RECOMMENDATIONS FOR PROMOTING RESEARCH INTEGRITY
INTRODUCTION – SCIENCE, RESEARCH AND SOCIETY

SCIENCE AND RESEARCH

The aim of science is to increase our understanding and knowledge beyond what is already known of the physical, biological and social worlds. Research is, therefore, required to help determine the nature and principles of what is being studied. Knowledge and understanding are obtained and improved through the processes of experimentation and observation, argumentation and evidence finding, study and thinking. Such activities represent the basic tenets of research. Moreover, in order to increase our knowledge, the findings and results of these endeavours need to be analysed, verified, disseminated and discussed.

However, scientific research is not conducted in a vacuum. Science impacts on all aspects of society, i.e. political, economic and cultural, therefore, science and society are inherently interconnected. As stated by the Monitoring Activities of Science in Society Expert Group “in principle, every person in society is a stakeholder when it comes to the role of science in society…”. Notwithstanding the historical tradition of the science-society relationship, it is only relatively recently, i.e. during the twentieth century, that recognition and acknowledgement of the importance of science to society, as indicated by public support, has increased substantially. So much so that research now represents a significant feature of all societies, through both public and private financial investments as well as forming the basis for numerous policy decisions. Scientific knowledge is considered valuable in and of itself, and curiosity about where we come from, what we are made of, and the environment around us is a key driver in our development, both as a species and as individuals. As the physicist Richard Feynman has remarked

“With more knowledge comes a deeper, more wonderful mystery, luring one on to penetrate deeper still. Never concerned that the answer may prove disappointing, with pleasure and confidence we turn over each new stone to find unimagined strangeness leading on to more wonderful questions and mysteries – certainly a grand adventure.”

Much of the support for science and research stems from the improvements these endeavours have brought to people’s lives, e.g. economic growth and helping to alleviate social need. For example, health research has contributed enormously as a social good

through the understanding, treatment and alleviation of illnesses and diseases. Moreover, this science-society nexus is now a key consideration in national and international policy decision making, as evidenced by the European Commission’s implementation of numerous science-society initiatives as part of the Sixth (FP6) and Seventh (FP7) Framework Programmes (e.g. the “Science and Society” programme during FP6 and the “Science in Society” programme for FP7).

Therefore, an important social contract or covenant exists between science and society. Scientific endeavours receive substantial financial and political support on the understanding that such research will benefit society. For instance, the preamble to the Convention on Human Rights and Biomedicine, affirms that research in biology and medicine should be used to benefit present and future generations. In addition, Article 27 (part 1) of the United Nations’ Universal Declaration of Human Rights states that “everyone has the right…to share in scientific advancement and its benefits”. Therefore, public funding for research comes with the expectation that this work will reap rewards for society.

However, the credibility and integrity of the science system is considered to be essential to its continued worth. This indicates that public support for science is not unlimited, but conditional. A 2010 Eurobarometer survey, conducted for the European Commission found that 58% of Europeans did not trust scientists to be truthful about controversial scientific issues. Such support relies on the public continuing to trust the individuals and institutions conducting research. Moreover, progress in science requires not only public trust, but also the trust of the scientific community.

The “Climategate” controversy began in November 2009 when approximately 1000 hacked e-mails from the Climatic Research Unit (CRU) of the University of East Anglia (UEA) were posted on the internet. The debate fuelled by the content of the e-mails called into question the work and reputation of the CRU, the reliability of climate science in general and the conclusions of the Intergovernmental Panel on Climate Change (IPCC). In response to the ensuing controversy, the UEA commissioned two inquiries the first of which examined a number of CRU publications to address allegations that climate data used by the CRU had been “dishonestly selected, manipulated and/or presented to arrive at pre-determined conclusions that...

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were not compatible with a fair interpretation of the original data”. The inquiry panel found no evidence of deliberate scientific misconduct in any of the work of the CRU. The second inquiry, the Independent Climate Change E-mails Review, investigated allegations relating to the behaviour of the CRU scientists with regard to their handling and release of data, their role in presenting their results publicly and their approach to peer review. This independent review found that the rigour and honesty of the CRU scientists was not in doubt. In addition, it was found that the behaviour of the CRU scientists did not prejudice the balance of advice given to policy makers nor did it undermine the conclusions of the IPCC assessments to which the CRU contributed. Nonetheless, the independent review also found that there was a “consistent pattern of failing to display the proper degree of openness” both by the CRU and the UEA, which risked the reputation of the university itself and the credibility of UK (United Kingdom) climate science. The impact of the “Climategate” affair was further compounded by a number of errors found in the IPCC Fourth Assessment Report. As a result of which the credibility of the IPCC was called into question. Therefore, the InterAcademy Council (IAC) was asked to conduct an independent review of the processes of the IPCC. The IAC stated that the IPCC assessment process was successful overall, however, a number of recommendations were made in relation to how it could be improved. These included that: an executive committee should be established to govern the IPCC, which should include at least three independent members and individuals from outside the climate research community; there should be stronger enforcement of the IPCC peer review procedures; there should be greater clarity (in terms of the amount of available evidence and the level of agreement between experts) when outlining the probability or uncertainty of particular climate change events; and that the processes by which the IPCC produced its assessment reports be made as transparent as possible. Despite the fact that the prevailing scientific evidence still supports the conclusion that climate change is occurring, there has been widespread negative reporting of climate science, which has greatly undermined public trust in and perception of issues relating to climate change. Consequently, support for specific policies to address climate change have also been negatively affected.


11 ibid.


The Irish Council for Bioethics recognises that the issues of promoting integrity in research and discouraging misconduct are not confined to the areas of science and health science, but they apply to all disciplines of research including the social sciences and the humanities. However, given the greater coverage this topic has received in relation to science- and health science-based research, the Council has focused on these disciplines in order to elucidate the main issues pertaining to research integrity throughout this document.
INTEGRITY IN RESEARCH

Continued public trust and confidence in science is contingent on the level of honesty and integrity exhibited by those within the scientific community. Consequently, increased public support for science and research has been accompanied by an increased interest in and concern about how such research is conducted. Researchers and research institutions are, therefore, expected to be accountable to the public, who as taxpayers provide much of the funding for research. It has been suggested that many researchers are in fact working for the public and as such “public servants” (and also as professionals in their own right) they have a duty to conduct their research in a responsible manner. Moreover, national governments as well as other international executive bodies, such as the European Commission, that administer funding for research on behalf of their citizens, also have a responsibility to ensure that this investment in research achieves its objective, i.e. providing some benefit to society.

According to the European Commission Expert Group the policies and procedures required to oversee the effective management of research funding should include standards in probity and integrity. In addition, the Organisation for Economic Co-operation and Development (OECD) has remarked that “at a time when scientific advances are considered to be critical in areas such as economic competitiveness, health, national security, and environmental protection, public officials are strongly motivated – indeed obligated – to ensure the highest levels of integrity in research”. Research integrity has, thus, emerged in recent years as a critical topic in policy research and has gained significant political and public attention. Cultivating an environment that encourages research integrity is, therefore, considered to be an important aspect of the scientific community’s public accountability.

16 Steneck (2007) op. cit.
18 ibid.
WHAT IS RESEARCH INTEGRITY?

Integrity has been identified as a fundamental value for all forms of research, for researchers and for those who host or fund research activity. Integrity in research relates to the standards by which research activities are performed or conducted. These research standards are generally referred to as the responsible conduct of research or good research practice (GRP). A number of obligations feed into an individual researcher’s motivation to uphold these standards of GRP, namely his/her obligations to him/herself, to other researchers and to the general public. Notwithstanding these underlying obligations, upholding standards in research refers to the application of particular ethical (and personal) values. Values that cannot, and should not, be separated from the research enterprise. Taken collectively, these core values encompass the concept of research integrity, they include the following:

- **Honesty** – in proposing, performing and reporting research.
- **Reliability and Accuracy** – in conducting the research and in communicating the results.
- **Objectivity** – conclusions should be based on the accumulated evidence and should avoid improper bias.
- **Impartiality and Independence** – avoiding conflicts of interest, whether from commissioning or interested parties, from ideological or political pressure groups and/or from economic or financial interests.
- **Open Communication** – ensuring openness and collegiality in interactions with other researchers, including the sharing of resources; transparency and honesty in communicating with the public.
- **Duty of Care** – to participants in and objects of research, whether human beings, animals or the environment.
- **Fairness** – in acknowledging the contributions of others to your work; in providing proper references and crediting the work of others; and in peer review.
- **Responsibility for Future Science Generations** – upholding standards and responsibilities for mentorship and supervision in the education of junior researchers.

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24 ibid.
25 European Science Foundation (2010) op. cit.
26 Committee on Assessing Integrity in Research Environments et al. (2002) op. cit.
These values are generally incorporated into guidelines and procedures that researchers should follow. However, while such guidelines are important and necessary, it has been argued that such rules may only set the minimum standard for behaviour rather than striving for the ideal.\footnote{ibid.} Responsible research, therefore, requires more than just following a set of rules. The National Academy of Sciences (NAS) in the US (United States) has identified integrity as a “key dimension of the essence of being a scientist and not a set of externally imposed regulatory constraints”.\footnote{ibid.} In addition, Nicholas Steneck has argued that rules guiding GRP should be supplemented with “good judgment and a strong sense of personal integrity”.\footnote{Steneck (2007) op. cit.}

Integrity, therefore, includes not only a practical and/or compliant aspect, but also a moral or ethical aspect related to a given individual’s personal responsibility for his/her actions as a researcher. Therefore, actions that violate standards of GRP equate to research misconduct and represent a contravention the core values expected of all researchers.

Broadly speaking it is important to differentiate between problems that are related to science and society, i.e. the socio-ethical context of research, and problems related to scientific integrity, which encompass activities defined through standards and codes of conduct. Nonetheless, while a distinction can be made between the concepts of research integrity and research ethics they are not completely disconnected.\footnote{European Commission (2007) op. cit.} As noted above, science and research are not conducted in isolation and researchers need to be
aware of the wider societal considerations and implications of their work. This broader responsibility encompassing the social aspects of research is encapsulated in the idea of the socially responsible or “civic scientist” as proffered by a number of commentators.31,32 Research integrity should, therefore, be seen from a more holistic perspective that goes beyond the traditional, narrow conception of simply upholding the standards of GRP. This holistic notion of integrity was captured by Khanyile et al. who referred to integrity as an ethic to be nourished and maintained through individual self-reflection, continuous bi-directional (vertical and horizontal) communication within and between the scientific community and also validated through dialogue with society as a whole.33

WHY IS RESEARCH INTEGRITY IMPORTANT?

This notion of a researcher’s personal integrity and personal responsibility is an integral provision of the social contract between the general public and the research community. Therefore, while research developments can have a positive societal impact, the failure of researchers to conduct their activities with integrity, e.g. through misconduct or other questionable or inappropriate behaviour, can also have a serious negative impact on both the research community and society as a whole. Incidences of misconduct can tarnish the image and diminish the credibility of the whole research enterprise. In addition, research misconduct is an abuse of public funds and undermines the trust of the public and decision makers in research results as a basis for policy.34 In this regard, research misconduct can be said to have many victims, including:35

- **Patients** treated in or as a result of fraudulent clinical trials.
- The **decision maker**, with doubts whether the data before him/her can be relied upon.
- The **taxpayer** or company whose money is wasted.
- The **research record** is contaminated with fraudulent data which may be difficult to eradicate.
- The **reputation** of research is diminished in the opinion of all.
- The **public**, whose faith in research of all types is undermined by misconduct.

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34 European Commission (2007) op. cit.
35 ibid.
Dr Werner Bezwoda of the University of the Witwatersrand, Johannesburg had reported positive results for a clinical trial, which treated breast cancer using a combination of high-dose chemotherapy (HDC) and bone-marrow transplants. Before beginning a large-scale international follow up study, it was decided to conduct an independent review of Bezwoda's data in 2000. This review found that the original study protocol was actually written just before the review began. The reviewers were only provided with records for 58 of the 75 patients from the HDC group (none of which contained signed consent forms), but were denied access to patient records from the control group. The majority of these 58 individuals were ineligible to be enrolled in the study and in some cases their treatment differed from that outlined in the original protocol. The protocol had not been reviewed by the university’s research ethics committee (REC). The results of Bezwoda’s study were invalidated, he admitted to committing misconduct and was fired by the university. Following this audit, concerns were raised about an earlier HDC study published by Bezwoda in 1995. The positive results from this earlier study had a significant impact on the treatment of cancer globally and led to a greater acceptance of HDC treatment. However, a review identified serious problems: it had not been submitted for REC approval; the protocol for the study had apparently only been written following the first audit in 2000; records for only 61 of the 90 patients from the study could be found and none of these contained a signed consent form; many of the patients should have been ineligible to participate in the study; the study was not a true randomised trial and in some instances the treatments patients received differed from those outlined in the published article. The review also revealed that there were at least three deaths, which could possibly be attributed to the treatment, which were not documented in the published article. The review found that the published results could not be validated and were not based on verifiable data.

The relationship between science and society can, therefore, be badly damaged as a result of misconduct, culminating in diminished public support for research. Without confidence and belief in research and researchers the public can become more disillusioned and sceptical of scientific progress. However, greater integrity in research can counteract such negativity and facilitate greater trust and support in the whole

39 It was also found that a number of other studies published by Bezwoda also did not undergo REC review.
research enterprise. In this regard, integrity is a major component in the cycle of positive feedback: greater integrity from researchers engenders more public support and trust, which benefits the research community through increased funding opportunities and more academic freedom, thus facilitating further advances in research. The corollary of this is that these advances in research, for example in the fields of science and medicine, can bring substantial benefits to society as a whole.
Encouraging Greater Integrity in Research

Greater integrity in research is clearly very important, as reflected by the increased attention this area is receiving amongst both policy makers and the general public. Research integrity has also been identified as a key issue in relation to the governance of research.\(^{42}\) Much activity has been, and is, focused on ways to engender a greater degree of integrity in the research community. However, ensuring integrity in research is a complex task.

Generally speaking, efforts to foster greater research integrity can be categorised into two basic approaches. The first approach focuses on the promotion of research integrity through educational and developmental initiatives to instill the concept and value of research integrity into the research community (both individually and collectively). This involves a positive approach to promoting new norms of research practice and behaviour incorporating GRP.

The second approach focuses on corrective or deterrent measures to minimise the likelihood of research misconduct and other problematic behaviours. This involves the establishment of procedures to investigate and handle incidences of misconduct and the imposition of penalties and sanctions when misconduct is confirmed.

It should be noted that these two approaches, i.e. promotional and deterrent, are not mutually exclusive, but rather they are complementary. Moreover, it has been recognised that neither approach is wholly successful when employed in isolation.\(^{43,44}\) For example, as noted by Xavier Bosch, punishing an individual for engaging in misconduct makes no sense without also taking measures to prevent similar incidences of misconduct occurring again.\(^{45}\) Encouraging greater integrity in research, therefore, requires a more comprehensive approach incorporating both aspects, i.e. a balance needs to be struck between the promotion of research integrity on one hand and preventing and punishing misconduct on the other.\(^{46}\)

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43 Committee on Assessing Integrity in Research Environments et al. (2002) op. cit.


46 European Science Foundation (2010) op. cit.
PROMOTION OF RESEARCH INTEGRITY

According to the NAS, GRP is not distinct from research, rather “competency in research entails responsible conduct and the capacity for ethical decision making”.\(^{47}\) Practicing research integrity could be considered as part of the ethos of being a researcher, \(i.e.\) as Carl Mitcham has noted, part of an individual researcher’s ethical responsibilities.\(^{48}\) An essential factor in promoting greater integrity in research involves educating and training researchers in GRP.

THE CORE AREAS OF GOOD RESEARCH PRACTICE

Recognition of the need for education in GRP is reflected in the number of documents, which discuss best practice in this area. While the level of detail and exact focus may vary between different guidance documents, fundamentally they all tend to cover the same core topics relating to particular aspects of a researcher’s activities when planning, conducting and/or reporting research.

The core topics for education in GRP tend to be grouped under the following fundamental headings:\(^{49,50}\)

1. Data Management Practices
2. Authorship and Publication
3. Peer Review
4. Conflicts of Interest and Commitment
5. Mentor and Trainee Responsibilities
6. Collaborative Research
7. Research Involving Human Subjects
8. Research Involving Animals
9. Research Misconduct

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\(^{47}\) Committee on Assessing Integrity in Research Environments et al. (2002) op. cit.


\(^{49}\) Steneck (2007) op. cit.

\(^{50}\) Committee on Assessing Integrity in Research Environments et al. (2002) op. cit.
DATA MANAGEMENT PRACTICES:

Data are a fundamental element of research, i.e. all research produces and utilises data in one form or another. Data, therefore, represent a very valuable research resource, not only as part of an existing project, but also with relevance to potential future research stemming from it. Training in GRP involves ensuring that all parties involved in research (i.e. researchers, institutions, funding bodies, study participants, etc.) are made fully aware of their legal obligations and ethical responsibilities with regard to the collection, use, storage, sharing, ownership and subsequent disposal of any data used and/or generated during a given research project. These responsibilities are of particular importance where the data involved represent personal information about or pertaining to another individual. Ethical and data protection issues associated with the principles of autonomy and informed consent as well as the rights of privacy and confidentiality become fundamental considerations of GRP in such cases.

