

# FRAUD AND MISCONDUCT IN BIOMEDICAL RESEARCH

Fourth Edition

*Edited by*

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## 3 What is research misconduct?

*Drummond Rennie and C Kristina  
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### Introduction

The central questions that we address in this chapter are these: Do we need strict definitions for what constitutes research misconduct? And if we do, what should they be? In the USA, the issue was framed by the Commission on Scientific Integrity thus:<sup>1</sup>

'How narrow or broad should the federal definition be? Specifically, should it include other misconduct beyond fabrication, falsification, and plagiarism? How should questions about intent and honest differences in interpretation of data be addressed? How should the line be drawn between serious and less-serious offenses?'

A very different view has been presented for the Scandinavian countries:<sup>2</sup>

'In the Nordic countries, formal definitions have never been considered critical or even feasible, since dishonesty is regarded as ranging from minor deviations from good scientific practice to obvious misconduct. Scientific dishonesty has therefore been broadly characterized, and the establishment of a verdict relies on sound judgement rather than rigorous definitions.'

The differences between these two positions depend on the experiences, attitudes, and opinions of the groups of scientists, lawyers, administrators, and politicians who formulated them. But these are themselves shaped by the ethos and conditions of the respective countries from which they come. In the 1970s and 1980s, numerous events, widely reported in the media, forced the USA to produce definitions of unacceptable conduct that satisfied lawyers and would withstand the test of litigation. In a small country such as, say, Denmark, where clinical scientists live near each other, personal accountability to an individual scientist's colleagues may matter more and be easier to achieve than in the USA, where research centres may house hundreds of scientists and be separated by thousands of miles. Nevertheless, when a very serious case emerges, as happened in Norway with the revelation of Sudbø's multiple falsifications,<sup>3</sup> attitudes can harden, and institutions face up to what is a universal challenge.<sup>4</sup> Moreover, the

nature of good science does not differ from country to country. Science is accessible all over the world, published by international journals that expect the same standards of all researchers. In this chapter, we will examine why we need a definition of research misconduct, what that definition should be, and whether it should apply universally.

### Can formal definitions be avoided if good research practices are promoted?

Although, ever since the Ten Commandments, there have been instructional tracts promoting good behaviour that are freely available and universally taught, the prohibited offences continue to be committed. Teaching good practices is essential. But when theft occurs, we demand an official reaction, according to rules that give teeth to investigators, and power to those who adjudicate and sanction.

In its Code of Practice for Research, the fledgling UK Research Integrity Office (UKRIO) declared that 'a strong emphasis on promoting good practice is seen as preferable to a regulatory or statutory model'.<sup>5</sup> It may be preferable – but it is an unrealistic solution. To expect promotion of good practices to solve the problem flies in the face of the extensive and well-documented experience in the USA, where prolonged and energetic efforts, mandated by law, have been made for over 20 years to promote, advertise, and teach good scientific practices.<sup>6</sup> Such efforts are necessary, but by no means sufficient, and in the absence of statutes or official regulations and sanctions for non-adherence, cases of serious research fraud will continue to be grievously mishandled. While essential, mere instruction cannot prevent, or assist in handling, the many egregious acts of misconduct that occur in any extensive human enterprise, including research.

### Why do we need a definition?

Scientists, especially those who find it hard to imagine anyone can stoop to falsifying the scientific record, commonly start from the position that 'everyone knows' that such and such an action, when committed during the pursuit of science, is wrong. They may have difficulty understanding the need for standards.<sup>7</sup> We, however, believe firmly that unless we have clear definitions of research misconduct, at the very least we shall always be at cross-purposes when discussing how to prevent it, and how to deal with allegations as they arise. It is a basic tenet that it is unfair to make a researcher liable for conduct that is not already clearly defined as being wrong. In the USA, and increasingly in other countries, findings of research misconduct are being challenged in court, so a robust definition, able to withstand legal assault, is legally required.

The basic fairness inherent in human relations, reaching far beyond legal requirements, mandates that people be able to know the rules of the game in which they are playing and by which they are being judged. It is not fair to punish people through *ex post facto* pronouncements. This is particularly essential when a career, reputation, and livelihood (or, in some places, life) may be on the line.<sup>7</sup> The consequences to a researcher of an accusation of research misconduct are always very serious, putting the researcher under great psychological pressure, and often straining the researcher's

financial resources. For the accused, a finding of misconduct is a catastrophic event. Given that science can operate only in a climate of trust, loss of reputation effectively ends that scientist's career and wrecks his or her life and livelihood. The gravity of the consequences increases the need for a clear definition, lest frivolous accusations from individuals who merely dislike a scientist's behaviour destroy good researchers. As the size of a research enterprise grows, so do the numbers of people involved, the costs, and the size of the rewards. With the increase in the stakes, so grows the importance of getting the research right, and the need to respond effectively when things go wrong.

Acts of misconduct distort the research record, and so waste the time and efforts of others. They may, in the field of medicine, result in faulty and possibly dangerous treatments. They will, if unchecked, unfairly inflate the reputations and positions of those who commit them. They are therefore destructive of science, and often profoundly demoralizing to those in the perpetrator's institution who suspect the truth. To give an example, we once served on a panel as outside members adjudicating a very simple case of misconduct in the laboratory. Through serious administrative bungling, the whole issue had escalated to the point that the institution was split into warring factions, constructive work in some departments had largely ground to a halt, and one professor recorded having attended over 300 meetings on the matter.

As a cumulative consequence of the above, more and more findings of research misconduct are being challenged in court. We do not have the luxury of staying isolated from the legal system. Unless the definition satisfies the law, we shall perpetuate legal confusion, and guarantee injustice for accused, accuser, and society. This definition must satisfy scientists and serve the interests of science itself, as well as the public who pay for, and can benefit from, the research. If such issues are to be resolved fairly and promptly, each institution must have a proactive system already in place that defines the process to be followed after an allegation has been made. If this is not done, the institution's response will always be reactive, hurried, inefficient, at variance with that of other institutions, unfair, biased, and often at odds with the law.

