Consultation on the review of Section 24 of the Animals (Scientific Procedures) Act 1986

Response by the Wellcome Trust

June 2014

Key Points

- The Wellcome Trust is committed to ensuring that information relating to the use of animals in the research we fund can be widely accessed and used in a manner that makes clear the harms and benefits that research creates.
- Whilst we recognise the need for a more open and transparent framework, it is essential that this remains proportionately robust to provide adequate protection for: personal health and safety; confidential and commercially sensitive information including intellectual property (IP); and the competitiveness of the UK in the life sciences sector.
- We see option 2b as the most appropriate of the options presented in the consultation. There are however three main areas of concern that require further clarification and detail in the legislation: who in particular the option 2b statutory bar is intended to apply to, the definition and scope of "malicious intent" and ensuring that appropriately broad protection for IP is reflected in FOIA exemption guidance.
- Any legislative framework must provide clear protection for IP, which, as the Impact Assessment sets out, would include novel ideas, scientific hypotheses, protocols, procedures and research plans as well as commercially exploitable IP such as patents.
- Confidence and trust in the UK life sciences sector is necessary to maintain the UK as a global competitive research environment in which to operate. Insufficient protection for commercially sensitive and confidential information and a disproportionate regulatory burden on public and private research bodies could have a negative impact on the UK life science sector.

INTRODUCTION

1. The Wellcome Trust is a strong advocate of developing a more open dialogue between the research community and the public, to engage the public with why animal research is necessary for scientific research and development, how the research is regulated in the UK and how animal care and welfare is maintained. In support of this objective the Wellcome Trust is a signatory to the Concordat on the openness on the use of animals in research in the UK launched in May 2014.

2. The Wellcome Trust is a member of the UK Bioscience Sector Coalition and has fed into the UKBSC response to this consultation, with which we are in agreement. This paper provides further comment from our perspective as the UK's leading charitable funder of biomedical research.

3. The Wellcome Trust welcomes the review of S.24 to move towards greater transparency regarding the use of animals in research. This response highlights areas of the

consultation that require further clarification and makes a number of suggestions to ensure an open, proportionate approach.

RESPONSES TO THE CONSULTATION QUESTIONS

Option 1: Do nothing. Retain Section 24 in its current form.

27. Under the current legislation, information can only be released where it does not contain information provided in confidence. Technically, this prevents disclosure of information even when the provider has no objection to its disclosure.

Question 1: Do you believe we should retain Section 24 in its current form? Please provide comments to explain your answer.

Yes
No
Don't know

4. Current provisions of S.24 are incompatible with the Government's policies on openness and transparency, as the Home Office cannot release any information received in confidence under the Animals (Scientific Procedures) Act (ASPA) 1998, even when the provider has no objection to its disclosure or even where it is already available in the public domain. Furthermore there is a lack of understanding as to who S.24 applies to.

5. S.24 in its current form does however restrict the number of Freedom of Information Act (FOIA) (2000) requests received by the Home Office. We would urge the Government to consider how any changes to S.24 may increase the resources required of the Home Office and to make appropriate provision for this, to ensure that the Home Office response times and processing of project license applications are not adversely affected.

Option 2a: Repeal Section 24 and amend ASPA, creating a criminal offence of malicious disclosure of information about the use of animals in scientific research

28. All information may be disclosed provided it is not exempted from release under the Freedom of Information Act 2000 (FOIA). If information is disclosed with malicious intent (defined in the legislation), it will be a criminal offence. (This option does not include the statutory bar as under option 2b).

Question 2: To what extent do you believe, if at all, that this option meets the Government's primary objective of increasing openness and transparency about the use of animals in scientific research? Please provide comments to explain your answer.

Very much so
To some extent
Not at all
Don't know

6. This option provides inadequate protection and support for the efficient operation of the UK biosciences sector and would undoubtedly undermine the UK's competitiveness in this field.

7. The operation of this policy option would entirely depend on the legal definition of "malicious intent" and how this would be applied. The difficulty arises that the releaser may sincerely believe that the release of information is morally right and should be in the

public domain and as such they might not be behaving 'maliciously' in disclosing protected information (it would not be intended primarily to damage the owner, but rather to protect the animals). The release of such information might nonetheless be reckless and could damage the owner of the information and the owner's IP in a way that was not foreseen or intended by 'the releaser'. This option is likely to lead to extremely difficult and lengthy legal cases, over whether the intent was indeed "malicious" and whether 'the releaser' is therefore legally culpable.