AUTHORSHIP AND PUBLICATION:

The publication of research results is a crucial aspect of research. Publication is important for a number of reasons: it facilitates the dissemination of new knowledge and information, but it is also necessary for the verification, replication and discussion of the results of research.\textsuperscript{51,52} In addition, publishing the results of research is important in

\textsuperscript{51} Steneck (2007) op. cit.

determining the risk-benefit relationship with regard to research involving human subjects: Research on humans, whether involving them physically or information relating to them, always entails some degree of risk. However, this risk is offset against the potential benefits accruing from the research, e.g. in the form of medical or scientific advances. Failing to publish the results of such research would, effectively, mean that the participants were placed at risk without the opportunity for any benefit to arise, which is unethical.

Given that publication is such an important facet of the research process, GRP training in appropriate authorship practices is considered essential. Therefore, GRP requires researchers to receive training in the appropriate assignment of authorship credit, i.e. based on a given individual’s contribution to the research and the production of the publication itself.53 Moreover, individuals need to be made aware of their responsibilities in providing sufficient detail regarding the methodologies used and the results achieved; in avoiding self-plagiarism (i.e. duplicate publication) or fragmentary publication of their own work; 54 in acknowledging the influence the work of others has had on their project; and in correctly citing and referencing previously published work.

In addition, it should be noted that peer-reviewed journals and national and international editor associations have implemented or are implementing stringent policies regarding acceptable authorship practices. These measures represent an acknowledgement of the importance the research community is now placing on integrity and GRP.

PEER REVIEW:

The peer review process underpins the whole research enterprise. Peer review has been identified as an essential component of research and the self-regulation of professions. The process of peer review is important in determining the merit of a given project to receive funding or to be published. Given the potential impact the peer review process can have on a research project, on the researcher(s) involved and potentially on public policy, the reviewers involved have serious responsibilities.55 Good research practice requires the review process to be conducted independently, transparently, fairly and to be devoid of any bias or external influences. Education in GRP should make individuals aware that when they are conducting a review they are in a privileged and powerful position, which should not be abused. For example, confidentiality with regard to the information made available during the review process is fundamental to its success.56


54 Fragmentary or salami publication refers to the process of publishing smaller subsets of results from the same research study in a number of different publications.

55 Steneck (2007) op. cit.

Peer review also has a role to play in quality control and in the self-regulation of research as it entails a detailed assessment of grant proposals or draft publications. In addition, although limited in its efficacy, the peer review process can help in identifying certain forms of research misconduct (e.g. plagiarism or data falsification).57

CONFLICTS OF INTEREST AND COMMITMENT:

Individual researchers often have a number of specific goals or interests they wish to achieve, for instance, professional development, advancing scientific or medical knowledge, or making discoveries that benefit society. However, given the individualistic aspect of such interests this may result in a certain degree of competition or conflict between the interests of different researchers. Competing demands may also be placed on an individual’s time, resources or loyalties, which may be considered as conflicts of commitment.

It should be noted that conflicts of interest are not inherently wrong and may, ultimately, be unavoidable given the complex nature of research enterprises.58 Nonetheless, GRP requires particular interest to be paid to specific conflicts of interest centred on potential financial gains, work commitments, as well as intellectual and personal considerations.59,60 For example, the possibility that a researcher might benefit financially from a research project should not influence or compromise his/her honesty, accuracy and objectivity in conducting the research. The proportion of research funded by industry is likely to increase in the coming years, particularly given the support of such academic-industry partnerships from a policy perspective (e.g. as part of the Lisbon agenda). Therefore, it is important that the potential influence, both positive and negative, that industry funding may have on the research enterprise is taken into consideration. For example, a number of studies have indicated that research sponsored by industry was much more likely to provide pro-industry conclusions.61,62 While not indicative of any wrongdoing, it has been suggested that studies with such conflicts of interest should undergo greater scrutiny to help “understand and monitor the unintended consequences of academic-industry collaboration”.63

Upholding GRP requires individuals to take responsibility in recognising where potential or actual conflicts of interest could arise in order to avoid problems. However, where conflicts of interest are unavoidable, responsible conduct dictates that the onus should be on the individual to report and disclose this fact.

58 Steneck (2007) op. cit.
59 UK Research Integrity Office (2009) op. cit.
60 Steneck (2007) op. cit.
63 Bekelman et al. (2003) op. cit.
On 17th September 1999, the 18 year old Jesse Gelsinger, died following his participation in a phase I clinical trial for a new gene therapy treatment at the Institute of Human Gene Therapy (IHGT) of the University of Pennsylvania.\textsuperscript{64,65} He experienced a massive immune response to the adenoviral vector being tested in the trial and died four days later. Following Mr Gelsinger’s death the Federal Drug Administration (FDA) launched an investigation of the IHGT and the university’s Institutional Review Board (IRB). The FDA’s inspections revealed “gross violations of good clinical practices, good laboratory practices, record keeping requirements and good manufacturing practices with respect to the vector itself”. One of the major problems was that toxicities experienced by a number of participants in the trial were not accurately reported to the FDA or the university’s IRB.\textsuperscript{66} In addition, the study protocol was modified (unknown to the FDA or the IRB) so that the finding of such toxicities would no longer require the study to be stopped. The FDA also found that the informed consent process was seriously flawed as it failed to inform potential study participants of the likely discomfort and the possible risks, including potentially life-threatening adverse events, associated with the trial.\textsuperscript{67} Moreover, due to pre-existing conditions, Mr Gelsinger should have been ineligible to participate in the trial, yet he was still enrolled. It also came to light that Dr James Wilson the principal investigator in the trial owned stock in a company, which funded human gene therapy research at the university, and he also held a number of patents relating to gene therapy methods and techniques.\textsuperscript{68} In addition, the university also owned stock in the same company. While told that Dr Wilson and the university might receive some financial benefit from the study, potential participants were not made completely aware of the extent of the financial interest those running the trial had in its success. Mr Gelsinger’s family sued the university and the three main physicians involved on the basis that his choice to participate had not been fully informed and he would not have taken part if he had known of the undisclosed risks and the financial interests of the researchers.

\textsuperscript{67} ibid.
MENTOR AND TRAINEE RESPONSIBILITIES:

From the research perspective, the term trainee refers to anyone that is learning to be a researcher under the supervision and guidance of an established researcher (i.e. the mentor), which may include undergraduate or postgraduate students, postdoctoral fellows or other research staff. Both the mentor and his/her trainee have certain responsibilities towards each other with regard to GRP. The ultimate goal of research training is to produce independent researchers and the mentor/supervisor has an integral role to play in this process.\(^69\) The task of the mentor is to impart his/her knowledge, skills and experience in conducting research to the trainee as well as offering support and guidance. In reciprocation, the trainee brings new ideas and points of view to the research group as well as providing a source of labour for research activities.

An important aspect of the mentor-trainee relationship is that each party is not only aware of the role they have to play, but also the expectations that the other party has placed on them. The mentor-trainee relationship is complex and multifaceted, which can give rise to certain conflicts, for example, how much of his/her time a mentor allocates to each trainee, how much time and opportunity for research each trainee gets, who should receive credit for successful research and who owns the results. Good research practice requires such issues to be appropriately managed to help maintain a productive and supportive research environment, and to ensure that both the mentor and the trainee benefit from the relationship. Therefore, a mentor should take into account his/her existing commitments (e.g. his/her own research and publications, his/her teaching obligations, his/her other trainees, and other personal commitments) before deciding whether or not s/he should take on supervising another trainee.\(^70\)

The mentor also plays a vital role in the training and education of those researchers under his/her authority, which includes instruction in GRP. Such training can occur through formal mechanisms (e.g. courses, tutorials and workshops), but much of it occurs informally through a trainee researcher’s observations and experiences of practices within the research environment under the auspices of his/her mentor.\(^71\) Trainees are likely to assume that the practices and behaviours they witness within their immediate research group are appropriate.\(^72\) Therefore, in terms of GRP, it is important for a mentor to be cognisant of his/her position as a role model and to lead by example in maintaining a research environment that upholds and values research integrity.

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\(^{69}\) Steneck (2007) op. cit.


\(^{72}\) Steneck (2007) op. cit.
COLLABORATIVE RESEARCH:

Collaboration, whether conducted between different research groups within the same institution, between different institutions in the same country or as part of an international research project, is now a major aspect of the research enterprise. Such collaborations are often conducted to make use of the distinctive knowledge, expertise and resources that the different researchers involved possess. The same issues pertaining to GRP still apply for each individual researcher and research group, however, the increased complexity of the collaborative research relationship brings additional considerations for those involved. For example, as a basic starting point the roles and responsibilities of each of the research partners need to be clarified (e.g. identifying the principal investigator, who will conduct each aspect of the research, who is responsible for drafting publications, etc.) and how these will contribute to achieving the overall project goals.\(^{73}\) In addition, agreements regarding the sharing of information, resources and expertise need to be resolved from the beginning of the collaboration. The development and implementation of a management plan encompassing all aspects of the collaborative research project can help to ensure that all parties are aware of their position and function.\(^ {74}\) Communication between all parties is, therefore, an integral factor in ensuring that collaborative research projects are adequately managed and conducted responsibly.

RESEARCH INVOLVING HUMAN SUBJECTS AND ANIMALS:

Issues pertaining to research involving human subjects and animals are significant topics in their own right and primarily come under the remit of research ethics. There are a host of national and international regulations, conventions and protocols, dealing specifically with the ethical, legal and social issues arising from such research activities.

In terms of research involving humans, a major aspect of such research relates to acquiring the necessary approval from the appropriate research ethics committee prior to conducting any research. Human subjects may be directly involved in the research or the research could utilise personal information pertaining to them. Conducting such research ethically and responsibly requires a number of principles to be taken into consideration, namely: autonomy and respect for persons; beneficence and nonmaleficence; and justice.

Particular ethical concerns also need to be considered in relation to research involving animals, for example, the amount of pain and suffering the animals might undergo. Accordingly, responsible research needs, at all times, to be cognisant of the “three Rs” (i.e. replacement, reduction and refinement).

Given the major ethical considerations involved in research involving human subjects or animals, appropriate education in GRP for such research will be encompassed in the research ethics training that individuals receive. However, guidelines and legislation in

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\(^{73}\) Gustafsson, Hermerén and Petersson (2006) op. cit.

\(^{74}\) Steneck (2007) op. cit.
these areas of research are constantly evolving, which places particular obligations on the researchers involved. Accordingly, such researchers require support and assistance in meeting and upholding these obligations. Host institutions, therefore, have an important responsibility in ensuring their researchers are kept up-to-date with regulatory changes by transferring information to them as well as through the research ethics review process.

RESEARCH MISCONDUCT:
Good research practice requires that all parties performing research be informed and aware of the activities and behaviours that are deemed unacceptable and to know how to identify them. In addition, those concerned should be aware of the relevant regulations, policies and procedures relating to research misconduct and their responsibilities stemming from such policies. Instruction with regard to misconduct in research often encompasses specific sessions relating to reporting misconduct and the role of whistleblowers, how alleged incidences of misconduct will be investigated, as well as the likely penalties and sanctions for confirmed cases of misconduct.
EDUCATION IN GOOD RESEARCH PRACTICE

Having identified the core areas encompassing GRP, the question, therefore, arises about how researchers should be educated in terms of research integrity generally and with respect to these core areas in particular.

The importance of the explicit, formal aspect of education in GRP was acknowledged relatively recently (i.e. within the last two decades). Prior to this it was generally presumed that responsible ideals in research would be sufficiently covered during the existing research training process and that standards and best practice in research would be passed informally from generation to generation. Moreover, since incidences of research misconduct were seen as rare, explicit education and training in GRP was not considered to be necessary at that time. However, more recently the attention of the research community has changed from the previous reactive approach (i.e. of only dealing with research misconduct if and when cases arose) to a more proactive approach encouraging greater focus on, and fostering a culture of, research integrity amongst the research community as well as trying to prevent misconduct.

FORMAL EDUCATION IN GOOD RESEARCH PRACTICE

Formal and explicit education in GRP is now well recognised as being integral to inculcating the principles and values of research integrity and GRP amongst researchers. Nonetheless, despite the general agreement on the need for, and importance of, formal education, there is a lack of consensus about how the knowledge, skills, attitudes and behaviour of responsible research should be taught and by whom.

In order to answer such questions, it is necessary to clarify what the overall aims and objectives of the education process are. According to Michael Kalichman the obvious goals are a reduction in research misconduct and an increase in GRP, which entails “promoting a common understanding and practice of accepted standards of scientific conduct”. However, a number of commentators have argued that education about research integrity should involve more than just learning specific rules of behaviour or simply following guidelines, particularly given the potential ethical issues involved.

76 ibid.
79 Kalichman (2007) op. cit.
80 ibid.
For example, the NAS in the US has argued that integrity in research should be developed in the context of the entire research education programme. Accordingly, such a focused and integrated educational approach would be more likely to achieve the following objectives:\(^{82}\)

1. emphasize that responsible conduct is central to conducting good science;
2. maximize the likelihood that education in the responsible conduct of research influences individuals and institutions rather than merely satisfies an item on a “check-off” list for that institution;
3. impart essential standards and guidelines regarding responsible conduct in one’s discipline;
4. enable participants in the educational programs to develop abilities that will help them to effectively manage concerns related to responsible conduct of research as they arise in the future; and
5. verify that the first four objectives have been met."

\(^{82}\) Committee on Assessing Integrity in Research Environments et al. (2002) op. cit.
The NAS goes further by recommending that educational programmes in GRP should focus on developing and fostering abilities that bring about responsible conduct. These abilities are listed below:

- **Ethical sensitivity** – being able to identify the ethical dimensions of a given situation within the research setting, as well as the relevant guidelines, standards and regulations that apply in such situations.

- **Ethical reasoning** – being able to develop defensible rationales for the choices one makes and actions one takes.

- **Moral motivation and commitment** – being able to prioritise moral values over other more personal values or interests (e.g. ambition and career progression or institutional loyalties) as well as identifying and integrating these moral values with one’s professional values.

- **Survival skills** – being able to perform the fundamental and, at times, complex tasks associated with one’s professional discipline with integrity. Such tasks include basic research design, methodology and analysis, as well as report writing, applying for funding, and teaching and supervising students and other trainees.

This type of educational model is about internalising the concepts of GRP in a deeper way, by providing individual researchers with a framework to help them rationalise and deal with complex ethical issues, which may not always entail clear-cut answers about which behaviours are right or wrong. Part of this process involves teaching them to not only recognise appropriate versus inappropriate behaviour, but also imparting a greater degree of understanding about why a given behaviour is inappropriate.

In 2007 Ms Rebecca Uzelmeier, who was a doctoral student at Michigan State University in the US, was found to have fabricated and falsified data in her research notebook on a number of occasions by using data from one experiment to represent data and results from a completely different experiment. In addition, it was found that in her thesis she had falsified and fabricated autoradiographic films, computer images, the documentation of her results as well as data, numerous figures and slides. Based on these findings of misconduct a paper submitted for publication and her supervisor’s grant application were withdrawn. Ms Uzelmeier was dismissed from the university and also debarred for five years from working for any agency of the US government or from acting in an advisory capacity to the US Public Health Service (PHS).

83 ibid.


In 2008, Ms Roxana Gonzalez, a graduate student at the Carnegie Mellon University in the US, was found to have falsified data and results relating to six different publications. In addition, Ms Gonzalez had allowed one of her collaborators to unknowingly present the falsified results from one of the papers at a major national conference. On a separate occasion another colleague included results from Gonzalez’s research in a grant application to the NIH, not knowing that some of these results had been falsified. The sanctions against Ms Gonzalez were specified for a three year period and included: exclusion from serving in an advisory capacity to the PHS; a requirement for strict research supervision on any future projects she was involved with; a requirement to write letters approved by the Office of Research Integrity to all her collaborators and co-authors on the tainted publications clarifying all incidents of data falsification; and a requirement to send similar letters to the editors of all the journals concerned stating that, due to her use of falsified data, each of the relevant papers needed to be retracted or corrected.

WHICH EDUCATIONAL METHODS TO USE?

It has been suggested that established and well recognised techniques of adult education would be the most effective approach to take in the teaching of GRP. This involves providing instruction in GRP in the context of an individual’s overall education programme, i.e. as part of his/her core curriculum, in relation to professional skills training and as an element of mentor-trainee interactions. Kligyte et al. take this suggestion further by stating that education in GRP needs to be embedded within the broader context of an individual’s continued career development. Following this rationale, education in GRP should, therefore, begin early in an individual’s research training process, ideally at the undergraduate level, and should continue over an extended period, preferably throughout the entire education programme. Competency, information retention and the ability to apply the concepts and principles of integrity and GRP should be evaluated through assessments and review processes and by monitoring research practices.

