1319 authors/326 articles) and the US (252/67), the most represented countries are Japan (75/14) and Turkey (50/10), although in some cases a single author has contributed to multiple retracted articles.

**Conclusion.** Our investigation highlights the importance of ethical compliance in scientific research, particularly regarding IC. While IC lapses were a significant reason for retractions, they often coincided with other ethical breaches. The predominance of retractions in research articles emphasizes the need for enhanced vigilance and transparency in research conduct, especially in Health Sciences. Swift retractions within a year of publication underscore the importance of robust review processes. The association of retractions with journals of modest impact factors suggests vulnerabilities in resource-limited journals. Also, the cases of retraction due to participants' change of availability to take part in the study highlight the importance of adequate disclosures during informed consent. Lastly, China's prominence in retractions related to IC emphasizes the necessity of enforcing ethical standards in research integrity on a global scale and particularly in specific countries. Overall, our findings stress the urgency of strengthening ethical practices and research integrity to enhance the accuracy and accountability of scientific publications in relation to informed consent.

**References:**

- <http://retractiondatabase.org/RetractionSearch.aspx?>
- <https://www.nature.com/articles/d41586-023-03974-8>