Universities UK

RESEARCH COUNCILS UK

Report of the UK Research Integrity Futures Working Group

Chair: Professor Dame Janet Finch

September 2010

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Contents:

NB: When reading this report, please note that where dates or recommendations appear out of date this is due to delays caused to the original publication date and the development of recommendations by the 2010 General Election and the period of purdah preceding the election.

1. Executive Summary and Recommendations

1.1 Executive summary

1.1.1 The Research Integrity Futures Working Group (the working group) was established in the spring of 2009 to consider:

- existing arrangements for research integrity in the UK;
- the terms of reference for any new arrangements for research integrity from 2010;
- the mechanics and governance arrangements of any function, including issues of independence and relationship to key stakeholders and sponsors;
- funding and resourcing required; and
- the look and feel of the service that would be required by employers, researchers and sponsors.

1.1.2 In addition to using the experience and expertise of group members, the working group commissioned a report from the science policy consultancy 'People Science and Policy' (PSP). The PSP report was used by the working group as a source of advice and information.

1.1.3 In defining research integrity, the working group used the UK Research Integrity Office and Research Councils UK definitions[1] as a basis for this report. These are reproduced at Annex VII.

1.1.4 The working group concluded that action is needed now in the UK because:

- innovative research-based industries are of major economic importance to the UK and, in the life sciences for example, research integrity sustains the reputation of the UK as a high quality research environment capable of complying with regulatory standards;
- developments in national systems across the world mean the UK risks losing its reputation as leading in this area;
- increasing concern that the pressures of modern research may conflict with requirements for research integrity mean that these requirements need to be continuously re-emphasised across the research community;
- universal principles of research integrity apply across the disciplines, but there has thus far been no systematic approach towards implementation across all research areas;
- major breaches of these principles at the international level have undermined public confidence in research;
- periodic concerns in the UK around high profile research issues which have undermined national confidence;

[1] Set out in the *UKRIO Procedure for the Investigation of Misconduct in Research*, 2008, and the *RCUK Policy and Code of Conduct on the Governance of Good Research Conduct*, 2009

- increasing international collaboration in research requires transparent systems, so that those from different research cultures can be reassured of the standards applying in each country;
- international research community concern in this area has been evidenced by the *OECD Practical Guide on Research Misconduct*, April 2009;
- current UK arrangements are sometimes portrayed as less than transparent, with examples of bad practice "swept under the carpet", and there is limited evidence to contradict that view;
- the imminent end of funding for the UK Research Integrity Office (UKRIO) creates a need to ensure that its work is maintained, promoted and extended to all disciplinary areas;
- the second World Conference on Research Integrity takes place in Singapore, July 2010 where the UK should demonstrate that it continues to lead on research integrity as it does on research excellence.

1.1.5 *The key role of employers of researchers*

While there is an urgent need for a clear and joined-up approach at national level, the working group agreed that the primary responsibility in the UK, as in most other countries, must remain with employers of researchers. This does not only mean universities, but also includes industry and health service trusts/employers as well as national research organisations and institutes.

Employers are responsible for ensuring that researchers are trained and managed to acceptable standards. They should also investigate any reported failures. Some groups of employers are members of registered professions. For them, the employer's responsibilities are supplemented by already established regulatory arrangements, such as those set by the General Medical Council (for further examples see Annex VI). The working group does not propose that these should be displaced or duplicated, since the high level of research activity in the health service clearly points to the need to retain these facilities, and align any new function with those arrangements. Also, key areas of science, such as research leading to the licensing of medicines, are already regulated by laws which name the authorities responsible for licensing, inspection and enforcement. However, despite the existence of bodies with interests in this area, including statutory regulators, UKRIO has, for instance, found it necessary to advise some of its enquirers on how to address their concerns in this area.

1.1.6 *A single advisory and support body*

The UK and its employers of researchers would benefit from a single body to provide guidance and advice across the many universal issues that are common to all research disciplines. This would be more efficient than current disparate approaches, and beneficial to organisations both in terms of management and representation. A clear repository for leadership, but not regulation, would also be more effective across the UK. This would not obviate the need for actions relevant only to certain disciplines, research designs or sectors.

Such a national body would not have powers of regulation or investigation powers into poor practice or misconduct, but should be there to provide advice and support to research employers and assurance to research funders. This would be achieved

through assistance with the promotion of training and good management systems, and providing expert advice where appropriate. A national body should, however, do this on behalf of all major research employers and with the active support of all research funders, to ensure consistency of approach and advice available.

1.1.7 *Building on the UK's strength*

The UK currently occupies a strong position in many fields of research and this must be maintained and built upon. The working group, however, considers that there are strengths and weaknesses with current arrangements in the UK. More data and information on the true position of research integrity in the UK is required.

A national body to succeed and build on the work of UKRIO should be responsible, in consultation with the relevant stakeholders, for ensuring the collection and analysis of data and empirical evidence about research integrity in the UK, taking account of developments in an increasingly competitive research environment. This should include data on the systems to manage research integrity, and on incidences of allegations and investigations of poor practice and misconduct.

1.1.8 The working group has considered carefully whether such a national body should also take on the role of light-touch review and benchmarking of employer systems, with feedback to individual employers on the robustness of their systems in relation to others. This could provide assistance to employers to help ensure that they have best possible systems in place, provide assurance to funders, and most importantly provide assurance to the wider public that good systems are in place and are independently reviewed. It might also obviate the need for individual funders to undertake separate and multiple audits in this area, which would be more onerous for research employers as well as for funders. There is at this stage nevertheless some concern that this might be seen to be too close to some form of regulatory work, and might undermine the role of the advisory and promotional work.

1.1.9 However, this proposal as intended would not in any way be a regulatory function. Any specific reports on a particular employer's systems would be for that employer only. The number of systems reviewed in any year would only be a limited sample - no more would be possible without a much higher and undue level of resources than currently proposed. A summary overview of the main findings from the reviews each year would provide wider assurance, primarily to the public, but also to funders, that independent review of systems was in place. It could also indicate areas where all employers might be able to learn from best practice or give attention to potential areas for development. If there were particular weaknesses or failings perceived in a system they would first be drawn to the attention of that employer for them to address.

1.1.10 It is recommended that such a role should be developed over the period currently proposed, but not as an immediate activity. The nature of this role will need to be carefully considered by the Board, in close consultation with relevant research employers. Initial reviews undertaken by say 2012 would be on a voluntary basis, and then allow further consideration about this role and approach after that. Overall this would help to strengthen the system of self-regulation which is seen as vitally important.