### What should our approach to a definition be?

In this chapter, we make the assumption (which we suspect does not hold in most countries) that whatever definition is adopted, there are bodies empowered to give meaning to the definitions and able to investigate, adjudicate, and sanction such behaviours.

The definition should not include actions occurring during the practice of research but that are not peculiar to research and that are already sanctioned by law – for example, murder, blackmail, arson, sexual harassment, and so on. An argument can be made to widen the definition to include all crimes that affect research. For example, malicious sequestration of crucial scientific data or specimens may amount to theft, but, since the law is unlikely to be brought to bear on the perpetrator given the specimens' trivial monetary value, perhaps theft in such circumstances should be included. However, we believe such misbehaviours should best be left to individual research institutions to discipline. Sox and Rennie<sup>8</sup> have described a case of multiple fabrications performed by a single researcher, who, because he used his own falsified research

'data' and publications in further applications for government research grants, is, at the time of writing, serving a prison sentence for defrauding the US government. Here, the university's investigation and adjudication had to do with whether there had been falsification of the research record, and only when that had been proven did the government step in and charge him with the monetary fraud. (See also the Swedish Medical Research Council's comments in Box 3.1.)

**BOX 3.1 Extracts from paragraphs 6 and 7 of guidelines for the work of The Swedish Research Council's Expert Group for Investigation of Suspected Research Misconduct\***

6. ... It cannot be ruled out that dishonesty in research, besides entailing liability for breach of duty or misconduct at work, may also constitute another offence. People who, for example, receive research grants by entering fabricated or distorted data in their applications may presumably, in certain cases, be deemed to have committed fraud. This offence is defined as being committed: 'If a person by deception induces someone to commit or omit to commit some act that involves gain for the accused and loss for the deceived' (*Swedish Penal Code*, Chapter 9, Section 1).

7. The notion of 'good scientific practice' is given a limited definition in the Expert Group's work. It would, of course, be an advantage in terms of the rule of law if either the requirements of 'good scientific practice' or the kinds of documents that may be deemed to constitute deviations from such practice could be specified in advance. This is hardly feasible. However, it is paramount that the notion of 'good scientific practice' should not, in this context, be interpreted so broadly that protests may be lodged against new ideas and new methods in research. Deviations from good scientific practice may, for example, consist in fabrication of data; theft or plagiarism of data, hypotheses, or methods without the source being cited; or other distortion of the research process (e.g. incorrect inclusion or exclusion of data, or misleading data analysis that distorts the interpretation).

\*Adopted by the Research Council's Board on 29 September 2004.

## Jerks or crooks?

In science, as in all professions, there are numerous individuals whose behaviour may be rude, insensitive, selfish, arrogant, incommunicative, disruptive, and in numerous ways obnoxious and uncollegial. This does not invalidate their science nor necessarily mean that they are guilty of anything more than being hard to abide, so, as one of us (CKC) has written, 'We have to have a definition that separates the crooks from the jerks.'<sup>9</sup> The latter are the scientists who refuse to share data after publication even if it is a condition of publishing; who refuse to give credit; who continually republish their

own data; who fail to mentor and bring forward their juniors, but appropriate from them instead. These are the scientists whose 'little murders', in Jules Feiffer's phrase, sever the delicate threads of trust that hold our community together. The behaviours of jerks do much to poison relations with their fellow researchers, but are usually ones that should be left to their employers, who must have their own standards, to monitor and sanction.

## Definition: the importance of uniformity

Physical laws do not change from country to country, and the practice of science and the scientific method must be fundamentally the same throughout the world. Uniform definitions of what constitutes bad scientific behaviour therefore make sense. As an illustration of the problem, one of the authors (DR) is an editor of a large international medical journal, based in the USA, but receiving a high proportion of manuscripts from outside the USA. Scientific journals publish papers depending on their quality, and not on the institution, city, or country of origin. Editors, then, are forced to start with the assumption that scientists everywhere are held to the same standards of accountability.

In the case of multiple falsifications mentioned above,<sup>8</sup> we noted that authors in the USA, who are governed by regulations on research misconduct and are held accountable if allegations are raised against them, are effectively held to a higher standard than those in almost all other countries. The editors also know from published experience that if the same allegations concerned a paper received from the majority of other countries, the matter would not be pursued and the authors not held accountable.<sup>10-15</sup> Such cases, in the absence of clear definitions and of any processes for dealing with allegations, typically remain unresolved for many years. Given the appalling experience of editors dealing with accusations brought in other countries, some have begun to wonder whether the time has come for US journals to accept papers only from countries with effective definitions and processes in place.

In addition, since many institutions lack the expertise, the will, or the money to set up the mechanisms for resolving allegations of research misconduct on their own (and have their validity tested in court), everything is much easier for institutions when there is some central authoritative statement from some respected body that defines behaviour so egregious that it must be sanctioned. So, it all starts with a clear definition.

## Conditions and criteria necessary for any workable system

Any definition must, then, be universal in two senses: universal geographically, and universal across all research disciplines and not confined to clinical research. The definition and other rules governing research misconduct must be promulgated by some official and widely accepted body having the legal power to make them stick, and these rules must be published. A definition of what constitutes research misconduct is necessary, but, by itself, is insufficient. We assume that such a definition must be accompanied by a process having the following elements:

- Notice to those accused of the charges against them.
- Opportunity to respond to the charges and to all evidence used to draw conclusions.
- Opportunity to have an advocate or representative accompany all those participating in official proceedings (including those accused, those serving as witnesses, and those bringing allegations).
- Appropriate powers in those charged with performing investigations to have access to all relevant evidence and witnesses. An investigation cannot stand if those charged with establishing relevant facts do not have full access to all relevant evidence and witnesses. This may require subpoena power in some settings.
- Separation of investigation and adjudication (i.e. those who perform investigations and make findings of fact should be separated from those who judge the totality of the case and impose sanctions).<sup>1,16</sup>
- Meaningful consequences for those who violate standards, for institutions that countenance misconduct, and for any form of retaliation against those who, in good faith, raise questions about the propriety of scientific conduct.
- The opportunity for appeals. After a proceeding is complete, there must be at least one opportunity to seek review of the procedures and fairness employed in reaching the conclusions.
- Timeliness. Justice delayed is justice denied, so it is essential that the times by which each stage of the investigation and adjudication is to be concluded be specified.

