

POTENTIAL CONFLICTS OF INTEREST IN RELATION TO NAMED PERSONS

Introduction

1. This document seeks comments on the implementation of a system to ensure avoidance of significant scientific, financial or other conflicts of interest among individuals (named persons) fulfilling the role of Named Veterinary Surgeon (NVS) or Named Animal Care & Welfare Officer (NACWO) under the Animals (Scientific Procedures) Act 1986 (ASPA). The formal closing date for responses is **Monday 2nd July 2012**. However, we would welcome early responses to enable arrangements to be put in place by late 2012 to coincide with implementation of Directive 2010/63.

Background

2. In relation to the appointment of named persons, Section 6(4)(b) of the Animals (Scientific Procedures) Act 1986 (ASPA) states that an application for a certificate of designation must include the names of one or more NVSs and NACWOs “appearing to the Secretary of State to be suitable for that purpose”. We take the view that suitability relates not only to the training and experience of the nominee but also to the absence of any significant conflict of interest.

3. The concept of potential scientific conflict of interest was raised by the Inspectorate in 1993 with the conclusion that all animals under procedures should be accessible to independent observation by at least “three pairs of eyes”. In 1994, the Animal Procedures Committee confirmed this advice which is now included in the Guidance to the Act (see **Annex A**).

4. We have received legal advice that a person who is a “controlling financial or scientific mind” should be presumed not to be suitable as a named person in the absence of compelling circumstances to the contrary. However a mere financial interest in the outcome of research should not debar a person from being a named person. Whilst inspectors are likely to be familiar with the scientific involvement of named persons in authorised projects, mechanisms are not currently in place to make them aware of potential financial involvement. We believe this makes it difficult for inspectors to advise the Secretary of State of the suitability with respect to financial involvement of those being nominated for these roles.

5. The determination of suitability of a nominee for the role of a named person is a matter of policy judgement. In effect, a named person must not be in a position where he or she does not put their over-riding welfare obligations to the animals first. The Secretary of State would be able, more readily, to make such a policy judgement given a written declaration of the scientific, financial and other relevant interests of the nominees.

Proposals

6. We are proposing to extend the application form for a designated establishment to include the following:

- a. Brief details of the training and experience of each nominee (in addition to the current requirement for qualifications) which the applicant believes make the nominee suitable for the proposed role as a named person;
- b. A signed declaration by each nominee of their relevant potential conflicts of interest which will include:
 - i. financial interests such as directorships and significant shareholdings;
 - ii. significant research interests, together with alternative provisions for the oversight of the animals to minimise any risks of conflict of interests where appropriate;
 - iii. interests of close relations/friends which may be relevant (e.g. if the spouse or a sibling of the nominee is a director or major shareholder of the establishment);
 - iv. any other relevant matters.

7. We propose that the declaration by named persons should be renewed, in a similar format, approximately once every five years and that this should be arranged so that the renewal of the declaration for all the named persons at an establishment coincide. This will not, of course, remove the onus on named persons to promptly inform certificate holders of any significant changes in circumstances during the five year period.

8. An example of such a declaration is provided at **Annex B** which includes guidance notes as to what factors the Home Office will consider relevant in deciding whether a nomination as a named person is suitable. Neither the payment of a salary or consultancy fee to a named person, nor the provision of professional support to a research project where the named person does not have a substantial interest in the scientific outcome, will normally be considered to preclude suitability. Inspectors will be able to provide advice to applicants if in doubt.

9. We also propose to require certificate holders and named persons (through their certificate holders) to notify the Home Office as soon as practicable of any significant changes to their declaration regarding potential conflicts of interest. We will do this through a standard condition on certificates of designation. Certificate holders will also be reminded of this requirement annually when they receive their notice of fees.

We would welcome views on these proposals.

Impact

10. Given that we believe examples of potential conflict are rare under current arrangements, we are proposing a system which we believe will achieve its aim whilst minimising the impact for stakeholders of this requirement.

11. We propose to add the necessary declarations and additional condition in relation to existing certificates in tandem with the transitional provisions for Directive 2010/63.

12. For new establishments, we will simply add the necessary declarations to the application forms for designation of establishments and likewise for amendments to designations. A similar form will be used for the re-declaration by named persons at five year intervals. We propose to remind certificate holders of the requirement to notify the Home Office of any significant change in interests as part of the current annual fee collection process.

13. We do not therefore expect this new requirement to add significantly to the regulatory burden.

Is our assumption correct? We would welcome further and better information, including estimated costs and other details, to help refine our assessment.

How to respond

14. When responding please state whether you are responding as an individual or whether you are representing the views of an organisation. If responding on behalf of an organisation, please make it clear who the organisation represents and, where applicable, how the views of members were assembled.

15. A response can be submitted by letter or email to:

Animals in Science Regulation Unit
Home Office
4th Floor, South West
Seacole Building
2, Marsham Street
London
SW1P 4DF

Email: aspd-brp@homeoffice.gsi.gov.uk

16. This consultation is open to everyone, but we would particularly like to hear from individuals and organisations with a direct knowledge of the relevant issues. **The formal closing date for responses is Monday 2nd July 2012.**

Additional copies

17. This consultation can be found at: <http://www.homeoffice.gov.uk/science-research/animal-research/> and is also available from the Animals in Science Regulation Unit at the address above. You may make additional copies without seeking permission.

