

**Enabling researchers to report concerns about human  
genome editing research: report for the WHO Expert  
Advisory Committee on Developing Global Standards  
for Governance and Oversight of Human Genome  
Editing**

**Nicola Perrin**

**February 2021**



© World Health Organization 2021

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: “This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition”.

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization (<http://www.wipo.int/amc/en/mediation/rules/>).

**Suggested citation.** Perrin N. Enabling researchers to report concerns about human genome editing research: report for the WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing, February 2021. Geneva: World Health Organization; 2021 (WHO/SCI/RFH/2021.05). Licence: [CC BY-NC-SA 3.0 IGO](#).

**Cataloguing-in-Publication (CIP) data.** CIP data are available at <http://apps.who.int/iris>.

**Sales, rights and licensing.** To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see [www.who.int/copyright](http://www.who.int/copyright).

**Third-party materials.** If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

**General disclaimers.** The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

The named author alone is responsible for the views expressed in this publication.

## Contents

1. Introduction.....	1
2. Methodology.....	1
3. Context.....	2
Terminology.....	2
Barriers to reporting concerns.....	2
The value of open reporting.....	3
4. What mechanisms are needed to report concerns? .....	4
A clear reporting mechanism.....	5
A transparent process for investigations.....	6
Support and protection for those raising concerns.....	7
5. How can a mechanism for reporting concerns best be delivered?.....	7
References.....	10

## 1. Introduction

Concerns have been reported that some researchers, both in China and the United States of America, knew about Dr He Jiankui's work with human genome editing but that no one reported it before the announcement of the birth of genome-edited babies (1). One explanation is that those researchers indicated that they did not know where and how to report concerns about his research (2).

As a result, the WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing wanted to consider whether and how to encourage and support whistleblowing among the research community in order to prevent a similar occurrence in the future.

The International Commission on the Clinical Use of Human Germline Genome Editing (set up by the United States National Academy of Medicine, the United States National Academy of Sciences and the United Kingdom's Royal Society) recently called for the establishment of "an international mechanism by which concerns about research or conduct of heritable human genome editing that deviates from established guidelines or recommended standards can be received, transmitted to relevant national authorities, and publicly disclosed" (3).

An article by the Science, Health and Policy-Relevant Ethics in Singapore (SHAPES) initiative, National University of Singapore, also concluded that "an international governance mechanism for reporting unethical germline gene editing is needed", and that the World Health Organization (WHO) would be well placed to take the lead (4). The authors proposed that the reporting mechanism be attached to the WHO International Clinical Trials Registry Platform.

This paper is intended to inform the Expert Advisory Committee's discussions. It explores whether there is a need for an international reporting mechanism, what form one might take and where responsibility might rest.

## 2. Methodology

The Expert Advisory Committee commissioned this work to explore possible mechanisms to encourage and support whistleblowing, with a focus on approaches that could work at national, regional and global scales. Desk-based research and scoping to map the landscape was undertaken to assess approaches used in different sectors, including academic research, health care, aviation, environmental protection and sport. In addition, a stakeholder workshop with whistleblowing experts was held in October 2020 to explore some of the issues raised in further detail.<sup>1</sup>

---

<sup>1</sup> The experts attending the workshop were as follows: C. Fred Alford (Emeritus Professor, University of Maryland, and author of *Whistleblowers: broken lives and organizational power*); Carl Elliott (Professor in the Center for Bioethics and the Department of Pediatrics, University of Minnesota, currently working on a book about whistleblowing in research on human subjects); Tom Mueller (independent investigative journalist, author

This report looks at the importance of the cultural context, considers the mechanisms that are needed to allow effective reporting, and finally considers options for a possible approach to encourage best practice for research in emerging technologies.

While the starting point for the work was the need for a reporting mechanism in genome editing research, the challenges, barriers and potential mechanisms also apply across other research fields. The scope of the discussion is therefore wide ranging, and it may be more appropriate to consider reporting approaches for emerging technologies more broadly.