## Experience in the USA

Before moving on to precise definitions, it is useful, in understanding the need for a definition and a process, to look at what has happened in the USA. In this section, we will discuss *process* as much as *definition*. We do so because having definitions for what is wrong behaviour must surely imply that allegations will be followed by action. Without such a process, defining acts that are wrong is a meaningless exercise.

In view of the sheer size of the scientific enterprise and research output in the USA, it is perhaps not surprising that it was the first country to see scientific misconduct as a national problem, requiring a national response. The gradual evolution of the idea of misconduct specifically relating to scientific research is well illustrated in the USA, and it is worth our while contrasting this history with the very different history in the UK, despite the fact that no one has ever shown differences in the nature or quality of science or the integrity of scientists between the two countries. The long-drawn-out fight over the definition of research misconduct in the USA provides useful lessons to any other country establishing standards. Moreover, the great gulf between lawyers, accustomed to dealing with misconduct of every sort, and scientists, trained to trust, but verify, is well illustrated in the history of the development of regulations governing research misconduct in the USA.

We have summarized the turbulent history in the USA of scientific fraud during the late 1970s to the year 2001.<sup>17,18</sup> In brief, a few individual cases, occurring usually at prestigious research institutions such as Yale and Harvard, were extensively reported in the media. While the public, who by and large paid for the science, got its collective mind around the idea that scientific degrees did not necessarily guarantee rectitude,

the world was treated to the spectacle of venerable institutions and scientific societies in states of confusion and denial, making up their own rules as they went along, in the harsh glare of media attention. The institutional responses were patently idiosyncratic, frequently bungled, sometimes illegal, and often unfair.

Members of the US Congress soon became involved, and started holding public hearings, citing their responsibilities to safeguard the public purse. At the hearings, it soon became clear that there was little common ground between the members of the scientific establishment who were brought in to testify, and the legislators, by and large lawyers, who grilled them. The scientific miscreants on display, and the eminent leaders of the learned societies, together managed to make themselves look recalcitrant and science look bad.

The representatives of the scientific establishment, by making self-interested assertions that the problem was vanishingly rare<sup>19</sup> (assertions for which there was never any evidence, and which every new case plainly showed to be false), achieved the seemingly impossible: making the members of Congress appear to be better scientists than those whom they questioned.

It was obvious to members of the US Congress, nearly half of whom are lawyers, immersed in legalistic thinking, that regulation was required. Scientists argued for self-regulation while each new case undermined that argument, proving to the public that in such an emotional issue, when outsiders threaten to intrude, the professions 'circle the wagons' and have to be forced to do the right thing. It became clear that powerful members of Congress, who read the newspapers and understood the public's indignation at discovering that the scientists whom they funded were not always pure, would intervene to force regulation. They would claim the right to reach into all research organizations receiving government money – which effectively meant all such institutions. In the face of this perceived threat, and to assist the two sides in understanding each other as well as the issues as a prelude to drawing up regulations, two large umbrella organizations, the American Association for the Advancement of Science (AAAS) and the American Bar Association (ABA), set up a series of exploratory meetings in the mid-1980s. In 1989, the first regulations were enacted, and a body set up: the Office of Scientific (later Research) Integrity (OSI, ORI).

The definition of misconduct adopted in 1989, under Congressional pressure, was as follows:<sup>17,20</sup>

'Fabrication, falsification, plagiarism or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research.'

This definition caused problems for many reasons. Everyone agreed that fabrication, falsification, and plagiarism (FFP) were antithetical to good science. But the phrase 'other practices that seriously deviate' was immediately seized upon by the Federation of American Societies for Experimental Biology (FASEB), who argued that this clause could allow penalties to be applied to novel or breakthrough science. The Federation mobilized its members to remove this phrase completely and limit the definition to FFP.<sup>21</sup> As we noted:<sup>17</sup>

'Underlying the objections to the "other practices that seriously deviate ..." clause is the fear that the vague language will result in application of a vague and misty standard of misconduct that cannot be known in advance. It seems fundamentally unfair to stigmatize someone for behavior they had no way of knowing was wrong. Unhappily, consideration of cases shows that some of the most egregious behaviors, abuse of confidentiality, for example, are not covered by the FF&P label. We cannot have a definition that implies that this sort of behavior is not wrong. Moreover, since we cannot possibly imagine every scenario in advance, the definition must ensure that perpetrators of acts that are deceptive and destructive to science are not exonerated. If they are, the public and our legislators, applying the standards of common sense, will rightly deride the outcome as nonsensical.'

Since the ORI, the government office charged with oversight of scientific integrity within biomedicine (the research field controlled by the US Public Health Service) never invoked the 'other practices ...' clause, but the other large scientific grant-awarding government agency, the National Science Foundation (NSF), did, researchers funded by different government agencies effectively came to be covered by different definitions of research misconduct. In addition, ORI announced that it would not take cases of alleged plagiarism if the authors of a work had been coauthors together. ORI's decision was purely administrative, and designed to reduce the number and complexity of their formidable backlog of cases – not least because such cases proved singularly awkward to sort out. By definition, ORI asserted, all such cases fell into the category of 'authorship disputes', and would not be examined for the elements of plagiarism. NSF never instituted such a policy, and continued to examine cases where students or co-workers alleged that their contributions had been appropriated by another without cause or attribution. No system in which some could have their complaints examined while others could not would succeed for long.

Science is a risky enterprise, often requiring much trial and error. No one could possibly undertake scientific experiments if error was construed as misconduct. As Mishkin<sup>22</sup> has pointed out, 'misconduct' in legal parlance means a *wilful* transgression of some definite rule. Its synonyms include 'misdemeanour', 'misdeed', 'misbehavior', 'delinquency', 'impropriety', 'mismanagement', and 'offence', but not 'negligence' or 'carelessness'.

Distinguishing error from misconduct requires making a judgement about intent. While scientists are often cowed by this necessity, citizens routinely make them in other settings, most notably in an established criminal justice system that employs juries.

