
Independent Investigation
into Animal Research
at Imperial College London

December 2013

Acronyms

3Rs: Replacement, reduction and refinement of the use of animals in research

AAALAC: Association for Assessment and Accreditation of Laboratory Animal Care

AWERB: Animal Welfare and Ethical Review Body

BUAV: British Union for the Abolition of Vivisection

CBS: Central Biomedical Services

dNVS: Deputy Named Veterinary Surgeon

HOLO: Home Office Liaison Officer

NACWO: Named Animal Care and Welfare Officer

NTCO: Named Training and Competency Officer

NIO: Named Information Officer

NVS: Named Veterinary Surgeon

PEL: Establishment licence

PIL: Personal licence

PPL: Project licence

QA: Quality assurance

Contents

Chapter 1: Introduction	5
Conduct of the investigation	5
Preparation of the report.....	6
Chapter 2: Executive summary	7
The Animal Welfare and Ethical Review Body	8
Operation of Central Biomedical Services	8
Training and competency assessment.....	9
Culture, leadership and management.....	10
Table 1: Summary of recommendations	11
Chapter 3: Lay summary of the independent enquiry into animal research at Imperial College London	14
The Animal Welfare and Ethical Review Body	14
Operation of Central Biomedical Services	14
Training and competency assessment.....	15
Culture, leadership and management.....	15
Chapter 4: The Animal Welfare and Ethical Review Body	16
Summary of Process	16
Committee's investigation.....	17
Committee's observations and findings	17
AWERB process and staff involvement.....	17
Administration of the AWERB process.....	18
AWERB and the 3Rs	18
Recommendations.....	19
The local AWERB process.....	19
The central AWERB process	20
Administration of the AWERB process.....	20
Chapter 5: The Operation of the Central Biomedical Services	22
Committee's investigation.....	22
Committee's observations and findings	22
Operational structure	22
Operational standards	23
Communication and working practices.....	24
Animal welfare concerns.....	25
Recommendations.....	26
The operational structure	26
Operational standards	27
Communication and working practices.....	27
How concerns about animal welfare were managed and reported	28

Chapter 6: Training and competency assessment	29
Background	29
Committee’s investigation.....	29
Committee’s observations and findings	29
Recommendations.....	30
Chapter 7: Culture, leadership and management	31
Background	31
Cultures and communities of people	31
Current leadership and management structures	31
Committee’s investigation.....	32
Committee’s observations and findings	32
Recommendations.....	33
Strategic leadership – developing a vision and action plan	33
Senior management	33
Further improving the culture of the 3Rs	34
Chapter 8: Conclusions	36
Annex 1: Membership of the committee	37
Annex 2: Terms of reference for the committee	38

Chapter 1: Introduction

- 1.1 On 14 April, 2013, the British Union for the Abolition of Vivisection (BUAV) wrote to Imperial College London with a dossier that compiled a wide range of allegations concerning the conduct of animal experimentation at the institution. The dossier was based on an undercover investigation in one of the animal facilities within the College.
- 1.2 The dossier put forward evidence of a number of instances of poor welfare practice that in the BUAV's view would constitute infringements of the Animal (Scientific Procedures) Act 1986 (as amended to incorporate the changes brought in by the European Directive, 2010/63/EU). They alleged a variety of failures that included: exceeding severity limits; poor monitoring and staff cover; poor surgical practice and anaesthesia; administration of analgesics; approaches to the killing of animals.
- 1.3 The BUAV also released a video to the public taken by the undercover investigator that purported to demonstrate some of the instances of poor animal handling and welfare practice.
- 1.4 The Home Office began an enquiry into the allegations, while at the same time Imperial invited Professor Steve Brown, Medical Research Council's Mammalian Genetics Unit, Harwell to chair an independent committee to investigate and assess the approach to animal care and welfare across the College. The membership of the committee is listed in Annex 1.
- 1.5 The terms of reference agreed by the committee are given in Annex 2. The role of the committee was *not* to investigate the specific allegations made by the BUAV. Rather the purpose of the committee was to undertake a broad and detailed examination of all aspects of animal experimentation at the College facilities including areas such as ethical review, operations, compliance, training and management.
- 1.6 The committee agreed its terms of reference on 6 June, 2013 and established its approach to the conduct of the investigation (see below). The committee set out to provide a report describing areas of animal research that represented best practice at Imperial as well as those areas that fell short of the best standards practised within the UK (and more widely). Moreover, in so doing, the committee would deliver detailed recommendations for improvements, providing where relevant potential solutions. The committee also agreed that its report should be made publically available.

