The A S C
Animals in Science Committee

ANIMALS IN SCIENCE COMMITTEE

REPORT OF THE

LICENCE ANALYSIS SUBGROUP

1. Introduction

The project assigned to the Licence Analysis (LA) subgroup of the Animals in Science Committee (ASC) was to perform *post hoc* reviews of a sample of 'regular' licences, which would not normally be referred formally to the ASC. These included licences involving species other than non-human primates, with different severity ratings, and two regulatory licences. This was done in response to a recommendation made in September 2017 by the former Licence Referral Review subgroup (LRR) of ASC. The aim was to gain a broader view of the range of licences assessed by the Animals in Science Regulation Unit (ASRU), and to offer any appropriate advice to ASRU based on the findings. We now report on a review of eleven such regular licences, which had been granted by ASRU in the period 1 June 2017 - 6 August 2018.

2. Background to the Subgroup

Certain licences are formally referred to the ASC, according to the categories laid down in the Guidance on the Operation of the Animals (Scientific Procedures) Act, A(SP)A.[1] These stipulate that the Secretary of State will seek specific or general advice, as appropriate, on applications involving:

- the use of wild-caught non-human primates;
- the use of cats, dogs, equidae or non-human primates in severe procedures;
- use of endangered species;
- projects with major animal welfare or ethical implications;
- projects involving the use of admixed embryos falling into category 3 of the Academy of Medical Science report on Animals Containing Human Material and category 2 where the predominance of an admixed embryo is unclear or uncertain;
- projects which may invoke any of the 'safeguard clauses' in the Directive with respect to the purpose of primate use, proposals for the use of a great ape, or proposals to cause long-lasting pain, suffering or distress that cannot be ameliorated
- projects of any kind raising novel or contentious issues or giving rise to serious societal concerns.

Licence applications which fall within these categories are reviewed by the Project Licences Applications (PLA) subcommittee, chaired by the Chair of the ASC. Since November 2015 these licence applications have been circulated to all members of the ASC prior to the PLA subcommittee meeting, to allow them to comment or raise

[1] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/662364/Guidance_on_the_Operation_of_ASPA.pdf

issues of concern. Issues raised in this way are then notified to the applicants prior to their attendance at the ASC subcommittee meeting, to allow them to prepare their response. The PLA subcommittee then form their opinion in the light of all these discussions and comments, and these are communicated to the Secretary of State.

In July 2015, a Licence Referral Review (LRR) subgroup was established to review the process through which such project licence applications were selected by ASRU for referral to the ASC and review by the PLA subcommittee. As a result of the report by this subgroup[2] a recommendation was made to perform a *post hoc* review of a small number of representative licence applications which would not normally be seen by the PLA subcommittee, and to make general observations as they consider appropriate. As part of this work the LA subgroup has investigated the severity classification of non-human primate project licences, in response to concerns raised by some stakeholders regarding how non-human primate research is classified in the UK. This task of *post hoc* licence review was delegated to a new Licence Analysis task and finish group, with terms of reference set out in Appendix 1.

3. Process and Meetings

The LA subgroup analysed 11 licences between November 2018 and March 2019, from which information capable of identifying the applicant and establishment had been redacted. These were in several categories, seven rodent and four non-human primates (NHP) and encompassing experimental protocols in three severity ratings (severe, moderate and mild). Two were for regulatory testing; the remainder were research licences. Within each category the licences were selected randomly. The assessment followed a structured process, to facilitate a consistent approach across the varied types of work. For each licence in turn, members of the subgroup made individual assessments against a set of agreed questions, which were then discussed in a teleconference, and a summary was produced of the main findings. A preliminary report was then made of the analysis of all eleven licences, which formed the basis of discussions with ASRU inspectors on 25 March 2019, and a second meeting on 9 May to focus on special issues relating to regulatory licences. Further meetings of the group were held to agree the key points and recommendations for the group's report. This was presented to the full ASC committee on 9 December 2019, on 17 February 2020 after revisions to section 7, and in final form to the 18 May 2020 meeting.

