BBRSC, MRC and Wellcome Trust response to the Bateson Review Recommendations

July 2011

Recommendation 1: The Panel noted that the processes needed to maximise scientific quality and impact are already in place as part of mechanisms for the funding of NHP research, and concluded that each application for funds to support research using NHPs should be subject to rigorous review of the scientific value of the research, the probability of medical or other benefit, the availability of alternative approaches, and the likelihood and extent of animal suffering. In particular, care should be taken to ensure that the review is a dynamic process that keeps pace with and employs best current knowledge concerning animal welfare, scientific advances and changes in public perceptions.

Response: *The BBSRC, MRC and Wellcome Trust are committed to continuing the rigorous review of all grant applications, particularly where NHPs are requested. As mentioned in the report, research using animals must:*

- *be fully compliant with current Home Office legislation;*
- *be approved by a local ethics committee;*
- *be successfully independently peer reviewed; and*
- *demonstrate there are no non-animal alternatives and consider the 3Rs in experimental design.*

For each proposal that involves the use of animals, reviewers and funding panels are asked to assess whether animals are needed, whether the potential benefit justifies the adverse effects on the animals, whether the numbers are appropriate, and whether the species is the most appropriate.

In addition, since 2004, we have strengthened our procedures for assessing all grant applications requesting use of NHPs, cats, dogs and equines. These applications are now reviewed by the independent National Centre for the Refinement, Reduction and Replacement of Animals in Research (NC3Rs). Any concerns are explored with the applicants and funding is not awarded unless these are properly addressed. We will continue to work with the NC3Rs to ensure that all research we fund using NHPs is assessed appropriately and the research undertaken is of the highest standard in terms of science and animal welfare.

Recommendation 2: In considering research proposals, peer reviewers and panel members should critically examine the justification for the choice of species and whether human subjects could be used as alternatives. Consideration of the potential for alternatives should extend beyond rodent models; the potential of *in vitro* and *in silico* approaches should be considered, and the potential of other species as models should be fully explored before a decision is made to employ NHPs. Care should be taken to ensure that peer reviewers and panel members collectively possess the full breadth of knowledge and experience to assess all the relevant options.

Response: *We select a range of peer reviewers on the basis of their expertise for the application which they are being asked to review. The justification for the use of NHPs in grant applications is fully scrutinised as part of the peer review process. As mentioned above, all grants requesting NHPs are reviewed by the NC3Rs, which critically examines the need for primates in the proposed research. Where necessary, NC3Rs seeks*

clarification or further information from applicants. This further information is provided to the funding panels to inform their decisions.

We ensure that peer reviewers selected include scientific experts who are users and non-users of primates. Our funding panels are made up of scientists with expertise covering the range of scientific areas in which the panel assesses applications; in circumstances where there is insufficient expertise on the funding panel, guest panel members can be brought in for the discussion of specific applications to ensure that the full breadth of knowledge and experience is available to assess all the relevant options.

Recommendation 3: It is an ethical imperative that maximum benefit be derived from studies employing NHPs. When considering research proposals, funders should take into account the nature of the organisation to which the researcher is affiliated, with regard to the extent of integration of teams working in different fields and at different points along the spectrum of science from fundamental to applied. They should consider whether any structures or processes are in place to facilitate knowledge transfer or to ensure the exploitation of outcomes of the proposed work. They should also take into account the researcher's plans for knowledge transfer or other exploitation. Funders should encourage data-sharing and should consider creating or supporting on-line repositories for digitised data which may be made freely available to other researchers.

Response: *All aspects of a grant application are taken into account, including the quality and track record of the individuals and institutions involved, and any associated mentors or sponsors. We encourage interdisciplinary and collaborative working that enables researchers to achieve the best possible results. Research Council applicants are required to complete a section "pathways to impact" giving information on plans to ensure the outputs of the research are taken further and these are taken into account by funding panels.*

We are committed to ensuring that the outputs of the research we fund, including research data, are managed and used in ways that maximise public benefit. As part of our terms and conditions, funded researchers must follow data sharing and open access policies[1] and provide a data management and sharing plan in their grant applications. As part of the open access policy, researchers must make all publications available through open access repositories; for MRC and the Wellcome Trust they must be made available on UK PubMed Central.

We will investigate the feasibility of creating or supporting on-line repositories for digitised data to facilitate sharing of data between researchers.

Recommendation 4: Science policy-makers together with the public sector, private sector and charitable funders of research should commission a working group to develop proposals for a mechanism (output-scanning) to identify research results with potential to deliver improvements to healthcare or other significant benefits to society, and to assess the extent to which the potential benefits are achieved. The stakeholder bodies

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www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTX035043.htm.
www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Open-access/index.htm
www.mrc.ac.uk/Ourresearch/Ethicsresearchguidance/Datasharinginitiative/Policy/index.htm
www.mrc.ac.uk/Ourresearch/Ethicsresearchguidance/Openaccesspublishing/Positionstatement/index.htm
www.bbsrc.ac.uk/organisation/policies/position/policy/access-research-outputs.aspx
www.bbsrc.ac.uk/organisation/policies/position/policy/data-sharing-policy.aspx

should develop mechanisms to facilitate exploitation of new knowledge derived from NHP studies for clinical or other benefits to society.