1.2 Recommendations

The Research Integrity Futures Working Group therefore recommends:

Recommendation 1:

From 2010[2] the UK should have a single body to lead on the common issues of research integrity across all disciplines, all types of research, and all research establishments. The body should seek to establish common core criteria and promote these in all areas.

Recommendation 2:

The body should have no direct regulatory or investigatory functions, but should have responsibility for:

- advice on regulatory and investigatory issues;
- the promotion and development of training in research integrity;
- the development of common standards and approaches;
- providing support to employers and researchers;
- liaison with professional and editorial associations and with similar research integrity bodies overseas;
- co-ordinating the collection and analysis of data, and coordinating research on the UK system;
- developing a system of light touch reviews of an annual sample of employer systems and their efficacy, benchmarking these against general and higher standards, with a summary report for funders and the wider public on the assurance about appropriate standards obtained from this; and
- representing the UK at an international level.

Recommendation 3:

The UK-wide body should support research employers by:

- communicating both the minimum acceptable and highest possible standards for ensuring research integrity;
- providing advice on what is reasonably required of all employers of researchers in all areas of research;
- clarifying what should be considered as malpractice, misconduct and poor practice;
- supporting employers so that they can identify and deal with cases of serious misconduct or criminal behaviour to be reported outside the immediate employer of the researcher(s).

[2] Since the time of writing, continuation funding until October 2010 has been made available to UKRIO.

Recommendation 4:

The UK body responsible for the promotion and development of research integrity should be a body which is clearly associated with UK research employers and is seen to operate independently of, but in collaboration with, research funders, regulators and other groups of stakeholders. It should not be so closely associated with the functions of research funders or others as to undermine its credibility as a provider of advice and support to research employers. Its Board should consist of suitably qualified and experienced people selected by its stakeholders. The Board should be accountable to stakeholders for the funding they provide and the work programme it undertakes, with sufficient resources to appoint staff and fund programmes as appropriate.

Recommendation 5:

For the immediate future, Research Councils UK and Universities UK working together should lead the establishment of a new body in succession to UKRIO on behalf of other funders and stakeholders. The interim arrangements, to be in place if at all possible by May 2010[3], should be in collaboration with other working group partners.

Recommendation 6:

The Office, in support of the Board, should consist of an Executive Director supported by a small secretariat. They would be funded to deliver the activities in recommendations 1, 2 and 3 above. We estimate that this will require an annual budget of up to £400,000. This will only need to be £250,000 in Year 1 (2010-11) as that will be a nine-month year[4], rising to £350,000 for a full year in Year 2, and £400,000 in Year 3, when all recommended functions should be in place. Requirements beyond that should be reviewed after Year 2. We recommend that the costs should be divided on a reasonably equal basis between four partner groups: Research Councils UK; the UK Higher Education Funding Councils; the UK Departments of Health; and the major non-public sector funders, with office accommodation and related services being provided by Universities UK. If further funding is required in due course to strengthen the work of the Board and its Office this might be sought from additional funders and stakeholders in the public sector and beyond.

Recommendation 7:

The proposed interim arrangements should be in place by May 2010[5] to ensure continuity from the work of UKRIO. If a short delay in that timescale is unavoidable then funding for UKRIO at its present levels, to maintain service, should be continued until the new body is established.

Recommendation 8:

The Board of the new function should, at an early stage, consider carefully issues surrounding how to deal with the confidential nature of information they may hold in relation to Freedom of Information requests.

[3] Since the time of writing, continuation funding until October 2010 has been made available to UKRIO.
[4] Ibid.
[5] Ibid.

Recommendation 9:

To reflect both continuity and change from the previous arrangements the new function should be called the Research Integrity Service.

2. Introduction and background

2.1 The Research Integrity Futures Working Group was established because of the increasing awareness of research integrity, in part occasioned by some recent high-profile cases of failure and the threat that any similar failures might pose to the UK's international reputation. While the likelihood of a major failure in the UK was considered low, its impact could be considerable. The UK's position as an excellent site for research investment and as a partner of choice is critically dependent upon our reputation for research excellence, which includes good governance by research employers. The membership and terms of reference of the working group are at Annexes I and II.

2.2 The UK Research Integrity Panel in the Health and Bio-Medical Sciences and the supporting UK Research Integrity Office (UKRIO) was established by a consortium of funders from across the four countries, including the Medical Research Council (MRC) and Biotechnology and Biological Sciences Research Council (BBSRC) (being the UK Research Councils operating in the bio-medical sciences area), Departments of Health, Universities UK and the UK Higher Education Funding Bodies. It was intended as a pilot in one sector for the provision of a service to a wider range of research employers. This pilot was due to end in 2009. The UK Panel oversaw the establishment in Universities UK of a UK Research Integrity Office. Half of the requests for advice from UKRIO now come from outside the health and bio-medical sciences. Advice was therefore needed on how the work of the panel and the office should be continued and developed.

2.3 Other research funders, including Research Councils UK (RCUK), also sought assurance about the management of research conduct and research integrity across all disciplines. To avoid duplication it was agreed to review the UK approach to research integrity in a coordinated way on behalf of all major stakeholders and funders.

2.4 More information about developments in the promotion and assurance of research integrity in the UK and internationally is set out in Annex IV.

3. Working procedures

3.1 *Meetings of the working group*

The working group met twice, in June and November 2009. The first meeting identified the key issues and commissioned a background report. The second reviewed the commissioned report and considered what recommendations to make.

3.2 *'People Science and Policy' report*

An independent review of some of the key issues was commissioned from the science policy consultancy partnership 'People Science and Policy' (PSP). They

also reviewed the evidence from earlier consultations carried out by UKRIO and RCUK, and sought evidence from a range of organisations and individuals. The report helped identify key issues to be addressed, and future options for taking forward the work previously developed by UKRIO, RCUK and other bodies, and informed the deliberations of the working group. The full report is available on the PSP website: http://www.peoplescienceandpolicy.com/

3.3 *Recommendations to sponsors*

Recommendations from the working group were agreed in broad outline at the second meeting. Further refinement leading to these approved recommendations was also developed in the drafting of the working group report. The working group is grateful to Dr Eve Jagusiewicz of UUK and Ms Chloë Somers of RCUK (and her predecessor Dr Riaz Bhunnoo) for their work in facilitating the meetings and report.

4. Strengths and weaknesses of the current UK position

4.1 *Increasing awareness of research integrity issues*

The development of activities supporting the management of good research conduct and research integrity in the UK has increased in recent years (see Annex IV). Many funders, learned societies, and employers have set out requirements for those they fund and for their professional members. However, currently it is very difficult to know how frequently issues arise where these requirements are not met. Anecdotal reports suggest about 1-2 formal allegations per research organisation over the last four-five years, with little evidence on less formal issues which may have been raised.