Kligyte et al. have suggested that greater success in GRP training is likely be achieved by linking educational efforts to the day-to-day practices researchers undertake and by providing individuals with mechanisms to enable them to deal with the ethical issues they are likely to encounter. Interpreting this point further, while educational programmes outlining the main principles of responsible conduct as they apply to research in general

87 Committee on Assessing Integrity in Research Environments et al. (2002) op. cit.
88 Kligyte et al. (2008) op. cit.
89 Committee on Assessing Integrity in Research Environments et al. (2002) op. cit.
90 ibid
91 Kligyte et al. (2008) op. cit.
are certainly worthwhile, relying on this “one-size-fits-all” approach to training in GRP may not be wholly satisfactory. Consequently, there have been calls to also implement educational programmes that focus on aspects of GRP that are discipline-specific.\textsuperscript{92,93}

Moreover, programmes incorporating a major active learning component are seen as integral to facilitating the development and application of such ethical problem-solving mechanisms. Active learning methodologies make use of both vertical and horizontal communication, discussion and interaction, i.e. between the instructors and the trainees, as well as inter-trainee interactions and discussion groups, to encourage the engagement and participation of the trainees in the learning process. Problem-based learning through the use of specific case studies and vignettes or role-playing exercises is a commonly employed approach to elucidate specific aspects of GRP. Despite a number of recommendations favouring the use of established adult learning techniques in GRP education, a cursory comparison of the range of specific educational methods used in GRP training indicates that such recommendations are not always heeded.

Education in GRP is important not only for trainee researchers, but also for more established researchers and senior scientists. Such education of senior researchers is beneficial for a number of reasons, firstly to ensure that these individuals are aware of and uphold the principles of GRP in their own research practices. Secondly, because these individuals are involved in training the junior researchers within their group either directly (through formal courses) or indirectly (by example) they would need to be cognisant of the principles of GRP in order to impart them to others. However, as noted above, training in research integrity has only been explicitly addressed in the last 20 years or so, therefore, many individuals in senior research positions may have had limited formal education in particular aspects of GRP.

Nonetheless, despite the desirability of educating researchers at all levels in GRP, engendering the involvement of senior researchers could prove challenging. For example, such individuals may not consider that they are in need of additional training in this regard given their existing research experience and in light of their existing work schedule.\textsuperscript{94}

How can the participation of such senior researchers in GRP educational programmes be encouraged? As things stand the majority of training programmes in GRP tend to cater to junior researchers. However, broadening the scope of these programmes to encompass senior researchers may not, necessarily, result in greater participation. Additional efforts may be required to encourage the buy-in of senior researchers. For instance, involving faculty members, senior research staff and principle investigators directly in the formulation and development of an institution’s educational programme and overall policy with regard to GRP, may help in the recognition and acceptance of such

\textsuperscript{92} Bulger RE and Heitman E (2007). Expanding Responsible Conduct of Research Instruction across the University. Academic Medicine 82(9): 876-878.

\textsuperscript{93} Kalichman (2007) op. cit.

measures. Moreover, if senior administrators (e.g. the Vice President for Research) within a given institution were to indicate their support for GRP education programmes it might encourage greater participation by researchers at all levels.

In addition, it has been suggested that the voluntary accreditation of institutions by authorised bodies could have a significant impact on institutional efforts to uphold research integrity and GRP. Perhaps providing some form of accreditation or certificate of completion for courses or training in GRP may engender greater support among the target group of senior researchers. Notwithstanding voluntary measures to encourage senior researchers to undertake education in GRP, such training could be made a requirement under certain circumstances. In some jurisdictions, junior researchers are required to undergo training in GRP as a stipulation of certain funding grants [e.g. from the German Research Foundation (DFG)]. In the US, both the National Institutes of Health (NIH) and the National Science Foundation (NSF) as research funders, in conjunction with their agencies (the Office of Research Integrity (ORI) and the Office of the Inspector General (OIG) respectively), have recently implemented policies requiring funding recipients to undergo instruction and training in GRP. The NSF policy is confined to undergraduate and postgraduate students and postdoctoral fellows. The NIH policy is somewhat different in that it applies to all trainees, fellows, participants and scholars in receipt of the designated funding awards.

Moreover, the provision of GRP training to a junior researcher (whether as a condition of funding or otherwise) is part of the remit of his/her mentor. As a minimum measure this would require that a supervisor be aware of the relevant institutional guidelines and policies regarding research integrity, in order to inform his/her trainees. Moreover, a number of organisations recommend that principle investigators and other researchers should be required to undergo some level of mentorship training prior to becoming a mentor. Given that such mentorship training is likely to incorporate different aspects of GRP, senior researchers would, therefore, also receive some education in GRP at the same time. Additionally, senior researchers at faculty level could be invited to facilitate and coordinate such mentorship seminars and workshops. Perhaps such individuals could also absorb new knowledge of research and mentoring practices, including GRP, through

95 Committee on Assessing Integrity in Research Environments et al. (2002) op. cit.
96 Pimple (2008) op. cit.
97 Committee on Assessing Integrity in Research Environments et al. (2002) op. cit.
101 The applicable awards are: any NIH training, career development award (individual or institutional), research education grant, and dissertation research grant.
102 UK Research Integrity Office (2009) op. cit.
this mechanism. For example, Pfund et al. noted that many of the individuals who had facilitated a mentor-training seminar, at the University of Wisconsin-Madison, found it to be a positive experience and one that precipitated a change in their own approach to mentoring.104

EDUCATION IN GOOD RESEARCH PRACTICE THROUGH DIFFERENT FORMATS

Short Courses
In many cases educational efforts in research integrity and GRP take the form of short courses. Typically such courses consist of series of 90 – 120 minute seminars conducted over four to six sessions.105 These courses are seen as a useful format for providing trainees with an introduction to some of the core issues associated with GRP, for example, authorship and publication practices, conflicts of interest, data management or research misconduct. Generally speaking such courses involve an initial didactic, lecture-like approach to introduce the topic, its related issues and the relevant regulations and procedures that apply. Problem-based learning techniques and discussion groups are regularly employed to help trainees to understand, discuss and assimilate the information. The main limitation of these short courses is that the finite amount of time available, necessarily, means that the scope and coverage of such courses may be somewhat restricted. Moreover, concerns have been raised about the ability of such brief courses to fully engage the trainees and to facilitate the assimilation and retention of the information provided over a longer time period.106

Full-Semester Courses
Full-semester courses are often considered to be an improvement on short courses. The longer period of instruction, for example, one to three hours per week over 12 – 15 weeks, facilitates the coverage of more topics and in greater detail following the initial introductory module. In addition, full-semester courses are more likely to involve numerous instructors, which may provide a broader perspective for the trainees on the issues covered. Longer courses can also enable continuous assessment approaches to learning to be employed (e.g. written assignments), as well as periodic examinations. However, GRP is seen as such an important aspect of the research enterprise that full-semester courses may not provide wholly sufficient training. Some advocates of GRP education have, therefore, suggested that short and/or long courses should be given over a number of years as opposed to being confined to the initial research training period.107

105 Committee on Assessing Integrity in Research Environments et al. (2002) op. cit.
107 Steneck and Bulger (2007) op. cit.
Workshops

Another method for teaching GRP involves the use of one-off workshops. These often provide detailed coverage of a small number of related topics, for example authorship and publication. Trainees may be asked to attend a number of workshops, focusing on different topics, as part of their educational process. The number of attendees at workshops tends to be much larger than at short courses or full-semester courses, e.g. several hundred as opposed to 5 to 30. While the large size may represent a more practical and cost-effective option, it may also impinge on the degree of active learning and instruction tailored to the knowledge base of individual trainees.108

Computer-Based Learning

Computer-based modules have emerged in recent times as another approach to training in GRP. Given the increasing desire to provide education in GRP to more and more individuals, computer-based initiatives may represent an attractive option. Such programmes are relatively cost-effective to implement when compared to instructor-led courses. Moreover, they can be customised to cover specific aspects of the curriculum for different audiences of trainees, with different knowledge bases. Computer-based modules can, therefore, cater to a larger and broader spectrum of individuals. In addition, the format of computer-based educational programmes not only facilitates the assessment and examination of each trainee’s knowledge, but also the evaluation and audit of the course/module itself. For example, the Collaborative Institutional Training Initiative programme utilises voluntary and anonymous user surveys to continually assess the effectiveness of the course in providing training in GRP.109 Different aspects of the programme can be modified and adjusted to take such user-survey results into account. However, despite the positives, the “hands off” and remote online nature of computer-based education programmes is considered to provide limited individualised instruction, does not enable instructor-trainee and/or trainee-trainee interactions and includes limited facility for active learning.110

108 Committee on Assessing Integrity in Research Environments et al. (2002) op. cit.
110 Committee on Assessing Integrity in Research Environments et al. (2002) op. cit.
Despite the assertions espousing the benefits of education and training in GRP, some concerns have still arisen about the effectiveness of such education. For example, a study by Anderson et al. suggests that the relationship between training in GRP and decreasing misconduct and other problematic behaviour, i.e. that they are inversely proportional, may not, necessarily, always hold true. Understandably, Anderson et al. expressed some concern about their findings and called for further research to assess and evaluate the effectiveness of GRP training in reducing problematic behaviour.

Similar calls have been made by other commentators in respect of the need for further research into the effectiveness of GRP education. However, it has been noted that in order to assess the effectiveness of various GRP educational programmes properly it is important to know what each participant’s baseline level of knowledge of GRP was before they underwent the training. Measuring the effectiveness of a given educational programme should, therefore, involve both pre- and post-training evaluations of the participants. This would enable a more definitive assessment of the programme to be made, which would help to determine which aspects of training needed to be modified or improved. Moreover, the relative success of using different approaches to training could also be assessed. In addition, such evaluations would facilitate the provision of more targeted and individually-tailored or discipline-specific educational programmes. For example, individuals could be grouped together according to their level of knowledge and understanding of GRP or they could be grouped according to their knowledge of GRP in a specific discipline. It has been suggested that educational courses or programmes targeted in such a way would be more likely to engage participants when compared to generic, “one-size-fits-all” courses offering the same instruction to everyone without reference to any individual’s pre-existing knowledge, experience or discipline.

Whether considered effective or otherwise, formal education in GRP represents only part of the solution to achieving the goals of decreasing research misconduct and increasing GRP. Success in this regard also depends on the individual him/herself as well as the environment or research culture s/he operates in.

According to Michael Kalichman, the focus of education in GRP can be limited to three specific purposes: empowerment, understanding and attitude. Formal training programmes in GRP should satisfy the purposes of empowerment and understanding.

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112 Heitman et al. (2007) op. cit.
113 ibid.
114 Kalichman (2007) op. cit.
115 Bulger and Heitman (2007) op. cit.
116 Kalichman (2007) op. cit.
as reflected in the NAS’s argument that GRP education should imbue trainees with ethical sensitivity, ethical reasoning, moral motivation and commitment, and survival skills.\textsuperscript{117} Satisfying the final purpose of attitude, i.e. whereby trainees are positively disposed to promoting an environment that values GRP, relies on more than just formal training programmes. According to Kalichman (who uses the term responsible conduct of research or RCR) “if the factors external to RCR courses are not aligned in favor [sic] of RCR, the lessons of RCR education will be greatly devalued and the outcomes will be diminished”.\textsuperscript{118} Moreover, promoting positive attitudes towards research integrity requires evidence that GRP is highly valued not only by those teaching these concepts, but also by the institution in which the research is being conducted.

It is clear that the research environment and culture that an individual operates in can have a significant impact on the values they place on, and the approach they adopt to, research integrity. Joining a research group is a formative and influential stage in a trainee researcher’s development. Such individuals are likely to absorb and apply the practices and behaviours that they observe their research group peers participating in. It is understandable for these individuals to assume that the activities they witness are considered acceptable in that environment.\textsuperscript{119} Where certain patterns of behaviour are omnipresent within a particular group, such behaviour will tend to become the norm, i.e. part of the “culture” of that particular group. Therefore, although certain behaviours may go against the principles of responsible conduct, where such behaviours become embedded in the culture of the research environment, individuals within that cultural peer group are more likely to emulate these behaviours.

MENTORS AND THE RESEARCH ENVIRONMENT

All research groups operate under the authority of a principal investigator or senior researcher, who to a greater or lesser extent represents a leader, a supervisor and, crucially, a mentor to those within his/her group. Such individuals, therefore, exert significant influence on the culture and environment that persists within their research group and to a lesser degree amongst their peers. Understandably the level of interest and degree of importance these mentors place in GRP will have a direct impact on their junior colleagues.\textsuperscript{120}

Therefore, a major factor that can influence how an individual researcher perceives research integrity and GRP and the values they place in these ideals is the relationship between the researcher and his/her mentor. Indeed the mentor-trainee relationship has been identified as one of the main modes of education in GRP.\textsuperscript{121} However, it has also been recognised that education and training in research integrity by this mentorship

\textsuperscript{117} Committee on Assessing Integrity in Research Environments et al. (2002) op. cit.
\textsuperscript{118} Kalichman (2007) op. cit.
\textsuperscript{119} Steneck (2007) op. cit.
\textsuperscript{120} Committee on Assessing Integrity in Research Environments et al. (2002) op. cit.
\textsuperscript{121} Anderson et al. (2007) op. cit.
mechanism alone is no longer sufficient. In terms of providing comprehensive training in GRP, the mentor-trainee relationship, while important, is considered by some to be too narrow and not, necessarily, sufficiently in-depth in its coverage of all the different aspects of GRP. In addition, unlike formal educational programmes, training in GRP via the mentor-trainee relationship is predominantly conducted on a one-to-one basis, therefore, the trainee researcher may forgo the opportunity for, and benefit of, interactions in an educational setting with his/her peers. Allied to this, the mentor-trainee relationship is dependent on the time and effort both parties contribute to it, but training in GRP and research integrity represents only part of the overall educational process embodied by the mentor-trainee relationship.

Mentors are tasked with providing guidance and instruction in multiple facets of research (e.g. methodologies, analysis, funding applications, authorship and publication) to their trainees with the ultimate objective of helping them to develop into independent researchers. Education and training in research integrity and GRP has been identified as an integral part of this developmental process. Part of a mentor’s responsibility in this regard is to show leadership and to set an example to all those within his/her research group, through his/her own behaviour and actions as well as his/her attitude to the behaviour of his/her peers in relation to research integrity.122

However, a recent study by Anderson et al. indicates that mentorship may be associated with both positive and negative effects on the practices of trainees.123 In the case of the early-career researchers surveyed, mentoring lowered the odds of a researcher engaging

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122 Committee on Assessing Integrity in Research Environments et al. (2002) op. cit.
123 Anderson et al. (2007) op. cit.
in problematic behaviours in specific areas of research (e.g. data, methods, cutting corners, the use of funds and peer review). Financial mentoring (i.e. instruction in writing grant and contract proposals) amongst the same early-career researchers was associated with increased odds of reporting the problematic use of funds. In the case of the mid-career research group surveyed by Anderson et al., mentoring did not alter behaviour.

Given the recognised importance of mentoring and the mentor-trainee relationship in helping to encourage greater integrity and GRP, there is now more interest in developing courses and training programmes to better educate senior researchers in their roles and responsibilities as mentors, particularly with regard to GRP. For example, in the US a number of universities have implemented various mentorship training programmes such as, the University of Pittsburgh, the University of Wisconsin-Madison, Columbia University, and Northern Illinois University. The ORI website provides information on a number of these mentorship courses and other resources including guidance documents relating to mentoring produced by the NAS and the NIH. In the UK, both the Wellcome Trust and the UK Research Integrity Office (UKRIO) recommend that individual researchers tasked with supervising students and junior researchers should receive appropriate support and training.130,131 The DFG in Germany recommend that research institutions establish standards for mentorship that are binding for all principal investigators or research group leaders.132

It is, therefore, important for mentors and other senior scientists to continue to receive education and training in GRP throughout their career. Their acceptance and participation in such endeavours is an indication of their commitment to uphold the values and principles of research integrity. Such commitment would help to highlight the importance of integrity in research not only to junior researchers within a given group, but to the research community more generally and also to a wider-scale audience of policy makers and the general public. As noted previously, public perception of, and trust in, research is likely to improve if the research community is shown to be acting and behaving responsibly and with integrity.

124 Annual Trainer-of-Trainers Conference implemented by the Survival Skills and Ethics Program at the University of Pittsburgh. For more information see the website: [http://www.skillsandethics.org/survival_skills_ethics/conference_for_trainers.htm](http://www.skillsandethics.org/survival_skills_ethics/conference_for_trainers.htm) accessed on 14 July 2010.
125 Pfund et al. (2006) op. cit.
126 For more information see the website: [http://ori.dhhs.gov/education/products/columbia_wbt/or_mentoring/conclusion/index.htm](http://ori.dhhs.gov/education/products/columbia_wbt/or_mentoring/conclusion/index.htm) accessed on 19 July 2010.
127 For more information see the website: [http://ori.dhhs.gov/education/products/niu_mentorship/mentoring/memain.html](http://ori.dhhs.gov/education/products/niu_mentorship/mentoring/memain.html) accessed on 19 July 2010.
129 National Institutes of Health (1999) op. cit.
131 UK Research Integrity Office (2009) op. cit.
132 Deutsche Forschungsgemeinschaft (1998) op. cit.
THE ROLES AND RESPONSIBILITIES OF OTHER STAKEHOLDERS

Other stakeholders in the research enterprise also have an important role to play in promoting research integrity and encouraging GRP.