Response: *We will discuss this recommendation with the relevant organisations and considers ways in which it could be taken forward.*

Recommendation 5: The Review Panel applauded the efforts by some of the grant-holders to deliver 3Rs improvements as part of or alongside their major research outcomes, and particularly their willingness to publish the results of such work. The Panel also noted that funders require implementation of the principles embodied in "Responsibility in the use of animals in bioscience research - Expectations of the major research council and charitable funding bodies" as a precondition for receiving funds. In defining research grant terms and conditions, funders should take particular care to encourage, and where appropriate require, the active dissemination of 3Rs improvements through the international research community and should ensure that appropriate monitoring and enforcement procedures are in place to encourage full compliance with all aspects of the 'Responsibility' guidance.

Response: *As noted in the recommendation, our grant terms and conditions require that researchers abide by the core principles set out in "Responsibility in the use of animals in bioscience research - Expectations of the major research council and charitable funding bodies". Our grant terms and conditions also require award holders to report any new procedure likely to reduce the number of animals for research or testing, or to replace or refine their use and to disseminate such advances through the usual scientific channels to all those who might make use of it.*

Funders have recently made significant progress in the development of systems to enable the dynamic tracking of research progress, outputs and outcomes and to encourage active dissemination of findings. The MRC e-Val system actively requests information from MRC grant holders about 3Rs advances. The Wellcome Trust is also introducing a system that will enable 3Rs outputs to be collected. And the BBSRC is working with other Research Councils to introduce an outcomes system which will request similar information; this is scheduled to be in place by the end of 2011.

We endeavour to ensure that research we fund using NHPs maintains the highest standards of animal welfare in accordance with the 'Responsibility' document. We work closely with the NC3Rs to assess the accommodation and welfare standards of NHP facilities both in the UK and overseas, including periodic site visits.

Recommendation 6: Researchers using NHPs have a moral obligation to publish results - even if negative - in order to prevent work being repeated unnecessarily. In considering grant applications, funding bodies should take into account the previous publication performance of applicants and their research groups. Where there has been a history of limited dissemination or exploitation, the funders should consider with particular care the likely balance of the animal welfare cost against the potential benefits arising from funding that application.

Response: *Grant holders are required to publish the results of their research as part of the terms and conditions of the award. We clearly recognise the importance of negative results being published in order to prevent work being repeated unnecessarily; while it is not within our power to make journals accept papers for publication we will continue our discussions with publishers and other organisations to encourage the publication and recognition of the value of negative results This issue also arises in other areas of research such as clinical trials.*

Since 2009, all MRC grant holders are required to submit information on outputs and outcomes of their work annually via an online system (e-Val); BBSRC is working with other research councils to introduce an outputs system by the end of 2011. And as described, the Wellcome Trust will also be introducing a complementary system to enable all research developments and outputs to be reported and captured on an ongoing basis. This should allow monitoring of publications from every grant and will help us identify and investigate grants using NHPs where work has not been published.

Publication record is always considered in grant applications to the funders – all grant applications require details of the researchers' past performance, including publication record, which is assessed by funding panels.

Recommendation 7: Conducting the highest quality NHP research demands a range of skills and resources. Funders should take care to ensure that the teams and infrastructure involved in a funding bid are fully appropriate to the requirements of the intended research.

Response: *To ensure that the teams and infrastructure involved in a research application are fully appropriate to the requirements of the intended research, the consideration of all applications includes an assessment of the appropriateness of the research environment, the track record of the applicants in the field and whether there is a firm foundation to take the work forward. Primate research in the UK is now concentrated in a few centres where the range of experience is broader.*

Recommendation 8: Highly invasive and long-term NHP research often carries a high welfare cost. In such cases, funders should take particular care only to fund projects with a very high likelihood of producing scientific, medical or social benefit. Wherever possible, funders should take steps towards encouraging a preferential or complementary use of less invasive techniques such as neuroimaging and transcranial magnetic stimulation.

Response: *We base all funding decisions on scientific excellence, taking into account impact including the potential for high health and/or socio-economic impact. As funders, we will encourage our researchers, through our guidance to applicants and via review by the NC3Rs, to further develop the use of less invasive techniques such as neuroimaging and transcranial magnetic stimulation, where this is appropriate.*

In addition, we fund the independent NC3Rs who are launching an initiative to accelerate the translation of alternative technologies into use in the lab.