### 3. Context

#### Terminology

The language used is important (5). The term “whistleblower” – defined as “a person who informs on a person or organization regarded as engaging in an unlawful or immoral activity”<sup>2</sup> – while first used with the intent of being supportive (6), can have negative connotations. The equivalent translations in many European languages, for example, are often negative (snitching, betraying, leaking, squealing, dirtying one’s own nest) (7). The term “reporting” may be perceived as more neutral, with no attribution of blame, and is used for example in the aviation sector with the intent of reducing the likelihood of repeat safety incidents. An alternative, and perhaps the most supportive, term is “speaking up”. A number of organizations are introducing “speak up” approaches in order to emphasize an open culture that encourages early warnings.<sup>3</sup> This document focuses on “reporting concerns” as a more neutral term.

#### Barriers to reporting concerns

As a starting point, it is helpful to understand the reasons why people often do not raise concerns about wrongdoing or unethical activity. These appear to be consistent across many sectors, including research (8–11). First, there is the belief that speaking up is futile – nothing will be done. Second, there is concern that those who speak up will experience retaliation – there could be legal, financial and reputational impacts, or implications for their career, if they “put their head above the parapet” and report concerns. And third, there can be practical issues – there is often uncertainty about how, where and to whom to report concerns.

More generally, and perhaps more importantly, there are issues relating to the background cultural context. There is often a culture of silence, a feeling that something is “not my business” and it is better to look the other way. This may be particularly true in a research context, where the “culture is that you respect confidentiality and that when people reveal things in confidence to you, you respect that confidence” (12).

---

of *Crisis of conscience: whistleblowing in an age of fraud*); Owen Schaefer (Centre for Biomedical Ethics, Yong Loo Lin School of Medicine, National University of Singapore); and Leigh Turner (University of Minnesota Center for Bioethics, School of Public Health, and College of Pharmacy).

<sup>2</sup> Oxford English Dictionary.

<sup>3</sup> See, for example, the National Guardian’s office of the United Kingdom National Health Service (<https://www.nationalguardian.org.uk/>).

## The value of open reporting

Our research suggested that an underlying requirement, if matters of concern are to be actively reported, is a supportive scientific culture. An emphasis on values-based education, with particular attention to research integrity across all training, is essential. This should be demonstrated from the top down, across research institutions, funding bodies and senior leaders in research. Institutions need leadership that upholds the ideals of research integrity, and supports the policies that help implement them.

Implementing appropriate reporting structures is an important part of developing an open culture, because it helps to create a culture where the expectation is that concerns about perceived research misconduct should be openly raised. This should be seen to be about promoting the best possible science, and should be consistent with, rather than opposed to, a culture of scientific challenge and progress.

One sector that has particularly emphasized the need for a culture that encourages the reporting of misconduct is sport. The World Anti-Doping Agency highlights the importance of protecting the integrity of sport, and this is backed up by the provision of a robust mechanism to report wrongdoing (Box 1).

### Box 1. World Anti-Doping Agency

The [World Anti-Doping Agency \(WADA\)](#) was established in 1999 to oversee implementation of and compliance with the World Anti-Doping Code, the document harmonizing anti-doping policies in all sports and all countries. The fact that WADA is custodian of a clear anti-doping code means that there is a solid foundation for all its activities. WADA also has a clear statement on [gene doping](#), which is prohibited, and there is expectation that any violation of the prohibition would be reported.

WADA places particular emphasis on improving the culture of sport, with the aim to “create and maintain a zero-tolerance culture for doping” to protect the clean athlete and the integrity of sport, and to stop people “quietly accepting” doping. A wide-ranging education and awareness programme operates internationally. The message is that “speaking out exemplifies the kind of leadership, courage, and character consistent with the spirit of sportsmanship and fair play”.

#### Reporting mechanism

There is a dedicated Intelligence and Investigations Team, which can instigate rigorous investigations in response to allegations of wrongdoing. There is a clear reporting mechanism, with a dedicated “speak up” [website](#) to report concerns about violations. The secure confidential process is open to anyone. A clear whistleblowing policy and process includes details of the procedures for investigation of misconduct and protection for whistleblowers. While operating globally, WADA also collaborates with both national and sport-specific mechanisms to follow up allegations, and works with the Association of National Anti-Doping Organizations.