Research Institutions

Chief amongst these stakeholders are the research institutions (e.g. universities, institutes of technology and hospitals), where the bulk of the research activity actually takes place. These institutions have a responsibility to both manage and support the research conducted within their domain. Part of this process involves the development and implementation of specific standards and policies to govern research practices. In many cases, these policies are reflective of particular legal and regulatory requirements, for example, the need to establish processes and committees for the ethical appraisal and evaluation of research involving or relating to human subjects.

Developing and applying specific policies and guidelines for research integrity and GRP is another important aspect of managing research at the institutional level. For instance, such initiatives might include a code of conduct for all researchers, a whistleblower’s charter and/or policies to handle allegations of misconduct. Research institutions can, therefore, lead by example in their commitment to promoting greater integrity in research, i.e. they can exert a “top down” influence on all researchers under their authority. However, researchers within a given institution need to be made aware of these policies and their own concomitant responsibilities stemming from them. Therefore, the policies need to be openly publicised and communicated throughout the research institution.

Developing and communicating guidelines and policies in relation to GRP, provides a mechanism by which an institution can highlight the importance it places on research integrity. In effect, such policies help to set the tone for the institution’s willingness to acknowledge, discuss and address issues pertaining to integrity in research, which can help to inculcate them into the general ethos of the institution.

Not alone are institutional guidelines and policies pertaining to research integrity beneficial in their own right, they also represent a valuable resource to be used during the GRP training process. As noted above, education in research integrity and GRP has been receiving more attention amongst the national and international research community in recent times, which is a reflection of its increased importance to the research enterprise. Nonetheless, it has predominantly been left to individual institutions to develop and provide their own educational programmes in GRP. Understandably, different institutions vary in the scope and quality of the educational programmes they provide.

133 Vasgird (2007) op. cit.
134 Committee on Assessing Integrity in Research Environments et al. (2002) op. cit.
Funding Bodies

Research cannot function without funding, therefore, funding bodies have a role to play in helping to promote and encourage research integrity. Funding bodies are in a position to make the allocation of funds contingent on certain criteria being satisfied. In some instances, more stringent conditions regarding research integrity may be tied to the allocation of funding. For example, in the US research institutions applying for Federal funding through the NSF are required to provide educational programmes in GRP to the junior researchers that will be working on the funded project. The equivalent NIH policy requires funding recipients at all levels (i.e. junior and senior) to undergo training in GRP.

Professional Bodies and Societies

Members of professional science and research societies and bodies are required to abide by certain rules and codes of conduct with regard to their actions and behaviours. These bodies are, therefore, well placed to provide leadership and to set an example to their members in relation to the promotion of GRP and integrity in research. The attitude and approach such societies take towards GRP feeds into the accepted norms and values of their professional members.

The promotional measures professional societies can take in this regards are generally grouped into a number of specific categories, which include:

- developing, communicating and enforcing codes of conduct;
- publishing guidelines and policies pertaining to different aspects of research conduct; and
- developing and disseminating specific educational material.

However, research is a dynamic and constantly evolving process. It is considered important that codes of ethics and guidelines also evolve to ensure ethical considerations remain to the fore. This requires societies to be proactive in their approach to the development of standards for GRP and to monitor and review their policies periodically. In addition to influencing attitudes and behaviour to GRP at a national level, professional societies and their international parent organisations can have an impact internationally. Prime examples of this are the publication and authorship guidelines for biomedical journals produced by the International Committee of Medical Journal Editors (ICMJE). Since the initial publication of these guidelines in the 1970s, they have evolved through a number of editions, which take account of the prevailing issues and concerns pertaining to authorship and publication practices in research. The ICMJE guidelines have since been adopted by numerous journals, and the societies and organisations that publish them, which indicates the level of impact such measures can have in terms of promoting

136 ibid.
this aspect of research integrity. Moreover, requirements outlined by the ICMJE have become standards that are widely incorporated in education and training in GRP.

Larger-Scale International Initiatives

The importance of promoting research integrity and combating misconduct in research has been acknowledged at a broader European and global level. This issue is considered to be particularly pertinent given the increasing frequency and importance of international collaborative research projects. For example, the European Commission convened an Expert Group to provide guidance on the key issues and areas where the Commission could take action with regard to promoting research integrity. The Expert Group published a report, “Integrity in Research – A Rationale for Community Action” in 2007, in which it recommended that the Commission: consider initiatives to promote the adoption of standards and definitions by institutions within Member States; consider making the adoption of national standards a condition for eligibility to receive Commission funding; and consider promoting the discussion of research integrity at the level of public policy.

Stemming from the recommendations of the Expert Group the European Network of Research Integrity Offices (ENRIO) was recently established. This initiative was facilitated through funding provided by the European Commission to support the trans-national exchange of experience between existing national research integrity structures in Europe. The objectives of the ENRIO are:

1. To facilitate discussions and share experience and possible solutions in relation to:
   • The investigation of allegations of misconduct in (academic) research; and
   • Training and education with regard to good practices in research;
2. To report discussions and develop proposals relating to the above; and
3. To liaise and work in partnership with other organisations with European or global interests in research integrity.

In addition, the European Science Foundation (ESF) has recently established the Member Organisation Forum on Research Integrity. One of the objectives of this ESF Forum is to act as a platform for the exchange of ideas and best practice in promoting and safeguarding research integrity and combating misconduct in research. In addition, the ESF Forum aims to support and encourage organisations which do not yet have appropriate structures in place to learn from the experiences of others and to initiate debates in their respective communities on adequate models. The activities of the ESF

138 Macrina (2007) op. cit.
139 European Commission (2007) op. cit.
141 For more information see the ESF website: http://www.esf.org/activities/mo-fora/research-integrity.html, accessed on 25 February 2010.
Forum will also take into consideration the actions of other organisations in this field to ensure that the approaches developed are compatible with and complementary to each other. In order to achieve these goals the ESF Forum has established four working groups:

1. Raising awareness and sharing on good practices
2. Develop a European code of conduct
3. Check list for setting up national structures
4. Research on research integrity

The Forum intends to produce an integrated report based on the activities and findings of the different working groups. However, an executive report was presented at the Second World Conference on Research Integrity held in Singapore in July 2010, which incorporated the conclusions of the four working groups.142 This document contains the European Code of Conduct for Research Integrity that the ESF developed with the European Federation of National Academies of Science and Humanities - ALL European Academies (ALLEA). It is envisaged that the European Code of Conduct will be “used as a reference point for all aspects of research activities, complementing existing codes of ethics and complying with national and European legislative frameworks”.143 In addition to the European Code of Conduct, the executive report also includes further recommendations regarding the promotion of research integrity as well as good practice in all scientific disciplines. It is hoped that the European Code of Conduct may further progress the development of a global code of conduct for integrity in research.

As part of its remit the ESF Forum also intends to build on the parallel activities of the OECD Global Science Forum (GSF) on Research Integrity. The OECD GSF produced a consensus report from a workshop it held in 2007 entitled: “Best Practices for Ensuring Scientific Integrity and Preventing Misconduct”.144 This consensus report represents a reference document on the issues of scientific integrity and misconduct and focuses on the practical and administrative aspects of dealing with allegations of misconduct.

The ALLEA is involved in examining ways to ensure the integrity of scientific research through the use of education as well as through the use of sanctions and enforcement. In this regard the ALLEA produced a “Memorandum on Scientific Integrity” in 2003 with the aim of promoting the application of general standards of scientific conduct in research.145 More recently, the ALLEA has been assisting Working Group 2 of the ESF Member Forum in the production of a European Code of Conduct for Research Integrity.

Beyond Europe, various other large-scale initiatives to promote scientific integrity and combat misconduct in science have been implemented. For example, the Committee

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142 European Science Foundation (2010) op. cit.
143 ibid.
144 OECD Global Science Forum (2007) op. cit.
on Freedom and Responsibility in the conduct of Science (CFRS) of the International Council for Science issued a “Statement on promoting the integrity of science and the scientific record” in 2008.\footnote{International Council for Science Committee on Freedom and Responsibility in the conduct of Science (2008). Statement on promoting the integrity of science and the scientific record. International Council for Science, 3p. Available online at: \url{http://www.icsu.org/Gestion/img/ICSU_DOC_DOWNLOAD/2136_PD_FILE_CFRS_statement_research_integrity_09_2008.pdf}, accessed on 10 March 2010.} One of the recommendations given by the CFRS argued for the establishment of national monitoring and advisory mechanisms for research integrity. These mechanisms were to include, amongst other measures, dealing with misconduct, providing national oversight for research integrity issues, overseeing and providing advice to institutions, developing and reviewing codes of conduct, and facilitating the harmonisation of international standards for scientific conduct.

The United Nations Educational, Scientific and Cultural Organization (UNESCO) also conducts certain activities relating to integrity in research. For example, the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) was established to provide advice to UNESCO regarding its programme concerning the ethics of scientific knowledge and technology and also to act as a forum for the exchange of ideas and experience.\footnote{For more information see the website: \url{http://www.unesco.org/new/en/social-and-human-sciences/themes/science-and-technology/comest/}, accessed on 13 July 2010.} COMEST is also heavily involved in devising “an international declaration on science ethics that could serve as a basis for an ethical code of conducts [sic] for scientists…”\footnote{For more information see the website: \url{http://www.unesco.org/new/en/social-and-human-sciences/themes/ethics-of-science-and-technology/science-and-technology/comest/comest-background/}, accessed on 13 July 2010.} At the recent extraordinary session of COMEST in June 2010, the agenda included discussion on COMEST’s “Draft Report on Science Ethics”.\footnote{UNESCO World Commission on the Ethics of Scientific Knowledge and Technology (2010). Draft Report on Science Ethics. UNESCO, Paris, 34p. Available online at: \url{http://unescdoc.unesco.org/images/0018/001884/188498e.pdf}, accessed on 13 July 2010.} In this draft document scientific integrity is highlighted as a major ethical challenge for science. Moreover, the draft report suggests, in relation to the challenge of ensuring integrity in the scientific enterprise, that “a full response to this challenge needs to combine education, training and awareness-raising with effective procedures to detect, investigate and punish serious cases of scientific misconduct”\footnote{ibid.}. 

\phantomsection\footnote{ibid.}
RESEARCH MISCONDUCT

WHAT CONSTITUTES RESEARCH MISCONDUCT?

Defining and clarifying exactly what constitutes misconduct in research is recognised as an important aspect of addressing the problem and implementing effective remedies. The answer to this question, therefore, can have significant implications given the negative impact incidences of misconduct can have on the entire research enterprise and on society in general.

Definitions of research misconduct tend to focus predominantly on the issues of falsification, fabrication and plagiarism (FFP), with a range of other types of misconduct often categorised as questionable research practices (QRP). Generally speaking:\(^{151}\)

- **fabrication** involves intentionally making up results and recording and/or reporting them;
- **falsification** involves manipulating or altering research processes or changing or omitting data; and
- **plagiarism** involves the appropriation of another individual's ideas, research, results or words without giving appropriate credit for them.

However, there has been a significant amount of discussion in relation to the lack of uniformity in the definitions of research misconduct used and in their interpretation both within and between different countries and institutions. For example, the Federal Policy on Research Misconduct adopted by the Office of Science and Technology Policy (OSTP) in the US defines research misconduct as “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results”.\(^{152}\) Furthermore, under the OSTP Federal Policy additional conditions need to be met for a given activity to be considered misconduct, that is: it must represent a significant departure from accepted practices of the relevant research community; it must have been committed intentionally, knowingly or recklessly; and it must be “proven by a preponderance of evidence”.\(^{153}\) While this detailed definition helps to clarify the concept of misconduct, it by no means encompasses all forms of research behaviour. For example, Nicholas Steneck has argued that the OSTP definition establishes a minimum standard against which acceptable behaviour can be measured, but it does not imply that all behaviours falling outside this definition are acceptable.\(^{154}\)

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151 European Science Foundation (2010) op. cit.
153 ibid
154 Steneck (2007) op. cit.
Utilising a broader conception of research misconduct would, therefore, facilitate the inclusion of other forms of inappropriate and unacceptable behaviour. For instance, as suggested by the GSF of the OECD, misconduct might also be considered to include various QRP under a number of different headings including: \(^{155}\)

- **data-related misconduct** – failing to preserve or retain primary data, bad data management and storage practices, and withholding data from the research community;
- **research practice misconduct** – using inappropriate research methodologies, poor research design, experimental, analytical or computational errors, violating human subject protocols, or abusing research animals;
- **publication-related misconduct** – claiming undeserved authorship (i.e. “guest” or “honorary” authorship), denying authorship to other contributors, artificially increasing publications by using fragmentary/salami publications, and failing to correct errors in the publication record;
- **personal misconduct** – inappropriate personal behaviour or harassment, inadequate supervision or mentoring of trainees, insensitivity to social or cultural norms; and
- **financial and other misconduct** – abusing the peer review process, misrepresenting one’s credentials or publication record, misuse of research funds, and making malicious allegations of misconduct against others.

Some of these behaviours while unacceptable and subject to legal, national, institutional or social penalties may not, necessarily, constitute research misconduct since they do not affect the integrity of the research record itself. \(^{156}\) Therefore, the definition of research misconduct chosen can have implications for the application of sanctions and penalties for inappropriate behaviour. The ESF has recommended that the sanctions applied for a given incidence of misconduct are proportionate to the seriousness of the activity or behaviour. \(^{157}\) A major factor in determining the seriousness of the offence relates to whether it was committed intentionally, knowingly or recklessly. Research misconduct is, therefore, not considered to include honest error on the part of the researcher or honest differences of opinion. However, proving the intention behind misconduct is difficult and such proof should be based on the available evidence. \(^{158}\)

\(^{155}\) OECD Global Science Forum (2007) op. cit.

\(^{156}\) European Science Foundation (2010) op. cit.

\(^{157}\) ibid.

\(^{158}\) ibid.
HOW MUCH MISCONDUCT OCCURS?

Efforts to govern research misconduct also require the prevalence of this behaviour to be quantified. However, acquiring accurate, quantitative information on the frequency of research misconduct can prove difficult. The lack of reporting has been identified as a major factor in the dearth of knowledge available on the prevalence of misconduct.\(^\text{159}\)

Therefore, recently there have been calls for increased research into this phenomenon, for example from the European Forum on Good Clinical Practice,\(^\text{160}\) as well as the ESF and the ORI.\(^\text{161}\) Nonetheless, as noted above, definitions of research misconduct can vary, which, depending on the exact definition chosen, could affect the results of any research into the prevalence of research misconduct.

A range of estimates are available regarding the frequency of misconduct and while it is often suggested that misconduct is committed by a limited number of individuals, there are suggestions of a dichotomy between the number of cases reported and the number of cases actually occurring.\(^\text{162,163}\) It is certainly true to say that the number of cases


\(^{160}\) ibid

\(^{161}\) Mayer and Steneck (2007) op. cit.


of misconduct confirmed through official mechanisms is relatively small, for example, in Denmark between 2006 and 2008 the Danish Committees on Scientific Dishonesty (DCSD) found just two cases of misconduct.\textsuperscript{164,165,166} In addition, findings from the ORI in the US, for the period 1994 – 2003, reported 133 cases of misconduct with an annual average of 13 cases per year.\textsuperscript{167} Moreover, since the late 1990s the combined number of confirmed cases from the US research integrity agencies equates to an annual rate of approximately one case for every 10,000 researchers (i.e. 0.01\%).\textsuperscript{168} However, even a single case of research misconduct can have a disproportionate negative impact.

Despite the low numbers of misconduct cases reported, it has been suggested that these confirmed cases might not accurately reflect the actual incidences of misconduct being committed, \textit{i.e.} they may only represent the “tip of the iceberg”. Many commentators believe that, while attitudes may be changing, most misconduct is still not reported. For example, in an anonymous survey of 3247 researchers in the US, conducted in 2002, 1.4\% of respondents admitted to plagiarism and 0.3\% admitted to falsification of data.\textsuperscript{169} In addition, 15.5\% of respondents admitted changing the design, methodology or results of their study in response to pressure from a funding source. Moreover, 33\% of the respondents admitted to committing at least one of the ten most serious offences listed on the survey questionnaire.\textsuperscript{170} Another US survey, conducted in 2006, asked 2212 scientists how many times they had witnessed suspected cases of misconduct over the period 2002-2005.\textsuperscript{171} In total 164 of the respondents (7.4\%) stated that they had observed 201 probable instances of misconduct during that time, \textit{i.e.} approximately three incidents of misconduct per 100 researchers per year.

More recently, a meta-analysis was conducted on a number of surveys, which asked scientists about their conduct, and/or that of their colleagues, when carrying out research.\textsuperscript{172} It should be noted that this review only focused on behaviours that can

\begin{thebibliography}{99}
\bibitem{168} Steneck (2007) op. cit.
\bibitem{170} The top ten offences listed in the survey were: Falsifying or ‘cooking’ research data; Ignoring major aspects of human-subject requirements; Not properly disclosing involvement in firms whose products are based on one’s own research; Relationships with students, research subjects or clients that may be interpreted as questionable; Using another’s ideas without obtaining permission or giving due credit; Unauthorised use of confidential information in connection with one’s own research; Failing to present data that contradict one’s own previous research; Circumventing certain minor aspects of human-subject requirements; Overlooking others’ use of flawed data or questionable interpretation of data; and changing the design, methodology or results of a study in response to pressure from a funding source.
\bibitem{172} Fanelli (2009) op. cit.
\end{thebibliography}
“falsify or bias scientific knowledge through unjustified alteration of data, results or their interpretation”, and did not include plagiarism or other professional misconduct (e.g. guest authorship or the exploitation of junior researchers).173 The results indicated that on average 1.97% of respondents admitted to fabricating, falsifying or modifying data or results at least once. In addition, up to 33.7% of respondents admitted to other QRP. In relation to observations of misconduct committed by others, the meta-analysis indicated that an average of 14.12% of respondents were aware of colleagues who had fabricated, falsified or modified data or results. In addition, between 6.2% and 72% of respondents were aware of colleagues who had committed other QRP. The results of this meta-analysis would suggest that incidences of misconduct and QRP are more prevalent than previously estimated.

