

Research Integrity in the Framework of FNR Funding

Definition of Research Integrity (EC, 2007, p.3)

Integrity in research concerns the standards by which research activities are performed.

The New Oxford Dictionary defines integrity as **the quality of being honest and having strong moral principles**, alternatives are that, to have integrity is to be steadfast in adherence to strict codes of conduct.

For researchers this might be defined as **the quality to conduct research worthy of the trust of others**. Research integrity is a fundamental value for any and all research, for researchers and those who host or fund research activity

The Varieties of Misconduct (OECD, 2007, pp. 3-4)

- 1. Research Misconduct
 - Fabrication of data
 - Falsification of data
 - Plagiarism
- 2. Data-related misconduct
- 3. Personal misconduct
- 4. Research practice misconduct (including ethical issues)
- 5. Publication-related misconduct
- 6. Financial, and other misconduct

At the core of the spectrum of inappropriate behaviours is "Research Misconduct", consisting of Fabrication, Falsification and Plagiarism (FFP).

According to the government of the United States, **Research misconduct** is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- Fabrication is making up results and recording or reporting them.
- **Falsification** is manipulating research, materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- **Plagiarism** is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit, including those

obtained through confidential review of others' research proposals and manuscripts.

Research misconduct does not include honest error or honest differences of opinions.

Other research misconducts include:

Data-related misconduct

- Not preserving primary data
- Bad data management, storage
- Withholding data from the scientific community

Personal misconduct is.

- Inappropriate personal behaviour, harassment
- Inadequate leadership, mentoring, counselling of students
- Insensitivity to social or cultural norms

Research practice misconduct (including ethical issues)

- Using inappropriate (e.g. harmful or dangerous) research methods
- Poor research design
- Experimental, analytical, computational errors
- Violation of human subject protocols
- Abuse of laboratory animals

Publication-related misconduct

- Claiming undeserved authorship
- Denying authorship to contributors
- Artificially proliferating publications ("salami-slicing")
- Failure to correct the publication record

• Financial, and other misconduct

- Peer review abuse e.g., non-disclosure of conflict of interest, unfairly holding up a rival's publication
- Misrepresenting credentials or publication record
- Misuse of research funds for unauthorised purchases or for personal gain
- Making an unsubstantiated or malicious misconduct allegation

Preventing and dealing with misconduct (OECD, 2007, pp. 11-13)

The FNR embraces two approaches that may be followed concurrently:

- 1. **Prevention:** focuses on the underlying systemic factors that can push susceptible individuals over the threshold of violating established scientific norms.
- 2. **Deterrence/enforcement:** aims to exclude guilty individuals from the scientific community, thereby also deterring others by demonstrating the dire consequences of committing misconduct.

The FNR considers that information and training are keys in order to avoid research misconduct to happen. Therefore the FNR includes a section on research misconduct in its information sessions on the respective instruments.

Furthermore the FNR invites all researchers applying for an FNR instrument to read the OECD document: Best Practices for Ensuring Scientific Integrity and Preventing Misconduct (www.oecd.org/sti/gsf) and discuss potential issues with their hierarchy inside their institution.

The FNR handles cases of research misconduct suspicions according to international best practices.

Bibliography & further reading:

OECD: Best Practices for Ensuring Scientific Integrity and Preventing Misconduct, 2007 (www.oecd.org/sti/gsf)

EC, Integrity in Research - A Rationale for Community Action, Final Report - Expert Group meeting, Brussels (BE), 22-23 March 2007 (http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1320

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT GLOBAL SCIENCE FORUM

Best Practices for Ensuring Scientific Integrity and Preventing Misconduct

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1. Rationale

Misconduct in research (for example, fabrication, falsification, and plagiarism) damages the scientific enterprise, is a misuse of public funds, and undermines the trust of citizens in science and in government. Misconduct is a special concern for governmental administrators, who are the primary constituency of the OECD Global Science Forum. On behalf of the public, and to achieve societal benefits, they fund, oversee and evaluate research, much of which is conducted directly in public institutions or is otherwise sponsored by governments. 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.

Widespread attention has recently focussed on a few cases of misconduct in research. Their significance, the damage done, and potential preventive measures are debated by scientists, government officials, the press, and concerned members of the public. Recognising that the issue affects all of these stakeholder communities and that, like science itself, the problem has a major international dimension, the OECD Global Science Forum sponsored an international consultation of government-designated officials and experts, based on an initiative from the Delegations of Japan and Canada. On February 22-23, 2007, in Tokyo, the Global Science Forum and the Ministry of Education, Culture, Sports, Science and Technology of Japan (MEXT) held the *Workshop on Best Practices for Ensuring Scientific Integrity and Preventing Misconduct*.

The goal of the OECD Workshop was to deepen the understanding of the underlying phenomena, to identify the range of possible solutions and, based on experience, to enumerate the pros and cons of various practical measures, lessons learned and good practices. This report summarises the deliberations that took place in Tokyo. Its findings and conclusions pertain to all domains of basic and applied science: the physical and life sciences, social and behavioural sciences, and the humanities.

Ensuring integrity in science is a complex, multifaceted task, touching upon education, publication, the functions of scientific and academic institutions, and the responsibilities of funding agencies. The present report refers to all of these, but its main focus is on the practical and administrative dimensions of dealing with allegations of misconduct. A number of countries are currently creating, modifying, or reviewing their administrative mechanisms for dealing with such allegations. For these countries, the Global Science Forum workshop and report should be particularly timely, by providing an opportunity for international consultation, and for learning from the experiences of others. Workshop participants addressed the issue of integrity in international collaborations, and they deliberated about possible new steps that might be needed to deal with special problems created by the differences in the ways that collaborating countries deal with allegations of misconduct. This matter will be the subject of follow-on work by the Global Science Forum.

2. Background

This report is based on the Tokyo workshop, and on information compiled during the preparations for the event. A preliminary version of the report was provided as input to the "World Conference on Research Integrity" that was held in Lisbon on September 16-19, 2007¹. The document was subsequently modified, and reviewed by the Chair and Vice-Chairs of the Global Science Forum. They approved and accepted this final version of the report on behalf of the Forum, and authorised its release to the general public.

It is important to state explicitly that this report is of an informative and advisory nature, without any attempt to instruct governments regarding what they should do in the matter of misconduct in research. The Global Science Forum, and the participants of the Tokyo workshop, have neither the authority nor the inclination to impose any prescriptive measures on sovereign governments. In addition, it is recognised that there is not an all-embracing, one-size-fits-all global solution, due to the considerable diversity among countries in such variables as the overall structure of the science system, the roles of public and private institutions, the status of researchers (e.g., whether they are public servants), the legal system, and historical traditions and customs. Even so, and within the constraints imposed by these legitimate differences, benefits could be derived from harmonising definitions, rules and procedures, sharing information internationally, and encouraging cooperation among officials and administrators who are responsible for promoting and enforcing integrity in research.

The Tokyo workshop was attended by over 50 government-appointed representatives of 23 countries, 2 invited experts, and the OECD secretariat. It was chaired by Professor Makoto Asashima of Japan and Dr. Nigel Lloyd of Canada. To supervise the workshop preparations, fourteen GSF delegations nominated members to the International Steering Committee (ISC). Delegations also designated national experts who were interviewed by the GSF secretariat. A detailed annotated agenda was prepared based on these interviews.

The Global Science Forum of the Organisation for Economic Co-operation and Development is a venue for consultations among senior science policy officials of the OECD member and observer countries on matters relating to fundamental scientific research. The Forum's activities produce findings and recommendations for actions by governments, international organisations, and the scientific community. The Global Science Forum's mandate was adopted by OECD science ministers in 1999, and an extension until 2009 was endorsed by ministers in February 2004. The Forum serves its member delegations by exploring opportunities for new or enhanced international co-operation in selected scientific areas; by defining international frameworks for national or regional science policy decisions; and by addressing the scientific dimensions of issues of social concern.

The Global Science Forum meets twice each year at OECD headquarters in Paris. At these meetings, selected subsidiary activities are reviewed and approved, based on proposals from national governments. The activities may take the form of studies, working groups, task forces, and workshops. The normal duration of an activity is one or two years, and a public policy-level report is always issued. The Forum's reports are available at www.oecd.org/sti/gsf.