Conduct of the investigation

- 1.7 The committee undertook its investigation employing a mixture of approaches including:
 - a. Interviews of Imperial personnel
 - b. The examination and discussion of a wide variety of relevant documents requested from Imperial
 - c. A visit to the animal facility described in the BUAV allegations

- 1.8 We interviewed a wide range of Imperial personnel including animal facility technical staff, Named Animal Care and Welfare Officers (NACWOs), animal facility managers, junior and senior scientists (including personal [PIL] and project [PPL] licence holders), the Named Veterinary Surgeon (NVS) and a Deputy Named Veterinary Surgeon (dNVS), senior academic staff and administrators. In total we carried out 30 interviews. We emphasised to all interviewees that any comments or information they provided would be unattributed and that we would preserve their anonymity in our report.
- 1.9 We requested and received from the College a large number of documents covering a wide variety of activities that impinge upon areas that pertain to the terms of reference of the committee such as management, ethical review, operations and training.
- 1.10 We visited the animal facility that was the focus of the BUAV allegations. The visit was conducted by the Hammersmith Site Manager and Director of the Central Biomedical Services (CBS) and allowed us to survey the quality of facilities and routine husbandry. Although we did not observe any experimental procedures being undertaken during our tour, the visit allowed us to explore further the processes for supervision and monitoring of procedures, along with general standards of animal care and welfare.

Preparation of the report

- 1.11 Based on the evidence gathered the committee focused its deliberations on four areas:
- a. The Animal Welfare and Ethical Review Body (AWERB) process
 - b. The operations of the CBS
 - c. Training and competency assessment
 - d. Culture, leadership and management
- Our report is divided into these four areas, but where appropriate we discuss links or synergies between them.
- 1.12 For each area, we provide a background to current working practices at Imperial along with the committee's aims during its investigation. We summarise our findings based on the interviews undertaken and documents examined and, based on these findings, make recommendations.
- 1.13 The committee considered its overarching responsibility was to deliver where necessary recommendations for change that would ensure that Imperial was a leader, both within the UK and internationally, in the development and application of the 3Rs (the replacement, reduction and refinement of animals in research).

