

## MANAGING RISKS OF RESEARCH MISUSE

### A joint Biotechnology and Biological Sciences Research Council (BBSRC), Medical Research Council (MRC) and Wellcome Trust policy statement

*As funders, BBSRC, the MRC and the Wellcome Trust strive to support research of the highest scientific and ethical quality that will advance knowledge and its application to deliver benefit to the public. We recognise, however, that there is a risk that the results of some types of research which are funded in line with this objective, could also potentially be misused to cause great harm (for example, to develop biological weapons). In this statement, we set out a shared approach to managing these types of risks, and describe how we think the broader research community should play their part.*

We have agreed a common joint position on managing risks that the outputs – in terms of the knowledge, products and/or technologies – resulting from the research we support could be misused for harmful purposes, as elaborated at **Annex A**. While our position is restricted to the life sciences, we believe the principles and approach set out could be readily applied to other research disciplines.

Research which poses significant risks of this type has been referred to as ‘dual use research of concern’. In our position statement, we adopt the US Government’s definition of this term, which is “life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products and technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, material or national security”.

Our joint statement covers issues such as: balancing benefit and risk; dissemination of research; international collaboration and training; promoting good research practice; and ensuring public trust. While such risks must be considered and managed in an appropriate manner, our view is that responsibly conducted research – including that involving potentially harmful biological agents – must not be unduly restricted. Indeed, such research will be absolutely vital in the fight to combat disease and address other major societal challenges.

We believe that a system based primarily upon self-governance by the scientific community, but drawing on the inputs of other key stakeholders, will ultimately provide the most effective means of managing risks of misuse. We suggest that the community, of which we as funders are part, should take active steps to further develop mechanisms of self-governance, and that through doing so the community can ensure that responsibly conducted research is not unnecessarily obstructed. Crucially, this process must be underpinned by an active ongoing dialogue between researchers and other key stakeholders, including Governments and security services.

BBSRC, the MRC and the Wellcome Trust each have rigorous processes in place for ensuring that the research we support is of the highest scientific quality and conforms to all relevant ethical and regulatory requirements. In light of concerns over research misuse, and in consultation with our research communities, we have implemented five key provisions in our grant application processes and funding requirements to help ensure that risks of misuse associated with research proposals are identified and assessed during the grant funding process, where it is possible to do so.

These five steps are:

- inclusion of a question on application forms requiring applicants to consider short and medium-term risks of misuse associated with their proposal

- explicit mention of risks of misuse in guidance to external experts who peer review grant applications as an issue to consider
- development of clear guidance for funding committees on this issue and the process for assessing cases where concerns have been raised
- modification of guidelines on good practice in research to include specific reference to risks of misuse.
- a requirement to notify funders, and other relevant authorities, of any change in the status of a dual use risk or any new risks that may emerge during the course of a funded research project that were not anticipated in the original application.

These actions are intended to heighten awareness, and are a means of helping to identify possible risks of misuse at an early stage. Ultimately what matters most is people's motives, and an awareness of the possible motives of research users. The changes we have implemented in our processes will not be sufficient on their own to prevent misuse by somebody with the primary intent to do harm, nor will they identify new risks that arise as the research progresses. Other processes within the research environment are therefore also important. These include effective research governance at the local (institutional) level, appropriate levels of caution in making appointments, provision of appropriate training and education, and compliance with existing biosafety and biosecurity regulations.

## ANNEX A

### BBSRC, MRC and Wellcome Trust position statement on dual use research of concern and research misuse

#### Introduction

1. The Biotechnology and Biological Sciences Research Council (BBSRC), the Medical Research Council (MRC) and the Wellcome Trust (WT) are committed to supporting research of the highest quality across the biological and biomedical sciences with the aim of improving human, animal and plant health and advancing understanding of biological systems.
2. The three funders recognise that there are risks that certain avenues of life sciences research, progressed with the legitimate intention of advancing knowledge and improving health and wellbeing, may also be misused to cause harm. A very limited degree of so-called 'dual use' potential may be present across many research areas. It is the small subset of research with the greatest potential to yield knowledge, products or technologies that could be misapplied for malevolent applications has been termed "dual use research of concern" (**Box 1**).