WHY DOES RESEARCH MISCONDUCT OCCUR?

In order to devise appropriate measures to prevent research misconduct and to deal with it when it occurs it is necessary to understand what might have caused such behaviour.

There are a range of internal and/or external factors, which might influence an individual to commit misconduct. In some instances, it could be argued that such behaviour could have an underlying pathological cause,174,175 i.e. some individuals are likely to commit misconduct regardless of the circumstances they find themselves in. However, the idea that the causes of research misconduct can be limited to just a few delinquent individuals is no longer considered wholly valid. Evidence suggests that additional “contextual” factors may influence the behaviour of an individual researcher.

Many of these external causes are interconnected with the way in which the existing research evaluation and reward system operates. Individual researchers face substantial competition for research funding awards as well as in securing and maintaining positions within research institutions. In some instances the combination of competitive pressure and an individual’s own personal motivations to succeed (e.g. ambition, egoism or greed) in his/her career could lead to misconduct. For example, a number of high profile cases of research misconduct have involved established researchers with distinguished careers.

While competition within the research enterprise is valued because it can increase the efficiency and productivity of researchers, it may also adversely impact on their objectivity and integrity.176 This competition can, therefore, perpetuate the “publish or perish” focus within the research community, whereby an individual researcher is valued based on his/her research output and quantity of publications.177,178 Moreover, external pressures

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173 ibid.
175 OECD Global Science Forum (2007) op. cit.
177 Gustafsson, Hermerén and Petersson (2006) op. cit.
178 Fanelli (2010) op. cit.
can lead to conflicts of interest, which in some cases may increase the temptation for individuals to take short cuts in some aspect of their research (i.e. funding applications, research methodology, analysis or publication). The concomitant pressure to publish at all costs, prompted by the publish or perish culture, may increase the bias in research publications against negative results.\textsuperscript{179} Financial pressures may also impinge on research integrity. In the discussion of their survey, Martinson et al. have indicated that some researchers are willing to modify their results to appease their funders.\textsuperscript{180}

The pervading attitude and culture within a given research group or institution is also likely to have an impact on the prevalence of misconduct. If an individual operates in an environment where research integrity does not appear to be valued, promoted or upheld, then s/he is more likely to adopt a similar attitude. Hence, the emphasis earlier in this document placed on the importance of both formal and informal education and training in research integrity and GRP.

Dr Jan Hendrik Schön was a physicist, who worked for Lucent Technologies at the Bell Laboratories in the US. Schön’s research focused on organic semiconductors and between 1998 and 2001, in conjunction with twenty collaborators, Schön produced on average one research paper every eight days.\textsuperscript{181} Despite Schön’s improbable publishing productivity and the inability of other researchers to repeat his experimental success, the suggestion of research misconduct was only raised following the publication of a paper in Science in December 2001.\textsuperscript{182} In 2002, in response to further allegations of misconduct, Bell Laboratories established a committee to investigate the allegations; it did not have any formal policy in place to deal with incidences of research misconduct.\textsuperscript{183} The investigation committee examined 24 specific allegations and confirmed that Schön had committed scientific misconduct in at least 16 of these.\textsuperscript{184} The committee found that Schön had manipulated and misrepresented data on a number of occasions. The committee also found that appropriate laboratory records had not be “systematically maintained” and virtually all of the primary data had been deleted from his computer. All of his original devices and samples had been damaged or discarded.\textsuperscript{185} Following the committee’s report, Schön was fired by Bell Laboratories and numerous publications were retracted. In addition, the University of Konstanz revoked Schön’s PhD (Doctor of Philosophy) in 2004, and he was also sanctioned by

179 ibid.
180 Martinson et al. (2005) op. cit.
182 ibid.
183 ibid.
185 ibid.
the DFG in Germany. The investigation committee found that Schön had acted alone in perpetrating the misconduct and cleared all of his co-authors of any allegations of misconduct. However, the committee raised the question of whether the co-authors involved had upheld their professional responsibility to ensure the validity of the data used and the claims made in the papers they were involved with. In effect, by agreeing to be a co-author such individuals were implicitly endorsing the validity of the research in question.

OVERARCHING FRAMEWORKS FOR HANDLING MISCONDUCT AND RESEARCH INTEGRITY GOVERNANCE

Whatever the cause, and despite efforts to promote research integrity and GRP, some incidences of misconduct will still occur. It is important, therefore, that mechanisms are in place to deal with these cases as and when they arise. Moreover, the way in which cases of misconduct are dealt with and the consequences for those responsible may also have a deterrent effect and discourage others from committing misconduct. From a national perspective, devising a suitable overarching framework involves striking a balance between individual and local responsibility and structures on the one hand and coordination at a national level on the other. Accordingly, there are a range of different mechanisms or frameworks in operation in different countries to address research misconduct and research integrity governance (for a summary table, see Appendix C). These frameworks vary in terms of their scope and coverage, in their application (e.g. whether voluntary or mandatory) and in their legislative basis. While specific types of framework can be clearly distinguished, the actual situation may be more complex, with more than one framework operating between institutions and within a given country at the same time.186 The different frameworks of governance can be categorised as follows: no structures; individual institutions; agency/professional body; local with national oversight; national.

NO STRUCTURES

In some areas there are no structures or guidelines in place to handle allegations of misconduct. Adopting such an approach, in essence, relies on the self-correcting and self-regulating nature of the scientific and research enterprise. The ability to verify, reproduce and build on the results of others is a major component of research, which is facilitated (at least in part) by the publication process. However, the effectiveness of such processes in detecting misconduct has been called into question.187 For example, peer review may

186 European Science Foundation (2010) op. cit.
help in identifying certain forms of misconduct relating to publication and authorship (e.g. plagiarism or image manipulation), but it is likely to miss other incidences of misconduct.

The lack of formal structures to deal with research misconduct is likely to have wider implications for the research community and the research enterprise as a whole. Research relies heavily on public and political support and funding, which in turn is interconnected with the level of trust placed in the research community. Failing to implement adequate structures to deal with misconduct might increase public scepticism and decrease trust in the transparency and accountability of research overall. Similarly, the lack of guidelines and procedures could be taken to reflect the general attitude towards research integrity within the research community, which is unlikely to deter some individuals from committing misconduct. Indeed, in some countries, it was only after revelations about major cases of misconduct came to light that efforts to establish a dedicated national coordinating framework progressed significantly, as was the case in Norway, Germany and Austria.\footnote{188,189,190}

From a practical perspective, the lack of procedural guidelines may prevent sufficient knowledge and expertise developing within a given institution to deal with incidences of misconduct. Investigations would, therefore, tend to be ad hoc and inconsistent, which is unlikely to facilitate due process. Moreover, without adequate support mechanisms, whistleblowers are less likely to come forward.

**INDIVIDUAL INSTITUTIONS**

This framework involves the development and implementation of locally adopted guidelines for GRP and handling allegations of misconduct within each research institution. In such situations, the responsibility for implementing policies and guidelines generally falls on either an ad hoc or a standing committee within a given institution.

Adopting this self-regulatory approach can feed into the general institutional culture surrounding integrity in research. Local leadership can increase the visibility of procedures for investigating misconduct and GRP guidelines within the local research community.\footnote{191}

Moreover, since investigations are dealt with in-house, those involved would have knowledge of the local situation and circumstances.

Nonetheless, a number of issues have been highlighted in relation to such institutional self-regulation. For example, managing procedures for investigating misconduct locally could represent a serious conflict of interest.\footnote{192} Confirmation that misconduct has occurred


\footnote{189 Deutsche Forschungsgemeinschaft (1998) op. cit.}


\footnote{191 Hiney M (2009) op. cit.}

\footnote{192 OECD Global Science Forum (2007) op. cit.}
within a given institution could seriously damage its reputation. Therefore, it might be in that institution’s interest to withhold details of such cases, which could potentially prejudice an investigation. Concerns over the objectivity, independence and transparency of investigation procedures could prove detrimental to public trust in and the perception of the ability of the research community to police itself. Moreover, any suggestions of bias within the investigation procedure might also deter whistleblowers from coming forward. Coordinating all aspects of procedures for investigating misconduct within an institution also raises questions about how appeals would be dealt with.

Another potential issue is that an ad hoc or standing committee tasked with handling incidences of misconduct within a given institution may not have the opportunity to develop the requisite skills and experience in handling cases. To mitigate such problems, a given committee could interact with and learn from similar committees from other national and international institutions. While this could prove beneficial, there are also likely to be certain inconsistencies and differences between institutions in how individual misconduct cases are handled and in the sanctions applied.

**AGENCY/PROFESSIONAL BODY**

Under such a framework a professional body, a funding agency or a learned society would develop procedures or policies for handling allegations of misconduct. Such a system has been adopted in Germany where there are two agencies involved in the governance of research integrity, namely the DFG and the Max Planck Society for the Advancement of Science (MPS). Any university or research institution in receipt of funding from either of these agencies is required to have mechanisms in place to handle cases of scientific misconduct. This approach can facilitate greater consistency since procedures can be outlined by a single agency, which can help to standardise mechanisms for dealing with misconduct across different research institutions. While the primary role of investigating cases of misconduct in research lies with the individual university or institution, the DFG also has an investigatory role in cases where public funding is involved. Accordingly, the DFG has established an independent Committee of Inquiry on Allegations of Scientific Misconduct to investigate accusations against applicants, funding recipients, DFG-funded staff and reviewers.

However, the fact that guidelines and procedures are implemented at a local level within a given institution could lead to some inconsistency in the compliance with and the implementation of such procedures. Nonetheless, additional steps can be taken to alleviate such issues. For example, for research funded by the MPS, the primary responsibility for conducting preliminary misconduct investigations rests with the host

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193 Hiney (2009) op. cit.
194 OECD Global Science Forum (2007) op. cit.
institution, however, a representative from the MPS must also be involved.\textsuperscript{196} On the other hand, in cases investigated by the DFG’s Committee of Inquiry, all sanctions for misconduct are applied by the Joint Committee (i.e. the DFG’s main decision-making body) based on the recommendations of the Committee of Inquiry.\textsuperscript{197} These sanctions include the following: a reprimand; a ban from submitting funding proposals for between one and eight years; a request to reimburse research funds already received; a request to retract publications or to publish a correction or erratum; a ban from conducting peer review for the DFG; or prevention from being elected to other DFG bodies. The application of sanctions by a single body enables greater uniformity and consistency in the punishment of similar offences, which may not be the case where sanctions are applied by individual institutions.

Moreover, the fact that policies and procedures emanating from agencies or professional bodies are developed by research peer groups, is considered to improve their credibility and, thus, encourage their acceptance by the research community. The direct involvement of professional bodies or societies and funding agencies in devising the guidelines and procedures can also encourage a greater focus on integrity and GRP amongst the research community. For example, upholding the rules of and providing education in GRP could be a precondition for the receipt of funding, as is the case in the US for funding provided by the NIH and the NSF.

Having developed guidelines and procedures, learned societies, professional bodies or funding agencies can assume an advisory and oversight role. In Germany, the DFG has established a committee of scientific research ombudsmen to provide advice and assistance to all researchers in relation to good conduct in research and issues of misconduct. In the interests of transparency, institutions are required to inform the DFG about any cases of misconduct that they have investigated. The ombudsmen collate and produce a report on these cases (with the identifying details removed), which provides an account of the number of cases, the types of misconduct involved and the actions taken.\textsuperscript{198}

Agencies and professional bodies could potentially utilise their position of authority to ensure greater fairness and independence within the system as a whole, for instance by providing an appeal mechanism outside of the institutional setting. Notwithstanding this oversight position, agencies and bodies may not have the requisite resources to ensure compliance amongst all institutions and researchers.\textsuperscript{199} The remit of such a body would also be limited to individuals and institutions who are members of such bodies or societies or in receipt of their funding.


\textsuperscript{197} ibid.

\textsuperscript{198} Hickling Arthurs Low Corporation (2009) op. cit.

\textsuperscript{199} Hiney (2009) op. cit.
LOCAL WITH NATIONAL OVERSIGHT

With this framework, policies, procedures and guidelines for handling research misconduct are agreed at a national level. The policies and procedures themselves would be implemented locally, within each research institution, but a national body would be tasked with providing oversight. With a national remit, a coordinating body could potentially provide oversight for both public and private sector research.200

A number of countries within Europe have implemented this type of framework. For example, in the Netherlands, the National Board for Scientific Integrity (LOWI) was established as an independent body to provide advice and oversight for all Dutch universities and institutions of the Royal Netherlands Academy of Arts and Sciences (KNAW) and the Netherlands Organisation for Scientific Research (NWO), as well a number of institutes who fall under the remit of the main funding agencies.201,202 Though, it should be noted that the remit of the LOWI does not encompass research in the private sector.

Sweden’s Central Ethical Review Board recently established (January 2010) a new expert panel on research misconduct, which is tasked with investigating suspected cases of research misconduct at higher education institutions.203 This new expert panel replaces the Swedish Research Council’s Expert Group on Misconduct in Research, which operated between 2002 and 2009. The new panel intends to build on the experience and knowledge acquired through the work of the original expert group.

The UKRIO is an independent advisory body (established in 2006) that offers support to researchers, universities and research institutions (in both the public and private sectors) with regard to scientific integrity and best practice in handling cases of misconduct.204 The UKRIO is supported both by government and by the major regulators and funders of health and biomedical research within the UK. Initially the remit of the UKRIO only covered research in health and bioscience, but this has subsequently been expanded to encompass providing advice and guidance for all fields of research.

A single national oversight body can provide consistent advice and support to all institutions, which is likely to encourage greater equality and transparency in how investigations are handled and how sanctions are applied.205 For example, in 2008, the UKRIO produced a “Procedure for the Investigation of Misconduct in Research” in an effort to standardise how research misconduct investigations are conducted and ensure

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200 European Science Foundation (2010) op. cit.
202 ALL European Academies (2003) op. cit.
204 For more information see the UKRIO website: http://www.ukrio.org/sites/ukrio2/about_us/index.cfm, accessed on 30 July 2010.
205 European Science Foundation (2010) op. cit.
greater thoroughness, objectivity and fairness.\textsuperscript{206} It was envisaged that this Procedure would complement existing processes and disciplinary procedures within research institutions. Moreover, the UKRIO has also put together a Register of Advisers, which consists of individuals with extensive knowledge and experience about different aspects of research integrity and misconduct. Members of this Register of Advisers provide confidential guidance and support in response to concerns raised in relation to research. They may also be co-opted to act as external, independent experts as part of an institutional misconduct investigation.

As the national authority, there is greater scope for the development of professional competence and experience in handling incidences of misconduct and GRP.\textsuperscript{207} For example, as a consequence of investigating more cases and/or by participating in international initiatives on best practice with similar authorities from other countries.

Establishing a single national oversight body might also limit the potential for conflicts of interest as well as providing the opportunity for an independent appeal mechanism. The LOWI in the Netherlands offers such an appeals facility for cases investigated at a local level, where either the complainant (i.e. the whistleblower) or the respondent (i.e. the accused individual) can express their dissatisfaction with how the case was addressed.\textsuperscript{208} In such instances, the LOWI can advise the host institution to investigate the case again. The LOWI can make recommendations in relation to different misconduct cases, but abiding by these recommendations is voluntary. In addition, the application of sanctions is the responsibility of the host institution and is subject to civil and labour legislation.

Part of the responsibility of a national oversight body is to inculcate a culture of integrity within the research community. A number of efforts have been made in this regard in the Netherlands. The Association of Universities in the Netherlands (VSNU) implemented the \textit{Netherlands Code of Conduct for Scientific Practice} in 2004, which outlines the general principles of desirable conduct that all university-based researchers should aim to uphold.\textsuperscript{209} In addition, the KNAW, VSNU and the NWO, in conjunction with the ALLEA also published a guidance document on GRP entitled “Memorandum on Scientific Integrity”, which all staff at the universities and publically-funded research institutes are expected to abide by.\textsuperscript{210}

Fostering this culture relies on the buy-in and active participation of the research community, which may be affected if oversight procedures are not seen as transparent or are considered overly bureaucratic.

\begin{footnotesize}
\begin{enumerate}
\item[	extsuperscript{206}] For more information see the UKRIO website: \url{http://www.ukrio.org/sites/ukrio2/the_programme_of_work/procedure.cfm}, accessed on 30 July 2010.
\item[	extsuperscript{207}] ibid.
\item[	extsuperscript{208}] European Science Foundation (2008) \textit{op. cit.}
\item[	extsuperscript{210}] ALL European Academies (2003) \textit{op. cit.}
\end{enumerate}
\end{footnotesize}
NATIONAL

With the final framework, guidelines and policies to deal with research misconduct and GRP are covered by national legislation. Generally speaking, a national body or committee is charged with implementing this governance framework. A number of countries have taken the step to establish a national coordinating body for research integrity, which is underpinned by legislation. The National Commission for the Investigation of Scientific Misconduct in Norway is one such example. The National Commission was established under the Law on Ethics and Integrity in Research (which came into force in 2007). The National Commission is an independent body whose remit is to investigate allegations of serious research misconduct in all fields of research in public or private research institutions.