8. The interpretation of "malicious disclosure" in the legislation, is however unlikely to provide adequate protection for IP because only the owner of the IP is in a position to understand the IP and so it would not always be possible for any other 'releaser' of information to fully understand the impact of release on the scientist and his or her institution. The definition of "malicious" would need careful consideration, as 'the releaser' of the information may be unaware or unconcerned of the value of the information being released or the potential adverse consequences that could arise, and as such may not believe they are being "malicious". The "malicious disclosure" test would therefore need to be expanded to include reckless disclosure where the result of the disclosure causes actual damage, including physical or emotional harm to an individual or damage to the IP.

Question 3: To what extent do you believe, if at all, that this option appropriately clarifies who and what is covered by the legislation? Please provide comments to explain your answer.

Very much so
To some extent
Not at all
Don't know

9. This option does not expressly state who it would apply to, whether this just be Home Office officials or others with a function under ASPA, including individuals employed at an institution. This option also does not address the sanctions that would result from malicious disclosure.

Question 4: To what extent do you believe, if at all, that this option provides appropriate protection for sensitive information (e.g. people and place details and intellectual property)? Please provide comments to explain your answer.

Very much so
To some extent
Not at all
Don't know

10. For the reasons given under Question 2, we do not believe that Option 2(a) could adequately protect sensitive information.

11. We would advocate that the only appropriate means of protecting sensitive information (by which we mean information relating to People, Places and IP) would involve ensuring that decisions about disclosure must be made in consultation with those who understand the information and the consequences of its release. As such this would primarily be the licence applicant/ licence holder working with the Animals in Science Regulatory Unit (ASRU). Option 2a would not provide this protection because a Home Office official (or other person) could disclose IP without any malicious intent but in a way that could cause considerable damage to the competitive edge of the research institution.

12. It must be clear that the term “intellectual property” is used broadly (as described in the Impact Assessment) and includes information such as novel ideas, scientific hypotheses, protocols, procedures and research plans. These constitute intellectual property for individual researchers and institutions; however it may not be apparent to ASRU what is/ is not IP as far as an institution is concerned. A lack of protection for such information would blunt the competitive edge of individual researchers and institutions and make the UK a less attractive place to carry out bio-scientific research and development.

Question 5: Would this option change any processes – directly or indirectly – associated with operating under ASPA, compared to the current regime? (For example, a change in the way a licence application is constructed). If you consider yes, please provide comments to explain your answer.

Yes
No
Don’t know

13. Currently under ASPA an applicant is required to disclose considerable detail on sensitive information (People, Places and IP) in order to gain authorisation to perform the scientific research in question. To be sure of protecting IP, under option 2a, far less detail in licence applications and technical documents might result, to mitigate the possible consequences of sensitive information being released. Committing less information to paper is not within the best interests of science or animal welfare, and would indeed contradict the aim of being more transparent.

14. We agree that “the new framework should not lead to disproportionate regulatory burdens being placed on public authorities or business” as outlined in the Impact Assessment, p11. However, relying on FOIA for the protection of IP would increase such regulatory burden, most notably on the ASRU who would have to determine what information is subject to exemptions from disclosure and to defend such decisions when challenged. Careful consideration should be given as to who is best placed to determine what is sensitive information. We would argue that often only the licence applicant/ licence holder would have sufficient knowledge to make the judgement as to what constitutes valuable IP to the institution.

Option 2b: As option 2a. The amended legislative framework would additionally include a statutory prohibition on disclosure of information relating only to people, places and intellectual property.

29. All information may be disclosed provided it is neither exempted from release under FOIA nor specifically contains information about people, places or IP. If information is disclosed with malicious intent, it will be a criminal offence.

Question 6: To what extent do you believe, if at all, that this option meets the Government’s primary objective of increasing openness and transparency about the use of animals in scientific research? Please provide comments to explain your answer.

