Freedom of Information – Independent Commission

Response to call for evidence issued on 9 October 2015

The Physiological Society submission

20 November 2015

The Physiological Society

The Physiological Society ("The Society") has represented UK and international physiologists since 1876. One of the principal reasons for the establishment of The Society was the recognition that experimental scientists should contribute to the development both of physiological knowledge and of the legislation that impacts on research conduct and progress, at that time specifically relating to the use of animals in research, a core component of the research The Society's Members undertake. As a result The Society has for over 100 years been working closely with related organisations and government in both the development and the refinement of legislation on the use of animals in research, including implementation of the '3Rs'.

The Society strongly supports greater openness concerning the use of animals in research. It was a founder organisation and signatory for the Declaration on Openness on Animal Research in 2010, and an active partner in the development and promotion of the Concordat on Openness in Animal Research, launched in 2014. Its Members are signatories to the Concordat and work actively to promote and achieve a greater public understanding of the need for, and the safeguards already enshrined in, the use of animals in research.

The Society and its Membership are strongly supportive of an environment in which Freedom of Information [FOI] is an expectation on public bodies, subject only to adequate protection of:

- personal information;
- information, including but not limited to the current FOI definition of intellectual property, requiring confidentiality for the public body to be able to operate in an internationally highly competitive environment;
- a 'safe space' in which regulators and the regulated can operate to maximise the benefits to the UK.

The Society therefore believes, and has previously expressed concern in Government consultations, that FOIA, as currently operated, fails to provide the second and third of the above protections as far as animal-based research is concerned. It therefore risks the UK bioscience sector's world-class research and the associated nationally-important social and financial outputs.

The Society wishes to emphasize some points that are directly relevant to our Membership, concerning the relationship between FOIA and the regulation of research involving animals.

The use of animals in research is regulated by EU Directive 2010/63 and thereunder the Animals (Scientific Procedures) Act (ASPA) 1986, as amended in 2013. During consultations with the regulators (the Animals in Science Regulation Unit of the Home Office [ASRU]) on revision of ASPA section 24, The Society was in agreement with ASRU that FOIA alone would currently be insufficient protection for UK animal-based research. This situation arises because of the legal requirement under ASPA to detail a large body of material solely for the purpose of gaining a licence to undertake the research. In many licences, much of this material is academically-confidential in the sense of being of value to scientific competitors. The Society is not aware of any other situation in which an equivalent regulatory requirement exists to specify so much confidential information to achieve a licence for an individual to operate.

Among The Society's concerns are aspects that relate to the Independent Commission's questions 1 and 6; they are summarised under the headings below.

Question 1. Protection for internal deliberations of public bodies

Research involving animals requires the writing and consideration by ASRU of a highly technical and detailed licence to operate under ASPA. The preparation for this 'Project Licence' requires multiple discussions between ASRU Inspectors, applicants and other members of the Institution to ensure that the scientific aims of the work can be met and that the welfare of the animals will be optimised, and thereby that the legal requirement for a successful harm:benefit assessment can be met. These discussions require written records to ensure proper understanding and coordination between all the parties involved, and in particular to assure legal compliance with ASPA. There is therefore a need for a 'safe space' in which full and frank exchanges can be had without concerns that written communication will risk burdensome FOIA requests and the potential release of information to scientific competitors or the public.

In terms of subsequent release, the information contained in and associated with the Project Licence is detailed and (despite the inevitable uncertainty associated with scientific advances) is intended in due course to benefit the health and wealth of the UK. In many cases the timescale over which such benefit may be realised is impossible to predict; many members of The Society are engaged in preclinical research, most of which does not have a predictable timescale for 'translation' to yield social or economic benefit. The only person(s) with the expertise to fully determine whether the details associated with a Project Licence could be further exploited for public benefit are the individual scientist(s) involved in the research. It is therefore essential for the scientific and economic future of the UK that any revised legislation recognises that it is the scientists within institutions who need to be able to control the release of the scientifically confidential information they have collated solely for the purposes of gaining a Project Licence to work under ASPA.

Question 6. The burden on public bodies

Because of the nature and length of the Project Licence, and the level of detail required, much of the scientifically confidential information is embedded within less sensitive material. There is therefore a major burden associated with redaction of such complex documents, much of which falls upon the individual scientists as the only person(s) able to identify what information would be of value to competitors. The time spent on these activities inevitably impacts adversely on the scientific endeavour, and therefore would result in reduced productivity. The combined costs of the time spent by experienced scientists and lawyers on FOIA requests in this delicate area become a major financial burden on public institutions.

The perceived risk of additional burdens associated with redaction will inevitably increase further the attraction for our members of undertaking their animal-based experiments abroad, where the bureaucratic load is generally much lighter; we are aware of examples of this happening already. The net result would be a loss of expertise and wealth from the UK, and a reduction in the oversight of animal welfare.

The Society therefore believes that FOIA is currently not adequate for protecting the academically confidential content of regulatory documents required for undertaking bioscience research involving animals. It does not generate confidence that there is the safe space required for the preparation and oversight of Project Licences under ASPA. Recent legal challenges under FOIA have generated major concerns over the bureaucratic burden to which scientists are liable, and

the associated financial costs to their institutions. This situation poses an on-going threat to both - research and the economy.

We hope that the Commission will consider how FOIA could be modified to protect the legitimate interests of research that requires the use of animals. In particular we hope for consideration of the unusual situation of having to generate a large body of confidential material for the sole purpose of obtaining a legally-required licence to undertake research.

Should further information on these issues be of help to the Commission we would be pleased to help further.

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