3. The Varieties of Misconduct, and its Consequences

A wide range of (mis)behaviours by scientists can be labelled "misconduct". Clarity and consistency in defining misconduct are prerequisites to establishing or evaluating an administrative system for processing misconduct allegations, and for understanding the underlying causes and effective remedies. A variety of administrative mechanisms and modalities (including prevention and investigation/enforcement) may be needed to deal correctly with the diversity of inappropriate behaviours. In particular, it is important to identify instances of misconduct that can be remediated via education, or that merit a full investigation, including procedures for establishing innocence or guilt.

¹ The report of the conference rapporteur, Dr. Peter Tindemans, can be found at www.esf.org/conferences/researchintegrity

During the course of preparing the OECD workshop, interviews with experts revealed a broad spectrum of types of misconduct by scientists, as shown in the following table²:

Core "Research Misconduct"	Research practice misconduct	
Fabrication of data	Using inappropriate (e.g., harmful or	
Falsification of data	dangerous) research methods	
Plagiarism	Poor research design	
FFP normally includes:	Experimental, analytical, computational errors	
Selectively excluding data from analysis	Violation of human subject protocols	
Misinterpreting data to obtain desired results (including inappropriate use of statistical methods)	Abuse of laboratory animals	
Doctoring images in publications		
Producing false data or results under pressure from a sponsor		
Data-related misconduct	Publication-related misconduct	
Not preserving primary data	Claiming undeserved authorship	
Bad data management, storage	Denying authorship to contributors	
Withholding data from the scientific community	Artificially proliferating publications ("salami-slicing")	
NB: The above applies to physical research materials as well	Failure to correct the publication record	
Personal misconduct	Financial, and other misconduct	
Inappropriate personal behaviour, harassment	Peer review abuse e.g., non-disclosure of	
Inadequate leadership, mentoring, counselling of students	conflict of interest, unfairly holding up a rival's publication	
ensitivity to social or cultural norms	Misrepresenting credentials or publication record	
	Misuse of research funds for unauthorised purchases or for personal gain	
	Making an unsubstantiated or malicious misconduct allegation	

At the core of the spectrum of inappropriate behaviours is "Research Misconduct", consisting of Fabrication, Falsification and Plagiarism (FFP). Various definitions of these terms are possible. For example, the United States government defines research misconduct in a way that has been adopted in some other countries³:

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

Fabrication is making up results and recording or reporting them.

² The chosen classification scheme is not intended to be exhaustive, or to constitute a universally valid intellectual framework for theoretical studies of research misconduct. In this report, it is presented merely as a way to summarise the information distilled from the expert interviews.

³ The definition given above is not unique. It can, for example, be broadened to include "... significant departure from accepted practices of the scientific community". Alternative broad formulations can be used, such as "Behaviour by a researcher, intentional or not, that falls short of good ethical and scientific standards". The latter text has been adopted by the Committee on Publication Ethics.

Falsification is manipulating research, materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit, including those obtained through confidential review of others' research proposals and manuscripts.

Research misconduct does not include honest error or honest differences of opinions.

There is general agreement that credible allegations of research misconduct (FFP) should be investigated, and that corrective actions should be undertaken if the investigation makes a positive finding. The same applies to financial misconduct, and harassment, which are in the province of accounting and administrative departments in research institutions and appropriate government agencies. At the other end of the spectrum are such phenomena as inadequate mentoring of students, or incompetence in performing research. For these, the internal mechanisms of the scientific community can, in most cases, provide effective remedies, without the need for formal investigative actions. But there are also intermediate categories of misconduct where science administrations may need to be involved. The establishment of an optimal mapping between the offence and the method/venue for dealing with it is difficult. It is complicated by the importance of determining whether an inappropriate action was deliberate, i.e., of establishing intent. This is notoriously difficult to do in any investigation. For example, if the validity of published results is questioned, the subsequent inability of the researcher to provide primary data may be the result of a genuine mistake or accident, but it could also be considered as *prima facie* proof of serious misconduct if it can be established that it was done deliberately to conceal an act of FFP.

Misconduct in research damages science, but its consequences also extend into the broader societal sphere. The following general areas where negative impact occurs were identified in the run-up to, and during, the OECD workshop:

- Harm to individuals and to society, if fraudulent research results in the release of an unsafe product or process (e.g., a drug or a therapy). Society may be harmed if false results become widely known and believed. The formal responsibility for protecting the public lies mostly outside the research administration system, and is assured by a well-developed structure of national laws, regulations, and institutions (e.g., the drug approval process). Even so, research administrations must assume responsibility for not burdening the regulatory process.
- Direct damage to science itself, by creating false leads for other scientists to follow, and/or forcing others to waste time, effort and money to reproduce fraudulent results. Fortunately, the research record is inherently self-correcting, since repeatability, verifiability and consistency are hallmarks of the scientific method. However, incorrect results can persist and mislead for extended periods of time.
- The degradation of relations among scientists, between senior researchers and students, and between researchers and agency programme managers.
- Damage to science through the undermining of the public's trust in science, and of the government's ability to foster and promote research in a competent and responsible manner. A possible consequence is a decline in the credibility of scientific analysis and advice on issues that have important implications for society. These issues (in such areas as health, environment, energy, national security) often have a major scientific component, and science-based laws and regulations may be needed to address them.

Conclusion A:

Instances of misconduct in research are regrettable, but real, occurrences within the scientific enterprise. Scientists, like all professionals, are subject to pressures and temptations, and they are no more nor less likely than others to behave badly. The prevalence of misconduct is difficult to measure but, when it occurs, the damage to science, and to the way it is perceived and utilised, can be severe.

Misconduct by scientists can take many forms, each affecting differently the stakeholders, such as researchers, institutions, government agencies, publishers, and the public. A well-designed strategy for promoting integrity should take this diversity into account by identifying the most appropriate methods and venues for dealing with each category of misconduct. As in other instances where society confronts individual wrongdoing, an optimal response contains elements of both prevention and enforcement. However, it is always better to prevent bad behaviour than to be forced to deal with its consequences. Accordingly, an optimal strategy consists of actively promoting integrity and deterring misconduct within all of the components of the scientific enterprise: universities and other research institutions, funding agencies, professional organizations (unions, academies, etc.), the publishing establishment, and in fora where scientists and the public interact.

4. Options for Dealing with Research Misconduct Allegations

Sections 4-7 of this report concern the practical, administrative aspects of dealing with misconduct allegations. The focus is on underlying principles and actionable procedures. It is worth repeating that no attempt is being made to devise a universal prescription for a system that all governments should put in place. Rather, the enumeration and analysis of the selected topics are meant to constitute a kind of "checklist" of issues that should be given consideration when creating or fine-tuning a system of national or local principles, rules, and procedures.

Given the inter-governmental status of the OECD Global Science Forum, this material is presented primarily for consideration by responsible public officials. Their role is a special one, and it is sometimes underappreciated. There is a body of opinion claiming that all matters pertaining to integrity should be handled exclusively within the scientific community, and in the context of the corresponding institutional frameworks (for example, academic departments at universities). However, government officials have certain responsibilities that they cannot delegate:

- They are formally accountable for the proper spending of public funds. In particular, they manage the granting process (including reviews of applications and monitoring of progress) which cannot function properly if it becomes compromised by dishonesty. As described further in Section 8, the granting procedures that agencies establish may have an effect on the prevalence of certain forms of misconduct (i.e., they can have a corrupting effect on susceptible individuals).
- They are responsible for public safety, which can be compromised by the consequences of misconduct in research.
- They fund (and are otherwise involved with) the education and training of researchers activities that are vital for promoting integrity and preventing misconduct.
- On a practical level, they are sometimes the only agents who have the means to conduct especially complex or difficult investigations, or ones that transcend national borders.