Responses: Confidentiality & Disclaimer

18. The information you send us may be passed to colleagues within the Home Office, the Government or related agencies.

19. Information provided in response to this consultation, including personal information, may be subject to publication or disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 [FOIA], the Data Protection Act 1998 [DPA] and the Environmental Information Regulations 2004).

20. If you want other information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence.

21. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

22. The Department will process your personal data in accordance with the DPA - in the majority of circumstances this will mean that your personal data will not be disclosed to third parties.

Help with queries

23. Questions about the policy issues raised in the document can be addressed to the Animals in Science Regulation Unit, Home Office (contact details as above).

24. You should also contact the Animals in Science Regulation Unit should you require a copy of this consultation paper in any other format, e.g. Braille, Large Font, or Audio.

What happens next?

25. Decisions taken in light of this consultation will be made public.

**Animals in Science Regulation Unit, Home Office.
21 May 2012**

**EXTRACT FROM GUIDANCE ON THE OPERATION OF THE ANIMALS
(SCIENTIFIC PROCEDURES) ACT 1986 [2000 ed.]**

CONFLICTS OF INTEREST

3.17 The Act makes provision for a number of individuals to assume responsibility for different aspects of the well-being of protected animals at designated establishments: certificate holders, project licence holders, personal licence holders, Named Animal Care & Welfare Officers, and Named Veterinary Surgeons.

3.18 The contractual relationships between, and other responsibilities of, these individuals can create conflicts of interest. There may also be occasions when one individual legitimately fulfils more than one of these of roles. For example, in most cases, project licence holders will hold, or will have held, a personal licence. For these reasons, the Secretary of State normally requires that, for any group of protected animals, at least three individuals should fill these five roles.

3.19 When a Named Veterinary Surgeon or Named Animal Care & Welfare Officer has (under any other of the statutory roles) a substantial interest in the scientific outcome of a programme of work, alternative provision should be made for the veterinary or welfare oversight of the animals in question.

CONFLICTS OF INTEREST DECLARATION

NAMED PERSONS UNDER ASPA 1986.

It is important that any named person¹ under ASPA must not be in a position where he or she does not put his/her over-riding welfare obligations to the animals first. A person with a controlling financial interest or a substantial interest in the scientific outcome of a project might be presumed not to be suitable as a named person in the absence of compelling circumstances to the contrary. In order for the Secretary of State to determine whether an individual nominated to be a named person is suitable, it is important to be fully aware of any real or perceived conflicts of interest which exist.

A separate declaration should be completed by each person nominated by a certificate holder to be a named person and should accompany the Application for Designation of an Establishment, or the Application for Change(s), as appropriate.

Full Name:

Position/
Establishment:

(Please tick the statement which applies.) Either:

I declare that to the best of my knowledge and belief neither I nor my spouse, partner, immediate family or close friends have any interests which might conflict, or be perceived to conflict, with my duties as a named person. Furthermore, if my situation should change, I will notify the certificate holder without delay.

I declare interests below for consideration and have also set out the action I am taking to minimise the risk of these interests coming into conflict, or perceived conflict, with my duties as a named person. I certify that the information included is, to the best of my knowledge and belief, accurate and complete. Furthermore, if my situation should change, I will notify the establishment certificate holder without delay.

Signed.....

Print Name.....

Date.....

¹ Named Persons under the Animals (Scientific Procedures) Act 1986 (ASPA) are those appointed under Section 6 of ASPA as a Named Veterinary Surgeon (NVS) or a Named day to day care person (NACWO).

Directorships & Shareholdings

Please list and briefly describe the following:

- Any directorships and partnerships you hold in companies which may have a direct or indirect relationship with the establishment;
- Any significant shareholdings in companies which may have a direct or indirect relationship with the establishment;
- Any other significant shareholdings in companies which may be engaging in large business transactions with the establishment.

As a guide, "significant" would be any shareholding in a private company or, in a public company, a shareholding amounting to more than 1%.

Research interests

Of the five key roles² under ASPA, please list all those which you will be fulfilling at the establishment. It is normally expected that these five roles will be allocated to not less than three individuals, that the key roles of certificate holder, NVS and NACWO will not be combined in one individual and that, where a named person has a substantial interest in the scientific outcome of a project, alternative provision will be made for the care and welfare of the animals.

Close relations and friends

Please list any possible conflicts of interests created by virtue of the employment, directorships, partnerships or significant shareholdings of close relations or close friends.

Any other matters

Please list any other matter which may give rise to a potential conflict of interest e.g. membership of committees/organising bodies with decision making or purchasing powers, beneficial ownership of property, etc.

² Holder of Certificate of Designation; Project licence holder, Personal licence holder; Named Veterinary Surgeon (NVS); Named day to day Care Person (NACWO).