Recommendation 9: The Panel noted that all funded NHP research, regardless of where it is conducted, should comply with the 'Responsibility' guidance and NC3Rs guidelines 'Primate accommodation, care and use', and that the NC3Rs had visited laboratories in the UK and overseas to give advice and to monitor compliance. The Panel's view was that funding bodies should take all necessary steps to satisfy themselves that work on NHPs funded by them outside the UK meets the standards acceptable in the UK.

Response: *We agree with this recommendation and note that the formal adoption of Directive 2010/63/EU in January 2013 should ensure consistent standards across Europe. We rarely fund work on NHPs outside the UK; for the instances where such work is funded researchers must prove that the animal welfare standards are equivalent to*

those expected in the UK[2]. Researchers must justify why the work should be undertaken overseas.

Recommendation 10: The Home Office should review its performance with the regard to the operation of the Animal (Scientific Procedures) Act to ensure that inefficiencies of processes or inconsistent advice to researchers do not create unreasonable delays or obstacles to appropriate NHP research. Accreditation of the enforcement processes to the appropriate ISO standard should be considered.

Response: *This recommendation is directed to the Home Office but we strongly support the need for efficient regulatory processes. We hope that in implementing the new EU Directive, the opportunity will be taken to remove unnecessary bureaucracy which does not result in animal welfare benefits.*

Recommendation 11: The recommendations of the Weatherall Report (Recommendations 13-15) concerned with addressing the impact of both the costs of work in the UK and harassment by activists should be followed up as a matter of urgency. Researchers in the UK using NHPs still experience an unacceptable level of personal risk. The risks and the high costs of NHP research are increasingly perceived as barriers to continued work in the UK.

Response: *Although value for money is a factor in assessing all research proposals, funders employ different methods to ensure the high cost of research involving NHPs does not overly influence the funding decision. However, a major factor in the cost is the need to ensure the animals are kept in a way that maximises their welfare and we would not wish to see this compromised.*

We support the activities of Support4RS which provides advice and support to individuals and organisations in the public and university sectors that use animals in biological and medical research to help them deal with Animal Rights Extremism.

We are committed to engaging the public on the use of animals, including NHPs, in research, and support the activities of Understanding Animal Research (UAR) in raising public awareness and understanding of the reasons for the use of animals in research.

Recommendation 12: In their public engagement, the funders and researchers should avoid overstating and generalising the medical benefit of NHP research, since this cannot be substantiated in many cases. Instead, the statements should reflect the actual basis for funding decisions, recognising that these are often based on scientific value.

Response: *BBSRC and MRC applicants are required to include information on the potential economic and societal impacts of their research in a 'pathways to impact' statement in their application; we are aware that the pathways to impact for basic research are likely to be different to those for translational research. Applicants are advised to bear in mind the broad range of impacts that their research may have, spanning the advancement of scientific knowledge, health and wellbeing, economic competitiveness, policy development and the provision of skilled people to the workforce.*

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[2] www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC001897

Once the research is completed and published the likely impacts should be clearer and, as funders, we will aim to ensure that conclusions about impact are based on firm evidence.

The methodology for understanding and recognising the impacts of very basic research is an area that all funders recognise requires development, and we are working together on this.

Recommendation 13: The Panel noted that since the period under review, the funders had made progress in improving the collection of research outputs through standard end of grant templates and, in some cases, through annual data collection. The Panel recommended that a culture of routine output reporting should be embedded in all funded researchers and that provision of such data should be a condition of the grant. In particular, where grants were awarded on the promise of human health benefits, the grant-holders should provide evidence of interest in and use by the medical and biopharmaceutical sectors. Failure to regularly update funders regularly with relevant data should disqualify grant-holders from further funding.

Response: *Research funders are actively enhancing their monitoring and evaluation capabilities. In recent years considerable progress has been made to improve reporting and dissemination of output and achievement-related information – most recently via online tools and systems such as e-Val. The funders are also making progress on systematically extracting and analysing these data.*

Recommendation 14: The Home Office should reconsider their advice to research workers to destroy records after five years.

Response: *This recommendation is directed to the Home Office although we note that it is important researchers retain their data and records for long enough to allow them to be re-analysed, and the research to be repeated if necessary, if subsequent research points to different conclusions.*

Recommendation 15: Further reviews of the outcomes, benefits and impact of NHP research should be carried out periodically.

Response: *We will undertake periodic reviews of the outcomes, benefits and impact of NHP research. This will be easier now that we are routinely collecting data.*

The report states that "the Panel concluded that further comprehensive reviews of the outcomes of NHP research and the contributions made to scientific knowledge, animal and human medicine and other public goods should be carried out at intervals of, say, every 15 years. The reviews should not, however, be so frequent that the difficulties of identifying and measuring impacts are exacerbated". We agree that intervals of 15 years would be appropriate as it takes a significant time for much basic research to feed through into health or other impacts.