Chapter 2: Executive summary

- 2.1 In April, 2013, the BUAV presented a report to Imperial compiling a wide range of allegations on the conduct of animal experimentation at the College. The dossier was based on an undercover investigation at one of Imperial's animal facilities.
- 2.2 Following these allegations an independent enquiry was established and an independent committee formed (see Annex 1) to investigate and assess the approach to laboratory animal care and welfare across the College.
- 2.3 The committee set out to provide a report describing areas of animal research that represented best practice at Imperial as well as those areas that fell short of the best standards practised within the UK (and more widely). Moreover, in so doing, the committee would deliver detailed recommendations for improvements, providing where relevant potential solutions. The committee considered its overarching responsibility was to deliver recommendations that would ensure that the College was a leader, both within the UK and internationally, in the development and application of the 3Rs.
- 2.4 The committee conducted a large number of interviews of animal facility staff, scientists, as well as the senior leadership and administrators in this area. In addition, the enquiry examined a large number of documents covering the operation, management and ethical review of animal experimentation at Imperial.
- 2.5 Based on the interviews and documents studied, the committee focused its discussions and conclusions on four main areas:
 - a. The AWERB process
 - b. The operations of the CBS
 - c. Training and competency assessment
 - d. Culture, leadership and management
- 2.6 The committee found that husbandry was carried out to a high standard at the College, and the fabric and maintenance of facilities was also satisfactory. Moreover, animal experimentation is supported by a committed and engaged animal house staff, who are willing to do more in terms of developing new approaches to animal welfare and engaging further in providing support for *in vivo* experimental approaches.
- 2.7 The committee found however that Imperial did not have in place adequate operational, leadership, management, training, supervisory and ethical review systems that would enable the College to set the highest UK or international standards in the 3Rs and to be a world leader in developing ideas and practice in animal welfare. The committee therefore makes a number of substantive recommendations across the four areas, the implementation of which will be critical for Imperial to reach the standards in the 3Rs and animal welfare commensurate with its world-leading stature in scientific research.
- 2.8 We summarise in Table 1 the committee's recommendations. We emphasise that the recommendations are made as an integral package that reflect the changes that the committee conclude need to be put in place to deliver improvements in the 3Rs and establish Imperial as a leader in this area. We also advise strongly that the recommendations are studied carefully in the context of the narrative of

individual chapters that underpin our justification for each recommendation and their integration with the broader landscape of change that we recommend.

The Animal Welfare and Ethical Review Body

- 2.9 The committee found that the current AWERB process was not fit for purpose in terms of delivering improvements in the 3Rs. The local AWERB process conducted electronically fails to provide a forum for all staff to come together to review projects, consider the cost/benefit assessment and very importantly to deliver a dynamic process for the development and implementation of improvements in the 3Rs. The central AWERB process also did not engage scientists on a broad basis across Imperial, and thus there was no forum that could take a substantive and active role in reviewing approaches to animal experimentation, challenging existing approaches and delivering change in the 3Rs.
- 2.10 The committee recommends wholesale reform to the AWERB process that will ensure, as envisaged by the Home Office, that it provides the broad based underpinning to monitoring developments in animal experiments and providing a forum for the consideration of developments in the 3Rs and animal welfare practices at Imperial.
- 2.11 **Local AWERB process.** We recommend that the local AWERB process is reformed with the creation of two standing committees, one at South Kensington/St. Mary's, the other at Hammersmith. The committees should comprise key staff from animal facilities along with scientists, and should meet regularly to review project applications (with the scientists concerned), consider cost/benefit assessments, carry out retrospective reviews and actively develop programmes for development and implementation of the 3Rs. Meetings should be publicised and anonymised minutes made widely available at the College.
- 2.12 **Central AWERB process.** We also recommend that the central AWERB be reformed, establishing a new overarching role for this forum in setting and monitoring standards of animal welfare across Imperial. The central AWERB should periodically review and determine strategy in terms of animal welfare improvements and the development of the 3Rs. It will receive reports from the local AWERB, identifying and discussing strategic and operational issues that bear on the 3Rs. The central AWERB should be chaired by a senior faculty member such as a Dean. As with the local AWERB, meetings should be advertised and anonymised minutes made widely available.
- 2.13 A new senior administrative appointment should be established to instigate these changes and manage the AWERB process, both local and central.

Operation of Central Biomedical Services

- 2.14 With regard to operational structures and standards, the facilities at the Hammersmith animal facility that we visited were well equipped and the fabric of the building along with environmental controls appeared to conform to the Home Office Code of Practice. Housekeeping of animal holding and procedural areas was of a high standard and a high quality of animal husbandry was evident. However, in terms of operational structures and standards, communication and working practices, as well as the mechanisms for reporting animal welfare concerns, we found that there was considerable room for improvement and the

introduction of significant changes. These would have a substantive impact upon animal welfare and the 3Rs.