As the work of UKRIO has shown, concerns about research integrity are not confined to employers. Researchers, the press, and members of the public are taking an increasing interest in how research is conducted. As greater emphasis is placed on the use of research evidence by Government, policy makers, and other public bodies, this interest, and desire for reassurance, can only be expected to increase. 55% of all UKRIO's requests for assistance were submitted by individual researchers, and 15% by members of the public. Such a role must therefore form part of the remit of any new body, although further discussion about how best to address it, and the priority that it is given, will obviously have to be resolved at a future stage of the new body's establishment.

4.2 *Developments in postgraduate and post-doctoral training*

Developments in research training in the UK have included the implementation of the *Concordat to Support the Career Development of Researchers* (see http://www.researchconcordat.ac.uk/) and the provision of Roberts money to support generic and transferable skills training. UKRIO has worked with King's College London to develop related training in research integrity and has also provided input into other research organisations' programmes. Consortia of universities have sought to develop similar training, such as that provided by the company Epigeum in areas including ethics, publications, good practice and how to avoid plagiarism. The working group does not, however, know how widespread this

training is. Currently, what training exists is developing in an *ad hoc*, unstructured and inconsistent way as there are no national standards or expectations.

4.3 *Regulation across different research areas*

In some fields, such as health and social care, there has been considerable development in research governance, including research ethics and its management, which has permeated other areas. These developments, along with regulatory requirements in certain areas (see Annex VI), have reinforced awareness of the need for rigorous management. While this is most developed in health and social care, good research governance is essential in all fields and must be developed, and implemented, in ways appropriate to the field of study. For maximum coherence in a research system which is increasingly interdisciplinary there should be shared principles which span all research areas. These principles need further development, such as the agreement of both minimum standards and a 'gold standard' for research governance against which managerial systems and research practice can be assessed. Such a gold standard would need to be sufficiently flexible and nuanced to accommodate all research areas and disciplines.

4.4 *Developments in managerial systems and assurance about the operation and evenness of employer arrangements*

Developments in research governance over recent years have strengthened management systems in research organisations. How uniform this strengthening has been across research organisations and sectors is not clear. To some extent, this can be determined by the intensity and range of research which they conduct. There is limited information available on the nature of systems in operation to ensure research integrity and avoid misconduct, and how much they vary across institutions. The working group noted that there is no general oversight or review of the adequacy of employer arrangements. Oversight and review functions exist for organisations dedicated to health and social care research, but are less transparent in higher education institutions (HEIs). Greater transparency is desirable to ensure advice and support can be offered where necessary.

4.5 *Limitations in knowledge and data*

A particular weakness in the UK is that there is little reliable, publicly available data and analysis on the extent of alleged or confirmed failures in research integrity. Data and research from such countries as the USA and Germany suggest either that problems may be more prevalent in the UK than currently identified, or that these are identified and dealt with on a confidential basis by employers. There is a need for better data about the UK's situation, which will assist employers to develop policies and assure funders that matters of research integrity are properly addressed within institutions.

4.6 *Exchange of information between employers and funders*

One of the reasons for the uncertainties around breaches of research integrity remains the limited exchange of information that current systems permit. Many employers believe there is a limitation on the information that can be passed to other employers or professional associations, especially when staff leave before an investigation is concluded, or has even started. There is no comprehensive

framework for reporting cases. Some are reported to Research Councils UK and other funders. UKRIO has been consulted by UK employers (as well as researchers; regulators; funders; journals; members of the public; and others) since 2006 and is seen by some employers as the organisation best suited to recording cases. However, under current arrangements there are limitations on its role. This is a sensitive but not irresolvable legal issue, which will have to be addressed as awareness of research integrity grows. Alongside this are issues which arise from Freedom of Information requirements for publicly funded research. These also need to be addressed sensitively where there is a tension between public requirements for freedom of information and private rights to data protection.

5. Key requirements over the next five years

5.1 *Not regulation or investigation*

Consultations on research integrity have shown that there is no perceived requirement or appetite in the UK for a new body which would have regulatory or investigatory functions. Regulation already exists (see Annex VI) and in key areas there are authorities with statutory licensing, investigatory and enforcement functions. In addition, the registered professions are subject to procedures which may lead to suspension and potentially to disbarment. Any new regulatory function in these sectors would be likely to create overlap, uncertainty and inefficiency.

The working group therefore concludes that investigation of individual cases is best left to the employing organisations, within the context of sound institutional systems and procedures, as assessed against agreed criteria for the highest possible standards. Systems should be in place to offer support and advice, and to review procedures. Investigations are the responsibility of employing organisations in most other countries.

5.2 *A system for all disciplines and research locations*

In order to ensure coherence in the UK research integrity system overall, across all fields of study and disciplines, the common issues in research integrity are best driven by one body, providing a joined-up UK approach. This approach should relate to all employers of researchers whether they are universities, independent institutes, NHS trusts, industry, public research laboratories or charities. The same standards should apply whether the research is applied or fundamental, commissioned, contracted or investigator-initiated.

Standards and issues in this area are unlikely to differ because of location or subject specification. As individual disciplines and research areas recognise different research methods and designs, and as a result may have to deal with issues specific to them, in certain instances there may be good reason for different interpretations of the general criteria defining malpractice, misconduct and poor practice. However, the general principles should be the same. The working group considers that the same standards apply in private and public sector establishments, and it is highly desirable that any body charged with promoting research integrity commands confidence among both public and private sector research employers. Although a common standard and a shared body cannot be imposed upon employers or their funders, it is anticipated that employers would

welcome the opportunity for reputational gain which abiding by the accepted standards and practices would confer on their institutions.

Promoting research integrity should be as important to all employers of researchers as it is to any body representing its stakeholders. One well-signposted source of authoritative advice would benefit both research employers and their employees. Differing bodies competing in this role would be inefficient, confusing and burdensome for the research community.

5.3 *Support for employers and researchers*

A key role for the body, following on from the work by UKRIO, will be to provide support and assistance to employing organisations and researchers. This should include:

- raising awareness of research integrity and providing advice on management, mentorship and investigatory systems;
- being a repository for advice, and providing good practice guidance to inform employers in dealing with specific instances;
- providing advice and guidance on training in this area;
- maintaining a register of experts who can assist on particular matters;
- providing access to experts for individuals or organisations that need specific help;
- providing advice and support on appropriate systems to support and protect whistleblowers.

