

UK Research Integrity Office:

Protocol for responding to requests for assistance

Introduction

The United Kingdom has a world-class reputation for exceptional and innovative research. We have researchers of the highest calibre who do excellent and innovative work. But not all UK research is honest and robust. We must foster integrity in our research to:

- Retain the public's trust;
- Enhance this country's international reputation;
- Secure the best return on public funds; and
- Ensure the safety and wellbeing of research participants and patients.

The UK Research Integrity Office (UKRIO) was set up to support good practice in academic, scientific and medical research and to assist with the prevention and investigation of questionable practices and misconduct. Since 2006, it has provided independent and expert support across all disciplines. UKRIO is the only body in this country that offers dedicated support to the public and the research community on issues of research integrity.

Our advisory service

UKRIO has provided a comprehensive programme in support of research integrity since 2006. Use of our services has continued to grow year on year. Many leading research organisations, including over 50 universities, use our published guidance, which is endorsed by funding and professional bodies. It has become clear that employers and individuals value our confidential, independent and expert service and are willing to come forward and seek guidance from UKRIO. Our aim is to be the organisation of choice for all organisations and people across the UK to come to for these purposes.

A key element of our programme of work is UKRIO's Advisory Service. This provides independent, expert and confidential advice on the conduct of research, whether promoting good practice or addressing alleged poor practice and misconduct. It covers all subject areas and any issues relating to research practice.

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No other organisation in the UK has comparable expertise in providing such support, support which draws on the expertise of UKRIO's Register of Advisers.

Our Advisory Service is open to all, including members of the public, research participants, patients, individual researchers, research students and research organisations. UKRIO welcomes enquiries on general or hypothetical topics, as well as those on specific research projects, issues and cases.

UKRIO advises on issues of good practice in research. We also advise whistle-blowers and help those responsible to deal effectively with problems of poor practice and allegations of misconduct. Promoting and sustaining good research practice is a worthwhile object in its own right. It also reduces the risk of misconduct occurring.

Protocol for responding to requests for assistance

Requests for assistance are addressed according to a standard protocol. When an enquiry is received by UKRIO, it is assessed to determine whether it falls within our remit to address, namely that:

- It relates to academic, scientific or medical research.
- The research, researcher(s) and/or organisation(s) in question are based in, or have links with, the United Kingdom.
- The enquiry is not a matter that falls within the remit of a statutory regulator or other body whose legal or other responsibilities to address the matter would take precedence.

If an enquiry does not fall within UKRIO's remit, we explain to the person making the enquiry ("the caller") why this is the case and suggest which organisations might respond to their enquiry.

The enquiry is also assessed to determine whether:

- It concerns a situation that may require immediate action to prevent further risk or harm to research participants, patients or other persons, improper treatment of animal subjects of research, improper use or storage of human tissue, materials or personal data, or negative environmental consequences (a "Situation").
- It may involve criminal activity.
- The matter in question (including any persons or organisations involved) presents any potential or actual conflicts of interest, for UKRIO as a whole or for any of its staff or volunteers.

If the enquiry fulfils any of the above criteria, the Chief Executive, liaising with the Chair, takes appropriate action to address the issue(s) in question, informing the caller and recording the actions taken and the reasons for his/ her decisions in writing.

- If an enquiry involved criminal activity or a Situation, we would first strongly encourage the caller to report the matter to appropriate organisation(s), which we would identify for them.
- If this did not take place in a timely manner, UKRIO, despite its role as a confidential advisory body, reserves the right in such circumstances to make disclosures, in confidence if necessary, to relevant external bodies. Such a decision would be taken by the Chief Executive and the Chair, consulting with UKRIO's Board of Trustees, Advisory Board, staff or volunteers with relevant expertise, and/or legal counsel, as appropriate. In some cases, UKRIO may be legally required to make such disclosures. We also reserve the right to disclose details of our advice and correspondence if that advice is later misrepresented by a caller.
- If an enquiry presented any potential or actual conflicts of interest, the Chief Executive would determine how best to address this and inform the Chair, consulting him/her beforehand if the conflict was of a type and severity that posed a risk of fatally compromising UKRIO's response to an enquiry. Conflicts of interest involving the Chief Executive are reported to the Chair for action. Conflicts of interest involving the Chair are reported to the two Vice-Chairs for action; the Chair would recuse him/herself from any decision-making relating to the alleged conflict(s) of interest and agree to abide by the decision of the Vice-Chairs. Some conflicts of interest may be adequately addressed through declarations and/or special safeguards; in others, the conflict can be avoided by excluding particular staff members or volunteers from any involvement in that enquiry. The Chief Executive and the Chair would determine how best to address any conflicts of interest which related to UKRIO as a whole, consulting with UKRIO's Board of Trustees, Advisory Board, staff or volunteers with relevant expertise, and/or legal counsel, as appropriate. When an enquiry presented any potential or actual conflicts of interest, UKRIO would provide the caller with appropriate information regarding the conflicts and how they have been addressed.