Very much so
To some extent
Not at all
Don’t know

15. People, places and IP are the three key aspects that require protection from disclosure.

16. We urge the Government to give careful consideration as to who would be most appropriate to determine what information is classified as sensitive. Whilst information relating to People and Places is usually going to be fairly easy for ASRU to identify (although see our comments about triangulation in paragraph 49), ASRU may not always have the overall context, information or resources necessary to recognise what constitutes IP to an institution or researcher. Often only the licence applicant/ licence holder will have sufficient knowledge to determine what is IP. Careful consultation between ASRU and the licence applicant(s)/holders, would therefore be necessary to give the appropriate protection for sensitive information, particularly on IP.

Question 7: To what extent do you believe, if at all, that this option appropriately clarifies who and what is covered by the legislation? Please provide comments to explain your answer.

Very much so
To some extent
Not at all
Don't know

17. This option does not expressly state who the statutory bar would apply to, whether this just be Home Office officials or others with a function under ASPA, including those embedded within institutions with functions under ASPA. This needs to be explored further in consultation with the bio-sciences sector. This option also does not address the sanctions that would results from malicious disclosure.

Question 8: To what extent do you believe, if at all, that this option provides appropriate protection for sensitive information (e.g. people and place details and intellectual property)? Please provide comments to explain your answer.

Very much so
To some extent
Not at all
Don't know

18. As for Question 4, regarding option 2a, this will depend entirely on whether it is made clear in the proposed legislation that the term "Intellectual Property" should be interpreted broadly and would include information such as novel ideas, scientific hypotheses, procedures, protocols and research plans.

19. As per our response to Question 5 and Question 6, careful consultation with licence applicants and licence holders would be necessary in order to assess whether information amounts to sensitive information which should not be disclosed. Alternatively, the Project Licence Application Form could be split into sections for information which is not sensitive (which would include information relating to animal welfare) and information that is sensitive because it contains details of People, Places or IP.

Question 9: Do you agree that the additional statutory prohibition on disclosure is necessary to protect certain types of sensitive information? Please provide comments to explain your answer.

Very much so
To some extent
Not at all
Don't know

20. The consequences of sensitive information being released into the public domain are so serious, it is essential that the new legislation contains an additional statutory bar, to protect the inappropriate release of information relating to People, Places and IP, to uphold competitiveness of the biosciences sector in the UK.

21. It is essential that the statutory bar applies to the Home Office, as the Home Office would not always be best placed to determine what amounts to sensitive information. Clarification is needed as to whether the statutory bar would also apply to others with a function under ASPA, including those with a function under ASPA embedded within institutions. Arguably, information should be treated in the same way and given the same protection whether it is in the hands of the Home Office or research institutions. However, this needs careful consideration and consultation as extending the statutory bar to institutions should not prevent the disclosure of information when an institution wants to release it and should not prevent the future publication of research results.

Question 10: Would this option change any processes – directly or indirectly – associated with operating under ASPA, compared to the current regime? (For example, a change in the way a licence application is constructed). If you consider yes, please provide comments to explain your answer.

Yes
No
Don't know

22. Currently under ASPA an applicant is required to disclose a considerable level of detail of sensitive information in order to gain authorisation to perform the scientific research in question. Concerns about the potential release of IP or loss of competitive advantage are likely to increase the time and resource needed to prepare license applications, particularly those in the commercial sector, due to the need for increased legal scrutiny of applications.

23. We agree that "the new framework should not lead to disproportionate regulatory burdens being placed on public authorities or business" as outlined in the Impact Assessment, p11. Careful consideration should be given as to "who" is best placed to determine what is sensitive information and should be protected from disclosure. We would argue that often only the licence applicant/ licence holder would have sufficient knowledge to make this judgement and we therefore would like to explore further with the Home Office whether the Project Licence Application Form can be divided into parts including disclosable information and parts including information which cannot be disclosed as it relates to People, Places and IP. The parts including non-disclosable information should not include any information pertaining to animal welfare.

Option 3: Repeal Section 24.

30. All information may be disclosed unless it is exempted from release under FOIA. There would be no additional, or alternative, protection provided for confidential information other than that provided by the exemptions within FOIA.

Question 11: To what extent do you believe, if at all, that this option meets the Government's primary objective of increasing openness and transparency about the use of animals in scientific research? Please provide comments to explain your answer.