It is our opinion that this assessment should be made only at the time of adjudication, after the facts of a case of scientific misconduct have been determined: for example, 'words were copied' or 'no primary data have been produced'. This sequential approach has two salutary effects. First, it reduces the potential that the factual determinations will be obscured by other considerations. The danger otherwise is that – as has frequently happened – a panel's sympathy for the accused ('he's too young, too old, meant well', etc.) interferes with a rigorous analysis of events. Second, this approach introduces proportionality into the response – what, if any, consequence

should there be, in light of all the relevant circumstances? This factor is important in the final sense of whether the process 'worked' or not – both for participants and for observers.

### *The scientific dialogue model*

Originally, the ORI tried to keep misconduct proceedings in the hands of scientists rather than lawyers. The 'scientific dialogue model' that they advanced soon came under criticism for being unfair and flawed.<sup>17</sup> Changes were made, and the standards for responding to allegations gradually became more structured and legalistic so that results could withstand scrutiny from administrative tribunals. Defendants, faced by the loss of their livelihoods, hired lawyers to insist on their basic right to fundamental fairness and due process. Most fundamental among these rights are the rights to know and to respond to all evidence to be used against an accused. Unfortunately, these rights were all too easy to overlook while collegiality prevailed ('the scientific dialogue'), and where hard issues were not always faced directly or even-handedly.

### *The early 1990s: the heat increases*

Despite these problems, and the heat that they engendered, in February 1993 we concluded on a note of cautious optimism:<sup>17</sup>

'... practically everything to do with scientific misconduct is changing rapidly: the definition, the procedures, the law and our attitudes ... It will take time to accumulate a body of experience (a case law, as it were) and to get it right. The challenge is to seize the opportunity, to capitalize on the wealth of accumulating information, and to focus on the long-term goals of strengthening science and the society that depends on it.'

Our optimism was premature. In 1994, despite more than 20 years of widely publicized cases of misconduct, more than a dozen congressional hearings, years of regulations to them), and, first, an Office of Scientific Integrity and then of Research Integrity, there remained widespread division and dismay. The definition was still hotly debated, as was the process owed an accused scientist, the extent of federal oversight, how to protect whistleblowers, and how to prevent misconduct. At the same time, in the early 1990s, several high-profile cases were decided against government science agencies and their ways of proceeding.<sup>1</sup>

Asserting that the US Federal Government had an interest in professional misconduct involving the use of federal funds in research and which could affect the public health, a government Commission on Research Integrity (the 'Ryan Commission') was set up to examine the issue. Both of us were members. The Commission recommended that the definition of research misconduct (Box 3.2) should be 'based on the premise that research misconduct is a serious violation of the fundamental principle that scientists be truthful and fair in the conduct of research and the dissemination of its results'.<sup>1</sup> The Commission, which we will henceforth in this section call 'we', strongly recommended the development of a common federal definition of research

misconduct and other forms of professional misconduct related to research. With its definitions, we put forward examples within the report (Box 3.2).

### Box 3.2 US Commission on Research Integrity definitions of misconduct<sup>1</sup>

#### 1. Research misconduct

Research misconduct is significant misbehavior that improperly appropriates the intellectual property or contributions of others, that intentionally impedes the progress of research, or that risks corrupting the scientific record (the record encompasses any documentation or presentation of research, oral or written, unpublished) or compromising the integrity of scientific practices. Such behaviors are unethical and unacceptable in proposing, conducting, or reporting research or in reviewing the proposals or research reports of others.

Examples of research misconduct include but are not limited to the following:

- *Misappropriation*: An investigator or reviewer shall not intentionally or recklessly
  - (a) plagiarize, which shall be understood to mean the presentation of the documented words or ideas of another as his or her own, without attribution appropriate for the medium of presentation; or
  - (b) make use of any information in breach of any duty of confidentiality associated with the review of any manuscript or grant application.
- *Interference*: An investigator or reviewer shall not intentionally and without authorization take or sequester or materially damage any research-related property of another, including without limitation the apparatus, reagents, biological materials, writings, data, hardware, software, or any other substance or device used or produced in the conduct of research.
- *Misrepresentation*: An investigator or reviewer shall not with intent to deceive, or in reckless disregard for the truth,
  - (a) state or present a material or significant falsehood; or
  - (b) omit a fact so that what is stated or presented as a whole states or presents a material or significant falsehood.

#### 2. Other forms of professional misconduct

##### (a) Obstruction of investigations of research misconduct

The Federal Government has an important interest in protecting the integrity of investigations into reported incidents of research misconduct. Accordingly, obstruction of investigations of research misconduct related to federal funding constitutes a form of professional misconduct in that it undermines the interests of the public, the scientific community, and the Federal Government.

Obstruction of investigations of research misconduct consists of intentionally withholding or destroying evidence in violation of a duty to disclose or preserve; falsifying evidence; encouraging, soliciting or giving false testimony; and attempting to intimidate or retaliate against witnesses, potential witnesses, or potential

leads to witnesses or evidence before, during, or after the commencement of any formal or informal proceeding.

##### (b) Noncompliance with research regulations

Responsible conduct in research includes compliance with applicable federal research regulations. Such regulations include (but are not limited to) those governing the use of biohazardous materials and human and animal subjects in research.

Serious noncompliance with such regulations after notice of their existence undermines the interests of the public, the scientific community, and the Federal Government and constitutes another form of professional misconduct.

By defining the central terms used in the definition of misconduct, we obviated the problem endemic in institutional proceedings in which every investigative panel secured a dictionary and defined for itself key elements upon which its findings depended. This common and understandable impulse all too frequently compromised the integrity of individual misconduct proceedings, as the resulting ad hoc definitions did not pass the 'laugh', let alone the 'red-face', test. In addition to providing a fuller internal definition of plagiarism, our proposed definition explicitly addressed other issues upon which faculty review panels repeatedly stumbled. For example, we incorporated misconduct in reviewing papers or grant applications into the definition of offences outside acceptable professional conduct.