UKRIO staff then determine the main issues involved in the enquiry, seeking clarification, additional information and/or relevant background from the caller as necessary. With the caller's permission, UKRIO may seek additional information in confidence from other persons or relevant organisations.

Based on the information provided, UKRIO advises the caller on how the issues raised might be addressed. The guidance that we provide in response to an enquiry is determined case-by-case but draws on a wide variety of sources of best practice. These include, but are not limited to: relevant legislation; ethical standards for research; UKRIO's published guidance; requirements and guidelines for research practice or other relevant matters from regulators, Government, international organisations, professional bodies, employers, journals, research funders and other relevant bodies; the expertise of UKRIO's Register of Advisers; and UKRIO's wide experience in resolving issues of research integrity.

Advice and guidance from UKRIO aims to reflect professional best practice in the conduct of research and in addressing misconduct. UKRIO is not a regulatory body and has no formal legal powers; it exists to

advise and assist those who seek its help. UKRIO does not have a case investigation, adjudication or oversight role, but our representatives can and do participate in investigations at the request of a regulator, employer or other appropriate body or person. Guidance from UKRIO should not be viewed as a substitute for legal advice from suitably qualified persons.

Some enquiries are resolved quickly, with the caller needing no further assistance from UKRIO following our response. In such cases, we make it clear that we will provide further support should the caller require it. Other enquiries require long-term support, when UKRIO provides further guidance as the matter develops.

UKRIO's role is normally to advise, not to be an advocate or an intermediary. At the discretion of the Chief Executive and/or the Chair, UKRIO may take a more active role, such as raising concerns on behalf of an organisation or person. UKRIO has been able to intervene directly and successfully in situations where existing mechanisms to resolve matters have been ineffective.

- Any decision that UKRIO will take a more active role in a situation must take into account: the seriousness of the issue(s) in question; the credibility of the caller(s); and the likelihood of confirming the issue(s) from alternative and credible sources.
- Prior to making their decision, the Chief Executive and/or the Chair will consult with UKRIO's Board
 of Trustees, Advisory Board, staff or volunteers with relevant expertise, and/or legal counsel, as
 appropriate.
- If UKRIO does take a more active role in a situation, it will stress throughout to all parties that it is a confidential advisory body, rather than a regulator, and has no formal legal powers.

Anonymous enquiries to UKRIO

UKRIO sometimes responds to requests for assistance where the caller wishes to remain anonymous. As UKRIO does not have an investigatory, adjudicatory or oversight remit, our Advisory Service is still able to offer guidance without knowing the identity or affiliation of the caller.

We remind callers that enquiries to UKRIO are confidential, subject to the caveats described elsewhere; however, we make it clear that we will still provide assistance if they do not wish to disclose their identity.

Guidance provided by UKRIO in response to an enquiry is based solely on the information given by the caller. Accordingly, our response may be limited if only partial information is forthcoming. Acting with sensitivity at all times, we would inform the caller of this and encourage them to provide as much information as possible without revealing their identity.

Acting with due sensitivity

Enquiries to UKRIO can involve issues of a serious, sensitive or contentious nature, for example:

- Allegations that persons involved in research have suffered harm, injury or death.
- Improper treatment of animal subjects of research
- Improper use or storage of human tissue, materials or personal data.
- When the caller, or a member of their family or a friend, is a participant in the research in question.
- When the research in question relates to a medical condition of the caller, or that of a member of their family or a friend, or when the caller has some other personal interest in the research.
- When the field of research is new, particularly specialised or the subject of considerable debate in the academic, scientific or medical communities.
- When the research in question deals with emotive issues or has been the subject of public debate and concern.

Even when an enquiry involves relatively straightforward matters, the caller may be nervous about approaching UKRIO. For example, members of the public, unfamiliar with research, can be extremely anxious when they first contact us. A researcher may feel that they will suffer detriment if it becomes known that they have sought advice from UKRIO or raised concerns about possible research misconduct. A person seeking guidance from UKRIO because they are the subject of a research misconduct investigation will understandably be suffering from stress.