5.4 *Development of standards and approaches*

Another major role for such a body should be to develop and promote the appropriate application of standards. This may involve bringing together and enhancing the various different approaches and codes in place at the moment. Any new body should seek to help employers and researchers identify key issues in research integrity management, in setting the highest standards, and ensuring the avoidance of malpractice and poor practice. These issues are explained further in Annex VII, but there are also other codes which need to be considered and brought together. Any new body should work with funders and employers, researchers and professional associations, journal editors and other key players, to refine and develop these definitions to a common high standard. In time, the new body should seek to establish requirements for research integrity (both for research conduct, and for institutional management systems) which are appropriate in different settings and proportionate to different levels of risk. Because of the intense public interest in health research, and the economic impact of the UK's international reputation in biomedical science, the body should continue to support research in the NHS. The Department of Health expects the body to build on UKRIO's work with the NHS, which includes developing close working relationships with the National Research Ethics Service, with the regulators and professional bodies that have statutory responsibilities for the investigation of misconduct and fraud in health and social care.

5.5 *Development and coordination of training*

Employers have responsibility for training researchers and staff responsible for research integrity. However, as the *Concordat to Support the Career Development of Researchers* has shown, some aspects of training can benefit from a nationally recognised approach.

To assist with developing awareness of such issues the new organisation should also lead on the promotion of training in research integrity. This is a significant undertaking and should be carried out in partnership with existing providers to maximise efficient use of resources. There are already some developments in this area, but they have a low profile which needs to be raised. Promotion of training for researchers and managers should be a specific function for the new body, to be taken forward with employers and the Research Concordat Strategy Group, the national programme championing the professional and career development of researchers.

5.6 *Liaison with editors and professional associations*

The proposed body should not focus on specific disciplines or professions, but on the core issues of research integrity which apply to all those who undertake research (see Annex VII for definitions). It should establish and maintain contact with academic and professional editors, with professional associations, and with research integrity organisations overseas both to maintain awareness of issues of concern to them and to provide a forum for resolving them.

5.7 *Analysis and research*

A key weakness identified in the current UK arrangements for research integrity is the absence of any reliable data or analysis on the prevalence of issues of alleged or proven instances of malpractice or poor practice. It is recommended that the new body should be charged with collecting anonymised data and reporting on:

- numbers and types of allegations of malpractice and poor practice;
- cases where employers have deemed allegations sufficiently robust to lead to formal investigations;
- unresolved cases terminated by resignation or departure;
- cases which have led to formal disciplinary charges; and
- number of types of charges which have been upheld.

5.8 *Assurance to funders and the public*

In 2001, the Department of Health introduced a managed system of research governance. In 2005, this was reinforced by a statutory statement of standards (the Department of Health Research Governance Framework for Health and Social Care). However, the UK system as a whole does not offer sufficient assurance to the public or research funders that existing research integrity systems function effectively and are robust. In the past, this has been a concern for auditors and those responsible for risk management. The need for reassurance in this area should be kept as light touch as possible. However, light-touch reassurance is a

function which the proposed body might discharge, which could be achieved by an annual review to test the adequacy of a sample of systems. This would provide assurance at national and international levels with minimal burden to the system. This role might be developed over the next five years, with perhaps 5% of research organisations reviewed annually. It is not recommended that this be implemented immediately as the approach to be taken will need careful consideration by the new Board, including issues about data protection and freedom of information, but this light-touch role should be developed during the first years of the new service.

5.9 *UK representation at international level*

UK employers of researchers are represented internationally in various fora, such as OECD, UNESCO, ESF. Other stakeholders – organisations which employ researchers, professional associations, academies, funders, editors – also represent the UK internationally, depending on the nature of the activity. However, a single coherent voice from the UK may sometimes be required. It is recommended that the proposed organisation would be the main voice for the UK at an international level.

Recommendation 1:

From 2010[6] the UK should have a single body to lead on the common issues of research integrity across all disciplines, all types of research, and all research establishments. The body should seek to establish common core criteria and promote these in all areas.

Recommendation 2:

The body should have no direct regulatory or investigatory functions, but should have responsibility for:

- advice on regulatory and investigatory issues;
- the promotion and development of training in research integrity;
- the development of common standards and approaches;
- providing support to employers and researchers;
- liaison with professional and editorial associations and with similar research integrity bodies overseas;
- co-ordinating the collection and analysis data, and coordinating research on the UK system;
- developing a system of light touch reviews of an annual sample of employer systems and their efficacy, benchmarking these against general and higher standards, with a summary report for funders and the wider public on the assurance about appropriate standards obtained from this; and
- representing the UK at an international level.

[6] Since the time of writing, continuation funding until October 2010 has been made available to UKRIO.

6. Clarity of definition

6.1 *Research integrity, research conduct, research ethics and research practice*

A general understanding of what research integrity means exists, but it is often expressed by different terms such as research conduct (or misconduct), research practice and research ethics, used interchangeably or as overlapping terms. In their report, PSP describe some of the different terms and some of the confusion surrounding the definitions[7]. Annex VII sets out the UKRIO and RCUK definitions, which the working group has used for this report. One of the functions of the new body proposed should be to work towards a widely accepted single definition.

6.2 *Distinguishing between poor practice, poor conduct and serious misconduct*

The research community is obligated to instil and adhere to the highest standards of research integrity. However, this does not mean that every weakness or failure in following the highest standards is automatically malpractice or misconduct. Occasionally, minor weaknesses in training, oversight, or a genuine belief that best practice was being followed, will result in poor practice or poor performance. These instances may require correction, but not necessarily formal inquiry, penalty or sanction.

The working group considers that an important role for the new body should be to clarify these distinctions and provide guidance to the community and to employers of researchers on what should be viewed poor performance, poor practice, dubious or questionable practice, and serious misdemeanour, malpractice or misconduct. The group recognises that there will always be border areas where attention will need to be paid to the circumstances of individual cases. The lower levels are matters which should properly be dealt with inside the employing organisation. Serious misconduct, which could undermine the UK's reputation for high standards, should however, not be tolerated in any way, but addressed by employers, with appropriate sanctions applied.

Recommendation 3:

The UK-wide body should support research employers by:

- communicating both the minimum acceptable and highest possible standards for ensuring research integrity;
- providing advice on what is reasonably required of all employers of researchers in all areas of research;
- clarifying what should be considered as malpractice, misconduct and poor practice;
- supporting employers so that they can identify and deal with cases of serious misconduct or criminal behaviour to be reported outside the immediate employer of the researcher(s).