4 Summary of Main General Points

The analysis of the eleven licences, revealed significant variability in quality throughout many elements of the licences, and a number of areas for improvement

[2] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/680009/Licence_Referral_Review_for_publication_v2_pub.pdf

were identified as set out below. It is important to note that our analysis was based on the information provided in the licences and is not a judgment on the quality of the work itself.

1. Project titles
2. Scientific rationale
3. Project plans
4. Justification of the numbers of animals requested
5. Severity classifications
6. Justification of benefits
7. Service licences
8. 3Rs descriptions
9. Non-technical Summaries

1. Project titles

A clear descriptive title is important not only to identify the project but also to allow for effective searching of published non-technical summaries. For example, if a licence focuses on a particular disorder, this should be specified by name within the title. We note that the advice on the annotated licence which stated “there is no character limit, but it is sensible to keep this reasonably short” may have contributed to some titles being too short or unclear.

Recommendation:

1.1 The applicant should ensure that project titles should be descriptive or specific enough to summarise the work proposed briefly and clearly.

2. Scientific rationale

A clearly defined experimental rationale is an essential component of a robust experimental plan, such as those contained in a licence. The approach to such a rationale could include the clear outline of the scientific questions being asked, or the inclusion of the specific hypotheses, that enable the applicant to demonstrate why they are proposing the work, the incremental change in knowledge that will result, and the benefits of such knowledge. It should also include justification for the particular species and the particular lines and modifications of any genetically altered animals which are proposed.

Recommendations:

2.1 ASRU should consider whether the new licence application form should include a question that specifically asks for the scientific rationale.

2.2 The applicant should ensure that the scientific rationale underpinning the projects is clear.

2.3 In licences where the use of genetically altered animals is stated, applicants must provide the rationale for the use of the particular lines and modifications, and ASRU should ensure that this has been done.

3. Project plans

In order to assess whether the proposed benefits might outweigh the harms, it is essential to have a well-described project plan and a clear outline of what will happen in the programme of work covered by the licence. The project plan could be described in a decision tree with clearly defined stages (such as a diagrammatic plan of work with flow charts). It is expected that the applicant has an idea of the work flow when drafting the project licence so a detailed project plan should be possible. *In vitro* and pilot steps should also be included in the work plan as well as decision points for the work flow as it is difficult to assess the project when important details of the overall project are missing.

Recommendations:

3.1 In line with the guidance given in the annotated project licence, applicants should provide clear project plans with descriptions of decision points for the overall project including *in vitro* and pilot steps.

3.2 ASRU could consider whether including a descriptive figure within the NTS would be beneficial.

4. Justification of the numbers of animals requested

Two key components of a licence application are the justification of the numbers of the animals requested and the experimental design principles that have been used to calculate these numbers. These include adequate descriptions of power calculations, statistical analysis, blinding, randomisation and reporting. While it is understandable that providing exact numbers of animals to be used in a project is difficult, without an explanation of the basis for the numbers it is not possible to be confident in the appropriateness of the number of animals requested. For example, for an experimental licence that did not involve breeding, estimates should be provided according to an experimental plan of X experiments with Y groups, each group containing Z animals (according to the relevant power calculations). Such an estimate for each experiment type allows the justification of the number of animals requested and provides clarity for anyone reviewing the licence in order to conduct a harm-benefit analysis. For those regulatory licences where animal numbers are defined in the test guidelines, these should be referenced to justify the number of animals to be used.

Recommendations to the Applicant:

4.1 Typical experiments should be described including the number (or range) of animals to be used.

4.2 The licence should include an experimental (and where possible statistical) justification for the numbers of animals to be used, and a description of how this figure was determined.

4.3 Where genetically-altered (GA) animals are included, an explanation and breakdown of the number of GA versus non-GA animals should be provided. Where the breeding of GA animals is required, these numbers should also include an estimation of how many non-GA animals will simultaneously be produced.