Very much so

To some extent
Not at all
Don't know

24. Whilst the most 'open' of the Policy options presented, this option would wholly fail to provide the protection that the sector requires for personal health and safety and valuable IP. FOIA exemptions could in principle be applied to provide protection from disclosure, however this would be heavily reliant on the ASRU applying the exemptions correctly and/or defending the applicability of such exemptions when challenged, for which they may not have the necessary resources.

25. We believe this option would be highly detrimental to the scientific research environment within the UK due to the lack of adequate protection for valuable IP.

26. The number of FOIA requests has increased (147%) over the last 5 years in the UK[1], suggesting in the UK at least there is an increasing awareness of the availability of FOIA. Requests have also come from overseas bodies keen to access the UK's IP and so it is essential that the statutory bar in option 2b applies. We believe that the Home Office is likely to be completely overburdened with FOIA requests and unable to operate effectively as a result if the statutory bar in Option 2b is not put in place.

Question 12: To what extent do you believe, if at all, that this option appropriately clarifies who and what is covered by the legislation? Please provide comments to explain your answer.

Very much so
To some extent
Don't know

27. Everyone would only be able to rely on FOIA exemptions. Key concerns focus on whether the Home Office would have sufficient information to make appropriate decisions about the disclosure of information or the necessary resources to deal with an increased number of FOIA requests.

28. Information provided to ASRU by the commercial sector is not subject to FOIA in the hands of a commercial entity but once provided to ASRU it would be subject to FOIA (and a statutory bar if Option 2b is adopted). Therefore, removal of s.24 is likely to have the biggest impact on private sector research institutions as their information is not disclosable under FOIA and in the hands of ASRU their information is protected from disclosure by s.24. They will have the same concerns as the academic research sector that ASRU will not always have sufficient understanding to know what constitutes valuable IP and so there has to be a mechanism for private research institutions to make clear to ASRU what is IP if that information were to become subject to an FOIA request.

Question 13: To what extent do you believe, if at all, that this option provides appropriate protection for sensitive information (e.g. people and place details and intellectual property)? Please provide comments to explain your answer.

Very much so
Not at all
Don't know

[1] http://www.jiscinfonet.ac.uk/surveys/information-legislation-management-2013/

29. There is some protection for people and places under FOIA. The FOIA exemption relating to Health and Safety (Section 38) may be applied, but this relies on proof that to release the information would "endanger the safety" or "the physical or mental health" of an individual – something that is not always easy to demonstrate prospectively. Individuals may also be identified through triangulation using other information provided in the documents.

30. FOIA is ambiguous over the protection of IP. IP is not currently defined in FOIA but rather is referred to in Guidance relating to various exemptions including Section 41 (Confidential Information) and Section 43 (Commercially Sensitive Information). The term "IP" is often used in the context of having commercial value, whereas in scientific terms the protection is needed for the ideas and future work of scientists even when there is no clear commercial value at risk. Most academic research is, almost by definition, at the pre-commercial stage, but it does indeed have economic value to the institution because novel ideas are what give an academic institution its competitive edge in the application for research funds.

31. An aspect that is frequently ignored in the operation of the FOIA in relation to technically-complex material is that only the technical author can understand the potential impact of release, yet it is often only the lawyer who can understand which sections of the FOIA can be used to provide protection. Given the time pressures for responding to FOIA requests, it becomes very difficult to assess what can be protected under which section of FOIA within the timeframe. This leads to expensive discussions and a high risk of failure to protect adequately, which is not a satisfactory means for protecting the UK's research IP. The same consideration would apply to FOIA requests to ASRU, with the added complication that the licensee would also need to be part of the discussion, given that ASRU officials often do not have the specific knowledge to determine which aspects of licensing documents constitute valuable IP.

Question 14: Would this option change any processes – directly or indirectly – associated with operating under ASPA, compared to the current regime? (For example, a change in the way a licence application is constructed). If yes, please provide comments to explain your answer.

Yes
No
Don't know

32. The same issues apply as for our responses to Question 5 and Question 10.

33. Whilst the process involved in licence applications may not change, this option could cause a change in the behaviour of licence applicants. The risk of information being released into the public domain could result in scientists minimising the detail of information they put in licence applications. Such behaviour would not be in the best interests of science or animal welfare.