[7] PSP, 2009, *Review of Current UK Arrangements for the Oversight of Good Research Conduct and Research Integrity*, §2.3, pp.4-5, §2.8, pp.8-9, §4.2.1, p.17

7. Implementation proposals

7.1 *A single, independent UK body*

The working group has recommended that, provided there is support for this approach across the research community, a single body should cover all research disciplines, locations and types of funding. This should not initially have any remit for undergraduate student research, but should otherwise cover all areas post-graduation. In the longer term this would be an independent body established and funded by, but at arms' length from, the major funders. It should be run with the active support of the major funders and research organisations and be accountable to them for their contributions to its costs and the resulting programme of work. Its members might be appointed by them in consultation with other employers, research funders, and learned societies/academies. Ideally, in the longer term, various options should be considered and evaluated to determine the most appropriate form for the organisation of this function. One option would be a company limited by guarantee, with a Board of suitable standing, and the ability to appoint staff and fund programmes as it considers necessary. This is however not considered viable, necessary or desirable in the shorter term.

Recommendation 4:

The UK body responsible for the promotion and development of research integrity should be a body which is clearly associated with UK research employers and is seen to operate independently of, but in collaboration with, research funders, regulators and other groups of stakeholders. It should not be so closely associated with the functions of research funders or others as to undermine its credibility as a provider of advice and support to research employers. Its Board should consist of suitably qualified and experienced people selected by its stakeholders. The Board should be accountable to stakeholders for the funding they provide and the work programme it undertakes, with sufficient resources to appoint staff and fund programmes as appropriate.

7.2 In the short term, there is insufficient capacity, readiness or funding to put such a body in place now. At the time of writing of this report, UKRIO funding will cease by May 2010[8]. The second World Conference on Research Integrity takes place in July 2010. The UK needs transition arrangements in place by May/June 2010. The working group has identified UUK and RCUK as the lead sponsors on behalf of the other funders and stakeholders and recommends that UUK and RCUK jointly lead the arrangements currently proposed. The group proposes that these arrangements be established for five years initially, with a review after three years. Any longer term arrangements can then be finalised at that stage.

7.3 The present arrangements the working group proposes should consist of a strong Board overseeing panels that cover all the relevant trans-disciplinary and trans-sector interests, including representation from the bio-medical, natural and physical, and the human and social sciences. The Board itself should include representatives from publishing and the media, as well as leading researchers and those with expertise in ethical and legal aspects of research. Without strong

[8] Since the time of writing, continuation funding until October 2010 has been made available to UKRIO.

representation at a sufficiently high level, and visible endorsement from stakeholders, the body will lack the means to function effectively.

7.4 It is important that the new body is recognised both in the UK and internationally. It will be critical that it has visible and strong leadership from the Chair and the Executive Director.

7.5 The new body will also need to act on behalf of all contributing stakeholders and, like UKRIO, be clearly associated with UUK and other bodies representing research employers and others including funders. The group noted particularly that Research Councils UK is a major employer and funder covering all disciplines and funding in a variety of different ways, and that it is the equivalent of RCUK which often takes the lead on these matters in other countries. The working group is strongly of the view that initiative and leadership from RCUK and UUK, working closely together and with other funders, will be critical if transitional arrangements are to be in place by May 2010. This will entail the establishment of a representative Board, the agreement of remit (as outlined above) and agreed lines of reporting. This should be achieved by establishing a small secretariat with an appropriate budget to take forward the work on behalf of all contributing funders. These recommendations will of course have to be agreed by the RCUK Executive Group and UUK Board, as well as the sponsors themselves, before they can be taken forward.

Recommendation 5:

For the immediate future, Research Councils UK and Universities UK working together should lead the establishment of a new body in succession to UKRIO on behalf of other funders and stakeholders. The interim arrangements, to be in place if at all possible by May 2010[9], should be in collaboration with other working group partners.

8. Resource implications

8.1 The interim arrangements should be established initially for five years, with review after three, and would require:

- a supervisory board or panel with resources for three to four meetings a year;
- a chair to assist with the direction and promotion of the new work;
- an Executive Director with the competence and presence to drive forward this work, and make a visible impact over the next three to five years, supported by a small office staff. The group considers that the Executive Director will need to have relevant expertise in research policy and management, ethical and legal issues, and, along with the supervisory board and supervisory board chair, be able to take a lead in this field.
- a clear work programme with annual deliverables agreed between the Board, the sponsors and the Executive Director within two months of establishment;
- a salary bill including superannuation and social charges for the Executive Director, two programme managers and administrative support rising to approximately £250,000 a year;

[9] Ibid.

- a budget for travel and subsistence for the Board's work plus advisory panel, review and policy development purposes, building up to £50,000 a year;
- a budget for development of training and support work, data collection and research work building up to £100,000 a year (additional funds if required should be obtained from appropriate sources);
- office accommodation, equipment and IT services to be provided by Universities UK;

8.2 This would require an annual budget of up to £400,000. However the second programme manager might not be required until the second year. We would suggest that the budget might initially be provisionally set at £250,000 in Year 1 (for a nine-month year)[10], £350,000 in Year 2 including the employment of a second programme manager, and £400,000 in Year 3 when all recommended functions would be in place, with future requirements after that reviewed in Year 3.

8.3 The working group considers that these resources can be drawn from the funding currently provided for UKRIO, plus the additional funding expended from other funders in the pursuit of their obligations, which could now be rationalised and performed on their behalf by the new body. The group suggests that reasonably equal amounts could be provided by RCUK, the Funding Councils, the Department(s) of Health, and other non-public sector funders, with office accommodation and some services being provided by UUK. Other funders may also wish to contribute to this trans-disciplinary UK wide activity.

8.4 Although there can be discussion around these figures, prompt action is required in early 2010, to establish these arrangements by May/June 2010[11]. These recommendations should be considered on that timetable. The above are working figures, but it should be noted that the establishment of a secretariat will need to be reasonably costed to deliver the best service for the lowest cost.

Recommendation 6:

The Office in support of the Board should consist of an Executive Director supported by a small secretariat. They would be funded to deliver the activities in recommendations 1, 2 and 3 above. We estimate that this will require an annual budget of up to £400,000. This will only need to be £250,000 in Year 1 (2010-11) as that will be a nine-month year[12], rising to £350,000 for a full year in Year 2, and £400,000 in Year 3, when all recommended functions should be in place. Requirements beyond that should be reviewed after Year 2. We recommend that the costs should be divided on a reasonably equal basis between four partner groups: Research Councils UK; the UK Higher Education Funding Councils; the UK Departments of Health; and the major non-public sector funders, with office accommodation and related services being provided by Universities UK. If further funding is required in due course to strengthen the work of the Board and its Office this might be sought from additional funders and stakeholders in the public sector and beyond.