4.4 Other aspects of good experimental design such as randomisation, blinding, should be included. Applicants should be minded there are resources available to help with experimental design, for example the UK National Centre for Replacement, Refinement and Reduction of Animals in Research (NC3Rs) Experimental Design Assistant.

5. Severity classifications

In reviewing these eleven licences, the subgroup felt both the rodent and non-human primate protocols were generally categorised correctly according to the criteria outlined in Directive 2010/63, but we have some specific observations:

Part of the definitions of mild, moderate and severe, as set out in the Directive, includes a timeframe. For example, 'moderate' covers both short term-moderate pain, suffering or distress, and long-lasting mild pain, suffering or distress. Guidance is needed regarding what is considered to constitute short-or long-term.

In reviewing the licences the Subgroup considered severity classification according to Appendix G of the Guidance on the Operation of A(SP)A, namely that:

> *"Procedures on animals as a result of which the animals are likely to experience short-term moderate pain, suffering or distress, or long-lasting mild pain, suffering or distress as well as procedures that are likely to cause moderate impairment of the well-being or general condition of the animals shall be classified as moderate."*

The application of this principle is hampered by a variable interpretation of how 'likely' adverse events need to be in order to necessitate a change in protocol severity. In protocols classified as moderate, if any animals are expected to experience severe effects, then the protocol should be classified as severe according to the above guidance. Clarification is required on how 'likely' a side effect needs to be before it can be considered 'expected'.

Recommendation to ASRU:

5.1 In order to improve the consistency of severity classification across licences, more refined definitions are required of the durations envisaged by ‘short’ and ‘long-term’ harms, and of the distinction between ‘likely’ and ‘expected’ experiences of the animals.

6. Justification of benefits

The description of the proposed benefits requires both clarity and justification in order to perform the harm benefit analysis. It is therefore important to make clear, both in the licence and the NTS, what is the step change in knowledge to be expected from this specific programme of work, and why this particular increment in knowledge constitutes an important benefit. This is important in the case of a licence that follows on from a previous one, and especially in a long-term programme of basic research. We are aware that ASRU recognises these issues, especially in the light of the ASC’s Harm-Benefit Report, and that improved descriptions of benefits is an aim of the new licence application process.

Recommendations:

6.1 The applicant should make clear, both in the licence and the NTS, what is the step change in knowledge to be expected from this specific programme of work, and why this particular increment in knowledge constitutes an important benefit.

6.2 The ASC should monitor a range of licences prepared under the new system, to assess whether the benefits section (and the NTS) is improving as a result of the new guidance, or whether more consideration could be given to describing what is required from this section.

7. Service licences and regulatory testing

We recognise a difficulty in making a harm-benefit assessment in service licences within A(SP)A which are generic in nature. The A(SP)A guidance provides examples of legitimate multiple generic projects such as the breeding of genetically altered mice, the production of antibodies, and the conduct of a safety evaluation test. In the licences we reviewed, several involved safety testing and our comments below arise from this type of licence, in the first instance.

Various international regulatory frameworks require the evaluation of data from tests on substances in order to assess the risk of harmful effects to humans or the

environment.[3] In a licence application within A(SP)A from a contract research organisation, the identity of any individual compounds to be tested for regulatory purposes generally remains unknown. This means that the benefit of the eventual use of the specific substance to humans, animals or the environment - that would normally justify the harms to the animals involved in performing the test - is not currently considered under A(SP)A. Within A(SP)A, the only benefit against which to set the harm to the animals is the benefit of knowing whether a harmful effect is demonstrated by compounds under test or not. Hence the harm benefit analysis is limited to the test procedure itself, not the potential benefits to society of the substance which is tested using animals.

We noted that in one of the licences considered, the organisation performing the test described having a committee of responsible people which considered the likely benefits of a specific substance prior to being tested. In this respect the organisation appeared to be providing additional assurance on the harm-benefit analysis.