Based on the information gathered during the preparations for the Tokyo workshop, and at the workshop itself, it appears that dealing with misconduct in research is a shared responsibility of public officials, scientists and institutional administrators. The division of roles differs from country to country but, in general, three generic ways of handling misconduct cases can be identified:

- a) Ad-hoc committees established to deal with specific cases. Such committees are often composed of prestigious individuals, possibly under the aegis of existing university-based ethics committees. The advantage of this approach is that ethics committees already exist at many institutions, although they are often associated chiefly with the life/medical sciences, and handle matters relating to human experimental subjects and patients. While the work of these bodies is vital, it cannot be assumed that they can handle all cases of misconduct in research. Ethical issues (i.e., questions of right and wrong and fairness) underlie the very concept of misconduct, but the practical adjudication of concrete cases revolves more around the determination of facts and the careful analysis of events, documents and other data records. This, in turn, can be difficult to do without specialised expertise, as well as special-purpose rules, regulations and precedents. All adhoc processes suffer, to some extent, from a deficit of consistency, since the functioning of each individual committee depends critically on its makeup, i.e., on the preferences, opinions and experiences of its members. For misconduct investigations, fairness and consistency are critical attributes, which can be difficult to ensure in an ad-hoc process. Extending the mandate of ethics committees to handling cases of misconduct in research should be accompanied by careful analysis and, if needed, modifications of existing rules and procedures.
- b) Standing committees in research institutions. Some countries rely on standing entities (offices, officers, committees) and corresponding procedures, at the level of the institution (e.g., university, large laboratory) where the misconduct occurs. These can be responsible for receiving allegations, processing them (including conducting investigations), and recommending outcomes. Typically, these entities are not entirely autonomous: there is a measure of interaction with a government-mandated central national authority, for example, a funding agency. A system of this kind generally benefits from good acceptance by scientists, who prefer to put their trust in local arrangements that operate under terms and conditions that they can observe and understand. Acceptance by the community is a vital attribute of any misconduct-processing system. Scientists are understandably protective of their reputations and careers, which can be seriously damaged by allegations, or even mere rumours, of misconduct.

A purely local arrangement ensures consistency of procedures throughout a given organisation (for instance, a large university) but does not necessarily do so at the national level – a source of potential problems when allegations of misconduct involve more than one institution. The cost, workload and administrative overheads of maintaining standing bodies must also be considered. Furthermore, there may be an inherent conflict of interest that could lead to the unjustified suppression of cases, based on a desire to avoid unfavourable publicity for the local institution.

c) One or more dedicated committee(s) at the national level. This variant may be preferred by countries whose scientific communities are small, and where it may be difficult to establish committees of impartial scientists, free of personal conflicts of interest. Members of permanent national committees can be selected so as to represent a wide spectrum of relevant expertise (for example, detailed legal experience), drawing on extensive human resources. A national committee can establish a consistent track record of cases, and there are benefits from having a stable support staff, consistent long-term relations with funding agencies, and independence from the vagaries of changing national governments. A committee of this kind can play a major role in reviewing and fine-tuning its own procedures, in advising the government on misconduct-related policies, in maintaining a permanent record of misconduct-related information, and in coordinating with similar committees in other countries.

Countries that put in place formal procedures for dealing with misconduct allegations usually establish an <u>Inquiry</u> process, in which the allegations are received and evaluated, as well as an <u>Investigation</u> process which becomes activated if the Inquiry determines that this is appropriate. The two processes are dealt with in more detail in Sections 5 and 6 respectively.

Based on informal evidence presented at the OECD workshop, it may be the case that countries relying on ad-hoc committees generally report few cases of misconduct, and that the countries that have made a transition to more structured arrangements find that the number of cases increases. Such a transition can thus be difficult, since the public may incorrectly perceive an increase in dishonesty among scientists.

Regardless of the details of the system that is adopted in any country, the following *desiderata* were identified at the OECD workshop:

- To the extent possible, a uniform system should be adopted in each country. The question of international harmonisation of definitions, standards, and procedures deserves further study, given the growth in international collaborative research, and the increasing mobility of scientists.
- The pertinent principles, rules, and procedures should be clearly defined and well publicised. They should include the definitions of misconduct, and the steps for receiving and processing allegations. This promotes fairness (in both perception and reality) and ensures that the process will not be seen as arbitrary or deliberately targeted against any individual.
- Any system must be (and be seen as) scrupulously fair. A good way to ensure this is to distribute responsibility for the phases of the overall process (initial inquiry, investigation, adjudication, appeal) among the components of the system. Thus, for example, the entity (person or group of persons) that is responsible for the initial evaluation of an allegation (such as an ombudsman's office) would not be the same as the entity that decides on corrective measures or that considers an appeal. The feasibility of such an arrangement of "checks and balances" depends on local/national circumstances. Where it is implemented, it appears to work best when the entities are administratively independent of one another.
- The adopted system should only be as extensive as necessary to ensure the integrity of the research process. Understandably, some scientists worry that authorities may, inadvertently, set up oversight and reporting systems that are bureaucratic, unnecessarily burdensome, intrusive, or unfair. Others worry that the traditional openness and freedom of the research process could be jeopardised by excessive scrutiny and regulation. These legitimate concerns must be taken into account, and a special effort made to demonstrate the advantages of dealing with misconduct allegations in a confidential, fair and efficient manner. Monitoring and periodic evaluation are useful for ensuring that the system does not become too cumbersome or oppressive.
- The relationship to the national legal system must be defined and understood, considering that most of the misconduct-related procedures will take place at the administrative level. But there may be conditions under which reporting to legal authorities (i.e., regulatory, civil or criminal) may be necessary, provided that this is carried out in a systematic, consistent way. In such cases, care must be taken to ensure that the two processes interact constructively, with due recognition for national laws, administrative structures, traditions, and other circumstances.
- Even if the "local" system is adopted ("b" above), some overarching national governmental structure can be considered. At a minimum, its roles could be to provide a venue for consultations, evaluation, appeal, settling inter-organisational disputes, interfacing with authorities in other countries, or even taking over an investigation if the home institution is too small or otherwise can't do it. In addition, the local body can play an active role in preventing misconduct, e.g., setting standards for education and training of students and staff.
- There ought to be agreed-upon standards of performance, and periodic evaluation, as well as a mechanism for modifying the system based on the assessment results.

Conclusion B:

There is no universal optimal system for dealing with misconduct in research. Administrations are free to design and implement the system that meets their needs and is consistent with the way research is managed in a given country or institution, and is compatible with local laws and traditions. Nonetheless, interested administrations are encouraged to implement such a system and to publicise it in the relevant communities. Wideranging consultations with principal stakeholders are desirable: with researchers, funding agencies, scientific publishers, representatives of the public. Sections 4-7 of this report can serve as an unofficial "checklist" of issues to be considered and questions to be answered.

5. Responding to Misconduct Allegations

Misconduct allegations most often arise in a spontaneous, unsolicited way; for example, when a graduate student (or other collaborator of the accused scientist) suspects that data have been fabricated. A researcher in the same domain may become suspicious when unable to reproduce a measurement, or evidence may emerge from a computerised search for plagiarised text, or evidence may be discovered by potential employers during verification of claims made in a CV. All too often, the potential accuser has no idea where to turn with the suspicions, and such uncertainty can be a powerful disincentive to taking action. Those seeking to create, review, or modify a system for dealing with misconduct would benefit from seeking answers to the following questions regarding the all-important "first link in the investigative chain":

- Who is the first person/organisation to turn to with an allegation or suspicion? Is there a special office/officer located near the same venue as the person who suspects misconduct? If so, does the person receiving the allegation have special expertise or training?
- Is the receiving office/officer someone whose elevated standing (e.g., dean of an academic faculty, high-level official of a science ministry) could discourage a student or other person who is in the lower ranks of the hierarchy? Does the allegation have to be presented to a person who has authority over the accuser (for example, a departmental chairperson vis-à-vis a graduate student)?
- Is adequate information available to the potential accuser? Is there generally accessible information on a web site, for instance, or via an anonymous hotline? Is there someone to consult when merely a suspicion exists, without certainty or definitive evidence?
- Are there requirements/restrictions on who can be accused (and be an accuser)? Can anyone come forward with an allegation? Are there restrictions on substance (for example, work outside one's academic field, work not published in a peer-reviewed journal, "opinion"-type work)? Does suspect work need to be published, versus presented in a conference, or mentioned in a conversation?
- Are anonymous allegations accepted?
- Is there the equivalent of a "statute of limitations" for misconduct allegations?
- How does the system deal with frivolous or malicious accusations? Does bringing forward a false accusation itself constitute actionable misconduct?
- What is the receiving person's exact role and authority? Does he/she play a mediator role, or just decide the merits of the allegation?

Conclusion C:

Well-intentioned persons who have a legitimate suspicion that misconduct may have occurred should have access to local information and assistance. Recognising that suspicions of misconduct place both accused and accuser in vulnerable positions, the first administrative response should be characterised by sensitivity, confidentiality, objectivity, and fairness. Persons receiving a suspicion or allegation should have the appropriate competence, training and mandate (including links to higher-level authorities, should they be needed). If possible, these persons should have the authority to resolve conflicts that do not merit a full investigative proceeding.