We also researched and then recorded the legal reality in the USA that the 'standard of proof' required in civil proceedings is the 'preponderance of the evidence', not the higher standards of 'clear and convincing' or 'beyond a reasonable doubt'. These issues had derailed many an institutional proceeding and prevented them from reaching a finding. Another very important component of our work was the declaration that, while intent should be a necessary requirement for a finding of fabrication or falsification, a finding of carelessness suffices to support a finding of plagiarism.

We broadened the definition beyond the then-prevailing standard of 'fabrication, falsification, and plagiarism' to include other forms of unethical behaviour not then governed by any specific regulations (Box 3.2). Guided by actual cases, we defined research misconduct as (1) misappropriation (including plagiarism), (2) interference (e.g. tampering with someone else's research), and (3) misrepresentation. In addition, we included categories of lesser misconduct that, while not 'scientific misconduct', still warranted response. These included obstruction of misconduct investigations, retaliation against those participating in investigations, and non-compliance with research regulations. We recognized that, although research institutions might make their own rules, the governmental definition had, after 1989, become de facto the one in general use.

Definitions carry little meaning without effective procedures. In our report, we did not merely define bad acts, but laid out the rights and responsibilities of scientists. We recommended that educational programmes on research integrity should be required in institutions receiving federal money. We wanted, first, to ensure that information

about good professional conduct be provided as a fundamental element of education; secondly, to make discussion of these matters more common and less threatening; thirdly, to make it possible for the powerless to ask questions; and, finally, to make it harder for the clever sociopath to slide by. We recommended that there be 'funding for scholarship, teaching, and research in science ethics. Such funded research should include an experimental audit of the prevalence of data misrepresentation.' We also recommended that 'professional societies each adopt a code of ethics in research' and initiate 'activities that will further promote the ethical conduct of research and professionalism in science'.<sup>1</sup>

Recognizing that whistleblowers provide an important quality control mechanism in science, and mindful of the numerous examples of abuse of whistleblowers who had brought forward well-founded allegations, we set forth a detailed statement of principles - 'Responsible Whistleblowing: A Whistleblower's Bill of Rights' - in which we spelled out the rights and responsibilities of whistleblowers, of the accused and of their institutions.<sup>1</sup> For further discussion of whistleblowing, see Chapter 15.

Based upon our collective experience, the testimony presented at our meetings, our research, and information presented by commissioned papers, we made a number of recommendations about how misconduct proceedings should be conducted. For example, we advised that investigation and subsequent adjudication should always be separated organizationally; that 'legal, law-enforcement, and scientist-investigator staff participate in each federally conducted investigation and ensure that scientists participate in hearings and appeal procedures'; that 'those conducting investigations have subpoena power over persons and documents'; and that 'authorship or collaborative' disputes (those previously dismissed by the ORI, for administrative reasons) should be addressed by institutions and by federal funding agencies.

While our proposals protected institutional decisions from second-guessing if based on properly conducted procedures, they recognized the built-in conflicts that institutions can face when investigating their own scientists, some of whom might be influential and bring in large amounts of money. We proposed 'widespread, systematic public disclosure of all outcomes of federal research and research-related professional misconduct cases, with detailed, specific statements of their rationale, in view of the strong public interest in the disclosure of information underlying such cases'.<sup>1</sup>

We articulated the elements required for fair process, by articulating the various interests at stake in these proceedings - including those of the accused, whistleblowers, witnesses, and funding agencies. We recommended internal checks and balances throughout, even for the federal agencies providing the funding for research. We suggested approaches for streamlining processes, made numerous recommendations to improve the effective oversight of institutional performance, and broadened the array of sanctions that could be applied against those found guilty of misconduct, and against institutions failing to carry out investigations properly.

### The reaction

While the Commission's report was characterized by a disinterested observer, the editor of the *Lancet*, as 'a superb piece of analysis',<sup>23</sup> and many academics

pronounced themselves content with the Commission's definition,<sup>24</sup> it met with widespread condemnation by the leaders of the scientific establishment. Although the Commission consisted largely of scientists (as well as ethicists, administrators, and lawyers), the reaction from the scientific elite in the USA was immediate, loud, defensive, dismissive, confused, and self-contradictory. Given that the reaction was in response to a careful report based on the articulated 'fundamental principle that scientists should be truthful and fair in the conduct of research and the dissemination of research results', this reaction seemed at times hysterical. The President of the Federation of American Societies for Experimental Biology (FASEB) wrote to the Secretary for Health and Human Services that the 'Commission's report is so seriously flawed that it is useless as a basis for policy making and should be disavowed ... we find the definition to be unworkable, and therefore unacceptable'.<sup>25</sup> He was quoted in the press as calling the report 'an attack on American science'.<sup>26</sup> The same letter objected to what was called an expansion of the definition of plagiarism, even though the Commission had been guided in its definition by the Academy's own report, *Responsible Science*,<sup>6</sup> a report that the latter strongly endorsed.

The leadership of the National Academy of Sciences (NAS) also wrote a letter criticizing the Commission report. While acknowledging that the Commission 'repeatedly states that the primary investigative responsibility rests with the research institutions',<sup>26</sup> it brushed these statements aside in raising the bogeyman of a vast expansion of an intrusive federal bureaucracy if the Commission's recommendations were to be implemented. The NAS nowhere acknowledged that it was the abject failure of many research institutions to respond appropriately to allegations of misconduct that led to the Commission's original formation by Congress. The NAS failed to say that the report called for government agencies to investigate allegations only in certain very limited circumstances: in cases involving more than one institution, or where the institution had not conducted a proper investigation.<sup>27</sup> Nor did it note that the government already has such an oversight role, which would, if anything, be diminished if the Commission's recommendations were followed.

In hindsight, what was most threatening in the Commission Report was the 'Whistleblower's Bill of Rights'.<sup>1</sup> The Commission was accused of failing to 'protect adequately the rights of scientists who are accused of misconduct'. Yet what moved the Commission was not the rights of scientists who were accused, who already had excellent protections, but the plight of accusers who blew the whistle in good faith, and who were later proved right, but who suffered considerable harm, often from the guilty and their institution. The Commission had heard testimony from a great many in this position.