It was also noted that certain regulatory tests involving animals for which non-animal methods are available (e.g. skin and eye irritation and skin sensitisation) may be licensed for several reasons including, for example, because of the applicability domain of *in vitro* methods. Therefore, additional oversight may be appropriate, for example, in prospective or retrospective reporting of tests involving specific substances, and the reasons that such tests were considered necessary.

Recommendations:

7.1 Where a project licence covers a broad category of substances (e.g. potential medicines or pesticides), but the specifics of the substance to be tested are not known (e.g. its disease indication or chemical series), consideration should be given to the development of a system which provides local oversight of the justification for the specific substances being tested, and which allows the opportunity for ASRU to review this.

7.2 ASRU should develop a system for establishments to prospectively or retrospectively report the justification for each use of an animal test when non-animal methods are available.

7.3 While acknowledging that ASRU is aware of these above difficulties, the ASC should review whether it is appropriate for generic service licences (including those for breeding and antibody production) to use the same harm-benefit framework as research licences, in cases where the eventual use of the substance is not considered.

[3]The approaches or test conditions for regulatory tests are outlined in frameworks such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and Organisation for Economic Co-operation and Development (OECD).

8. 3Rs (Replacement, Refinement, Reduction) descriptions

The application of the 3Rs is a standard condition of each type of licence granted under the A(SP)A, i.e. establishment, project and personal licences. The 3Rs section in a project licence application is the applicant's opportunity not only to demonstrate considered and responsible animal use, but also an ongoing commitment to the 3Rs. A statement is expected of a positive intent to continue to look for opportunities to apply the 3Rs with ideas or examples.

In the Replacement section, sufficient assurance should be given that the animal use was justified and considered, including a demonstration of having searched the relevant literature for alternatives. These might include partial replacement, e.g. the use of *in vitro* screening or assays that formed part of the project work prior to the need for animals.

The Refinement section provides an opportunity to describe how the animal's welfare is improved both during the procedure and in the housing and care beyond the legislative minimum requirements demonstrating a continuing Culture of Care.

The Reduction section should describe initiatives taken to reduce the number of animals used and/or practices to be used throughout the project to optimise numbers. Furthermore, given the large numbers of animals which are bred for but not used in scientific procedures[4],any approaches to minimize such numbers should be described.

Recommendations to the Applicant:

8.1 Consideration of the 3Rs should be an active and ongoing process throughout the lifetime of the licence, taking into account best practices identified by the NC3Rs and other relevant bodies, and the relevant literature. In addition to reviewing project licences, the AWERB has a role in promoting the 3Rs and facilitating a broad uptake across the Establishment.

8.2 The AWERB should ensure that applicant has provided sufficient evidence of the consideration of potential replacements, including justification of why *in vitro* methods could not be used, and more indication of the applicant's plans to incorporate or investigate new methods.

[4]Home Office (2018) Additional statistics on breeding and genotyping of animals for scientific procedures, Great Britain 2017. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/754408/breeding-genotyping-animals-scientific-procedures-2017-hosb2718.pdf (Accessed 18 November 2019)

8.3 More evidence is needed of the use of mechanisms to ensure that animal use and breeding is appropriately managed to reduce any potential for animals being bred for scientific purposes and not used.

9. Non-technical summaries (NTS)

Since the enactment of the EU Directive, widespread problems have been identified in the quality of non-technical summaries of published licences, both in the literature and reported informally by lay members of AWERBs[5] [6]. The NTSs of the eleven licences we examined showed many of these shortcomings, both in summarising the content and in their readability to a lay person. We understand that at the time when the selected licences were granted, few applicants were making use of ASRU's Annotated Licence, which offers some guidance on good NTS practice. We also note that at the time of writing the report the NTSs for the licences we reviewed had not yet been published, over a year since they were granted.