In Austria, the Agency for Scientific Integrity (ÖAWI) was established in 2008, following the recommendations of a working group for a central and independent body with national responsibility for handling cases of research misconduct. The ÖAWI is responsible for the investigation and evaluation of alleged cases of scientific misconduct within Austria. The actual task of investigating and evaluating each case falls to the ÖAWI’s Commission for Scientific Integrity, which operates as an independent body.

In Denmark, the DCSD was established in 1999 by the Danish Ministry of Science, Technology and Innovation. The DCSD has a national legal jurisdiction, which was recently revised under an Executive Order. The DCSD is the central body tasked with investigating allegations and complaints about misconduct (i.e. dishonesty in research) in all fields of scientific research, within the public sector. Interestingly, unlike the majority of national bodies, the DCSD is comprised of three coordinated committees, each covering a specific area of research, namely health and medical science, science and technology and the social sciences. The chairperson of the DCSD decides which of the individual committees will handle a particular case.

In the US, the system is somewhat different again in that it operates through a combination of Federal and institutional approaches. The Federal Research Misconduct Policy, approved by OSTP, applies to all federally funded research and to proposals submitted to Federal agencies for research funding. There are two oversight bodies...
which operate at a national level, namely the ORI and the OIG.\textsuperscript{218} The ORI oversees
and directs the research integrity activities of the Public Health Service in the fields of
biomedical and health research. In this regard the ORI is responsible for overseeing all
research sponsored by the NIH. The OIG provides essentially the same role for research
funded by the NSF.

The presence of a coordinating, oversight body at a national level enables the provision
of consistent advice and guidance to all research institutions, which could potentially
include both the public and the private sector. For example, legislation in Denmark,\textsuperscript{219}
Norway\textsuperscript{220} and the US\textsuperscript{221} outlines a specific definition of research misconduct, which is to
be applied consistently to all cases at a national level. Moreover in Denmark, in addition
to the legislation, the DCSD has also implemented rules of procedure, which specifically
stipulate the processes involved in handling incidences of misconduct.\textsuperscript{222} In terms of
providing advice and support on GRP, the DCSD has also recently produced a guidance
document.\textsuperscript{223}

A national oversight body can develop the requisite experience and competency in
procedures to investigate misconduct, which would ensure independence and consistency
during investigations. In Austria, for example, the remit of the Commission for Scientific
Integrity is to provide a neutral and factual platform to facilitate the thorough and
objective investigation of alleged cases of scientific misconduct. The Norwegian system
engenders a degree of independence since any individual, university or other institution
can request that the National Commission investigate a specific case if it is considered
to be particularly complicated, has received substantial attention in the public domain or
because it involves possible conflicts of interest. In addition, the National Commission can
also initiate investigations of its own accord. The Danish model operates in a similar vein,
in that the DCSD can consider allegations of suspected misconduct submitted to it or it
can initiate its own investigations where the case is considered to be of sufficient social
interest or of importance to human or animal health, and there is a justified assumption
of misconduct. Once the consideration of a case is completed, the DCSD produces a
statement, which outlines the facts of the case, statements from the parties involved,
the DCSD’s deliberations and its conclusion.

The presence of a national coordinating body can also facilitate greater fairness and
consistency in the application of sanctions. For instance, if following an investigation the

\begin{footnotesize}
\begin{enumerate}
\item \textsuperscript{218} For more information see the Office of Research Integrity website: \url{http://ori.dhhs.gov} and the Office of Inspector General website: \url{http://www.nsf.gov/oig/}, both accessed on 4 June 2010.
\item \textsuperscript{219} Executive Order on the Danish Committees on Scientific Dishonesty (2009) op. cit.
\item \textsuperscript{220} Law on Ethics and Integrity in Research (Act of 30 June 2006) op. cit.
\item \textsuperscript{221} Office of Science and Technology Policy (2000) op. cit.
\end{enumerate}
\end{footnotesize}
DCSD confirms that misconduct has occurred it has the authority take a number of actions.\textsuperscript{224}

- inform the defendant’s employer if s/he is employed as a researcher;
- recommend that the project concerned be withdrawn;
- inform the relevant authority that supervises the research area concerned; and
- submit a police report if the offence is punishable by law.

Moreover, at the request of the employer concerned the DCSD can make a statement regarding its views on the degree of dishonesty (misconduct) involved, which aids the host institution in deciding on the appropriate penalty to apply.

In the US, both the ORI and the OIG can take a more active role in the application of sanctions. A number of factors are taken into consideration in deciding on the severity of sanctions to be applied, including: that agency’s decision on how serious the misconduct was; the degree to which the misconduct was done intentionally or recklessly; whether it was an isolated event or part of a pattern; and whether or not it had a significant impact on the research record, the research subjects, the research community (i.e. individuals and/or institutions) or public welfare.\textsuperscript{225} Accordingly, the actions taken range from just correcting the research record to suspension or debarment of the guilty individual.\textsuperscript{226} If an individual is suspended or debarred, s/he may be added to the, publically available, list of individuals excluded from the Federal funding programme.

In Norway on the other hand, following an investigation the National Commission issues a statement indicating whether or not scientific misconduct has occurred. However, it is the responsibility of the individual institution involved to decide on the appropriate sanctions to adopt.

Given its overarching position, a national coordinating authority can also serve as the recognised appeals body. Both the DCSD in Denmark and the National Commission in Norway serve as an appeals body for decisions taken by individual institutions. In the US, individual institutions are required to inform the relevant Federal agency (i.e. ORI or OIG) of any allegation of misconduct and to publish a final report upon completion of its investigation, which should include the administrative actions taken and the sanctions applied. The ORI and the OIG then have the discretionary power to review all such cases and can re-investigate a particular case if deemed necessary. It is also possible to appeal decisions by the ORI and OIG, for example, OIG decisions can be appealed to the Director of the National Science Foundation.\textsuperscript{227}

\textsuperscript{224} Executive Order on the Danish Committees on Scientific Dishonesty (2009) op. cit.
\textsuperscript{225} Office of Science and Technology Policy (2000) op. cit.
\textsuperscript{226} Sanctions include: appropriate steps to correct the research record; letters of reprimand; the imposition of special certification or assurance requirements to ensure compliance with applicable regulations or terms of an award; suspension or termination of an active award; or suspension and debarment in accordance with applicable government-wide rules on suspension and debarment.
Providing legislative backing to the coordinating body, increases its visibility and credibility both with the research community and in society in general. Moreover, openness and transparency on the part of the national body are part of its role in promoting GRP and preventing scientific dishonesty. In this regard, the DCSD publishes an annual report on its activities, which includes non-personalised details of all cases considered during that year and the outcome of each case. The National Commission in Norway does the same. Taking such steps indicates a commitment to foster integrity and discourage misconduct within the research community.

However, despite these benefits, compliance with regulations and guidelines laid down by the national coordinating body may have substantial resource implications for the research institutions involved.

While each of the different strategies have certain advantages and disadvantages associated with them it is generally agreed that the risk of misconduct occurring is likely to decrease with greater national oversight.

PROCEDURES FOR DEALING WITH MISCONDUCT

In general, the main responsibility for establishing and implementing mechanisms and procedures to deal with and investigate allegations of misconduct lies with each research institution. Having established the requisite procedures it is considered important that all staff within the institution (i.e. students, postdoctoral fellows, senior researchers, technicians and administrative staff) are made fully aware of them and what their respective responsibilities are in relation to these procedures. Moreover, both within and between countries the general requirements and components for procedures to investigate misconduct are broadly similar at the level of the institution. Accordingly, the ESF amongst others have identified a number of core features that should be incorporated into procedures for dealing with incidences of misconduct in research. They are detailed below.

UNIFORM DEFINITIONS

The categories and types of activities and behaviour that constitute misconduct or represent serious deviations from GRP should be clearly defined. This would help to alleviate any ambiguity with regard to which behaviours are considered acceptable and which should be avoided.

228 OECD Global Science Forum (2007) op. cit.
229 European Science Foundation (2010) op. cit.
CLARIFY RESPONSIBILITY AND JURISDICTION

Formulating a standard definition for research misconduct would also enable individuals to recognise inappropriate behaviour when committed by others. However, possessing such information would be of limited use, if these individuals were unsure about what should be done with this information. Therefore, it is considered important that the individual(s) or institutional office(s) responsible for managing the different aspects of the procedure to investigate misconduct are clearly identified, for example, who should allegations or concerns about misconduct be reported to.\textsuperscript{230} Outlining the processes and parties involved at each stage of the investigation procedure (i.e. receiving allegations, conducting investigations or issuing sanctions) can help improve the level of transparency of the procedure overall. Such transparency is considered important in avoiding or at least minimising potential conflicts of interest.

HANDLING ALLEGATIONS AND PROTECTING WHISTLEBLOWERS

It is important that the mechanism by which allegations of misconduct can be made and received is clearly understood and well publicised, within a given institution.\textsuperscript{231} This requires clarifying from whom allegations of misconduct will be accepted and to whom concerns should be raised. In addition, outlining the acceptable format by which concerns and allegations should be made, \textit{e.g.} oral, written or electronic, should also be made clear. Whether or not anonymous allegations of misconduct are permitted is also an important consideration.

Individuals willing to step forward and raise concerns about unacceptable research behaviour, \textit{i.e.} the complainant or whistleblower, are seen as an integral component of efforts to combat misconduct in research.\textsuperscript{232} So much so that, in some instances, a failure to report misconduct may be defined as a form of misconduct in and of itself. Nonetheless, whistleblowers are in a vulnerable position, given the potential impact the decision to speak out could have on their position within a particular institution and/or their career in general.\textsuperscript{233} In some instances, it may be the whistleblower him/herself who is viewed in a negative light. Therefore, in order to encourage more reporting of misconduct, particularly from within the scientific community, it is well recognised that systems

\begin{itemize}
  \item \textsuperscript{230} ibid.
  \item \textsuperscript{231} OECD Global Science Forum (2007) \textit{op. cit.}
  \item \textsuperscript{232} European Science Foundation (2010) \textit{op. cit.}
\end{itemize}
need to be in place to both encourage whistleblowers to come forward and to protect them from any detriment or potential retaliation or retribution as much as possible. Dooley and McCarthy have suggested, in relation to whistleblowing in the health setting, that individuals were less likely to have difficulties in reporting incidences of misconduct if they were “working in an institution with an open culture and policies in place which addressed the...errors of professionals in a supportive and creative way...”. In essence, individuals would be empowered to come forward. One form of protection that has been recommended is for an institution to establish a whistleblower’s charter. Protecting whistleblowers in this way reflects an ethical responsibility to uphold the principles of solidarity and reciprocity towards such individuals, given the potential negative impact of their coming forward. From an Irish perspective, there are currently two pieces of legislation in place, which provide protection to whistleblowers under specific circumstances. The Health Act (2007) offers protection to whistleblowers employed in the areas of health, mental health services and the social services in making complaints about the actions of a colleague, their employer or another health professional. The Safety, Health and Welfare at Work Act (2005) protects individuals from being dismissed or otherwise penalised for making a complaint or raising concerns regarding their health, safety or welfare at work.

In terms of protection, a whistleblower’s charter, or similar mechanism, could stipulate that a complainant’s confidentiality would be maintained to the greatest extent possible, while still facilitating the allegations s/he has made to be substantiated and investigated (where necessary). However, while a charter cannot resolve all potential problems for the whistleblower, implementing such measures indicates that a given institution recognises its reciprocal responsibility to support and protect these individuals.

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237 The protection applies to any individual who discloses information relating to a possible risk to the health and welfare of another individual or the public, or information relating to conduct that is likely to result in the misuse or substantial waste of public funds.
239 Steneck (2007) op. cit.
In 1996, Dr Nancy Olivieri, a haematologist working at the Hospital for Sick Children (HSC) in Toronto, became concerned about serious adverse effects of an experimental drug (deferiprone) she was trialling in patients with thalassaemia.\textsuperscript{240} When she informed Apotex, the pharmaceutical company who made the drug, that she was going to disclose her concerns to the patient’s participating in the trial, Apotex terminated the trial and withdrew all financial support. The company also invoked a confidentiality clause in the contract and threatened legal proceedings should Dr Olivieri make her findings public. Following the identification of further safety risks with the drug by Dr Olivieri through the use of liver biopsies, she informed the regulatory authorities and made arrangements for her patients to stop using deferiprone and revert back to their previous treatment. During this time Apotex continued to claim that deferiprone was safe and effective and proposed a new treatment regime for patients, which did not include liver biopsies as part of the monitoring procedure. An internal inquiry by the hospital authorities was established, which found that Dr Olivieri had acted inappropriately and had not fulfilled her reporting obligations in relation to the risks she had identified. The inquiry was later found to be flawed and based on malicious allegations, made by co-workers amongst others. Dr Olivieri was fired from her position as director of the research programme and was referred to the College of Physicians and Surgeons of Ontario for research misconduct. It later emerged that the University of Toronto and the HSC had been in negotiations with Apotex in relation to a multi-million dollar donation towards building a new biomedical research centre at the university.\textsuperscript{241} In 1998, Dr Olivieri contacted the Canadian Association of University Teachers for assistance, which established a Committee of Inquiry in 1999. In its report published in 2001, the committee found that: Dr Olivieri had not acted inappropriately; the HSC and the university had not provided sufficient protection and support to Dr Olivieri’s academic freedom; the findings of the initial inquiries were incorrect; and Apotex acted inappropriately in trying to prevent Dr Olivieri from informing patients, regulators and the scientific community about the risks associated with the experimental drug.\textsuperscript{242}

\textsuperscript{242} Thompson et al. (2001) op. cit.
PROCEDURAL FAIRNESS

It is important that procedures implemented to deal with misconduct are fair and equitable to all parties involved, i.e. both complainants and respondents. Moreover, such procedures are required to be legally robust to ensure individuals are adequately protected.\(^{243}\) Therefore, those accused of committing misconduct should have the right to due process and should be presumed innocent until proven otherwise.

In addition, those who bring forward an allegation of misconduct in good faith should not suffer any penalty for doing so. However, the question arises whether protections afforded to genuine whistleblowers should involve permitting individuals to make anonymous allegations against another party. Allowing allegations to be made anonymously is interconnected with the perception of fairness within procedures to investigate misconduct. While offering some protection to potential whistleblowers, permitting anonymous allegations may also facilitate an individual in making unfounded, vexatious or malicious allegations of misconduct against someone else.\(^{244}\) Unwarranted allegations could have a serious negative impact on the reputation and career of the accused individual.

In 1986, Dr Thereza Imanishi-Kari was accused of falsifying data for a paper she co-authored.\(^{245}\) A series of internal and external investigations followed, which culminated, in 1994, with the ORI finding that she had intentionally fabricated and falsified experimental data and results.\(^{246}\) Following this decision, the ORI and the Department of Health and Human Services took a number of administrative actions, which included debarring Dr Imanishi-Kari from receiving Federal grant and contract awards for ten years. Dr Imanishi-Kari asked for an evidentiary hearing in response to the findings of the ORI. This hearing represented Dr Imanishi-Kari’s “first opportunity to confront and cross-examine witnesses against her and to test the expert opinions on which ORI relied”.\(^{247}\) A Research Integrity Adjudications Panel was appointed to hear Dr Imanishi-Kari’s appeal. In June 1996, the Adjudications Panel concluded that the ORI “did not prove its charges by a preponderance of the evidence” and that no debarment or other sanctions should be imposed.\(^{248}\) Therefore, ten years after the initial allegations of misconduct were made Dr Imanishi-Kari was finally cleared of all charges.

\(^{243}\) European Science Foundation (2010) op. cit.

\(^{244}\) ALL European Academies (2003) op. cit.


\(^{247}\) ibid.

\(^{248}\) ibid.
BALANCING TRANSPARENCY AND CONFIDENTIALITY

Related to these issues is the need to strike a balance between the transparency and confidentiality of investigations into misconduct allegations. Protecting the privacy and confidentiality of individuals under investigation reflects due process. However, this entitlement to confidentiality is not absolute, particularly where efforts to maintain an individual’s privacy could compromise an investigation\textsuperscript{249} or if the alleged misconduct posed a risk to public health and safety.\textsuperscript{250}

Another important consideration in this regard relates to how, when and to whom the outcome of procedures to investigate misconduct should be publicised and disseminated.\textsuperscript{251}

FORMAT OF INVESTIGATIONS

A required component of any misconduct procedure is detailing how the investigative process will progress once an initial allegation has been substantiated. This could include: clarifying who is responsible for managing the different aspects of the investigation; providing guidelines and information on the timeframes involved in the investigation; and clarifying what standard of evidence is required to complete an investigation.