- 2.15 **Operational structures.** We recommend an increase in staffing levels that will allow the increased involvement of animal care staff with *in vivo* research programmes, reduce reliance on agency staff and ensure greater independent overview of animal welfare out of hours and at weekends. These changes will allow the development of technical competencies of CBS staff to undertake a wider range of licensed procedures.
- 2.16 **Operational standards.** We recommend that staff monitor theatre and procedure areas at least once daily and contribute to the supervision and competency reports of license holders. This should be allied to the recording of animals undergoing procedures and actions taken.
- 2.17 **Communication and working practices.** We recommend the development of a strategic plan for CBS that identifies work normally undertaken by animal facility staff at other establishments and institutes programmes to involve CBS staff in those activities. The aim is to further enhance and integrate the role of CBS staff in *in vivo* research programmes – an aim that should also be fostered by attendance of CBS staff at research group meetings.
- 2.18 **Reporting animal welfare concerns.** We recommend the introduction of standardised documentation to monitor animals during experimental protocols, allied to the availability of all relevant 19bs in the holding and procedure rooms. An unambiguous policy needs to be introduced and widely disseminated on the central role of the NACWO in responding to animal welfare concerns and ensuring appropriate action is taken throughout the process and documented. This should be allied to a clear restatement of the key role of the NVS and NACWO in animal welfare and the 3Rs, along with a clear route for escalation of concerns to the AWERB. We also recommend that the College’s penalty point system be re-examined, and self-reporting encouraged.

Training and competency assessment

- 2.19 The provision of effective training and the assessment of competency are critical for the successful operation of an animal facility and the implementation of the 3Rs. Failure to implement a robust training regime that is appropriately assessed will lead to poor standards of animal welfare and poor science. We found that the provision for training, supervision and competency assessment was *ad hoc*, and that there was little evidence of effective mechanisms for sharing information and best practice across staff. We noted again the opportunity for experienced CBS staff to play a role in training and competency assessment. We therefore make a number of recommendations that provide College-wide structures for the delivery of robust site-wide mechanisms for training and competency assessment.
- 2.20 We recommend a significant increase in resource for training and competency assessment, allied to a systematic site-wide review to develop mechanisms for dissemination and implementation of best practice. This should be accompanied by the appointment of a senior Named Training and Competency Officer (NTCO) who can lead the introduction of a systematic, site-wide process for assessing competency, as well as assessing trainers.

- 2.21 We recommend the establishment of a forum for the assessment across Imperial of progress in training and competency assessment, possibly as part of the reformed AWERB process. In parallel and building on this, there needs to be improved processes for identifying refinements in research procedures and incorporating them into training programmes and competency assessments.

Culture, leadership and management

- 2.22 Delivering the highest standards of animal welfare and science requires a culture of openness, trust and respect where teams of scientists and support staff work together. The committee aimed to investigate how both the culture of work along with the existing management structures contributed to standards of animal care and the development and implementation of the 3Rs. This included the interactions between the diverse groups involved in animal research at Imperial, the current management structures and the development of champions who will safeguard the highest standards of welfare. We found a strong emphasis on process and procedural issues to the detriment of focus on improvements in the 3Rs. Moreover, there are relatively limited opportunities for interactions that bring together and promote ideas and developments for the 3Rs between diverse groups. Overall, a culture of whole teams working together was lacking. We make a number of recommendations on culture, leadership and management that aim to build strengths in these areas at the College.
- 2.23 **Strategic leadership.** We recommend that Imperial develop a vision statement and action plan for the 3Rs, which underpins a College-wide aim to set the highest international standards and be a world leader in developing ideas and practice in this area. This should be a collaborative project involving the senior team and diverse groups working in animal research across the College. It will be beneficial to enlist experts in change management to foster a collegial and collaborative process that commands cross-institution ownership.
- 2.24 **Senior management.** The role of the NVS is both very demanding, and critical to the successful operation of the animal facilities. We therefore recommend that the NVS role should not be combined with additional statutory responsibilities. In addition, we recommend the creation of a new senior directorial role that will take overall responsibility for the delivery of bioservices at Imperial. The new appointee would be tasked with developing strategy across Imperial and delivering a world class programme in the 3Rs. The CBS Director, NVS, head of the AWERB, NTCO, Named Information Officer (NIO) and Home Office Liaison Officer (HOLO) would report to the new Director, who would co-chair the CBS Management and Strategy Group with the Dean of the Faculty of Medicine.
- 2.25 **Improving the culture of the 3Rs.** We recommend a number of actions to improve cross-institution working towards improvements in the 3Rs. These include an annual College prize to the team that has made an outstanding commitment or contribution in the development of the 3Rs. Importantly, the prize should recognise the contribution of diverse groups to the wider team's achievements. We also recommend the establishment of fora, in addition to the AWERB, for example focused workshops, to bring together the wider Imperial team to discuss and develop approaches to the 3Rs. Initiatives that bring together and encourage interaction between the Imperial team, either socially or professionally, are to be welcomed.