The NTS provides the applicant with the opportunity to share information about their work with a wider community, including members of the public who do not have a scientific background, and as such are a very important part of the licence. Given that these summaries will become public documents and be liable to scrutiny by a wide range of interested parties, we set out some specific recommendations below.

Use of understandable language

The main audience for the NTSs are members of the public and, therefore, to meet the A(SP)A requirement of using non-technical language, the NTS should be drafted in everyday English which would be easily understood, for example, by a young teenager. Technical or scientific language should not be used. If the use of specific scientific terms is essential, these terms should be explained in non-technical language. It is important that each section within the NTS is considered carefully so the entire NTS can be easily understood.

Recommendation:

9.1 Establishments should be urged not to submit licence applications to ASRU until the AWERB lay member or another non-technical person has agreed that the NTS has adequately summarised the programme of work in non-technical language.

Inclusion of relevant information

The **Aims and Objectives** section should clearly provide a summary of the programme of work, including that it involves animals, stating all the species involved.

[5]Taylor et al. Recommendations to Improve the EU Non-Technical Summaries of Animal Experiments. ALTEX 35(2), 193- 210, 2018.
[6]http://www.understandinganimalresearch.org.uk/news/communications-media/guidance-for-writing-a-nts/

Recommendation:

9.2 The new e-licensing system should ask a question that will prompt the applicant to describe the proposed programme of *animal* experimentation.

Benefits: It is important that the primary benefits presented are those expected of the programme of work within the licence itself, and that any potential wider benefits are described in realistic terms, rather than presented at too high a level.

Recommendation:

9.3 The benefits section of the NTS should focus on the benefits of the specific knowledge to be gained by the project and show restraint in presenting wider and future aspirations.

Harms: It is vital that those reading the NTSs have a proper understanding of what will happen to the animals used in the project. The NTS should therefore include sufficient detail of expected harms, especially those involved in more severe or potentially controversial protocols. To be cursory here is inappropriate and could be misleading.

Recommendation:

9.4 The new licence application system needs to state that all NTSs should clearly and accurately express whether the experimental protocols are mild, moderate or severe under Directive 2010/63, clearly stating the harms likely to be experienced by the animals involved, and the expected number of animals to be used in each protocol.

Recommendation:

9.5 The **3Rs section** of the NTS needs to explain the various steps taken to replace, refine and reduce in terms understandable by a lay audience. The refinement sections of some licences showed especial need to be made comprehensible. All three sections should demonstrate the continuous pursuit of progress and improvement, and in the case of replacement, explain why it is necessary to use animals in this project.

We welcome the fact that the applicant is encouraged to see the NTS as an intrinsic part of the licence application, rather than a burden at the end, but are concerned that this may not necessarily mean an improvement in readability. The ASC will examine the extent to which the new e-licensing system has helped improve the content and readability of NTSs, once a sufficient number of such licences have been written under the new system.

Recommendation to ASRU:

9.6 Consideration might be given to sharing good examples of NTSs to provide help to applicants.

10 General points

The licences reviewed appear to have been drafted without the use of the annotated licence, despite this guidance having been available to licence applicants for 18 months beforehand. The LA Subgroup is encouraged that guidance provided by the annotated licence is embedded in the new e-licensing system. It is expected that this will help address some of the issues around variability.

We also note a shift in emphasis from five-year programmes to amending a project licence on a more frequent basis. This may help address concerns about scientific justification and the inclusion of several thousand animals on individual project licences.

In making our analysis, we recognise that there are important aspects that ASRU consider in the process of granting a licence, outlined in the ASRU advice note on Harm Benefit Analysis[7], that are not included in the licence application. These include, for example, the experience and suitability of the personnel involved and facilities in which the work will be done, as well as the rationale for the Harm Benefit analysis itself. These elements of professional judgment (rather than the licence text alone) are critical to granting a project licence.