6. Investigating Misconduct

The rules and procedures for misconduct investigations should explicitly address the following issues and questions:

- For an ad-hoc local body, are there guidelines regarding such matters as:
 - The number of members and their affiliation (from inside/outside the institution where misconduct is alleged)
 - The areas of expertise that committee members need (including professional/judicial/procedural)
 - Avoidance of conflict of interest (and how conflict of interest is defined), including potential bias by local-level committees towards protecting the reputation of a home institution.
- How and under what authority does the investigatory body obtain the cooperation of the parties, especially those who are not themselves accused? Can they compel collaborators to provide data or testimony? What if they need cooperation from outside the institution? Does lack of cooperation with an investigation itself constitute misconduct?
- In cases involving collaboration among scientists from two or more institutions, questions of jurisdiction naturally arise, since parallel duplicative investigations are undesirable. One possible practical solution is to assign the task to the institution providing the greater share of the research funds.
- Can an investigation be enlarged as new evidence is discovered? Can it be extended to other institutions? If so, should additional committees be established? Is there a time limit on investigations? What happens if the accused resigns, stops the work, etc.? What happens if regulatory or criminal violations are uncovered? Does the misconduct investigation continue in parallel with other processes that may be triggered?
- Are there limits on the power/authority of the investigators? How much new work can they require (for example, repeating an entire series of experiments)?
- What is the source of funds for conducting an investigation? Do funding agencies provide any support?
- Questions of <u>fairness</u> are particularly important when dealing with misconduct, because the investigation process is a quasi-legal one; that is, it has many of the attributes of criminal or civil procedures, but is reduced in complexity and is meant to function more quickly. Moreover, the penalties can be severe, amounting to the destruction of a scientist's reputation and career. Precise definitions, policies and procedures for misconduct investigations are needed to prevent the perception (or, worse, the reality) of a "witch hunt", i.e., a process whose rules are contrived to persecute an individual, based on personal conflicts, or the unpopularity of a particular line of

research. At the OECD workshop, attention was called to the undesirability of labelling as "misconduct" the pursuit of research that is merely outside of the mainstream scientific consensus – a hazard that could be linked to overly-broad definitions of misconduct. Accordingly, when constructing investigative procedures, answers can be sought to the following questions:

- What are the conditions and rules of <u>confidentiality</u> for accuser and accused? Can "whistleblowers" be given anonymity and protected from retaliation, without generating spurious/frivolous allegations?
- What is the <u>standard of proof</u> in a misconduct investigation (e.g., preponderance of evidence, proof beyond a reasonable doubt)? Is there a presumption of innocence? How can the validity of the proceedings be ensured, given that the investigators may be prominent scientists, but legal amateurs? What if the accused is doing "unpopular science" that draws the hostility of colleagues? In cases where intentional misconduct is hard to distinguish from unintentional carelessness in carrying out research, how do the investigators establish intent?
- O How can the accused defend him/herself? Does he/she have access to documents, testimony? Can the accused confront accusers and witnesses? Can the accused be assisted by a lawyer during the proceedings? Does the accused have a right to question the composition of the investigating body? Can one set of allegations give rise to more than one investigation ("double jeopardy")? In general, how do the rights of the accused compare to those in a criminal or civil proceeding?
- What are the rights of appeal and review (by accuser or accused) at each step of the investigation?
- Who is notified of the progress of the investigation, and when? How much detail is provided (e.g., to the funding agency)? Can the agency provide feedback, suggestions, information? Can it play a more active role during the investigation?
- What are the conditions of access by journalists and the public to the outcomes and records of investigations? When are names named (those of the accuser and accused, and/or other persons involved in the investigation)? If no finding of misconduct is made, can the exonerated scientist require that a formal exoneration be published? How do requests for information relate to "sunshine" or freedom-of-information-type laws? Is it feasible to institute restrictions on speaking to journalists (a "gag order") during the investigation?

• Concluding a misconduct investigation

- Can disciplinary measures begin during the investigation (e.g., suspension of the research, withholding of a grant)?
- o Is there a fixed set of possible "verdicts"? Is it a simple guilty/not guilty system, or are shadings possible? Is there a reasonable and consistently applied relationship between the seriousness of the misconduct and the severity of the imposed punishment? Does the investigating body just make findings, or can it also recommend corrective actions (including the punishment of guilty individuals, retraction of tainted publications, and other measures to protect science and the public interest)? Can action be taken with regard to persons who should have exercised better supervision, even if they have not actively committed misconduct?
- What specific steps can be taken to restore a damaged reputation, and to restore a project that may have been delayed or disrupted during an investigation?
- O Is there any provision for protecting "innocent bystanders", such as graduate students whose projects may be terminated even if their work had nothing to do with the misconduct committed by the principal investigator?

Conclusion D:

Misconduct investigations must themselves satisfy the highest levels of integrity and accuracy, given that they are administrative procedures, and thus are not characterised by all of the standards and protections of the legal system. Fairness and credibility are critical, since the reputations of scientists are easily damaged and difficult to restore. Corrective actions should be commensurate with the seriousness of the misconduct, should be consistently applied, and should be aimed at undoing the consequences of misconduct. A good way to ensure these characteristics is via a well-defined and time-tested set of definitions, principles, and administrative arrangements. The issues and options enumerated in Section 6 of this report are a reference for designing the details of an investigative process.

7. International Considerations

National and local administrators actively promote integrity in research, but their work is particularly difficult when allegations of misconduct concern projects that involve collaborators from two or more countries. The principles, definitions, rules, and procedures may differ, or be absent, in those countries. Questions of authority and jurisdiction arise when more than one entity could investigate the same case. In addition, there may be purely practical difficulties linked to obtaining needed testimony and data. A finding of the OECD Tokyo workshop is that misconduct in international collaborations represents an important challenge. Among the recommendations of the workshop is strengthening contacts among the responsible national officials, and establishing an international venue that would allow them to: (a) share information about national definitions, rules, and procedures for dealing with allegations of misconduct; (b) cooperate on actual investigations, when there is a need to share data, physical records, or access to personnel; (c) develop generic models of misconduct-related documents for international research agreements (contracts, memoranda of understanding, founding documents for international research facilities, etc.); (d) harmonise national arrangements for dealing with misconduct, while recognising the legitimate intrinsic differences between national systems.

Conclusion E:

Responding to misconduct allegations in international collaborative projects is especially challenging due to possibly incompatible definitions, standards and procedures in participating countries. There are also purely practical problems associated with conducting inquiries across national boundaries, for example, linguistic barriers, and the lack of familiarity with institutional arrangements and personnel. Since the internationalisation of research is on the rise, it makes sense for competent national administrations to increase their level of cooperation, in order to understand one another's requirements and constraints. Harmonisation and convergence on definitions and procedures is also desirable. Interested countries are encouraged to undertake an international dialog among national practitioners. Initially, this dialog could take place under the aegis of the OECD Global Science Forum.

8. Causes, Contributing Factors, and Prevention

An act of misconduct in research is an instance of moral failure, where an individual makes an intentional choice to behave badly. The detailed examination and causal explication of any such act is inherently difficult. Given identical circumstances, one scientist would commit misconduct, whereas a hundred others would not. It has been argued that seeking causes and explanations is pointless: bad people will behave badly, and good people will behave well. This line of argument is overly simplistic. A more reasonable hypothesis is that some individuals have a propensity (or susceptibility) to misbehaviour, which can be aggravated (and lead to concrete acts of misconduct) by external factors, such as the ones listed below.

Identification of contributing factors can be useful for devising remedies and preventative measures. It should be understood, however, that acknowledgement of external influences in no way implies that the behaviour should be tolerated or excused.

During the course of preparations, and at the OECD workshop itself, the following potential causes and contributing factors were cited⁴.

Factors relating primarily to individual researchers and their careers:

- Pressure of severe competition for funds.
- Requirements to achieve significant positive results (and to publish extensively) in order to obtain and secure a staff position in a research institution, or to receive favourable consideration for future funding of research.
- Lack of knowledge/preparation about the realities and stresses of a scientific career.
- Pressure to achieve a desired result in the case of sponsored applied research.
- Assorted personal failings (e.g., a craving for fame, a desire to hurt colleagues, a general lack of moral rectitude).