Accordingly, all UKRIO staff and volunteers must act with due sensitivity and courtesy at all times when responding to enquiries to our Advisory Service.

Confidentiality and record-keeping

UKRIO keeps a confidential record of requests for assistance and subsequent discussions for internal purposes. No-one outside UKRIO has access to this record (not even our funders and supporters). No other parties are informed unless there is clear evidence of criminal activity or a Situation, as described above. As noted above, in such circumstances we would first strongly encourage the caller to report the matter to appropriate organisation(s), which we would help them to identify. If this did not take place in a timely manner, UKRIO reserves the right to make appropriate disclosures, in confidence if necessary, to relevant external bodies. In some cases, UKRIO may be legally required to make such disclosures. We also reserve the right to disclose details of our advice and correspondence if that advice is later misrepresented by a caller.

If a third party would be able to work alongside UKRIO to resolve an enquiry, or would be a more appropriate source of support, then UKRIO would approach that body only with permission from the person(s) making the enquiry. The exception to this, again, would be if there was clear evidence of criminal activity or a Situation, as described above.

When seeking views on an enquiry from members of our Register of Advisers, we would normally provide an anonymised summary of the matter. An exception would be when anonymisation would require the redaction of so much information as to make it impossible for Advisers to give any useful views on the matter. Regardless, all information about enquiries to UKRIO is provided to our Advisers in the strictest confidence.

We explain our confidentially provisions to anyone seeking advice from the charity; for example, via emails acknowledging requests for assistance and the enquiry submission form on UKRIO's website (see http://www.ukrio.org/get-advice-from-ukrio/).

UKRIO: way of working

UKRIO is an advisory body and not a statutory regulator. Advice and guidance from UKRIO is not mandatory. It is based on, and aims to reinforce, best professional practice in the conduct of research and in addressing questionable behaviour and misconduct.

We do not believe that researchers and their institutions need micro-management or additional regulatory oversight. Instead, we support them in conducting research that is of the highest quality and ethical standards. Our aim is a systematic and visible effort to promote and demonstrate integrity and high ethical standards in UK research.

As well as helping to ensure that standards for good practice are met, we provide support when things go wrong. We advise members of the public and researchers faced with bad practice and ensure that institutions achieve high standards when addressing challenges to research integrity.

The guidance that UKRIO provides must always be independent, confidential and informed by best practice. Our focus is on support that is appropriate, proportionate and useful. We are not in the business of creating additional burdens or bureaucracy for researchers.

UKRIO covers academic, scientific and medical research wherever it is carried out in the UK. We provide support for all academic disciplines, from the arts and humanities to the life sciences, and all research sectors: higher education, NHS, private sector bodies and charities. As a charity, UKRIO has a particular interest in research affecting the public good.

We are an independent body. Our funders and supporters do not determine whom we help or how we help them. We do not report to our funders and supporters on who has sought our assistance, why they

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have done so or how we responded. Further information on the confidentiality we offer can be found under 'Confidentiality and record-keeping', above.

Since UKRIO was established, it has become clear that individuals and organisations, who might otherwise be hesitant about sharing problems with a non-regulatory body, are more than willing to seek guidance from UKRIO on difficult issues. Our experience has been that organisations welcome the independent perspective UKRIO provides, while researchers and members of the public particularly appreciate our expert and confidential support.

Members of the public, individual researchers and research organisations trust UKRIO to provide independent, confidential and expert support. All who work for our organisation, both staff and volunteers, must adhere to the highest standards of integrity, objectivity, honesty and professionalism.

The role of UKRIO's Advisers

UKRIO is a small charity, staffed almost entirely by volunteers. The many successes of our organisation could not have been achieved without their generous and expert support. Some volunteers sit on our Board of Trustees or our Advisory Board, the bodies that oversee UKRIO's strategy and work programme, while others become UKRIO Advisers.

UKRIO draws upon its Register of Advisers when responding to questions and concerns about the conduct of research. Our volunteer Advisers play a vital and varied role in supporting UKRIO's Advisory Service, helping to ensure that we can offer expert guidance on the best ways to support good research practice and address poor practice and misconduct.

Advisers give their time to UKRIO *pro bono* and are not employees of the organisation. We pay reasonable expenses incurred by Advisers in the course of supporting UKRIO. Appropriate insurances and indemnities have been obtained to cover volunteers, including Advisers, when acting on behalf of UKRIO.

Our Advisers agree to comply with a Code of Conduct, which includes this protocol for responding to requests for assistance from UKRIO. The Code of Conduct for UKRIO's Advisers is available on our website www.ukrio.org.