A number of recommendations are made to the applicant, but we wish to remind AWERBs and ASRU of their responsibility to ensure that the applicant has followed these recommendations, and that local knowledge and expertise has been brought to bear before submission of the licence to ASRU. We would support ASRU to be stronger in returning applications in order to improve the quality of licence.

[7]The Harm–Benefit Analysis Process New Project Licence Applications Advice Note: 05/2015. Animals in Science Regulation Unit
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/660238/Harm_Benefit_Analysis__2_.pdf

Appendix 1 ASC Licence Analysis Subgroup Terms of Reference

Animals in Science Committee (ASC)
Licence Analysis Subgroup
Terms of Reference

1.0 Purpose

1.1 To review a selection of project licences and provide feedback to the ASC and Animals in Science Regulation Unit (ASRU).

2.0 Governance

2.1 The Licence Analysis (LA) subgroup is a task and finish group of the Animals in Science Committee (ASC). 'Task and finish' groups are topic-specific, time-limited groups established by the ASC to carry out in-depth studies and to take forward specific pieces of work.

2.2 Recommendations and final advice shall be the responsibility of the task and finish group members. These members will either physically be present at the meeting or participating by teleconference. On occasion, where members are not in attendance and subsequently disagree with a decision, this will be recorded in a note attached to the meeting minutes.

2.3 Other than in exceptional circumstances, the work of the task and finish group shall be passed to the full Committee for review and ratification. On any occasion where recommendations are not reviewed, or ratified by the full Committee, this should be made clear in such reports or recommendations made by the task and finish group.

3.0 Background

3.1 The Licence Referral Review (LRR) subgroup previously reviewed the process through which project licence applications were selected by for referral to the ASC Project Licences Applications (PLA) subcommittee and how they were reviewed by the PLA subcommittee. The ToR for the PLA subcommittee were subsequently amended to include a provision to allow a post hoc review of licence applications (selected at random or on the basis of certain characteristics) which would not normally be seen by the PLA subcommittee and to make general observations as they consider appropriate. This task has been delegated to the LA task and finish group, and these ToRs set out how the LA subgroup will analyse a selection of project licence applications, including species other than non-human primates and across different severity ratings, to gain a broader view of licences received and processed by ASRU.

3.2 As part of this programme, in response to concerns raised by some stakeholders regarding how non-human primate research is classified in the UK, the LA subgroup will investigate the severity classification of non-human primate project licences.

4.0 Membership

4.1 The Licence Analysis Subgroup membership comprises:

- Gilly Stoddart (Chair until19 May 2019)
- Donald Bruce (Chair from 20 May 2019)
- Sally Robinson
- Hannah Clarke
- Kathy Ryder

4.2 The range of expertise required for a task and finish group to achieve its objectives may require the skills, expertise and experience of the ASC members to be supplemented. To enable this, a task and finish group has the option to include co-optees, agreed by the group membership and ratified by the ASC, as required to see through the effective completion of its specific areas of work. Co-opted members must at all times adhere to the values and standards which apply to full ASC members and comply with rules on the recording of interests.[8]

4.3 Task and finish groups will normally invite a member of ASRU (to be identified in consultation with the unit's senior leadership) to attend meetings in order to present information to the group as requested. Such persons will be noted as 'observing' in any record of the group's discussions.

5.0 Expected deliverables

Selection of licences to be reviewed.

5.1 After consultation with the PLA subcommittee, the LA subgroup agreed to review six rodent project licences that were granted over the past 1-2 years. The licences will be selected at random but four will classified as severe, one will be classified as moderate and one will be classified as mild.

5.2 LA subgroup will also review four non-human primate project licences selected at random (two classified as moderate and two classified as mild). Although a limited sample, this will allow the LA subgroup to gain an insight as to whether they consider non-human primate research to be appropriately classified at this

[8]Section 7 (Conduct) and Section 11 (Recording of interests). ASC Code of Practice and Working Protocol. December 2015.
https://www.gov.uk/government/publications/animals-in-science-committee-code-of-practice

time. It will be unnecessary to review non-human projects classified as severe as the ASC is very experienced with these licences.