#### **Box1- definition of "dual use research of concern"**

In line with the 2014 United States Government policy<sup>1</sup>, "dual use research of concern" is here defined as:

"Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products and technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, material or national security".

3. In light of global events, we recognise that discussions regarding dual use research of concern have focused on studies that could directly result in, or enable the future development of, pathogens, toxins and technologies which could potentially serve as bioweapons. It is important to emphasise, however, that in most cases the risk of this occurring in practice will be remote. Furthermore other types of potentially harmful misuse of research exist, such as risks of research findings being used to stigmatise or discriminate against particular population groups.
4. Several expert groups have identified areas of research that might raise particular risks of harmful misuse (as summarised in **Box 2 below** – please note that this is not intended to represent an exhaustive list of areas in which concerns may arise). It must be emphasised that such risks are neither new nor restricted to high-tech areas of science. It is also important to note that these risks are by no means exclusive to research which directly involves the use of hazardous agents, and are not restricted to misuse for terrorist purposes.
5. Dual use questions relate to the risks associated with knowledge and inventions emerging from research, and are therefore distinct from questions concerning the

<sup>1</sup> United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (2014)

physical safety and security of laboratories working with hazardous agents – which are addressed by existing biosafety and biosecurity regulations. We recognise, however, that some work involving hazardous agents is raising new questions for biosafety. Accordingly, the risk of release of such agents from the laboratory (whether accidentally or deliberately) must be weighed up with other types of dual use risks in the decision over whether to pursue particular experiments involving these agents.

**Box 2 – examples of possible research areas raising dual use risks**

A committee convened by the US National Academy of Sciences in 2003<sup>2</sup> identified seven classes of experiment to illustrate the types of endeavour that would require careful review by informed experts. The experiments this committee specified are those that would aim to produce or are reasonably anticipated to produce one of the following effects:

- demonstrate how to render a vaccine ineffective
- confer resistance to therapeutically useful antibiotics or antiviral agents
- enhance the virulence of a pathogen, or render a non-pathogen virulent
- increase transmissibility of a pathogen
- alter the host range of a pathogen
- enable the evasion of diagnostic and detection modalities
- enable the weaponisation of a biological agent or toxin

An additional category has since been incorporated into the US Government policy 2014, to also include any experiments that would:

- generate or reconstitute an eradicated or extinct agent or toxin

In addition, other areas that might require careful consideration include

- the development of new technologies or tools with generic applications - such as in the areas of bio-processing or bio-fermentation scale-up - which could, for example, make it easier to synthesise or produce harmful agents.
- projects that carry very little potential for misuse, but where the risk would be greatly increased by emerging data or methodologies from other disciplines, for example, studies on a toxin that cannot currently be introduced easily to humans, but which might be deliverable by advances in materials science or aerosol physics

### **Balancing benefit and risk**

6. The BBSRC, MRC and WT consider that in order to address these legitimate concerns, it is important that appropriate processes exist at institutional, national and international levels for the review and oversight of research that could potentially be misused to cause harm. The funders have stressed the need for researchers to identify, consider and report cases of potential concern.
7. With regard to research involving harmful biological pathogens and toxins (affecting people, animals or plants), we believe strongly that such work will be absolutely crucial in the fight to combat the diseases that these agents cause and to improve our ability to respond to bioterrorist attacks and other potential threats. More generally, the BBSRC, MRC and WT consider that the creation and dissemination of scientific knowledge is a definite and tangible public good.