Perhaps the most persistent, peculiar, and revealing criticism of the report, and, indeed, of any proposed regulation, was the continuing allegation that regulation would impede scientific progress because truly original science might easily be labelled misconduct. In hundreds, even thousands of cases, this has never happened.

Finally, some scientists still claimed that, because science is 'self-correcting', no rules were necessary. The corollary of this position is that it does not matter if the record is never put right. In the medical field alone, however, the truth is that much science is never replicated, and this assertion says nothing about the costs - institutional and

human – imposed by gross fraud, the loss of morale among co-workers, the anger on the part of the public and politicians, and the outrage of the media.

Our report grew out of the failures of the past, including the failure of the 1989 government definition to stand up to legal challenge and to work effectively when applied to real cases. The vehemence of the reaction to the report, which proposed that scientists should be truthful and fair, and which was crafted to make it work in the real world of research and of lawyers, was telling. So was its widespread misrepresentation. Upon reflection, we conclude that this must stem from the fact that few of the scientists who objected had much experience in dealing with allegations of misconduct. Together, they suggest that scientists continue to feel threatened by the spectre that malicious allegations might be brought against them. Above all, objecting scientists failed to grasp the fact that, in this real world, legal challenges dominate the field, and that, in response to these realities, the Commission introduced precision – which in turn provides protections for those involved in misconduct proceedings, most especially the accused scientist.

### *The US government-wide regulations of December 2000*

During the ensuing five years, cases occurred and were reported in the media, and were summarized in regular reports from the ORI and the NSF. Gradually, as the media, the public, and the profession realized that the system was working in a routine and reasonably efficient manner, the heat died down. Meanwhile, the administration embarked on the lengthy process of making common regulations that would govern all types of research, not just those in biomedicine.

On 6 December 2000, after a two-month public comment period, the Clinton administration issued the new, government-wide regulations defining research misconduct and laying down the rules for investigation and adjudication of allegations of misconduct concerning research done with US federal funds (Box 3.3).<sup>28</sup> Since all important universities and research institutions receive such funds, these regulations have become institutional rules, although institutions are allowed to have their own additional rules if they wish to impose a higher internal standard.

We strongly believe that they should. And we say this because the new definition, confining itself to 'fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results', leaves out many actions that we find destructive of good science, and which are not covered by other laws. We were both involved in assessing one case in which a junior investigator had sequenced irreplaceable data and materials from her colleagues – an action that would not be judged to be scientific or research misconduct by the new regulations, although common sense would tell us that the investigator's conduct in the performance of research was wrong and damaging to science. We are troubled, then, that by making the definition too narrow, other egregious behaviours might seem to be condoned. It would send the worst possible signal if the academic community were to conclude that such behaviour – by default – was acceptable.

This new definition is again appropriately silent on prolonged non-compliance with other research regulations, such as the unethical treatment of human research subjects

#### BOX 3.3 Extract from US Federal Policy on Research Misconduct<sup>28</sup>

##### I. Research<sup>6</sup> misconduct defined

Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- Fabrication is making up data or results and recording or reporting them.
- Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.<sup>c</sup>
- Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- Research misconduct does not include honest error or differences of opinion.

##### II. Findings of research misconduct

A finding of research misconduct requires that:

- There be a significant departure from accepted practices of the relevant research community; and
- The misconduct be committed intentionally, or knowingly, or recklessly; and
- The allegation be proven by a preponderance of evidence.

<sup>6</sup>No rights, privileges, benefits or obligations are created or abridged by issuance of this policy alone. The creation or abridgment of rights, privileges, benefits or obligations, if any, shall occur only upon implementation of this policy by the Federal agencies.

<sup>c</sup>Research, as used herein, includes all basic, applied, and demonstration research in all fields of science, engineering, and mathematics. This includes, but is not limited to, research in economics, education, linguistics, medicine, psychology, social sciences, statistics, and research involving human subjects or animals.

<sup>d</sup>The research record is the record of data or results that embody the facts resulting from scientific inquiry, and includes, but is not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles.

or mistreatment of laboratory animals used in research, because there are already regulations governing these problems. And again, the new regulations do not supersede criminal or other civil laws that have nothing to do with the faithful reporting of good science (e.g. laws on sexual harassment).

The new rules drew extensively from the Commission Report. From the incorporation of interior definitions of critical terms and of states of mind for offences, to articulation of necessary procedural safeguards, the Report provided the rationale. We strongly recommend that anyone interested in the formulation of adequate institutional responses to allegations of research misconduct, read both the Commission Report and the US government regulations of December 2000.

### Lessons from the US experience

It took 20 years to achieve a set of widely accepted regulations in the USA. In the hope that examination and understanding of this experience might prevent a great deal of 'reinvention of wheels', we shall summarize here what we believe to be the essential elements. First, however, let us consider the *catalysts*:

- Repeated dramatic incidents resulting in publicity showing that research institutions operated in ignorance, denial, and cover-up; and there was recurrent shaming of institutions in the media (this is the present position in the UK and most other countries).
- A few powerful politicians, highly sceptical of the research establishment's reassurances that all was well, repeatedly exposing how thin these reassurances were, pushing for regulation, and, finally, exasperated by the do-nothing approach of science, forcing regulation tied to the continuance of federal research funds.
- Numerous meetings attended by representatives of science, lawyers, administrators, and legislators.
- The establishment of oversight offices predicated on the assumption that research misconduct was basically a clinical research problem. Followed by a gradual realization that misconduct can occur in every branch of research, from mathematics to the humanities, and that administering its regulations would be much easier if all researchers were governed by the same rules.
- Learning from experiment and hard experience. The 'scientific model' did not work when the unfairness and illegality of the process were exposed (usually by lawyers or journalists). Scientists had to learn that processes for appeal were necessary, and that investigation and adjudication should be separated. Gradually a case law built up, and the process was absorbed into those of administrative law.<sup>16,29,30</sup>
- Greater education all round. Everyone concerned came to realize that it is beneficial to ensure that students – no matter who their mentor is – receive certain baseline information about good practice, and that, because scientists are mortals, it made sense to have processes in place to deal efficiently and routinely with those who strayed.