[10] Since the time of writing, continuation funding until October 2010 has been made available to UKRIO.
[11] Ibid.
[12] Ibid.

9. Continuity with current arrangements

9.1 The UK's relatively strong current position can only be maintained and protected if the valuable developments to date – including those in the health and social care area, in the work of the UK Research Integrity Office (UKRIO) and that of RCUK – are continued without hiatus. They should be brought together wherever possible, and built upon so that there is no gap in 2010 between the termination of funding for UKRIO and the new body. The working group therefore strongly recommends that the proposed interim arrangements are put in place as quickly as possible, so that the new body can immediately take over the existing work developed by UKRIO, as well as strengthen and extend UK research integrity activities.

Recommendation 7:

The proposed interim arrangements should be in place by May 2010[13] to ensure continuity from the work of UKRIO. If a short delay in that timescale is unavoidable then funding for UKRIO at its present levels, to maintain service, should be continued until the new body is established.

9.2 A key issue in continuity will be how the new function will address issues related to Freedom of Information. This is a complex and sensitive matter where public and private interests are sensitively balanced. The Board will need to address these issues carefully, especially when assisting in review of employer systems.

Recommendation 8:

The Board of the new function should, at an early stage, consider carefully issues surrounding how to deal with the confidential nature of information they may hold in relation to Freedom of Information requests.

9.3 Lastly the working group has considered what name might be given to the new functions. This needs both to reflect continuity from what has been established in the last three years, and to represent a further step forward. It is proposed that this might be called the Research Integrity Service.

Recommendation 9:

To reflect both continuity and change from the previous arrangements the new function should be called the Research Integrity Service.

[13] Ibid.

Annex I: Membership of the Working Group

The working group was established by Research Councils UK (RCUK), Universities UK (UUK) and the UK Departments of Health (DH), in association with the UK Higher Education Funding Councils (HEFCs), the Wellcome Trust, the Association of Medical Research Charities (AMRC) and the Association of British Pharmaceutical Industries (ABPI).

Members:

- Professor Dame Janet Finch (Chair) Vice-Chancellor, University of Keele
- Mr Glyn Davies (Research Councils UK)
- Mr Simon Denegri (Association of Medical Research Charities)
- Dr Pablo Fernandez (Association of British Pharmaceutical Industries)
- Professor David Gani (Scottish Funding Council representing the UK Higher Education Funding Councils)
- Professor Shirley Pearce, Vice-Chancellor, University of Loughborough (representing Universities UK)
- Ms Catherine Quinn (Wellcome Trust)
- Professor Tom Rodden, Professor of Interactive Systems, University of Nottingham (Physical Sciences)
- Professor Tom Sorell, Professor of Philosophy, University of Birmingham
- (Arts and Humanities)
- Dr Marc Taylor (UK Department of Health with Mr Bill Davidson acting as alternate)

Joint Secretariat

Ms Chloe Somers (RCUK)
Dr Eve Jagusiewicz (UUK)

Annex II: Terms of Reference

The Working Group was asked to consider:

- existing arrangements for research integrity in the UK;
- the terms of reference for any new arrangements for research integrity from 2010;
- the mechanics and governance arrangements of any function, including issues of independence and relationship to key stakeholders and sponsors;
- funding and resourcing required; and
- of the look and feel of the service that would be required by employers, researchers and sponsors.

Annex III: People, Science and Policy Report

The consultancy People, Science and Policy was commissioned to provide a review of existing issues and perspectives on Research Integrity in the UK as in input to the working group's deliberations. The *Review of Current UK Arrangements for the Oversight of Good Research Conduct and Research Integrity* is linked to here for ease of reference. The report is that of the reviewers and does not necessarily reflect the views of the working group in all aspects, but provided valuable information and advice in the consideration of requirements.

The full report is available on the PSP website:

http://www.peoplescienceandpolicy.com/downloads/Research_Integrity_Report_Aug2010.pdf

Annex IV: UK and International Background

UK Background

1. Developments over the last decade

There has always been a concern to demonstrate that research is rigorous, properly conducted and properly reported for as long as research has been undertaken. With the enormous growth in research in the last half-century that concern has increased. Other pressures on researchers, including the pressure to publish innovative and exciting research, and the advent of the World Wide Web, have increased concerns that the pressures and temptations to poor practice and unacceptable conduct may have increased. Major steps have therefore been taken over the last decade by various relevant bodies to reinforce the importance of good research conduct and research integrity.

Significant UK developments have included the joint statement on *Safeguarding Good Scientific Practice* issued by the Director General of Research Councils and Research Council Chief Executives in 1998, the *Research Governance Framework for Health and Social Care* published by the Departments of Health in 2001 and updated in 2005, and the *Universal Ethical Code for Scientists* issued by the Council on Science Technology in 2006. In 2006 the UK Research Integrity Office was also established.

2. Department of Health Research Governance Framework

Over the last two decades particular concern has developed in Government and amongst the public about research involving human subjects. As a result the Department(s) of Health have taken a lead in ensuring that that a robust research governance framework exists in that area including, where appropriate, clear reference to regulatory requirements and ensuring appropriate ethical approval for all relevant research. The first Research Governance Framework was issued in 2001, and this was then updated in 2005. This can be found at http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_4108962 and covers the requirements of a high quality research culture, the key responsibilities of individuals and organisations, and matters dealing with such issues as information, ethics, health and safety, and finance.

3. UK Panel for Research Integrity in Health and Bio-Medical Sciences

Another major development in 2006 was the establishment of the UK Panel for Research Integrity in Health and Bio-Medical Sciences. This was established to provide an independent advisory body to support both research organisations and individual researchers, as well as members of the public, in order to further integrity in research and promote good practice in addressing misconduct in research. The Panel, supported by the UK Research Integrity Office (UKRIO) hosted by Universities UK, has during the last three years published two major guides in this area – *Procedure for the Investigation of Misconduct in Research* (September 2008), and the *Code of Practice for Research: Promoting good practice and preventing misconduct* (September 2009). UKRIO also offers a confidential advice and guidance service to research organisations, individual researchers and members of the public about the conduct of research. The Panel and UKRIO funding has at the time of writing been extended to May 2010[14] while this working group is reviewing future options in this area.

4. Research Councils UK

Research Councils UK (RCUK) is the strategic partnership of the seven UK research councils, who cover the full spectrum of academic disciplines, funding research in universities and independent research organisations, as well as employing researchers directly in their own research institutes. RCUK has been increasingly concerned with the promotion of good research practice both before and after the joint statement with the Director General of Research Councils in 1998.