Table 1: Summary of recommendations

Chapter	Recommendation
<p>Animal Welfare and Ethical Review Body</p>	<p>Reform the local AWERB review process creating two standing committees at South Kensington/St. Mary's and Hammersmith, meeting regularly and providing a forum for project review, cost/benefit assessment and development of the 3Rs.</p>
	<p>Ensure engagement of local AWERB committees with the wider research community, with scientists proposing new projects or amendments attending the local committee. Meetings should be publicised and anonymised minutes available to all Imperial staff.</p>
	<p>Current terms of reference of the AWERB includes the reviewing of strategy in terms of animal research, the 3Rs and welfare improvements; reviewing the outputs of local committees and considering PPLs involving severe protocols. The central AWERB should be reformed to more effectively, and more visibly deliver these responsibilities.</p>
	<p>The central AWERB should be chaired by a senior academic, such as a Dean, and include chairs of local AWERB committees. Meetings of the central AWERB should be publicised and anonymised minutes available widely across the College.</p>
	<p>Appoint a senior administrator to instigate and manage the reformed AWERB process.</p>
<p>Operation of Central Biomedical Services <i>Operational structures</i></p>	<p>Increase staffing levels to enable increased involvement of animal care staff with <i>in vivo</i> research programmes at Imperial.</p>
	<p>Ensure staffing resource allows for greater independent overview of animal welfare out of hours and during weekends, and also reduces reliance on agency staff.</p>
	<p>Promote the development of technical competencies of CBS staff to undertake a wider range of licensed procedures.</p>
	<p>Review the current barrier systems with a view to enhancing flexibility of staff working.</p>
	<p>Make a thorough assessment of the staff resource required to implement laboratory animal management software and the AAALAC accreditation process.</p>

<i>Operational standards</i>	Ensure that animal care staff monitor theatre and procedure areas at least once daily; contribute to the supervision and competency reports of licence holders; and record observations of animals undergoing procedures and actions taken.
<i>Communication and working practices</i>	Improve efforts to integrate the role and activities of CBS staff into the broader <i>in vivo</i> research activities of Imperial, including: developing a strategic plan for CBS development; identifying work ordinarily undertaken by research staff usually undertaken by animal care staff in other establishments; and develop programmes to involve CBS staff in those activities.
	Encourage the attendance of CBS staff at research group meetings.
<i>Reporting animal welfare concerns</i>	Introduce standardised documentation to monitor animals during experimental protocols; the outputs systematically reviewed by CBS staff.
	Make available PPLs at the level of the holding room and procedural area, using laptops or tablets as appropriate.
	Implement an unambiguous policy for action in the event of animal welfare concerns, emphasising the responsibility of NACWOs, particularly their role in ensuring appropriate action is taken throughout the process and documented.
	Communicate the key roles of NVS and NACWOs in the 3Rs to the research community at Imperial, and institute a clear route for escalation of animal welfare concerns via the AWERB.
	Encourage the 'self-reporting' process in a sympathetic manner, and re-examine the penalty points system.
	Include the PEL holder in the reporting of serious incidents that may result in infringements.
Training and competency assessment	Increase resources significantly for training and competency assessment, allied to a systematic site-wide review to develop mechanisms for dissemination and implementation of best practice.
	Appoint a senior NTCO.
	Implement a systematic, site-wide process for assessing competency, including assessment of trainers.