### What factors hold reform back? Professional societies

Constantly retarding the process of reform are several factors. Many distinguished scientists cannot accept that scientific misconduct can occur until it happens near them and they have to deal with it. More generally, it seems to be a human trait to seek power without accountability, so scientific organizations can be expected to oppose almost all regulation, including any amendment to even previously condemned regulations.

As an example, some bullfighters in Spain routinely shave the horns of the bulls that they face – sometimes by as much as five inches – to reduce their risk of injury, as this shaving impairs the weaponry, vision, and balance of the bull. It is well known that this occurs, and it is regarded as wrong. But when the Spanish government proposed a system of examinations to detect irregularities, the bullfighters went on strike, saying that they should be trusted to regulate themselves.<sup>31</sup> This example

illustrates a general issue, and merely points out that professional societies cannot be relied upon to remedy the problem – indeed, they and their prominent representatives have often made it worse. They rarely have the backbone to take effective actions to discipline their members. Indeed, even if they wish to, they lack the legal power to do so. In the case of science, there are so many such societies in so many disciplines that it makes little sense to approach the problem of research misconduct in this way.

We would all like our professions to behave in a way that, to most of us, would define professionalism – that is, to regulate themselves effectively. But our experience with scientific misconduct in the USA shows us that, as with bullfighters in Spain, there must be some higher body to force regulation upon researchers. We can expect that nothing much will happen in countries without effective systems in place, and change will occur only when the pain and shame of bad publicity becomes unbearable. Professional societies and large research institutions react defensively when this subject is raised, circling the wagons, and obfuscating the issue. They will go to great lengths to prevent outside government intervention, maintaining that there is no problem; that they have the problem well in hand; that the problem must be left in their hands, as others do not understand it; that the motives of outsiders are malicious and, no matter how constructive, constitute an 'attack on science'; and that research misconduct is too ineffable a construct to be pinned down in words by bureaucrats. Finally, they tend to assert that a model that focuses entirely on education and prevention, but is toothless when it comes to regulating actual misconduct, will make the problem go away, thus satisfying the press, the public, the politicians, and their fellow professionals. If left to professional societies, effective governance of research misconduct is unlikely to occur.

## The UK

### The Committee on Publication Ethics (COPE)

Editors are the first to see complete reports of investigations, and they put their journals' reputations behind what they publish. They are often the first people to be contacted when questions arise about the honesty of articles, and the ones expected to deal with the problem. Perhaps that is why those who have pushed for effective regulation in the UK are largely medical editors such as Richard Smith and Fiona Godlee of the *BMJ*, and Richard Horton of the *Lancet* (all prominent founder-members of the Committee on Publication Ethics, COPE), as well as the editors of this book, Michael Farthing and Frank Wells.<sup>32</sup> COPE is an extraordinarily effective organization, and has earned worldwide respect for the forthright way in which its members have tried to face up to the many ethical problems editors encounter. Its very success, however, has drawn attention to its limitations. It is largely an organization of clinical editors; and it has no power to mandate any definition of misconduct, secure evidence, or investigate, adjudicate and sanction serious misconduct. Various definitions of misconduct put forward by COPE are shown in Box 3.4.<sup>33</sup>

**BOX 3.4 Extracts from the Committee on Publication Ethics (COPE) guidelines on good publication practice<sup>33</sup>**

**Study design and ethical approval – definition**

Good research should be well justified, well planned, appropriately designed, and ethically approved. To conduct research to a lower standard may constitute misconduct.

**Data analysis – definition**

Data should be appropriately analysed, but inappropriate analysis does not necessarily amount to misconduct. Fabrication and falsification of data do constitute misconduct.

**Authorship – definition**

There is no universally agreed definition of authorship, although attempts have been made. As a minimum, authors should take responsibility for a particular section of the study.

**Plagiarism – definition**

Plagiarism ranges from the unreferenced use of others' published and unpublished ideas, including research grant applications, to submission under 'new' authorship of a complete paper, sometimes in a different language. It may occur at any stage of planning, research, writing, or publication; it applies to print and electronic versions.

**Dealing with misconduct – principles**

1. The general principle confirming misconduct is the intention to cause others to regard as true that which is not true.
2. The examination of misconduct must therefore focus, not only on the particular act or omission, but also on the intention of the researcher, author, editor, reviewer, or publisher involved.
3. Deception may be by intention, by reckless disregard of possible consequences, or by negligence. It is implicit, therefore, that 'best practice' requires complete honesty, with full disclosure.
4. Codes of practice may raise awareness, but can never be exhaustive.

**The Joint Consensus Conference of 1999 Statement**

In October 1999, 10 years after the USA had formally adopted regulations, a groundbreaking meeting was held in Edinburgh to debate the issue. In the words of its Consensus Statement:

'Patients benefit not only from good quality care but also from good scientific research. We all expect high standards of scientific and medical research practice. The integrity, probity, skill and trustworthiness of scientific and medical researchers are essential if public confidence is to be assured. In the design and execution of biomedical and healthcare research, public

participation is essential. The Joint Consensus Conference on Misconduct in Biomedical Research was convened in order to debate, address and offer guidance on key questions because "every single case [of fraud and misconduct] reduces public confidence, abuses the use of public and charitable funds, and causes insult and frustration to the vast majority of careful, honest workers".<sup>34</sup>

To understand the difficulties in deciding on a workable definition of research misconduct, it is useful to look at the one proposed in Edinburgh:

'Behaviour by a researcher, intentional or not, that falls short of good ethical and scientific standards.

No definition can or should attempt to be exhaustive. It should allow for change. The definition should not be read as being restricted to fabrication, falsification of data and plagiarism. It is intended to cover the whole range of research misconduct.'

This definition was doomed from the start. While it was an important evolutionary step for the UK, it fails as a definition in almost every respect. It is not universal, since it was developed in a closed meeting, where the principal interest was in clinical research, so the broad base and lengthy discussion necessary for useful consensus were never achieved. It was not official, having no mandate and no legal powers to make its recommendations happen.