In 2004 the research councils sought confirmation from funded research organisations that they could provide copies of good research practice policies, and in 2006 and 2007 they conducted annual surveys for reassurance that these policies were being followed through. Responses to these surveys demonstrated that reasonable procedures were in place, but identified some areas of concern. These included a level of research organisation concern that information about cases could not be shared because of Data Protection legislation; that information about individuals where there might have been concern about research conduct could not be shared with employers to whom they might have moved; and that management procedures for the positive promotion of good research conduct were perhaps in some need of strengthening. However, overall the level of reported misconduct appeared to be low.

5. Other organisations and associations

The Wellcome Trust, medical and other charities, government departments and other funders have all developed their own requirements and procedures. In 2008 these organisations came together with RCUK, Universities UK, the Funding Councils, the Department of Health and others to hold a major policy conference at the University of Keele (April 2008), which was followed by significant consultations with the wider research community by both RCUK and UKRIO. They identified a consensus that a unified approach representing all major funders would be found more acceptable to most research organisations. While there were inevitable differences in detail between the requirements of different disciplines, a core requirement across all disciplines was apparent, and most research organisations would not expect major differences of approach to different subjects. However, there was a major need to distinguish between poor performance or

[14] Since the time of writing, continuation funding until October 2010 has been made available to UKRIO.

minor misdemeanours, especially by more junior researchers, which required correction but not major penalties, and more serious "misconduct" which might bring research into disrepute. A unified approach to core issues would not of course obviate the roles of the professional associations in the various disciplines, as they will continue to provide much closer guidance on issues to their specific domains.

6. Research conduct and research ethics

Questions about the interaction between what previously might have been considered as research conduct and research integrity issues and those of research ethics have also become more apparent. The latter had previously been concerned primarily with the treatment of human and animal subjects of research, while the former was concerned with the integrity of research methods; the development, selection and application of evidence; and the reporting of research findings (often typically referred to as FFP – Fabrication, Falsification and Plagiarism). In a public and media atmosphere where such issues as informed consent, declaration of interests, misrepresentation and ghost authorship are of increasing concern, these two issues overlap strongly and to some degree merge. Unacceptable ethical behaviour increasingly has to be seen as a breach of research integrity or research misconduct.

International background

7. Developments in the USA

Developments in the UK have also been paralleled by developments at the international level. The lead here has often been taken by the USA where major developments took place in the 1990s. In 2000, Congress legislated that all federal agencies funding research were required to have systems in place to ensure research integrity. This included the right to investigate any allegations, though investigations are usually left to the research organisations themselves under supervision from the federal agencies. Because of the legalistic nature of the US system however, research integrity has been delimited to the areas of only FFP (Fabrication, Falsification and Plagiarism). The two major research funders in the US – the National Science Foundation (NSF) and the National Institutes of Health (NIH) have slightly different systems. NSF is tied to their systems for all fraud under the Inspector General for Research, who has formal legal investigatory powers. The NIH established the Office of Research Integrity (ORI), which has investigatory powers and works closely with research organisations. The NIH/ORI system also has two other significant factors. It is specifically charged under congressional legislation for the development of training in the area of research integrity, where it has been very active. NIH can commission research anywhere in the world for the benefit of the USA (whereas NSF is largely restricted to US research institutions). This means that the outreach of research integrity systems is to all other national domains where research might be commissioned. This, and increasingly collaborative research with the USA, whether funded from NIH, NSF or other federal agencies, has created strong pressure for other countries to have systems in place at least as strong as those in the USA.

8. Developments in other countries

Many leading research countries have significantly strengthened their research integrity systems over the last decade. In some cases such as Germany and Norway this has also been in response to individual cases of abuse in those countries (Schön and Sudbø), which have had major impact on confidence in the research system. This has led to national regulatory systems laid down by legislation in Norway, Denmark, Finland, Germany and other countries. In Germany the system is led by the Deutsche Forschungsgemeinschaft (German Research Foundation) and also includes a system of Ombudsmen at institutional and national levels, to whom individuals can take concerns either for arbitration or investigation. In other countries, such as Australia and Canada, less regulatory systems have been or are being developed. In Australia development of research integrity systems has been led by the Australian Research Council, and in Canada it is being developed by the Tri-Councils (the equivalent of RCUK) in association with the Canadian Department of Health. A number of relevant documents, from the UK and abroad, are listed for ease of reference in Annex V. In Europe, bodies such as UKRIO have banded together to form the European Network of Research Integrity Offices.

9. Increasing international collaboration

Over the last two decades there has also been an increasing amount of research conducted through international collaboration, or by researchers from one country carrying out work in others. As well as the need for consistent approaches to research integrity, this has raised issues such as the need for agreed international standards on matters such as informed consent, conflicts of interest, protection of subjects, and protection of anonymity. These factors have increased the need for a common approach within the UK which is acceptable at an international level

10. OECD, UNESCO and ESF

Issues of research integrity have also been addressed by discussions at the international level. The work and report of the OECD Global Science Forum has already been referenced. In addition UNESCO has an advisory body on ethical principles for the guidance of work in science and technology (COMEST). This is currently reviewing UNESCO procedures and requirements, and is likely to report in 2010. The European Science Foundation has also established a Members' Forum on Research Integrity, which is seeking to develop a pan-European approach to research integrity. This may be reported for discussion at the second world conference on research integrity.

11. World conference on research integrity

Much of this international development was drawn together in the First World Conference on Research Integrity sponsored primarily by the US ORI, the ESF and OECD under the Portuguese Presidency of the European Union at Lisbon in September 2007. This provided a major spur for national and international development of approaches to research integrity for the reasons reflected above. The second world conference on research integrity takes place in Singapore, July 2010. This completes the national and international background to the present developments in research integrity in the UK.