	Develop a forum for assessment both within and across animal facilities of progress in training and competency assessment, potentially as part of the reformed AWERB process.
	Develop improved mechanisms for identifying refinements in research procedures, and incorporating them into training programmes and competency assessments.
	Engage the Imperial's staff development unit to assist with implementation of these reforms.
Culture, leadership and management <i>Strategic leadership</i>	Develop a vision statement and action plan for the 3Rs, aiming to set the highest international standards and to be a world leader in developing ideas and practice in this area. This should be a collaborative project involving the senior team working with Imperial staff.
	Enlist help from experts in change management to foster a collegial and collaborative process and cross-institution ownership.
<i>Senior management</i>	Recommend that the NVS focuses primarily on fulfilling their statutory duties and responsibilities, championing this area for development of the 3Rs.
	Create a new senior directorial role with overall responsibility for the delivery of bioservices at Imperial. The CBS Director, NVS, head of AWERB, NTCO, NIO and HOLO would all report to the new appointee.
	The new Director would be tasked with developing strategy across Imperial, and would co-chair the CBS Management and Strategy Group with the Dean of Faculty of Medicine.
<i>Improving the culture of the 3Rs</i>	Consider establishing an annual Imperial prize for a team's commitment to the 3Rs, or the implementation of new developments or new innovations supporting the 3Rs. The prize would reflect the whole team's commitment and contribution.
	Consider other fora, in addition to the AWERB, such as focused workshops, that bring together the whole Imperial team for the development of new approaches for the 3Rs.
	Develop initiatives that bring together academic and support staff, both socially and professionally.

Chapter 3: Lay summary of the independent enquiry into animal research at Imperial College London

- 3.1 In April 2013 the anti-vivisection group the British Union for Abolition of Vivisection (BUAV) published a report and undercover video footage raising serious allegations about the conduct of animal research at Imperial College London. The allegations triggered a number of actions which included Imperial inviting Professor Steve Brown, Director of the Medical Research Council's Mammalian Genetics Unit, to set up and chair an independent committee to investigate how research using animals at Imperial is conducted, managed and overseen. The membership and terms of reference of the committee were at Professor Brown's discretion.
- 3.2 Professor Brown convened an expert committee whose members have expertise in all aspects of animal research from animal welfare and veterinary matters to public engagement. The membership of the committee is listed in Annex 1. The committee has undertaken a thorough review that included interviewing 30 scientists, technicians, vets and administrative staff, some of whom were featured in the BUAV allegations. The committee also requested and reviewed a wide range of documents from the College including minutes of meetings, and visited the building where animal research is conducted and which had been the focus of the BUAV film.
- 3.3 The committee's investigation focused on four important inter-related areas that are listed below. The committee found that the staff responsible for the day to day care of animals (for example animal welfare checks plus providing food, water and clean housing) were committed to animal welfare. It identified, however, that there was considerable scope for improvement in a number of aspects of the operation, management and oversight of animal research at the College and it has made a number of recommendations to address this.

The Animal Welfare and Ethical Review Body

- 3.4 All institutions in the UK using animals in research are required to have an Animal Welfare and Ethical Review Body (AWERB). This has a number of important responsibilities including reviewing the use of animals, ensuring that the welfare of the animals is given full consideration and providing a forum for discussing the 3Rs (that is how to replace, reduce or refine the use of animals). The committee found that the AWERB at Imperial was not fit for purpose and recommended that a new more rigorous process needs to be implemented with greater focus on the 3Rs and increased involvement from the scientists.