34. The ASRU would almost certainly receive a much higher number of FOIA requests under this option. This is likely to result in significant delays in the licensing process unless the ASRU has very significant additional resources available to deal with the increased volume of requests and defend cases brought to tribunal or the courts under FOIA. We believe the licensing system would become unworkable if Option 3 were pursued.

Impact Assessment

Question 15: Are there any additional costs or benefits that have not been identified in the impact assessment but should be taken into consideration? If yes, please state what they are, your reasoning for including them and any information which would help to quantify the impact, where possible.

Yes
No
Don't know

35. We believe the costs to ASRU and research institutions in responding to additional FOIA requests and the time taken to extract exempt information will be substantial.

36. This significant increase in costs is likely to occur under all proposed options, including option 2b, unless the format of licence applications were to be changed and streamlined to make clear to ASRU what information can and cannot be disclosed.

37. Licence application forms could be streamlined to enable the licence holder/applicant to indicate up-front to ASRU what information is sensitive and should not be disclosed. We would urge the Home Office to consider how this could work in practice and we would welcome the opportunity to participate in discussion on this.

38. We agree with the statement in the Impact Assessment, p9 that "These sectors make a significant contribution to the UK economy. This contribution to the UK economy may be at risk if the UK is perceived as too high-risk an environment to operate in, both in terms of a perception of insufficient protection of sensitive information and / or being placed under a disproportionate regulatory burden." We would expect that any legislation should minimise the risk of this potentially disastrous consequence and attempt to prevent any increased regulatory burden.

Question 16: To what extent do you agree or disagree with the risks and assumptions made in the impact assessment? Please provide comments to explain your answer.

Strongly agree
Agree
Disagree
Strongly disagree
Don't know

39. The Impact Assessment is well argued and presented and we would agree with the majority of the risks and assumptions outlined.

40. We strongly advocate that openness and transparency are necessary to correctly inform and help the public be engaged with the rationale behind the continued and necessary use of animals in scientific procedures, as stated in the Impact Assessment, p9. However, we believe that the release of highly technical information into the public domain is generally not likely to achieve such an aim when it is released out of context. Non-technical lay summaries, the publication of detailed annual statistics and the strategies/ activities which are encouraged in the Concordat on openness on animal research in the UK, are likely to be far more effective in achieving openness in animal research than technical information without the full context. There is a risk that the end result would lead to a more divided debate.

41. Broad and appropriate protection of IP and considering who is best placed to determine what needs to be protected from disclosure is key to provide adequate protection for the UK life sciences sector. We would further encourage the Government to consider streamlining the licence application process, to enable the licence applicant to indicate what is and is not sensitive information.

Question 17: Can you provide any further information which may help to quantify the scale or direction of the costs or benefits, as identified in the impact assessment, as a result of these proposals?

42. The costs associated with an increased number of FOIA requests are addressed under Question 15.

43. The much greater costs, which cannot be quantified, relate to the risks that additional regulatory costs and burdens, together with increased risks of release of IP, will discourage investment in the UK's bioscience sector by both commercial organisations and overseas public funding agencies (such as NIH). Given the sums quoted in the Impact Assessment, such costs would be disastrous for the sector and its employees. We strongly agree with the statements on p 5-6 and 9 (quoted above re Question 15 and 16) regarding the risks to UK industry.

Further questions

Question 18: With regards to options 2a and 2b, in what instances do you believe disclosure of information about the use of animals in scientific research is malicious? Please provide comments to explain your answer, using clear examples where possible.

44. Divulging names and places without the licensee approval would be malicious.

45. "Whistle-blowing" should be allowed in accordance with institutions own policies, but the right to do so must be reserved to those instances where 'the releaser' of the information reasonably believes there to be a violation of the law and is in the interest of protecting animal welfare. An individual must not release information about authorised procedures which whilst lawful, that individual may personally disapprove of.

46. The definition of "malicious" would need careful consideration, as 'the releaser' of the information may be unaware or unconcerned of the value of the information being released or the potential adverse consequences that could arise, and as such may not believe they are being "malicious". The "malicious disclosure" test would therefore need to be expanded to include reckless disclosure where the result of the disclosure causes actual damage, including physical or emotional harm to an individual or damage to the IP.