---

<sup>2</sup> Biotechnology Research in An Age of Terrorism: Confronting The Dual Use Dilemma. US National Research Council (2003) [link](#)

8. Where a particular avenue of research raises dual use risks of concern, the benefits of pursuing this work need to be described and weighted carefully against the risks – recognising that these risks may sometimes be hypothetical and hard to quantify.
9. We believe that regulatory processes must not unduly restrict essential research. Any additional regulatory requirements that may be introduced should apply only to those research projects where there is tangible cause for concern. We expect that this will represent a very small proportion of the many research projects undertaken in academic and other research laboratories supported by public and charitable research funders.

### **BBSRC, MRC and WT funding decisions**

10. To ensure that the research we fund is in line with our missions and is of the highest scientific quality, all BBSRC, MRC and WT-funded research is subject to independent expert review. Reviewers are required to consider whether the proposed methodology is appropriate for achieving the stated objective and are asked to raise any ethical or safety concerns that they have regarding a particular application. The BBSRC, MRC and WT have developed specific guidance for reviewers and applicants with regard to risks of misuse, as detailed in our joint policy statement.
11. As a condition of funding institutions in receipt of BBSRC, MRC and WT funds are responsible for ensuring that they comply fully with the requirements of all regulatory authorities for the storage, use and transfer of all potentially harmful materials, including pathogenic organisms, and any additional provisions to safeguard security that may be specified by such authorities. Institutions also accept full responsibility for the management, monitoring and control of all research work funded by grants, and for ensuring that permanent and temporary staff and students undertaking such work receive training appropriate to their duties. The funding bodies continue to work with their sponsored institutes to ensure high levels of compliance.
12. We encourage education and training on dual use research of concern to be provided for all individuals working in areas that hold the potential for dual use risks. Indeed, such training could form a practical component of a risk mitigation plan and be a system put in place to facilitate self-governance, as discussed further below.
13. BBSRC, the MRC and the WT would emphasise that it may be extremely difficult at the grant application stage to identify projects which could generate results that might theoretically be misused, and to assess accurately the extent of any such risk. Additional, ongoing assessment of potential risks should therefore be made at a local level through the lifetime of the project as the need arises. Researchers are also expected to notify funders, institutions and other relevant authorities of any change in the status of a project or any newly emerging risks in relation to dual use research of concern that may not have been identified at the grant application stage.
14. If a situation arose where concerns had been raised with the funders that an application had a serious risk of misuse associated with it, which could not be resolved via management strategies agreed with host institutions and investigators following peer review, then we would not fund that application. The funders anticipate, however, that such circumstances will be extremely rare.

## **Dissemination of research**

15. BBSRC, the MRC and the WT consider that it is essential to the progress of biological research and its ultimate application to major societal challenges, such as those in healthcare and food security, that researchers all over the world have access to research findings so that they can verify, build upon and apply this knowledge. In the vast majority of cases, the interests of the international research community, and ultimately the public, will be best served when the results of research are disseminated through publication in peer-reviewed journals and research datasets are made widely available for verification and re-use by the widest possible audience to achieve the maximum benefit from research outputs.
16. We would be concerned by the introduction of any limits on publication that threatened the principle of open communication in science. For the foreseeable future, we believe that the dissemination of research results in the context of scientific publication should be based on voluntary self-governance by the scientific community.
17. Openness and transparency in research will facilitate self-governance of dual use risks and could enable scientists and others to better identify those projects where the risk for misuse could be increased by emerging data or methodologies from other disciplines.

## **International collaboration and training**

18. We would likewise be concerned by the introduction of processes that could unreasonably restrict the ability of talented scientists from overseas to work and train in UK laboratories, or inhibit the ability of scientists in the UK to collaborate with scientists overseas. In considering the introduction of any changes to existing regulatory processes, the funding bodies would urge the UK Government to consider the immense contribution made by scientists from overseas to the UK science base and the crucial importance of international collaboration to the scientific enterprise. The funders would also be concerned by undue restrictions on the international exchange of materials in the context of normal academic research. We recognise the importance of appropriate security screening for all scientists of whatever nationality wishing to work in areas with the highest potential for misuse.