Factors relating primarily to the evolving nature of science and of the research enterprise:

- The negative aspects of fragmentation, isolation and specialisation. In some scientific domains, researchers work for long periods without adequate contact or interaction with colleagues who would be in a position to scrutinise and review their results. This can result in the proliferation of "lone wolf" researchers who may lose their grip on proper standards of conduct. But it can occur in large collaborations as well, if the project brings together individuals from vastly different scientific domains, and if collaborators do not adequately monitor one another's work.
- The proliferation of highly specialised, custom-built scientific instruments that can only be meaningfully operated by one researcher, thus making it difficult to independently verify that measurements are untainted or, in the event of controversy, to reproduce questionable measurements.
- The ready availability of complex, opaque software for statistical analysis and other manipulations (notably, image processing) that make it easier to commit and conceal falsification and fabrication.
- Lack of awareness of the rules and standards of proper scientific conduct, of the investigative processes that are in place, and of the penalties that can be imposed on those found guilty of misconduct. In some cases, individuals (especially students) may be truly unaware that certain behaviours (notably plagiarism) constitute misconduct.
- Misapplication of the mission-oriented research paradigm (where concrete, usable results are expected in the relatively short term) to the traditional curiosity-driven research process.
- Expectations and pressure from supervisors, sponsors or publishers for positive, unambiguous and significant results. In general, the prevalence of misconduct can be aggravated by an unsupportive or indifferent environment where integrity is ignored or downplayed.

In connection with the OECD workshop, a number of potential remedies were identified for lessening the prevalence of misconduct in research. These are listed below. There is a possible analogy to remedies that society uses to deal with criminality in general, in that there are two basic approaches that can be followed concurrently: (1) prevention; and (2) deterrence/enforcement. The first approach focuses on the underlying systemic factors that can push susceptible individuals over the threshold of violating established scientific norms. The second aims to exclude guilty individuals from the scientific community, thereby also deterring others by demonstrating the dire consequences of committing misconduct. Among specific steps that can be taken are the following:

⁴ As in Section 2 of this report (footnote 2), a *caveat* applies here, namely, that no attempt is made at presenting a complete and universally valid theoretical framework for understanding the causes of misconduct.

- Designing and implementing a formal system for addressing allegations of misconduct in research. The system should be tailored to local conditions and requirements, taking into account the issues and questions enumerated in Sections 4-7 of this report.
- Making the results of each investigation known in the scientific community, as a deterrent to similar occurrences⁵.
- Adopting definitions, standards, rules and codes of conduct. These can cover three areas: (1) good scientific practice (e.g., experimental design, laboratory safety, error analysis, data curation and access); (2) traditional ethics issues (e.g., rights of human subjects, handling of experimental animals, philosophical/moral aspects of research in human reproductive biology, defence-related research); and (3) misconduct as considered in this report.
- Promoting the internalisation of rules and standards via carefully designed and implemented educational measures. Curriculum design is a key issue, as is the question of when (at what stage of a scientific career) educational measures can be most effective.
- Incorporating instruction about responsible conduct of research in student curricula, and in the training of faculty, staff and technical personnel. Of particular value is instructing graduate students about the realities of scientific careers, including a realistic description of the pressures that can destabilise the lives of postdoctoral fellows and assistant professors.
- At the level of research institutions (e.g., university departments, large laboratories), actively fostering
 open and frank discussion of misconduct-related matters. Promoting collegiality and networking
 among colleagues to discourage isolation of the type that can harm susceptible individuals ("lone wolf"
 scientists) and to clarify collaborators' responsibilities within research collaborations. At the
 institutional level, rewarding those leaders who set an example by visibly adopting the standards of
 integrity in research.
- In hiring and promotion, rewarding quality of work rather than quantity of publications.
- To the extent possible, streamlining, rationalising, and simplifying the grant application and award system.
- In scientific publishing (and in grant applications) adopting clear, uniform standards for:
 - authorship criteria for papers, including obligations of co-authors
 - allowable types of image processing in published images
 - requirements for making primary and secondary data available to the general scientific community
 - conditions under which results will be published (i.e., with or without permission of the sponsor)
- Making use of computer-assisted tools (software) for detecting plagiarism in publications, proposals, reports, etc. Promoting the development of software for detecting fraud in images, data, figures, etc.

Conclusion F:

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Understanding the causes is useful for devising effective measures for preventing scientific misconduct, and for dealing with it when it occurs. A number of hypothetical causative factors are enumerated in this report, and, for each one, corresponding remedies can be devised. Of particular value are: educating young researchers, based on the existence of standards of conduct; fostering frank debate about misconduct at the institutional level; devising a credible and transparent system for dealing with misconduct allegations; publicising the results of completed investigations; streamlining and rationalising the process of hiring, promotion and grant review.

⁵ Privacy and confidentiality have to be respected when the results of investigations are publicly disclosed.

"Integrity in Research

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A Rationale for Community Action"

Expert Group meeting Brussels (BE), 22-23 March 2007

Final Report

Experts:

- ✓ Ms. Viara Barakova, Milray, BG
- ✓ Ms. Michelle Hadchouel, INSERM, FR
- ✓ Mr. Dirk de Hen, Secretary, Landelijk Orgaan Wetenschappelijke Integriteit (LOWI National Council on Research Integrity), NL
- ✓ Prof. Doutor João Lobo Antunes, President Portuguese National Council for Science, Technology and Innovation, PT
- ✓ Prof. Michael Farthing, Pro-Vice Chancellor for Medicine, University of London, UK
- ✓ Dr Andy Stainthorpe (Rapporteur), Head of the Research Integrity Office, UK

Disclaimer: Neither the European Commission nor any person acting on behalf of the Commission is responsible for the use which might be made of the following information. The views expressed in this report are the sole responsibility of the authors and do not necessarily reflect the views of the European Commission

A great deal of additional information on the European Union is available on the internet. It can be accessed through the Europa server (http://europa.eu.int).

"Integrity in Research – a Rationale for Community Action"

Expert Group meeting 22-23 March 2007

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I. Introduction

This paper outlines the issues considered by the expert group on Integrity in Research invited to provide guidance on the key issues, and a Rationale for Community Action. The subjects addressed in this document are the main areas, as seen by the Expert Group, where the Commission might act or where the Commission might lead or work to promote wider discussion. There are also some areas where the Commission might consider funding research within the RTD L3 or through other Directorates. Misconduct in research, in all its forms, is highly damaging and undermines public confidence in research and the use of research evidence in decision making in all fields. Public bodies leading policy for, and providing funding for research, have responsibility to ensure that they are investing in activities of the highest standards. The Commission should make a firmer commitment to ensuring that the research undertaken under its programmes is conducted with integrity. It should also seek to be informed that the work it funds is conducted to the highest standards and that any failures to meet those standards are investigated appropriately and the Commission informed of the outcome of those investigations. This work is relevant to all those Directorates General, which fund research.

II. Background

II. a) Definitions and Status Quo

National governments, the European Commission and a number of other bodies make large investments in research through national and international programmes. Much of this research is conducted in European universities and institutions as well as work co-sponsored with the private sector and with countries outside Europe. The European Commission has a responsibility to the European public to manage the funds assigned for research in a way that achieves the aims and objectives set out in the plans, allocating funding to accrue benefit to society. As an established funder of research, the Commission acting on behalf of the European Community and the Governments of member states has responsibility for oversight and management of a significant research budget. Commission policies and procedure are in place to achieve effective use of this funding, which should include standards in probity and integrity.

Europe has a reputation for high standards, timeliness and innovation in research. Member states and European organisations have a vested interest in protecting and where possible enhancing that image. It is perhaps not sufficient to believe that high standards in research are being applied in European institutes and universities but to demonstrate that this is the case through rigorous quality control and research audit. The Commission could contribute to international development and harmonisation of norms and standards. Towards the longer-term, the debate on standards might be initiated though the Social Accountability 8000 initiative (1).

Integrity in research concerns the standards by which research activities are performed. The New Oxford Dictionary defines integrity as *the quality of being honest and having strong moral principles*, alternatives are that, to have integrity is to be Steadfast in adherence to strict codes of conduct. For researchers this might be defined as the quality to conduct research worthy of the trust of others. Research integrity is a fundamental value for any and all research, for researchers and those who host or fund research activity.

There is a need to differentiate between the moral and the profession aspects of integrity in research. Although interrelated, for the purposes of differentiating matters handled under research integrity from those under research ethics, the distinction is helpful. Matters which require a researcher to be guided by moral principles could be argued fall within the domain of research ethics, those responses which can be defined within standards and codes as issue of research integrity. Defining integrity in terms of morals and virtue opens situations in which researchers might apply value judgements according to their moral principles, rather than resolve them by reference to standards and protocols (2).