47. Formal guidance in lay terms explaining malicious and reckless disclosure should be provided by the ASRU, so that those considering unauthorised release understand the limits of their legal rights to do so.

Question 19: What do you believe should be covered by the term 'intellectual property'? Please provide comments to explain your answer.

48. As stated in our response to Question 4, we strongly advocate that the term "Intellectual Property" should include information such as novel ideas, scientific hypotheses, protocols, procedures and research plans (as articulated in the Impact Assessment).

Without such protection, sensitive information and the UK's competitive position in the life sciences sector would be insufficiently and inadequately protected. We would welcome the opportunity to work with the Ministry of Justice (MOJ) on FOIA exemption guidance to ensure that the protection given to IP is explicitly broad and appropriate, as proposed by the Minister in the recent discussions of the Intellectual Property Bill[2]. We would also like to ensure that the Information Commissioner's Office (ICO) Guidance for the Higher Education Sector and FOIA is consistent with revised MOJ Guidance on what is covered by commercially sensitive information. There must be clarity and consistency between both the MOJ's and ICO's approach as to what is covered by IP and commercially sensitive information and the approach taken on IP by the Home Office when drawing up legislative changes to S. 24 and associated guidance.

49. The risk of triangulation should be carefully considered when determining the level of detail that could be disclosed from licence applications. Names, places and institutions could be inadequately protected if too much information from licences is released that would enable individuals to piece this together with information that is already available in the public domain through open access publications, where such identifiable information is included.

50. We maintain that only the licence applicant/ licence holder can truly determine what information in a licence is sensitive and should be protected from disclosure. Again we would recommend that streamlining applications into what information can and cannot be disclosed, could give adequate protection and we would welcome the opportunity to discuss this further with the Home Office.

Question 20: Do you consider that Section 24 of ASPA, being a statutory bar and an absolute exemption, provides greater protection for intellectual property than other qualifying FOIA exemptions?

51. Yes. Clearly an absolute bar on releasing information will always offer greater protection than FOIA exemptions where an assessment must be made by the public authority holding the information as to whether or not information should be disclosed.

Question 21: Are there are any other views or comments that you would like to add in relation to the review of Section 24 that were not covered by the other questions in this consultation?

52. We agree with the statement in the Impact Assessment, p1 that "It is not our objective to provide information so the public or other external bodies can conduct their own harm / benefit analysis as to whether a particular project should be initiated."

53. We also agree with the statement in the Impact Assessment, p13 that "There is no intention to introduce the ability for the request of information that was produced before the introduction of the legislation." Were the chosen policy option to have retrospective effect this would be extremely onerous and introduce a significant cost burden.

54. The Wellcome Trust's preferred policy option would be option 2b, subject to there being further clarification and detail in the legislation regarding the following three areas of concern:

[2] http://www.publications.parliament.uk/pa/cm201314/cmhansrd/cm140312/debtext/140312-0001.htm#14031264000002

a. Who in particular the option 2b statutory bar is intended to apply to, whether this just be Home Office officials or others with a function under ASPA.

b. The definition and scope of “malicious intent”. We believe it is unlikely that any definition could be sufficiently clear and/ or provide adequate protection for the owner of the information or the owner’s IP and needs to be expanded upon to deal with reckless disclosure.

c. The term “intellectual property” must be used in its widest sense and include information such as novel ideas, scientific hypotheses, protocols, procedures and research plans. MOJ, Home Office and ICO Guidance covering what amounts to commercially sensitive information must include novel ideas, scientific hypotheses, protocols, procedures and research plans to protect this IP.

55. We would urge the government to consult on the wording of the draft legislation, to ensure that the proposals are subject to rigorous public scrutiny given the importance of these issues to the strength of the UK biosciences sector and the UK’s economy.

Question 22: Which of the following best describes the organisation or professional interest that you represent? Please state the name of the organisation in the box below.

Academia
Commercial
Charity
Other Government department
A representative of an animal welfare organisation
A representative of an animal protection organisation
A member of an animal welfare organisation
A member of an animal protection organisation
An individual with a professional interest
A member of the public
Other (please specify):
Name of organisation if relevant: **Wellcome Trust**