## **Promoting research good practice and ensuring public trust**

19. It is the view of BBSRC, the MRC and the WT that a system based upon self-governance by the scientific community, but which draws in wider perspectives (as elaborated below), will ultimately provide the most effective means of managing risks of misuse, the assessment of which will often require expert scientific judgement. We consider that the community should take active steps to develop mechanisms of self-governance, and that through doing so it can ensure that responsibly conducted research is not unnecessarily obstructed (**Box 3**).

### **Box 3- Key elements of a self-governance approach**

Effective self-governance requires the research community to take clear and proportionate steps to ensure the risks of dual use research of concern are identified and addressed appropriately where they arise.

There are a range of regulatory requirements governing the safety and security of work on potentially hazardous agents with which researchers and institutions are expected to comply. In the UK, these include obligations set out in the Control of Substances Hazardous to Health Regulations (2002), the Anti-Terrorism, Crime and Security Act (2001) and the Export Control Act (2002). However, while several types of dual use risk may be captured by assessments required under these and other regulations, many will not. Therefore, it is important to have clear processes to also consider risks associated with the outputs of research, which sit alongside these other types of risk assessments.

The specific processes required may vary from case to case, depending on the risks and benefits associated with a project and the nature of the expertise required to make these assessments. It is not appropriate, therefore, to impose hard and fast requirements: however, key responsibilities exist at individual, institutional and community levels.

First and foremost, we recognise that we as **research funders** must take a proactive lead. We believe that the approach set out in this policy is proportionate, in balancing the need to address dual use risks, with the need to ensure that the benefits for society of responsibly conducted life sciences research are realised. We are committed to ensuring dual use research of concern is identified and assessed where possible both during the funding process and as research proceeds, and to raising awareness of these issues. Other parts of the research community, however, also have key roles.

**Individual researchers** have a responsibility to consider any dual use risks associated with their own research as it progresses, to report such risks to institutions, funders or regulatory authorities where appropriate, in a timely fashion, and to seek advice from these and other relevant bodies as required.

**Research institutions** should establish clear policies and processes for considering dual use risks wherever and whenever they emerge - providing advice and guidance to researchers they employ and actively monitoring the progress of research where potential risks are identified. This may entail, for example, having mechanisms to call on expert advice or to convene expert groups (this might include individuals with scientific, biosafety, security and ethics expertise) to assess risks and benefits associated with projects of potential concern. It also includes provision of appropriate training and education to all researchers working in areas where dual use issues could emerge, and having policies in place to ensure staff and students can raise legitimate concerns without fear of reprisals.

**Research communities** should work collectively to consider and respond to emerging dual use risks, and ensure their members are aware of their responsibilities. The development of internationally agreed codes of conduct and other common principles may play an important role. The community as a whole should actively seek to engage in open and inclusive discussions over emerging research areas that raise new concerns – ensuring that appropriate systems for governance and oversight are established that address legitimate risks where they arise and maintain the public's trust and support.

20. Discussions on such mechanisms will need to involve scientists from relevant disciplines and representatives of professional societies, funding agencies, regulatory bodies, and other key stakeholders at a national and international level. These should be open and transparent, and provide for wider public input and engagement as far as possible. It will be particularly important for the scientific community to maintain an active dialogue with governments and security services to ensure that their requirements and concerns are addressed. BBSRC, the MRC and the WT will continue to participate actively in these discussions, and initiate them where appropriate.
21. It is also essential that the international scientific community engages effectively with wider society in addressing these risks. The BBSRC, MRC and WT are committed to fostering public engagement on the issues raised by advances in biomedical science, and will consider how it can work in partnership with other organisations to engage a range of publics on the issues addressed in this statement.
22. In order to promote best practice in the conduct of research and maintain public trust, BBSRC, the MRC and the WT consider that the international scientific community must take proactive steps to ensure that its members are aware of potential risks and concerns relating to terrorist misuse of research, and of the regulatory and ethical responsibilities that they hold.

**15 July 2015**