WADA is funded by both national governments and the Olympic movements. There are significant resource implications in providing an operation on the scale of WADA, though this does also include a widespread testing regime.

#### 4. What mechanisms are needed to report concerns?

There has been an increasing emphasis on mechanisms to report, investigate and sanction wrongdoing and irresponsible behaviour across different sectors, and to support and protect those raising concerns. This is also true within a research context, with an increasing number of national and international codes of conduct and statements on research integrity, for example the Singapore Statement on Research Integrity (Box 2). The emphasis in these codes is mainly on research misconduct, including fabrication and falsification, although “irresponsible research practices that undermine the trustworthiness of research” are also mentioned.

There is currently no single global authority in science that would act as the obvious place to report unethical human genome editing. While WHO has a reporting line, this is intended to be used to raise concerns about WHO or WHO-funded research, rather than any research. While there are some organizations that play a similar role in different sectors, such as WADA, the model would not transfer directly to the research world, not least because of the significant resource implications, the varied national structures, and the lack of appetite to create a dedicated new entity. However, there are elements of best practice that can be drawn from other sectors.

Best practice suggests there are three key requirements for any mechanism:

- a clear reporting mechanism
- a transparent process for investigation
- support and protection for those raising concerns.

##### **Box 2. Ensuring research integrity**

Many countries, academies, professional organizations, and academic research institutions have developed codes of conduct for research integrity that set out principles of research integrity, standards and expectations to ensure best practice and trustworthiness, and the approach that should be taken to address misconduct in research. Examples include:

- All European Academies (ALLEA): [European Code of Conduct for Research Integrity](#), 2017 (13)
- UK Research and Innovation and Universities UK: [Concordat to Support Research Integrity](#), 2019 (14)
- United States National Academies of Sciences, Engineering and Medicine: [Fostering integrity in research](#), 2017 (15)
- Science Council of Japan: [Code of Conduct for Scientists](#), 2013 (16)
- Australian National Health and Medical Research Council: [The Australian Code for the Responsible Conduct of Research](#), 2018 (17)
- WHO: [Code of Conduct for Responsible Research](#), 2017 (18). The list of research wrongdoings specifically includes the failure to adhere to accepted ethical principles for the conduct of

research. An integrity hotline provides an independent service to take reports of wrongdoing confidentially, either by email or through a webpage.

A list of other guides and codes of conduct is available at the [Ethics and Integrity portal](#) and in the International Science Council [resources](#).

In addition, there have now been six [World Conferences on Research Integrity](#) (WCRI), and the WCRI Foundation was established in July 2017. The second World Conference on Research Integrity in Singapore (2010) focused on national and international structures for promoting integrity and responding to misconduct. The resulting Singapore Statement on Research Integrity included the principle that:

*Reporting irresponsible research practices: Researchers should report to the appropriate authorities any suspected research misconduct, including fabrication, falsification or plagiarism, and other irresponsible research practices that undermine the trustworthiness of research.*

The third World Conference on Research Integrity in Montreal, 2013, considered research integrity in cross-border research collaborations, and the fifth World Conference on Research Integrity in Amsterdam, 2017, proposed a registry for research on the responsible conduct of research. The Hong Kong Principles for Assessing Researchers, 2019, focused on ways to assess and promote research integrity among researchers.

### A clear reporting mechanism

One of the biggest barriers deterring people from reporting concerns is uncertainty about to whom, how and where to report issues. This is particularly true when considering research taking place outside one's own institution, or in a different country.

There are usually three ways that concerns can be raised.

- **Internally, within an organization or institution.** In a research context, the main responsibility for research misconduct lies with the employer or institution. Best practice is for a research institution to provide a well advertised, safe and confidential mechanism for reporting allegations. Some institutions do clearly advertise how to raise concerns but it is important to recognize that not every institution has such a mechanism, and there are wide variations in the abilities of different institutions and countries to respond appropriately to information received.

预览已结束，完整报告链接和二维码如下：

[https://www.yunbaogao.cn/report/index/report?reportId=5\\_24079](https://www.yunbaogao.cn/report/index/report?reportId=5_24079)