Moreover, it is not specific, nor does it provide clear guidance on the meaning of its critical terms. Indeed, it is so vague, non-specific, and all-encompassing that it is unworkable. What are 'good ethical standards'? In which field? In what circumstances? By whose judgement? There are whole areas of research – for example, research on stem cells, or on aborted fetuses – where ethical scientists hold strongly divergent opinions about 'good' standards. Worst of all, the definition includes unintentional behaviour that falls short of good scientific standards. If this sort of thing is misconduct, how could anyone ever dare to attempt science? In addition, the statement that the definition 'is intended to cover the whole range of research misconduct' is circular.

As to 'clear and fair process', although the specifics of handling accusations of misconduct are essential ingredients of any successful system, the Consensus Report says little or nothing specific about procedures, so most of the elements necessary for a useful system are undefined or absent. The US experience illustrates that getting the process right matters as much as having the right definition. In fact, one could posit that the low-key acceptance of the US Government definition of 2000 is rooted as much in the growing comfort that proceedings – if never pleasant – are not unfair or biased by design. Much can be learned from the US experience with process, both by those with institutional responsibilities and by those who are caught in a specific situation.<sup>16,29,30</sup>

**The UK Medical Research Council and the Wellcome Trust**

The US Congress had shown that a fail-safe way to attract everyone's attention and trump professional obfuscation is to link professional and institutional compliance to

funding. All institutions receiving government money had to adopt the government definition and process of investigation and adjudication as conditions of funding. While free to set up additional requirements and standards for their own researchers, few research institutions went to the trouble of devising extra rules, so the government regulations for research conducted with government money effectively became the universal regulations.

This seems to have been the approach of the powerful funders of research in the UK – the Medical Research Council (MRC) and the Wellcome Trust – who have used their financial clout to dictate institutional policy. The MRC published standards in 1997 (Box 3.5) and the Wellcome Trust, the largest research funder in the UK, published its Statement on the Handling of Allegations of Research Misconduct in 2002 (modifying it in 2005) (Box 3.6). It is clear that both borrowed heavily from the definition developed in the USA.

#### *The UK Research Integrity Office (UKRIO) and other countries*

In 2006, the UK began setting up a body, the UK Research Integrity Office (UKRIO), to try to address the issue of research misconduct.<sup>5</sup> We, and others, have recommended a move like this for many years.<sup>18,35</sup> Despite the strenuous efforts of clinical editors there, the UK is nearly two decades behind the USA and Scandinavia in introducing this sort of initiative.<sup>2</sup> The lessons repeatedly being played out across the globe, for example in the falsifications associated with some stem cell research in South Korea, are that countries without robust systems governing research misconduct already in place doom their entire research community to confusion and loss of credibility when incidents occur.

#### **BOX 3.5 Extract from UK MRC Policy and Procedure for Inquiring into Allegations of Scientific Misconduct<sup>a,b</sup>**

**Annex, Item 2.11:** Scientific misconduct or misconduct means fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting results of research and deliberate, dangerous or negligent deviations from accepted practice in carrying out research. It includes failure to follow established protocols if this failure results in unreasonable risk or harm to humans, other vertebrates or the environment and facilitating of misconduct of research by collusion in, or concealment of, such action by others.

It does not include honest error or honest differences in the design, execution, interpretation or judgment in evaluating research methods or results or misconduct (including gross misconduct) unrelated to the research process.

<sup>a</sup>Statement by the Medical Research Council, London, 1997.

<sup>b</sup>Under Item 1.2 ('Scope'), it is made clear that these policies and procedures apply only to those working for the MRC at the time of the allegations.

#### **BOX 3.6 Extract from Wellcome Trust definition of research misconduct (2002, modified 2005)<sup>a</sup>**

1.1 'Research misconduct' is defined by the Trust as:

The fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting results of research or deliberate, dangerous or negligent deviations from accepted practices in carrying out research. It includes failure to follow established protocols if this failure results in unreasonable risk or harm to humans, other vertebrates or the environment and facilitating of misconduct in research by collusion in, or concealment of, such actions by others. It also includes intentional, unauthorised use, disclosure or removal of, or damage to, research-related property of another, including apparatus, materials, writings, data, hardware or software or any other substances or devices used in or produced by the conduct of research.

1.2 It does not include honest error or honest differences in the design, execution, interpretation or judgement in evaluating research methods or results or misconduct unrelated to the research process. Similarly it does not include poor research unless this encompasses the intention to deceive.<sup>b</sup>

<sup>a</sup>In formulating these guidelines, the Trust has drawn on the Medical Research Council's Ethics Series, in particular *Good Research Practice* (December 2000) and *Policy and Procedure for Inquiring into Allegations of Scientific Misconduct* (December 1997) and the General Medical Council's *Good Practice in Medical Research*, Royal College of Physicians of Edinburgh (January 2000) and the Biotechnology and Biological Sciences Research Council's 'Statement on Safeguarding Good Scientific Practice'.

<sup>b</sup>Based on the definitions given in the MRC's *Policy and Procedure for Inquiring into Allegations of Scientific Misconduct* (December 1997) and the GMC's report *Good Practice in Medical Research* (2002).

## Conclusions

In this chapter, using the long and extensively documented US experience, we have argued for a clear and universal definition of research misconduct. We have described how definition and process are interwoven, and that the political fights that have occurred are the inevitable battles that take place when a profession asserts that it can govern itself while at the same time demonstrating to the public, who pay the bills, that it is unable to do so. The US definition of research misconduct is truncated and flawed. It is our opinion that when the scientific societies narrowed the definition to include only fabrication, falsification, and plagiarism (FFP), they made a serious mistake. That being said, the US definition, together with a clear process that has been tested in the courts, allows routine, prompt, and fair handling of cases and the assurance that bad actors will be held accountable.

As cases of bad scientific behaviour are reported from every country where the research enterprise goes forward, it should be no surprise that institutions and

countries are scurrying around to try to invent definitions for themselves. A good start would be for them to conduct a careful examination of the experience of others, such as the USA, and to look at their definitions. In particular, we believe that it would be useful to emulate the definitions recommended in the report of the Commission on Research Integrity.<sup>1</sup> Every country that sets up its own definition has to ask itself how the physical laws of science and scientific practice should differ across national boundaries – and if they do not, why universal definitions should not apply.

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