5.3 In addition, the LA subgroup may review licences identified by ASRU at the time of approval as being worthy of future consideration or other licences nominated for discussion by ASRU.

Review of project licences

5.4 The LA subgroup will be provided with the project licences for review and the LA subgroup will discuss them at face-to-face meetings, either in conjunction with PLA meetings, ASC meetings or at other times, as needed. If face-to-face meetings are not possible, a teleconference will be convened.

Timelines

5.5 Kick-off meeting: The LA subgroup and PLA subcommittee had a virtual meeting in November 2017 to agree on the types of project licences that will be considered and the process by which they will be reviewed. During this meeting the way in which the LA subgroup could consider whether they consider non-human primate project licences to be appropriately classified.

5.6 Licence review: ASRU will provide the LA subgroup with the requested licences by end of January 2018. It is expected that the review process will take approximately 6 months.

5.7 Reporting: the ASC will be updated during committee meetings and a short-written report will be prepared at the end of the project.

5.8 On completion of this workstream, the PLA subcommittee will consider the utility of this approach, and may nominate, or invite the LA subgroup to nominate, further workstreams.

Assessment of project licences

5.9 The LRR will determine how to assess the licences. This may include assessing, for example, draft licences considered by ASRU before a licence is considered compete and correct, the granted licence, and associated correspondence between ASRU and the applicant. If historical licences are reviewed assessments may consider published results and if the publications reflect the licence (for example, the number of animals reported in the publications compared to the numbers in the licence will be considered). A retrospective assessment of the actual benefit of the project compared to those stated in the licence may be considered. Other approaches to assessing the licences may also be considered.

5.10 The process by which the licences will be reviewed will be agreed by 6 November 2018. The ASC will be updated on how the selected licences will be assessed at committee meetings.

Review of project licences

5.11 The licences will be reviewed and a draft report on the licences to be reviewed will be presented to the ASC in August 2019.

6.0 Meetings and working methods

6.1 In the event that the task and finish group Chair is unable to chair a particular meeting or teleconference, it may be chaired by the task and finish group Deputy Chair or other representative nominated by the Chair.

6.2 Reports and recommendations made by the task and finish group will be reviewed by group members and ratified by the Chair. Reports and recommendations will be shared with the ASC, via the Secretariat, and signed-off at a full ASC Committee meeting.

6.3 Where possible the LA subgroup meetings will generally be held in person (for example in conjunction with PLA meetings or ASC meetings or independently of these meetings), however, remote meetings may be necessary.

7.0 Duration

7.1 It is anticipated that this work stream will be completed in September 2019. If the PLA subcommittee invites the LA subgroup to nominate further work streams new ToR will be adopted.

8.0 Confidentiality

8.1 Task and finish group members, and co-optees, will not misuse information gained in the course of their public service for personal gain or for political purpose, nor must they disclose any information which is confidential in nature or which is provided in confidence without authority. This duty continues to apply after any member, or co-optee, has left the ASC or its subgroups.

8.2 For task and finish Group meetings, confidentiality status of papers/discussions is clearly marked:

- Papers marked ‘OPEN’ can be discussed freely.
- Papers marked ‘CLOSED’ should be treated as confidential and not discussed outside of the task and finish group/ASC.
- Any meeting papers marked as ‘confidential’ can be returned to the secretariat to be disposed of securely.

9.0 Secretariat

9.1 The Secretariat will coordinate members' availability, arrange meetings and prepare meeting agendas/papers as required.

9.2 The Secretariat will draft meeting minutes which will be reviewed by the task and finish group and ratified by members and the Chair.

10.0 Task and Finish Group Stakeholders

10.1 There is likely to be broad interest in the output of this project and interested stakeholders may include, for example, the general public, animal protection groups and groups promoting research using animals; licence holders, ASRU, and the Expert Group for NHP neuroscience research in the UK.