II. b) Focus

Integrity in research can also be considered at a number of levels (individual, project, organisation, national) and controls and standards instituted to guide activities. In developing the rationale the Commission should explore the level at which it is most appropriate to provide direction in this area which is compatible with the principles of

subsidiarity. Consideration of the role and integrity at the systemic and institutional levels, including organizational, governance and legal issues has been explored in a number of disciplines (3). Promoting integrity in research at all level is of considerable importance and worthy of further discussion and research.

Although conduct in research can be defined in the most part by standards and rules, moral principles and ethical values cannot and should not be wholly removed or overlooked in such consideration. This work acknowledges the importance of these dimension to the way research is developed and conducted but does not attempt to explore or address these issues which are covered elsewhere (e.g. 4,5).

II c) National Mechanisms within Europe

Denmark

Three Committees on Scientific Dishonesty (DCSDs) investigate allegations of misconduct in research brought to their attention by a whistleblower with involvement in the case. The DCSDs have jurisdiction over those involved in public institutions and with respect to staff who have had academic training. The DSCDs are supported by a secretariat from the Danish Research Agency and have national responsibility. The Committees have legal standing with a High Court Judge as joint Chair.

France

France has no standing national body with responsibility to investigate or have oversight of allegations of misconduct in research. The Committee for scientific ethics or COMETS (COMité d'ÉThique pour les Sciences) acts in a consultative capacity including writing out 'recommendations about the definition, vindication and implementation of rules related to research deontology such as fraud, capture of scientific results, plagiarism and about the researcher's liability to CNRS and society. COMETS charter states it does not deal with individual situations, as those are the Director General's responsibility.

INSERM, has an Integrity Office with a Scientific Integrity Officer (*Délégué à l'Intégrité scientifique*) and nine regional mediators. The Integrity Officer requests the Director General to appoint an Investigation Committee that may include foreign experts. Conclusions reached by the Committee are passed to the Director General, who decides on the consequences. Universities have access to the same investigation and support services through INSERM.

Finland

Finland established a decentralized system to handle allegations of misconduct in research with the Finnish National Research Ethics Board handling appeals. The Committee published guidelines for the prevention, handling, and investigation of misconduct and fraud in scientific research. Although the composition and mandate of the Board are based on law, the effectiveness of the guidelines will depend on the voluntary commitment of the research community to comply with it.

Germany

The German Research Science Council (Deutsch Forschungsgemeinschaft DFG) set up an independent committee of scientific research ombudsmen. Universities have primary responsibility to investigate allegations and concerns in the conduct of research. DFG recommended universities and institutes appoint independent mediators who work to resolve situations of suspected misconduct in research. DFG also established a national Ombudsman service to advise and assist in questions of good conduct and on matters of misconduct. Receipt of public funding would be conditional upon adopting the mediator and ombudsman functions.

Netherlands

The Association of Universities in the Netherlands (VSNU), brought in the Code of Conduct for Scientific Practice from 2005. The Royal Netherlands Academy of Arts and Sciences (KNAW), together with the Association of Universities in the Netherlands and the National Research Council (NWO) issued a Memorandum of Scientific Integrity which all abide by. A National Committee on Scientific Integrity, which provides an advisory service to universities and the institutes of NWO and KNAW and has oversight of investigations, being able to require an institute to reinvestigate.

Portugal

The Portuguese Science and Technology Foundation, as the major agency for public funding and evaluation of R&D activities in Portugal, has clear rules against fraud and misconduct and utilises peer evaluation to assess individual grants, projects and institutions. Policy measures taken to foster research integrity in Portugal have been associated with strengthening scientific institutions and fostering their internationalization. The FCT (Science and Technology Foundation - Fundação para a Ciência e a Tecnologia) have established Associate Laboratories with consortia of research centres through long-term contracts.

Sweden

The Swedish Research Council's working group on misconduct in research investigates suspected irregularities in research at the request of universities and colleges. The judgment is limited to scientific issues only and it does not rule on other areas of misconduct, which remains the role of the University or Institute.

UK

The UK has set up the UK Panel for Research Integrity in Health and Biomedical Sciences. The Panel has an advisory role providing advice and guidance in the investigation of allegations in UK universities and institutions. It also provides advice and guidance to those raining concerns about the conduct of research. Although it does not have investigatory powers it can maintain oversight of investigations by agreement.

Table 1 Summary of National systems for the investigation of Misconduct in research

Country	National Office	Type of role	Limitations	Linkage to research funding
Denmark	Committees on Scientific Dishonesty (DCSDs)	Investigatory	All public sector institutes and universities and academic staff	National legal jurisdiction
France	No standing National office (Ad-hoc arrangements through INSERM and COMETS	Advisory and investigatory	Investigatory in cases of public funding	State control of institutions
Finland	Finnish National Research Ethics Board	Advisory and appeals	Universities voluntary	Voluntary sign up
Germany	DFG Ombudsman service DAAD role?	Advisory and investigatory	Investigatory in DFG funding	State funding conditional upon accepting
Netherlands	National Committee on Scientific Integrity	Advisory and oversight of investigations	All Universities and Institutes of NWO and KNAW voluntary	Agreement to work with the NCSI
Portugal	No standing National office	N/A	N/A	N/A
Sweden	Swedish Research Council's working group on misconduct in research	Advisory and investigatory on scientific issues	Universities voluntary	Agreement to work with the SRC
UK	UK Panel for Research Integrity in Health and Biomedical Sciences	Advisory	Advisory	No current linkage to funding

National independent organisations and academies with a commitment to the promotion of standards in research, particularly in scientific arenas such as European Federation of National Academies of Sciences and Humanities A C Stainthorpe - *Rapporteur for the EC Expert Group on Research Integrity*, Final version – 06 September 07

Alliance (ALLEA) and other international research organisations, such as the European Molecular Biology Organization (EMBO), might take part in the dialogue toward the promotion of integrity in research. The process might also engage with the professional regulatory bodies of member states, where appropriate.

II d) Links to other Commission activities

The Bologna Declaration recognised the central role universities played in developing European cultural dimensions and in particular promoting the concept of a Europe of Knowledge. The Bologna principles include statements on the promotion of European cooperation in quality assurance and the development of comparable criteria and methodologies. It recognises also that research is a component of the education process.

The Lisbon Council objective is for the European Community, and the European Research Area, to become the most competitive and dynamic knowledge economy in the world by 2010. These aims will be aided by demonstrating that the European Research Area operates to the highest standards of integrity. Promoting the integrity of research which takes place in European universities and institutes should be a fundamental component of the process of strengthening the European research education base.

This process will strengthen the competitiveness of European universities through the guarantee of quality and integrity of the data and outputs generated. Europe is facing considerable competitive pressures from the developing educational and research giants of Asia, China and India. The strength of European research lies in high standards of integrity and rigour, and in the well-established mechanisms and principles that go to the core of academic activity. European research should capitalise on these strengths. A mechanism of quality standards might be adopted to indicate that an institute supports the Commissions ideals. The European Commission might endorse such standards and promote *European Research Integrity*.

This would also enable Europe to provide world leadership in standards for integrity in research and promote European institutes as centres which can lead international programmes and take on commercial research contracts to exacting standards.

Mobility of researchers will be assisted through the adoption of universal standards for integrity in research, with researchers across the European Research Area all operating to the same basic standards and having a common expectation of leadership and for reporting concerns. The promotion of research integrity should facilitate discussion of harmonisation in research leadership and management issues and professional development across member states, which should have a positive impact on mobility.

The rationale should also guide the principles of the European Research Council (ERC).

II e) The Role of the Research Host (institutes/universities)

There is considerable diversity amongst member states with respect to the agency responsible to promote integrity in research and for the investigation of misconduct in research. In many member states this is the institutions/employers role. Some member states have national offices with responsibilities to investigate Other states have national offices with responsibility for the funding arising from a particular government department or agency. Other member states have national advisory bodies. There are member states without national bodies for research integrity. In most member states the institute or employer has responsibility to investigate and apply sanctions to those employees against whom allegations of misconduct or concerns about behaviour are upheld. Employer sanctions are typically those of the disciplinary procedure. In most member states institutes/universities (employers), are answerable to some grant awarding bodies and in other respects self-regulate. In many respects there are relatively few mechanisms to address corporate, condoned or concealed misconduct Most national bodies with responsibility for research integrity work with within institutes/universities. institutes/universities through cooperation and are not regulatory and have little influence in terms of sanctions to apply. National funding bodies liaise with institutes/universities and exercise varying degrees of involvement in and responsibility for investigations. They can impose sanctions on institutes/universities (typically for noncompliance with standards) and on individuals (for misconduct).