SANCTIONS AND ENFORCEMENT

Reaching agreement on the type and degree of sanction to be imposed is internationally recognised. Numerous guidelines in this area recommend that the sanctions imposed should be proportionate to the offence committed, \textit{i.e.} reflect the degree of departure from codes of GRP. Sanctions should also be applied consistently,\textsuperscript{252} regardless of an individual’s rank or position within the institution.

RIGHT OF APPEAL

A final requirement for a misconduct procedure involves outlining the acceptable appeal processes.\textsuperscript{253} This could include specifying on what grounds an appeal can be lodged, for example, an appeal based on scientific grounds or on procedural aspects of the investigation itself. Detailing the criteria upon which an appeal should be based is also important.

\textsuperscript{249} Office of Science and Technology Policy (2000) op. cit.
\textsuperscript{250} Steneck (2007) op. cit.
\textsuperscript{251} European Science Foundation (2010) op. cit.
\textsuperscript{252} OECD Global Science Forum (2007) op. cit.
\textsuperscript{253} European Science Foundation (2010) op. cit.
CONCLUDING SECTION

The Irish Council for Bioethics (ICB) considers that the credibility and integrity of research in all disciplines from science to the humanities is essential to its continued value and worth both as an enterprise in its own right and in its interconnection with society. In this regard the honesty and integrity of members of the research community feeds into the degree of trust and confidence the public places in research. Therefore, greater integrity encourages more public trust and support, which precipitates increased funding opportunities. Accordingly advances and developments in research, facilitated through such public support, can bring considerable benefits to society as a whole.

From a policy perspective, Ireland has committed to significant investment in research and development (R&D) with the aim of fostering a climate of scientific discovery and innovation, in order to support a knowledge-based, smart society. Notwithstanding a reappraisal of priorities in the current economic climate, the Government has recently reaffirmed its commitment to this investment strategy. For example, over the next two years the Government will provide €773 million in support of scientific research. Moreover, the Government has pledged approximately €2.4 billion, between now and 2016, “to drive further improvements in our national scientific, technological and innovation capacity” and to progress Ireland’s ability in R&D.

However, while significant funding has been allocated to science and technology research in recent years, similar investments have not been made in the area of research governance. The rational and responsible management and governance of research needs to be firmly based on good science and high ethical and legal standards. As the single biggest funder of R&D, the Irish taxpayer needs not only to be informed about the research s/he funds, but also to know that this research is conducted and reported properly, transparently and honestly. The ICB, therefore, recognises the importance of and the need to instil as deep a culture of integrity in research as is possible. In the Council’s opinion, achieving this goal requires the implementation of a comprehensive framework incorporating measures, which not only promote integrity, but also deter misconduct.

A review of existing efforts to deter misconduct indicates that there is, currently, no uniform set of policies and/or procedures for handling misconduct allegations in Ireland. Consequently, research institutions have to be relied upon to police themselves. However, institutions have taken different approaches to the regulation and investigation of issues of research integrity and allegations of misconduct, which has resulted in a lack of consistency in the level, scope and degree of development of policies and procedures within different Irish institutions. In preparation of this document, the ICB contacted 43 institutions involved in research, including universities, institutes of technology, hospitals


and others (see Appendices A and B) to establish if they had codes of practices in place relating to standards of GRP and the investigation of misconduct allegations. There was a 72% response rate to the survey and it was established that the majority of universities did have codes of practice in place. The situation in the institutes of technology was more fluid, however, many of the institutes were currently examining the issue in preparation of drafting policies. Teaching hospitals tended to rely on the policies drafted by their affiliated academic institute. Policies differed in relation to their scope and content and it was not always clear that they were actively and widely disseminated amongst the research personnel (most often available on the institution's website). With such ad hoc and, potentially, institution-specific approaches researchers may experience some difficulty in ensuring they are fully aware of and compliant with the policies that apply in a given institution. Moreover, there is also the danger of a lack of continuity of standards both within and between institutions.

Interest in research misconduct and research integrity in Ireland is increasing. For example, the Royal Irish Academy (RIA), in association with the Irish Universities Association (IUA), the Health Research Board (HRB), the Higher Education Authority (HEA) and Science Foundation Ireland held a workshop to discuss issues relating to research integrity within the Irish research sector in September 2009. Following this conference, the RIA in conjunction with its partners from the workshop established a working group, which produced a discussion document on issues pertaining to research integrity in August 2010.\(^\text{256}\) It should also be noted that a number of funding bodies have made their funding awards contingent on certain criteria being met, which relate to institutions establishing policies to handle incidents of research misconduct.\(^\text{257,258}\) In the case of the HRB, institutions in receipt of funding are also required to implement codes of GRP and establish local procedures for the investigation of cases of misconduct.

While such initiatives are to be welcomed, it is evident from an analysis of best practice internationally that coordination and oversight at a national level in terms of research integrity governance and policies for handling incidences of research misconduct is a necessity for Ireland. For example, the ESF has stated that “as a coordinated and nationwide agreed system emerges the robustness of the governance structure increases”\(^\text{259}\). In addition, the UKRIO has also recognised the need for greater coordination at a national level. Currently in the UK, responsibility for research integrity and research misconduct does not fall under the remit of a single organisation. Therefore, the UKRIO is actively collaborating with other organisations in the UK, such as Research

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\(^{259}\) European Science Foundation (2010) op. cit.
Councils UK and the Department of Health in an effort to harmonise and streamline guidance in this area.

In a number of countries, including Norway and Germany, significant development of the existing national framework only occurred in the aftermath of a major case of research misconduct. Ireland, therefore, has an opportunity to pre-empt a reactionary approach and build on best practice in this area. Given the negative impact a high profile case of misconduct could have for the Irish research sector, both in terms of diminishing public trust and support and damaging current and future funding, the implementation of a coordinating framework for research integrity governance represents a necessary and cost-effective investment at this time.

The ICB is of the view that Ireland should have a national coordinating body tasked with overseeing and managing efforts to encourage greater integrity in research and to handle allegations of misconduct. Following an extensive review of literature and best practice in this area, the ICB has concluded that the framework best suited to the Irish situation would be to establish a system with overarching national coordination, but which involves localised, institutional implementation.\footnote{Functionally similar frameworks operate in Austria, Norway and the US amongst others.}

Arranging a national framework in this way provides a number of advantages. For instance, there may be a range of different definitions for research misconduct in operation within different institutions in a given country, however, the advent of a centralised national coordinating body enables a single national definition to be devised, which can then be applied in all research institutions. The use of a specific national misconduct definition facilitates better awareness and understanding of research integrity amongst all researchers. Moreover, utilising a standard definition across all institutions takes account of important features of the modern research enterprise, namely the mobility of individual researchers and the proliferation of collaborative research. Hence, no matter which institution an individual is working in or what other researchers s/he is working with, all parties concerned would know whether or not a particular behaviour is deemed acceptable according to a standard national definition.

The national coordinating body, in conjunction with research institutions could, therefore, agree on the standard definition of misconduct that should apply. With regard to the scope of the misconduct definition to apply in Ireland, the ICB is of the view that such a definition should not be confined to falsification, fabrication and plagiarism, but should also incorporate questionable research practices. The Norwegian definition of misconduct, as stated in their legislation, defines misconduct as “falsification, fabrication, plagiarism and other serious breaches of good scientific practice that have been committed wilfully or through gross negligence when planning, carrying out or reporting on research”.\footnote{Law on Ethics and Integrity in Research (Act of 30 June 2006) op. cit.} A similar formulation could be applicable to research conducted in Ireland.
The national coordinating body could also ensure consistency by standardising the procedures for receiving allegations of misconduct, for handling and investigating such allegations and for applying sanctions should misconduct be proven. Given that the initial responsibility to implement these procedures lies with the research institutions themselves, the development of these procedures should be conducted in conjunction with the institutions.

The ICB proposes that under the devised procedures the institution concerned would ordinarily handle allegations of misconduct. It is envisaged that the role of the national coordinating body would include acting as an appeals body, or in cases where an institution considered a particular case to be beyond its scope or capabilities, a request could be made to the national body to intervene. Finally, the national body would also have the authority to initiate its own investigations should it feel a specific case was of sufficient national or public importance or where a case involved a potential conflict of interest. Adopting such an approach introduces a degree of flexibility within the overarching framework for individual institutions, while still utilising the independence, competence, and authority of the coordinating body, where necessary. The national frameworks adopted in Norway, Denmark and the US essentially operate in this manner.

The current lack of a national coordinating body for research integrity in Ireland restricts the opportunity to independently investigate cases of misconduct. Moreover, in the absence of a national coordinating body, appeals against the findings of misconduct investigations may, ultimately, require resolution through the courts. Should the national coordinating body serve as the recognised appeals body, the entity would require a legislative basis. It should be acknowledged that despite the provision of an appeals facility, the resolution of certain cases might still require recourse to the courts. However, empowering the national coordinating body to adjudicate on appeals should reduce the need for the courts to be involved.

Whether initiating its own investigation or as part of an appeals process, the national coordinating body would assemble a small panel of internationally recognised experts for the task. In order to ensure independence, avoid possible conflicts of interest and facilitate greater transparency, the ICB recommends that the members of the panel should be recruited from outside Ireland. The Austrian Commission for Scientific Integrity, which investigates allegations of misconduct at a national level, is made up of experts drawn from outside Austria. In addition, at least one of the members of the Norwegian National Commission for the Investigation of Scientific Misconduct must be drawn from outside Norway. Moreover, given the potential legal implications pertaining to misconduct cases, the ICB takes the view that the expert panel needs to contain an advisory member who has extensive knowledge of the Irish legal system. A similar provision regarding legal expertise is made in Austria, whereas in both Norway and Denmark individuals with judicial experience must chair their respective national bodies.
Where allegations of misconduct are substantiated following an investigation by the expert panel of the national coordinating body, that individual’s host institution should apply the sanctions. In line with the use of standardised investigation procedures, the national coordinating body, following consultation with the research institutions, will have set out the penalties for specific misconduct transgressions. Utilising such standardised sanctions ensures consistency, proportionality, and equality in the punishment of inappropriate behaviour irrespective of status or employer. Moreover, greater awareness and certainty of the penalties that would apply in a given situation may also deter some individuals from committing misconduct.

Increasing the awareness amongst the research community of what constitutes misconduct and how such actions are likely to be punished can be assisted by the regular collation and publication of misconduct cases. The ICB would favour a model in which all research institutions would be required to inform the national coordinating body of any misconduct cases they have investigated in a given year, the findings of these cases and the sanctions applied where misconduct was found. The national coordinating body would then produce an anonymised account of each case in its annual report. This report would serve as an educational tool for the research community by providing a context-based clarification of what constitutes misconduct. In addition, the publication of such a report would provide some basic information on the extent and frequency of misconduct within Ireland, which is currently lacking. Such knowledge of the prevalence of misconduct is an essential component in evaluating the effectiveness of the measures being taken to counteract misconduct. Another function of the publication of such a report would be to exhibit openness and transparency, which in turn is vitally important for public support of the research enterprise, and the sustained credibility of the research community. Annual reports providing anonymised accounts of misconduct cases are published by the national coordinating bodies of Denmark, Norway and Germany.

While openness and transparency are to be welcomed in relation to documenting proven cases of misconduct, consideration needs to be given to protecting an accused individual’s confidentiality until such accusations have been substantiated. Therefore, the ICB is of the opinion that, in line with due process and an individual’s right to privacy, every effort should be made to uphold the confidentiality of all individuals accused of misconduct, provided such confidentiality does not hinder the ensuing investigation. In the US, the Federal Policy on Misconduct contains such confidentiality provisions, which are contingent on the associated investigation being able to progress without impediment. Given that an individual’s confidentiality is not absolute, information about a particular accusation and subsequent investigation may, therefore, enter the public domain prior to the conclusion of the investigation. Notwithstanding the understandably negative impact a confirmed finding of misconduct can have on an individual, an allegation of misconduct, which has yet to be proven, can be equally damaging to an individual researcher’s reputation. Moreover, it should be recognised that in some instances the allegations made against an individual may be knowingly unfounded,
vexatious or malicious. Although such malicious allegations are likely to be rescinded following their investigation, and the perpetrator punished if s/he can be identified, the individual accused may still suffer some detriment. Therefore, in order to minimise the opportunity for such malicious allegations the ICB is not in favour of permitting anonymous allegations.

Nonetheless, the Council recognises the value in enabling concerns relating to possible misconduct to be discussed with the national coordinating body anonymously and in confidence prior to a formal complaint being made. In this way an individual could contact the national coordinating body, outline the concerns s/he has regarding behaviours and actions s/he has witnessed without having to provide any indentifying information about him/herself or the person to whom the concerns relate. This would enable an individual to avail of independent advice to help clarify whether or not the behaviour to which his/her concerns relate would actually constitute misconduct. This should help to reduce the probability of unfounded, and potentially damaging, allegations being made against an individual due to a misunderstanding or a misinterpretation of that individual’s behaviour on the part of the person raising the concern. While definitions and explanations of misconduct represent an important component of research integrity education programmes, a further facility to help individuals (especially junior individuals) to understand and clarify what constitutes misconduct, once they have entered the research environment, would be welcomed. Moreover, if such anonymous consultation with the national coordinating body indicated that the observed behaviour was likely to constitute misconduct then the person who raised the initial concern might be more confident about coming forward to lodge a formal misconduct complaint. Both the UKRIo and the National Commission in Norway facilitate such anonymous concerns and inquiries to be raised and discussed without having to enter into formal misconduct investigations. The confidential hotline provided by the UKRIo can be contacted by any individual researchers, research organisations or members of the public who have concerns about the conduct of research. While recognising that anonymous allegations of misconduct should not be permitted, it should still remain possible for an individual to make a formal allegation to the appropriate authority in confidence.

It must be acknowledged that whistleblowers are in a vulnerable position, and as highlighted by the Nancy Olivieri case in Canada, an individual’s personal and professional life can suffer dramatically as a consequence of their decision to report acts of misconduct. In light of this vulnerability and in recognition of the integral role whistleblowers play in counteracting misconduct, society has a commensurate responsibility to implement measures to protect these individuals. As previously described, to date, a rather piecemeal approach to protecting whistleblowers has been adopted in Ireland. However, recently there have been further calls from a number of sectors (including the Governor of the Central Bank, the Director of Corporate Enforcement and the Ombudsman) to

introduce a single and comprehensive piece of legislation to regulate this area. The ICB is of the view that a whistleblower’s charter and associated legislation must be enacted in Ireland in order to support efforts to deter scientific misconduct. Opinion 1/2006 (WP 117) of the European Commission’s Article 29 Working Party sets out the potential data protection implications of such schemes and gives guidance as to how their operation can be made compatible with European Union data protection law.\(^{263}\) Measures to protect whistleblowers, have been enshrined in law in a number of countries such as the UK and Norway.\(^{264,265}\)

The system proposed by the ICB would ostensibly cover all public research in all disciplines of science, health science, social science and the humanities. However, the issue of promoting research integrity and discouraging misconduct in private research and in public-private partnerships needs to be considered. This is particularly pertinent given the growth in the number of such public-private initiatives in research. In Denmark, private institutions involved in research have voluntarily adopted nationally agreed codes of conduct. However, where allegations of misconduct occur in the private research sector it is unclear whether or not the national coordinating body would be given the same level of access to conduct its inquiries and investigations. This is an area that will need to be considered by any national coordinating body.

Internationally many of the national research integrity frameworks adopted tend to focus predominantly on procedural aspects relating to counteracting research misconduct. However, while the use of corrective and/or deterrent measures, such as investigation procedures and the imposition of sanctions are very important in helping to limit the likelihood of misconduct, relying on such measures alone would be insufficient in fostering greater research integrity. Educating and training researchers in GRP is an essential factor in promoting integrity in research. Adopting a comprehensive national framework, which emphasises and integrates both promotional, educational initiatives and deterrent measures, appears on balance to represent a better opportunity to foster greater integrity in research. The overarching framework adopted by the National Commission in Norway follows this more holistic “dual” approach. The ICB endorses the Norwegian model and recommends that a similar approach be adopted in Ireland.

In Norway the National Commission promotes GRP through resources available on its website and through specific educational events (e.g. seminars). In the US, both the ORI and the OIG have developed policies, procedures, and guidelines relating to GRP and both provide online resources via their websites.\(^{266}\) Moreover, the UKRIO recently


\(^{266}\) The NSF has also funded additional beta sites to act as clearinghouses for resources on ethics education in science and engineering.
published a “code of practice” to provide guidance for individual researchers and institutions with regard to promoting good practice and preventing misconduct. In addition to issuing advice and guidance in relation to GRP, a national coordinating body could also provide teaching tools and resources, suggest curricula and conduct courses in specific aspects of GRP.

In relation to the specific content and extent of educational programmes in research integrity and GRP, these should be multi-faceted and encompass all aspects of an individual’s research and professional activities. Education should focus on providing an individual with a framework or mechanism by which s/he can recognise and understand what research integrity and GRP are; develop and foster his/her ability to uphold these values and principles; and appreciate the relevance and importance of these principles to the research enterprise, the research community and society as a whole.

Active and problem-based learning methodologies form the bedrock of the formal educational programmes that currently exist. However, it has been recognised that no single “one-size-fits-all” approach is likely to prove effective across all disciplines or all levels of individual experience. A comprehensive and integrated approach to formal education programmes is the most likely to prove effective. The ICB is, therefore, of the view that education and training in research integrity and GRP should begin early in an individual’s research career; should extend over an individual’s entire training period; and should continue throughout his/her career. It is important to continually review and evaluate educational programmes to determine their effectiveness and also to facilitate the development of more targeted, individually-tailored and/or discipline-specific programmes.