Annex V: Reference documents related to research integrity

Safeguarding Good Scientific Practice: A joint statement by the Director General of the Research Councils and the Chief Executives of Research Councils (December 1998)

Department of Health Research Governance Framework in Health and Social Care (published 2001 and revised 2005)

Universal ethical code for scientists (CST report, 2006)

UK Research Integrity Office (UKRIO) Procedure for the Investigation of Misconduct in Research (September 2008)

OECD Global Science Forum: Investigating Research Misconduct Allegations in International Collaborative Projects (A Practical Guide, April 2009)

RCUK Policy and Code of Conduct on the Governance of Good Research Conduct (July 2009)

UK Research Integrity Office (UKRIO) Code of Practice for Research: promoting good practice and preventing misconduct (September 2009)

Australian Code for the Responsible Conduct of Research (published by Australian Government, National Health and Medical Research Council, Australian Research Council and Universities Australia) Australian Government 2007, ISBN 18644964324

Danish Research Agency: Report on the rules governing research ethics (May 2003)

Stewards of Integrity: Institutional Approaches to Promote and Safeguard Scientific Practice in Europe (ESF Draft Report to be published April 2008)

Health Protection Agency: Principles of Good Scientific Practice (August 2005)

Mayer, T. and Steneck, N., *Final Report to ESF and ORI First World Conference on Research Integrity: Fostering Responsible Research* (Report of Conference 16-19 September 2007)

Committee on Publication Ethics (COPE) flowcharts on managing misconduct

General Medical Council:

Confidentiality: Protecting and Providing Information, 2004

Seeking patients' consent: the ethical considerations, 1998

Research: the role and responsibilities of doctors, 2002

Conflicts of Interest, 2004

Annex VI: Bodies with regulatory responsibilities in research

These include:

- GMC (General Medical Council) – for UK registered doctors doing research
- Nursing & Midwifery Council – for UK registered nurses and midwives doing research
- MHRA (Medicines and Healthcare Products Regulatory Agency) – for trials of new products
- Human Fertilisation and Embryology Authority
- Human Tissue Authority – who license and inspect organisations that store and use human tissue for purposes such as research, patient treatment, post-mortem examination, teaching and public exhibitions
- Home Office – for use of animals in research
- Foreign and Commonwealth Office ATAS (the Academic Technology Approval Scheme) for non-EU nationals requiring security clearance to work in specified areas
- Health and Safety Executive – e.g. for human pathogens
- DEFRA – e.g. for animal pathogens
- Information Commissioner's Office and PIAG (Patient Information Advisory Group) – for access to, and use of, personal information held by the NHS.

Annex VII: Definitions of Research Integrity

Taken from the *UKRIO Procedure for the Investigation of Misconduct in Research*, 2008

In discussing misconduct in research, which could be investigated using the Procedure, the following may serve as useful terms by way of guidance. Interpretation of the terms will involve judgements, which should be guided by previous experience and decisions made on matters of misconduct in research.

- Fabrication;
- Falsification;
- Misrepresentation of data and/or interests and or involvement;
- Plagiarism; and
- Failures to follow accepted procedures or to exercise due care in carrying out responsibilities for:
    - avoiding unreasonable risk or harm to:
    - humans;
    - animals used in research; and
    - the environment; and
- the proper handling of privileged or private information on individuals collected during the research.

For the avoidance of doubt, misconduct in research includes acts of omission as well as acts of commission. In addition, the standards by which allegations of misconduct in research should be judged should be those prevailing in the country in question and at the date that the behaviour under investigation took place.
The basis for reaching a conclusion that an individual is responsible for misconduct in research relies on a judgement that there was an intention to commit the misconduct and/or recklessness in the conduct of any aspect of a research project. Where allegations concern an intentional and/or reckless departure from accepted procedures in the conduct of research that may not fall directly within the terms detailed above, a judgement should be made as to whether the matter should be investigated using the Procedure.

Taken from the *RCUK Policy and Code of Conduct on the Governance of Good Research Conduct*, 2009

Unacceptable conduct includes each of the following:

Fabrication
This includes the creation of false data or other aspects of research, including documentation and participant consent.
Falsification
This includes the inappropriate manipulation and/or selection of data, imagery and/or consents.
Plagiarism

This includes the general misappropriation or use of others' ideas, intellectual property or work (written or otherwise), without acknowledgement or permission.

Misrepresentation, including:

- misrepresentation of data, for example suppression of relevant findings and/or data, or knowingly, recklessly or by gross negligence, presenting a flawed interpretation of data;
- undisclosed duplication of publication, including undisclosed duplicate submission of manuscripts for publication;
- misrepresentation of interests, including failure to declare material interests either of the researcher or of the funders of the research;
- misrepresentation of qualifications and/or experience, including claiming or implying qualifications or experience which are not held;
- misrepresentation of involvement, such as inappropriate claims to authorship and/or attribution of work where there has been no significant contribution, or the denial of authorship where an author has made a significant contribution.

Mismanagement or inadequate preservation of data and/or primary materials, including failure to:

- keep clear and accurate records of the research procedures followed and the results obtained, including interim results;
- hold records securely in paper or electronic form;
- make relevant primary data and research evidence accessible to others for reasonable periods after the completion of the research: data should normally be preserved and accessible for ten years, but for projects of clinical or major social, environmental or heritage importance, for 20 years or longer;
- manage data according to the research funder's data policy and all relevant legislation;
- wherever possible, deposit data permanently within a national collection.

Responsibility for proper management and preservation of data and primary materials is shared between the researcher and the research organisation.

Breach of duty of care, which involves deliberately, recklessly or by gross negligence:

- disclosing improperly the identity of individuals or groups involved in research without their consent, or other breach of confidentiality;
- placing any of those involved in research in danger, whether as subjects, participants or associated individuals, without their prior consent, and without appropriate safeguards even with consent; this includes reputational danger where that can be anticipated;
- not taking all reasonable care to ensure that the risks and dangers, the broad objectives and the sponsors of the research are known to participants or their legal representatives, to ensure appropriate informed consent is obtained properly,

explicitly and transparently;

- not observing legal and reasonable ethical requirements or obligations of care for animal subjects, human organs or tissue used in research, or for the protection of the environment;
- improper conduct in peer review of research proposals or results (including manuscripts submitted for publication); this includes:
  - failure to disclose conflicts of interest;
  - inadequate disclosure of clearly limited competence;
  - misappropriation of the content of material; and
  - breach of confidentiality or abuse of material provided in confidence for peer review purposes.

Annex VIII: Supporters of the UK Research Integrity Office (UKRIO)

UKRIO is supported by a number of UK organisations with interests in research, including:

- Academy of Medical Sciences;
- Association of the British Pharmaceutical Industry;
- Association of UK University Hospitals;
- Biotechnology and Biological Sciences Research Council;
- Committee on Publication Ethics;
- Department for Employment and Learning, Northern Ireland
- General Medical Council;
- Health Departments of England, Ireland, Scotland and Wales
- Higher Education Funding Council for England
- Higher Education Funding Council for Wales
- Medical Research Council;
- Medical Schools Council;
- Medicines and Healthcare products Regulatory Agency;
- Research Councils UK;
- Royal College of Physicians;
- Royal College of Physicians of Edinburgh;
- Royal Society;
- Scottish Funding Council
- Universities UK;
- and research charities including the Wellcome Trust.