The Commission might promote discussion of standards and codes used by Institutions with a view to promoting best practice and harmonising requirements for funders and any national bodies involved in promoting research.

II f) Misconduct in Research

Misconduct in Research takes many forms and damages the whole research community, is a misuse of public funds, and undermines the trust of the public and decision makers in research results as a basis for policy. Research has a very prominent profile and advances through research are often central to economic competitiveness, health, national security, and environmental protection.

Member states are strongly motivated and determined to eliminate misconduct in research in their national programmes and to cooperate with international agencies and bodies to ensure the highest possible integrity in research.

The European Commission as an international body sponsoring a programme of research of €0.521 billion (FP7 – 2007-2013) (6) has a responsibility to ensure that the:

- Research funds it manages on behalf of member states is conducted to the highest standards of integrity
- Commission sets high standards and principles which members states can share and emulate.

Misconduct in research is not, as is sometimes said, a victimless crime. The belief that, through repetition by other researchers, falsified or incomplete data will be revealed may be misplaced. Repeat studies may not be conducted and may not have the power to overturn published data based on manipulated or fraudulent practice. In reality misconduct in research has many victims, including:

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

Research has suggested that misconduct in research may occur at level of between 0.1 to 0.3%, (2) which is not rare and may be increasing, although there is little hard evidence for this figure, and it might reflect a greater willingness to report its occurrence. Although this rate of occurrence might appear small it is considerable impact in national, European and global terms. Misconduct occurs at between 1:1000 to 1:333, which by most definitions would not be considered rare. The European workforce of (EU-25) 1.2 million Full Time Equivalents (2004) (7) then at the lower level or 0.1% of researchers in Europe involved in misconduct this could mean 1200 researchers with a track record of misconduct across the EU25 states. This is not rare, but a level of occurrence which would require action in most circumstances.

II g) Research Integrity and Misconduct in Research

Misconduct in research is not new. It comes in many forms, is pernicious and invariably destructive. Definitions of the main forms of misconduct usually feature: falsification, fabrication and plagiarism, with a range of other forms of misconduct often summarised under the title of questionable research practice.

Plagiarism; the unauthorized use or close imitation of the language and thoughts of another author and the representation of them as one's own original work, is a common form of misconduct in research.

Example - Galileo Galilei reportedly claimed the work of others to be his own in the design of telescopes and the discovery of spots on the surface of the sun.

Falsification: manipulation of research data and processes or omitting critical data or results

Example – It has been suggested that Gregor Mendel, the Augustinian priest and scientist often referred to as the "father of modern genetics", manipulated his data to give ratios with less variation than he might have observed. The prominent statistician Fisher, analyzed Mendel's data and found the ratio in the F1 (first filial) generation to be implausibly close to the exact ratio of 3 to 1. It is perhaps hard to accuse Mendel of misconduct, as it is possible to

reproduce his experiments and demonstrate the accuracy of his hypothesis. It may be more appropriate to term this as an example of confirmation bias.

Fabrication: the act of intentionally falsifying research results and recording and reporting them in a journal article, in some jurisdictions, fabrication may be illegal.

Example – A more recent case; Jon Subdø, consultant oncologist and medical researcher at The Radium Hospital in Oslo published an article in the Lancet, which suggested that non-COX2-NSAIDs, like ibuprofen, reduced the risk of oral cancer in smokers. However, it turned out that the whole patient material was fictional with 250 of the invented patients having had the same birthday.

There is a wide range of other forms of misconduct in research, which are often summarised as Questionable Research Practice (2). It has been suggested that QRP might be considered as "less serious" but as QRP has a higher frequency (8) the impact on the research record might be of greater significance.

The Commission may choose to adopt a zero-tolerance of misconduct in research and require evidence that all those in receipt of public funds through Commission Research programmes are committed to adherence to national codes of practice for research and such international codes as might apply.

III Issues and Potential Way Forward

III a) Codes of Practice for Research

The Commission may wish to consider work to establish the principles that recipients of Commission funding should abide by. Minimal expectations would be the national standards in place in member states and recipient countries. The Commission may wish to specify some basic principles for those countries that do not have standards in place. The Commission may wish to work with member states to review the standards in place in member states and other states participating in Commission programmes.

The Commission could raise its profile in promoting integrity in research. It could build on existing work (European Charter for Researchers) to ensure that the issue of integrity features in all the Commission procedures including:

- the development of policy for research and research education
- the development of the research programme priorities
- the review of funding applications
- review of reports and outputs.

The Commission might take a leading role in the development of standards across Europe and bring together the lead offices in member states to promote debate of:

- the definitions of misconduct in research
- principles around the conduct of research
- standards for the conduct of research and for the investigation of misconduct
- the options for sharing information on case outcomes and those subject to sanctions
- the issues that arise in trans-national research projects

This would recognise that adoption of standards by universities and institutes is voluntary; as they are independent bodies the Commission may make recommendations and promote the adoption, development and harmonisation of standards, as a funding body it can set minimum standards for eligibility.

Such a Code of Practice for Research and other standards for the effective conduct and management of research should set standards for leadership and management of research. Standards for effective management might make reference to maximum student and researcher numbers under the management of a research leader. Loss of contact with a supervisor is a frequent factor in poor performance and misconduct. It could also make specific mention of minimum standards for those considered to be in positions susceptible to pressure (such as on commercially

sponsored projects?). It could also consider some more specific markers for the approach to mentoring (what might be expected – this might have to be a national annex).

In developing the Code it should be clear which components are the responsibilities of the institution and which are the responsibility of the individual.

III b) Codes of Practice and Trans-national Research

Variations in codes and standards in countries engaged in International research projects raise a wide range of issues including:

- Different standards and definitions what might constitute misconduct in one country might be acceptable in another
- Primacy in investigations which country or organisation should take the lead
- Role of the funding body
- Role of the National body
- Potential for a trans-national (European) body holding misconduct data

The might be potential for the Commission to take a leading role in the exploration of trans-national issues and the harmonisation of standards across Europe through the coordination of offices in member states as in III a above.

III c) Standards and Harmonisation

At the same time, the Commission may wish to assist the work of bodies responsible for research standards, regulatory bodies and member states to investigate where it might be possible to identify common standards in research across member states. There are examples of international standards in the field of research including the Helsinki Declaration (9), and update, and the EC directive on the management of clinical trials in member states (2001/20/EC) (10). Such an approach might accommodate local cultural codes and traditions (which might equate to greater tolerance or flexibility), where these do not compromise the principles in the standards.

Standardisation across member states, and beyond, would prevent practices generally accepted as misconduct in the international arena having no consequences for a researcher within a member state. Discussions on harmonisation might also provide the mechanism for such anomalies to be addressed.

By the same token the standards applied in the European Research Area should be promoted in developing countries, particularly those participating in Commission programmes. There might be a requirement for developing countries to provide certain assurances to the Commission. The Commission might take a more proactive role and promote European input into the development of Global *norms and standards*, engaging and sponsoring (with other interested bodies) in a global debate, facilitating input from all research active countries, to explore the evolution of standards in research.

III d) Minimum Standards of Eligibility to Receive Commission Funding

The Commission might consider making it a condition of involvement in Commission programmes that recipient organisations commit to certain standards of integrity in research. This could include the conduct of the institution, the systems it applies to the management of research and the standards of leadership and integrity it expects of its researchers, including students. The relationship between institute and student in the member states is often different to that of its employees. There is scope for development of codes and principles on the work of students that the Commission might stimulate.

This should apply to all those wishing to take part in Commission-sponsored or Commission-endorsed research programmes. Private sector partners would be required to commit to the same standards. The dividing line between sharing data and the need to protect intellectual property arising from Commission research programmes would need to be addressed in agreements between parties. This might be an area for wider discussion across member states.

In promoting a structured approach to professional development (as part of an institutional quality assurance mechanism), the Commission should ensure that this includes reinforcement of national and international standards in the conduct of research featured throughout.

Further work should be considered to review options for the harmonisation of certain legal variations and obstacles operating in different member states preventing closer cooperation in the field of research.

III e) Involvement of Member States

The Commission might wish to promote the proposal that all member states adopt a Code of Practice for Research (where this is not already in place). This should include the adoption of:

- a set of standards and principles for research (including reference to those established principles this could be a list)
- a robust programme of integrated education to emphasise responsibility and leadership in the promotion of good conduct and prevention of misconduct reinforced through continuing professional development
- a national mechanism for investigation of allegations of misconduct
- formal adoption of the national standards by institutes and universities
- involvement of appropriate professional bodies
- regular review and monitoring of progress in the field (could include data on the incidence of misconduct).