In Ireland, the importance of education in integrity in research and GRP has been acknowledged only relatively recently and predominantly relates to incorporating and integrating such training into existing structured PhD programmes. For example, a collaborative project, conducted between three Irish universities in 2006/2007, which related to postgraduate skills development, identified ethics and integrity in research as highly desirable qualities/skills for postgraduate students to obtain. More recently, both the IUA and the Irish Universities Quality Board (IUQB) highlighted ethics and integrity in the conduct of research as important skills that postgraduates should be trained in as part of their overall professional and disciplinary development in all fields of research.

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267 UK Research Integrity Office (2009) op. cit.
However, as things stand there are currently limited opportunities for junior researchers to undergo formal education in research integrity and GRP. Some formal training in GRP is available, via specific modules, seminars and workshops, in some institutions.271 The advent of different network initiatives between research institutions, such as the Dublin Region Higher Education Alliance, facilitates students from one institution accessing modules and courses available elsewhere, which could include courses in GRP.272 While the aforementioned developments are welcome, they are not sufficient. This is particularly the case with regard to education in GRP for undergraduate students, which needs to be implemented more comprehensively. While significant strides have been made in research ethics training in the last number of years, the same emphasis has not been placed on GRP. Where training has been instituted it tends to be restricted to certain disciplines, most notably, the health sciences. Given that many undergraduate students begin their professional life following receipt of their degree, the ongoing development of research integrity educational programmes at postgraduate level will not reach these individuals. Therefore, the ICB believe that there is both the scope and the necessity for educational programmes in GRP to be further developed and expanded at the undergraduate level in all disciplines.

Allied to the more structured, formal approaches to education in research integrity and GRP, are informal mechanisms whereby education and training occurs through observation and mentorship. The prevailing culture within an individual’s research environment can greatly influence his/her attitude towards research integrity and GRP. Given his/her position of authority the principal investigator or mentor of a particular group is likely to have a significant influence on the approach to integrity and GRP adopted within his/her research group. Thus, involvement in and commitment to educational programmes in research integrity by senior staff is vital. Both the IUQB and the HRB have recommended that research institutions should provide resources and training on research supervision to support mentors.273,274 Both bodies also recommend that institutions develop procedures and codes of responsibilities for supervisors, which has occurred in some instances. Furthermore, the National Academy for Integration of Research, Teaching and Learning (NAIRTL) is currently conducting a major project to develop a training framework and support strategies for staff involved in student supervision.275 Respondents to a survey of Irish academic and research communities conducted in 2009, as part of the NAIRTL project, were broadly in favour of implementing initiatives to provide such training and support for supervisors.276

271 For example University College Dublin offers the module - Advanced Research Skills for Biological Scientists. For more information see the website: http://www.ucd.ie/conway/education/graduate/ourmodules/programmecalendar/advancedresearchskillforbiologicalscientists, accessed on 14 September 2010.
272 For more information see the Dublin Region Higher Education Alliance website: http://www.drhea.ie, accessed on 14 September 2010.
273 Irish Universities Quality Board (2009) op. cit.
While advocating the need for a national coordinating body the ICB also fully endorses the measures being implemented at a European and international level in promoting research integrity and combating misconduct. A number of organisations in other countries are taking the initiative in this area and there is a real opportunity for Ireland to benefit from existing expertise and future exchange of best practice. The existence of a national coordinating body in Ireland would facilitate interactions with European and international organisations.

The ICB considers that, ideally, a dedicated, independent body should be established to coordinate issues pertaining to research integrity governance in Ireland. However, the ICB recognises that in the current economic climate this may not be feasible and that it might be more practical, if an existing entity were to assume the roles and responsibilities of a national coordinating body. Given the national remit and experience of the HEA in coordinating activities across the higher education sector, it is the view of the ICB, that the HEA is well placed to engage with stakeholders in the research community in order to establish procedures to deal with allegations of misconduct. Moreover, the ICB envisages that the educational aspects of promoting greater integrity in research would constitute an integral part of the new coordinating body’s responsibilities. Given its existing function in planning and policy development for higher education and research, the HEA would, therefore, be effectively positioned to implement and roll out educational programmes aimed at promoting research integrity. In addition, the HEA’s existing statutory footing would also facilitate a more expeditious adoption and implementation of any expanded functions. While there may be concern in relation to the resource implications of establishing a national coordinating body, albeit under the auspices of an existing entity, the financial requirements would be small relative to the profoundly negative impact that research misconduct cases can have both for science and society.

The existence of a national coordinating body would provide support and encouragement to the research community in meeting their obligations in terms of research integrity and GRP. Importantly, the advent of a national coordinating body would also increase the credibility of Irish research, which influences funding as well as public perception and the degree of trust in the research enterprise.
APPENDIX A: SUBMISSIONS SOUGHT BY THE IRISH COUNCIL FOR BIOETHICS

The following is a list of the organisations from which the Irish Council for Bioethics sought submissions:

The Adelaide and Meath Hospital, Dublin Incorporating the National Children’s Hospital
Athlone Institute of Technology
Beaumont Hospital
Coombe Women’s Hospital
Cork Institute of Technology
Cork University Hospital
Dublin City University
Dublin Institute of Technology
Dundalk Institute of Technology
The Economic and Social Research Institute
Galway-Mayo Institute of Technology
Health Research Board*
Health Service Executive
Higher Education Authority*
The Institute of Public Health in Ireland
Institute of Technology Blanchardstown
Institute of Technology Carlow
Institute of Technology Sligo
Institute of Technology Tallaght
Institute of Technology Tralee
Irish College of General Practitioners
Irish Universities Association*
Letterkenny Institute of Technology
Limerick Institute of Technology
Mary Immaculate College, Limerick
Mater Dei Institute of Education
Mater Misericordiae Hospital
NUI Galway
NUI Maynooth
Rehab Group
The Rotunda Hospital
Royal College of Physicians of Ireland
Royal College of Surgeons in Ireland
Royal Irish Academy*
Royal Victoria Eye and Ear Hospital
Science Foundation Ireland*
Sligo General Hospital
St Francis Hospice
St James's Hospital
St Patrick's College, Drumcondra
St Vincent’s University Hospital
Trinity College Dublin
University College Cork
University College Dublin
University College Hospital Galway
University of Limerick
Waterford Institute of Technology
Waterford Regional Hospital

Note: The Irish Council for Bioethics met with representatives from all organisations marked with an asterisk independently of the Council’s survey of Irish research institutions.
APPENDIX B: SUBMISSIONS RECEIVED BY THE IRISH COUNCIL FOR BIOETHICS

The following is a list of the organisations from which the Irish Council for Bioethics received oral and/or written submissions:

The Adelaide and Meath Hospital, Dublin Incorporating the National Children’s Hospital
Athlone Institute of Technology
Beaumont Hospital
Cork University Hospital
Dublin City University
Dundalk Institute of Technology
The Economic and Social Research Institute
Health Research Board*
Health Service Executive
Higher Education Authority*
Institute of Technology Blanchardstown
Institute of Technology Carlow
Institute of Technology Sligo
Institute of Technology Tallaght
Irish College of General Practitioners
Irish Universities Association*
Letterkenny Institute of Technology
Limerick Institute of Technology
Mary Immaculate College, Limerick
Mater Dei Institute of Education
Mater Misericordiae Hospital
NUI Galway
NUI Maynooth
The Rotunda Hospital
Royal College of Surgeons in Ireland
Royal Irish Academy*
Science Foundation Ireland*
Sligo General Hospital
St Francis Hospice
St James’s Hospital
St Patrick’s College, Drumcondra
St Vincent’s University Hospital
Trinity College Dublin
University College Cork
University College Dublin
Waterford Institute of Technology

Note: The Irish Council for Bioethics met with representatives from all organisations marked with an asterisk independently of the Council’s survey of Irish research institutions.
### APPENDIX C: OVERVIEW OF NATIONAL RESEARCH INTEGRITY GOVERNANCE FRAMEWORKS

The table below provides an overview of the national frameworks of research integrity governance in operation in a number of different countries.²⁷⁷

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>ORGANISATION</th>
<th>FRAMEWORK</th>
<th>ROLES AND RESPONSIBILITIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>Agency for Scientific Integrity (ÖAWI)</td>
<td>National</td>
<td>Advisory and investigatory</td>
</tr>
<tr>
<td>Croatia</td>
<td>Committee for Ethics in Science and Higher Education</td>
<td>National</td>
<td>Advisory and investigatory</td>
</tr>
<tr>
<td>Denmark</td>
<td>Danish Committees on Scientific Dishonesty</td>
<td>National</td>
<td>Advisory, investigatory and appeals</td>
</tr>
<tr>
<td>Finland</td>
<td>National Advisory Board on Research Ethics</td>
<td>Local with National Oversight</td>
<td>Advisory and appeals</td>
</tr>
<tr>
<td>France</td>
<td>National Institute for Health and Medical Research and National Centre for Scientific Research</td>
<td>Agency/Professional Body</td>
<td>Advisory and investigatory</td>
</tr>
<tr>
<td>Germany</td>
<td>German Research Foundation (DFG) and Max Planck Society for the Advancement of Science</td>
<td>Agency/Professional Body</td>
<td>Advisory, investigatory and issues sanctions</td>
</tr>
<tr>
<td>Netherlands</td>
<td>National Board for Scientific Integrity</td>
<td>Local with National Oversight</td>
<td>Advisory, oversight and appeals</td>
</tr>
<tr>
<td>Norway</td>
<td>National Commission for the Investigation of Scientific Misconduct</td>
<td>National</td>
<td>Advisory, investigatory and appeals</td>
</tr>
<tr>
<td>Spain</td>
<td>Spanish National Research Council</td>
<td>Agency/Professional Body</td>
<td>Advisory</td>
</tr>
<tr>
<td>Sweden</td>
<td>Expert Panel on Research Misconduct</td>
<td>Local with National Oversight</td>
<td>Advisory and investigatory</td>
</tr>
<tr>
<td>Switzerland</td>
<td>Swiss Academies of Arts and Sciences</td>
<td>Agency/Professional Body</td>
<td>Advisory, oversight and investigatory</td>
</tr>
<tr>
<td>UK</td>
<td>UK Research Integrity Office</td>
<td>Local with National Oversight</td>
<td>Advisory and oversight</td>
</tr>
<tr>
<td>US</td>
<td>Office of Research Integrity and Office of the Inspector General</td>
<td>National</td>
<td>Advisory, oversight, investigatory, appeals and issues sanctions</td>
</tr>
</tbody>
</table>

²⁷⁷ Some of this information is adapted from Hiney (2009) op. cit.
THE IRISH COUNCIL FOR BIOETHICS

Dr Dolores Dooley, Philosopher and Lecturer in Bioethics, Chairperson
Professor Alan Donnelly, Department of Physical Education and Sport Sciences, University of Limerick, Rapporteur on Research Integrity
Professor Andrew Green, School of Medicine and Medical Science, University College Dublin; National Centre for Medical Genetics, Our Lady’s Hospital for Sick Children, Crumlin
Dr Mary Henry, Retired Medical Practitioner and Former Independent Member of Seanad Éireann
Dr Richard Hull, Department of Philosophy, National University of Ireland, Galway
Dr Peter McKenna, Rotunda Hospital, Vice Chair
Professor John Vincent McLoughlin, Department of Physiology, Trinity College Dublin
Mr Stephen McMahon, Irish Patients’ Association
Mr Turlough O’Donnell SC, Practising Barrister and Former Chair of the Bar Council of Ireland
Professor Cliona O’Farrelly, School of Biochemistry and Immunology, Trinity College Dublin
Professor Richard O’Kennedy, School of Biotechnology, Dublin City University
Mr Asim A. Sheikh BL, Forensic and Legal Medicine, School of Medicine and Medical Science, University College Dublin, Vice Chair
Professor David Smith, Royal College of Surgeons in Ireland, Rapporteur on Research Integrity
Dr Sheila Willis, Director, Forensic Science Laboratory

SECRETARIAT

Dr Siobhán O’Sullivan
Ms Emily de Grae
Mr Paul Ivory
Ms Emma Clancy (until June 2010)

TERMS OF REFERENCE

1. To identify and interpret the ethical questions raised by biomedicine in order to respond to, and anticipate, questions of substantive concern.
2. To investigate and report on such questions in the interests of promoting public understanding, informed discussion and education.
3. In light of the outcome of its work, to stimulate discussion through conferences, workshops, lectures, published reports and where appropriate to suggest guidelines.
## LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ALLEA:</strong></td>
<td>ALL European Academies (European Federation of National Academies of Science and Humanities)</td>
</tr>
<tr>
<td><strong>CFRS:</strong></td>
<td>Committee on Freedom and Responsibility in the conduct of Science</td>
</tr>
<tr>
<td><strong>COMEST:</strong></td>
<td>World Commission on the Ethics of Scientific Knowledge and Technology</td>
</tr>
<tr>
<td><strong>CRU:</strong></td>
<td>Climatic Research Unit (of the University of East Anglia)</td>
</tr>
<tr>
<td><strong>DCSD:</strong></td>
<td>Danish Committees on Scientific Dishonesty</td>
</tr>
<tr>
<td><strong>DFG:</strong></td>
<td>German Research Foundation (Deutsche Forschungsgemeinschaft)</td>
</tr>
<tr>
<td><strong>ENRIO:</strong></td>
<td>European Network of Research Integrity Offices</td>
</tr>
<tr>
<td><strong>ESF:</strong></td>
<td>European Science Foundation</td>
</tr>
<tr>
<td><strong>FDA:</strong></td>
<td>Federal Drug Administration (US)</td>
</tr>
<tr>
<td><strong>FFP:</strong></td>
<td>Falsification, Fabrication and Plagiarism</td>
</tr>
<tr>
<td><strong>FP6:</strong></td>
<td>Sixth Framework Programme of the European Commission</td>
</tr>
<tr>
<td><strong>FP7:</strong></td>
<td>Seventh Framework Programme of the European Commission</td>
</tr>
<tr>
<td><strong>GRP:</strong></td>
<td>Good Research Practice</td>
</tr>
<tr>
<td><strong>GSF:</strong></td>
<td>Global Science Forum</td>
</tr>
<tr>
<td><strong>HDC:</strong></td>
<td>High-dose Chemotherapy</td>
</tr>
<tr>
<td><strong>HEA:</strong></td>
<td>Higher Education Authority (Ireland)</td>
</tr>
<tr>
<td><strong>HRB:</strong></td>
<td>Health Research Board (Ireland)</td>
</tr>
<tr>
<td><strong>HSC:</strong></td>
<td>Hospital for Sick Children (Toronto)</td>
</tr>
<tr>
<td><strong>IAC:</strong></td>
<td>InterAcademy Council</td>
</tr>
<tr>
<td><strong>ICB:</strong></td>
<td>Irish Council for Bioethics</td>
</tr>
<tr>
<td><strong>ICMJE:</strong></td>
<td>International Committee of Medical Journal Editors</td>
</tr>
<tr>
<td><strong>IHGT:</strong></td>
<td>Institute of Human Gene Therapy (of the University of Pennsylvania)</td>
</tr>
<tr>
<td><strong>IPCC:</strong></td>
<td>Intergovernmental Panel on Climate Change</td>
</tr>
<tr>
<td><strong>IRB:</strong></td>
<td>Institutional Review Board</td>
</tr>
<tr>
<td><strong>IUA:</strong></td>
<td>Irish Universities Association</td>
</tr>
<tr>
<td><strong>IUQB:</strong></td>
<td>Irish Universities Quality Board</td>
</tr>
<tr>
<td><strong>KNAW:</strong></td>
<td>Royal Netherlands Academy of Arts and Sciences (Koninklijke Nederlandse Akademie van Wetenschappen)</td>
</tr>
</tbody>
</table>
LOWI: National Board for Scientific Integrity (Landelijk Orgaan Wetenschappelijke Integriteit)

MPS: Max Planck Society for the Advancement of Science (Germany)

NAIRTL: National Academy for Integration of Research, Teaching and Learning (Ireland)

NAS: National Academy of Sciences (US)

NIH: National Institutes of Health (US)

NSF: National Science Foundation (US)

NWO: Netherlands Organisation for Scientific Research (Nederlandse Organisatie voor Wetenschappelijk Onderzoek)

OECD: Organisation for Economic Co-operation and Development

OIG: Office of the Inspector General (US)

ORI: Office of Research Integrity (US)

OSTP: Office of Science and Technology Policy (US)

ÖAWI: Agency for Scientific Integrity (Österreichische Agentur für wissenschaftliche Integrität)

PhD: Doctor of Philosophy

PHS: Public Health Service (US)

QRP: Questionable Research Practices

R&D: Research and Development

RCR: Responsible Conduct of Research

REC: Research Ethics Committee

RIA: Royal Irish Academy

UEA: University of East Anglia

UK: United Kingdom

UKRI: UK Research Integrity Office

UNESCO: United Nations Educational, Scientific and Cultural Organization

US: United States

VSNU: Association of Universities in the Netherlands (Vereniging van Universiteiten)
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