Failure of research institutions to adopt the national standards (within a certain period of time), should involve those institutions being subject to sanctions. The Commission should investigate options for the application of sanctions at the institutional, company and individual level. Sanctions many include exclusion from receipt of new funding for a period of time or restriction in the type of award for which applications can be made.

Problems may arise for large multi-centre projects should one institute be under sanctions which might prevent a worthwhile project proceeding. There might need to be contingency actions which enable the Commission to fund a specific project operating under a monitoring regime in a sanctioned organisation?

The introduction of such sanctions would require agreement with all members states for the adoption of standards and systems. Requirements may be phased in to member states, reflecting their ability to achieve compliance with the systems.

The Commission may choose to recommend that the management of decision-making and advisory committees and procedures abide by the principles and standards of research integrity and the Code of Practice. In so doing and in setting an example for the European Research Area the Commission might promote the adoption of such standards to the government committees and systems of member states. The UK has developed the Universal Ethical Code for Scientists which is promoted across government laboratories.

III f) Transparency and Access

The Commission should endorse transparency in research. The aim should be to make the processes of research, including the data collection and analysis, accessible to all. While the process of peer-review provides rigorous scrutiny of research in manuscript and application, transparency in research should provide readers access to:

- the complete data, its analysis and explanations
- details of the methodology and an explanation.

The goal is to make research accessible, understandable (to the non-expert), and facilitate replication.

Funders might increase the pressure for research data to be made available through open access. Journal editors could be invited to work within a set of research standards and principles, and move to serve the research record rather than secure high-profile publications in their journal.

III g) Security issues

Codes of Practice for Research should make reference to the Biological and Toxic Weapons Convention requirements and other aspects of bio-security and mechanisms to protect dual-use materials, equipment and knowledge.

III h) Intellectual Property

Codes of Practice for Research should also recognise the growing need to protect intellectual property from plagiarism, theft, copying and fraudulent use. This could present an interesting area for discussion. There could be linkage to transparency and the freedom to access data. In addition declaration of interests in an area of research which might conflict with other roles in this and other areas of activity could be explored.

III i) Peer Review

Although peer-review has a fundamental role to play in quality of research, the identification of misconduct in research is not the goal of the peer review process as it is currently practised during assessment of applications for publication or funding. Reviewers' primary role is not specifically to look for the fraudulent or the fabricated. It is therefore possible for reviewers to be misled by authors. Electronic systems exist that can aid the peer review process to identify misconduct (particularly plagiarism but also implausible raw data). Those who use peer review, such as research funders and journal editors, should reconsider the role of peer review in the detection of forms of misconduct. This could include an overt standard check for misconduct as part of the review process for funding or publication. The Commission could stimulate discussion and research in this field. Moreover the debate on the role of editors in publishing and oversight of the research might be encouraged.

III j) Measuring the Incidence of Misconduct in Research

As a funder of research the Commission should implement a requirement that the Commission Offices are informed of all projects where there is a *prima facie* case of misconduct. This should be introduced prospectively on all grants awarded after a certain date. The Commission should maintain information on those institutes where misconduct has occurred and on those individuals found to have committed misconduct. The Commission should make this information available to the Research Integrity Offices of member states and consider how this information is made available to the European public.

The Commission may also consider a retrospective survey of grants, enquiring of grant-holding organisations for details of any misconduct reports. This could include requests for details of allegations made, whether upheld, nature of any sanctions applied, issues faced in terms of international dimensions and impact on the project. A contemporary survey of recently completed awards could be conducted to explore whether project coordinators have received notice of concerns that they have not been able to act upon.

III k) Prevention

Emphasis should be placed on prevention through mechanisms to promote best practice and leadership. This should be reinforced through education and continuing professional development and an audit and inspection programme. The research culture should accept that rigour, inspection and review are part of quality assurance and assist credibility rather than challenging it. The aim would be to lead by example, placing emphasis and responsibility for promoting research integrity and adherence to its principles and standards on research leaders and the institute/university heads. A programme of research and debate could be encouraged to assess the best approaches in education and training to encourage integrity in research and prevent/eliminate misconduct.

III 1) Sanctions

The Commission might consider whether it is appropriate to apply sanctions. Sanctions could be applied to those individuals, organisations or nations that do not have meet standards set for receipt of funding from the Commission. Sanctions might take the form of restrictions on receipt of funding or participation in programmes or

making participation in programmes conditional upon enhanced monitoring regimes. The standards might apply for an individual could be the training levels (skills and experience) necessary to conduct a proposed piece of research. In the case organisation the requirement could be for a commitment to defined standards for research integrity, including:

- a mechanisms for the investigation of allegations of misconduct in research,
- a systems to promote a code of practice for research including regular formal training in agreed and or national standards
- a commitment to regular audit of research projects

At a national level there might be the expectation of a national commitment to promote certain standards for the management of research and the handling of allegations of misconduct in research.

The Commission might expect universities and other research organisations not to support applications for Commission funding from individuals proven to that have committed misconduct in research. The Commission might promote discussion of approaches that member states might adopt to promote good conduct in research and maintain public and confidence in research evidence.

III m) Protection Against False Allegations

Research reputations are very vulnerable. Accusations and the investigations of evidence that are not soundly based damage the standing and reputation of those involved to a considerable extent, particularly if they are in the media spotlight. The mechanism to investigate allegations and concerns needs to be sufficiently robust, objective, fair and sensitive to discern the *prima facie* from the mistaken, frivolous or malicious. Such a mechanism need to protect the confidential information of all the parties involved. The investigation system would be a component of the Code of Practice for Research. The Research Integrity Offices should share best practice of such systems through networking which should include the approaches used to protect against and handle false allegations, and deal with those who make wholly frivolous, malicious and vexatious allegations.

III n) Potential Initiatives

In supporting the harmonisation of principles, standards and systems for the promotion of good conduct in research, the Commission might consider liaison with national research integrity offices, which could extend to a network of European Research Integrity Offices (EuRIOs) similar to the Forum of NECs (link). This might extend to the Commission convening a conference or meeting of RI Offices in member states to address some of the more challenging issues, harmonisation of definitions, principles and systems, sharing best practice and consideration of some of the legal issues. A workshop on peer review might also be productive. In addition, the Commission might consider how to promote best practice in the developing world.

The Commission might review the potential to strengthen the audit of research performance of projects it funds. This could include individual interviews with those conducting the research, not just those leading the project. The proposal is to strengthen the research audit to the rigour of the fiscal audit.

The Commission might consider sponsoring a European Research into Research Integrity programme to address some of the issues raised above (including peer review, Conflict of Interest, transparency sanctions etc.), and others which might arise through the proposed workshops. The research programme could be run in conjunction with the national offices of member states. As much of the work would be based on survey or secondary data, the funding requirement would be low and it would facilitate cooperation and comparison of systems across member states and with other partners in Commission projects.

A further area for research could be into a study of the best approach for the support of education and training towards the full integration of research integrity within professional development and training programmes (graduate to retirement) and the appropriate use of research audit.

IV Recommendations

- 1) The Commission might consider initiatives to promote the widespread adoption of standards and definitions by eligible institutions in member states;
- 2) The Commission might consider making the adoption of agreed national standards a condition for eligibility to receive commission funding;
- 3) The Commission might consider promote the discussion of integrity in research at the level of public policy.

V References

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- 10) 2001/20/EC http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_121/l_12120010501en00340044.pdf

VI National Body Websites

Country	Websites
Denmark	http://fist.dk/site/english/councils-commissions-committees/the-danish-committees-on-scientific-dishonesty
France	http://www2.cnrs.fr/en/8.htm http://www.inserm.fr/en/inserm/organisation/comites/dis/index.html
Finland	http://www.tenk.fi/ENG/function.htm
Germany	http://www.dfg.de/en/dfg_profile/structure/statutory_bodies/ombudsman/index.html
Netherlands	http://www.knaw.nl/english/index.html
Portugal	http://www.fct.mctes.pt/
Sweden	http://www.vr.se/mainmenu/researchethics/organisation/theswedishresearchcouncilexpert
	grouponresearchmisconduct.4.ad4587110fa0c3e8ca80003546.html
UK	http://www.ukrio.org.uk/home/index.cfm

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