Operation of Central Biomedical Services

- 3.5 Animals used in experiments at Imperial are cared for by staff in Central Biomedical Services. This includes vets and animal technicians. The animal technicians mainly carry out husbandry duties along with the daily checks of the animals (predominantly rats and mice). The vets and senior technicians provide advice to the licence holders (usually scientists) carrying out the experiments, for example on whether the welfare of the animals is such that the experiment should be stopped. Only those individuals who are licensed by the Home Office are allowed to carry out procedures on animals that may cause them pain, suffering, distress or lasting harm.

- 3.6 The committee found that animal technicians were committed to high standards of animal welfare but that they were under-resourced and under-utilised. It also found that communication between the vets, animal technicians and scientists could be improved, particularly around the issue of reporting of animal welfare concerns and deciding what intervention was necessary (for example whether the experiment should be stopped). The committee has made a number of recommendations to address the issues it identified, including the need to recruit more animal technicians.

Training and competency assessment

- 3.7 Ensuring that all staff involved in the care and use of animals used for research purposes are appropriately trained and supervised and that their competency is regularly assessed is essential for maintaining best practice and protecting animal welfare. The committee found that the approach to training, supervision and competency assessment at Imperial was *ad hoc*. It has made a number of recommendations to address this including increased resource allocation to support training.

Culture, leadership and management

- 3.8 Responsibility for high standards in animal research lies with a number of individuals at any institution, including Imperial. Some individuals, such as those with licences, have a legal responsibility under the Animals (Scientific Procedures) Act 1986 (amended), while others have a responsibility for setting and implementing the College's standards and culture. The committee found that there was a level of complacency at the College with little opportunity for challenge or bringing in new ideas and that there was scope for improvement in the culture, management and overall leadership. The committee has recommended a new senior level appointment to provide a more coordinated and College-wide approach to the 3Rs and delivering first class animal research to the highest standards.
- 3.9 Further information can be found at:

<http://licensedtokill.buav.org>

<http://www3.imperial.ac.uk>

Chapter 4: The Animal Welfare and Ethical Review Body

Summary of Process

- 4.1 The AWERB process at Imperial is carried out at two levels, a central AWERB, and a local AWERB, each with distinct functions. There is also a 'basic' process for consideration of minor amendments.
- 4.2 Local AWERB membership comprises the Site Manager/NACWO, the NVS, the lay member, the applicant and a peer reviewer, who can be nominated by the applicant.
- 4.3 The local AWERB is responsible for new and renewal PPL applications and considers major amendments, including increasing severity limits, or adding species. It is usual practice for the local AWERB to carry out its business electronically.
- 4.4 The central AWERB comprises a lay Chair, NVS and deputies, the AWERB administrator, NACWOs and Site Managers, Director of CBS, Research Scientists including PIL and PPL holders, and the Establishment licence (PEL) holder. Other lay members sit on the committee. The Chair may co-opt additional expertise, for example, a statistician, on to the committee from time to time. The committee meets every two months.
- 4.5 The central AWERB deals with applications that include substantial (severe) severity protocols, special species and will consider other applications where there has been doubt at the local AWERB concerning cost/benefit or other issues. The central AWERB receives a report of PPLs recently approved through the local AWERB process.
- 4.6 The central AWERB has in addition a wide variety of functions including:
 - a. Monitoring the performance of the local AWERB process
 - b. Considering reports of interim (retrospective) reviews
 - c. Providing a forum for discussion of issues relating to the use of animals, including best practice and changes to legislation
 - d. Receiving reports from the NTCO
 - e. Promulgation and distribution of information on the 3Rs
 - f. Reviewing annual returns to the Home Office
 - g. Reviewing breeding programmes and monitoring potential over-breeding
 - h. Monitoring the use of Schedule 1 killing
 - i. Receiving reports on infringements and producing appropriate recommendations
- 4.7 The basic AWERB process considers minor amendments when, in the opinion of both the NACWO and NVS, no statistical input, peer review or lay person involvement is considered necessary. The basic AWERB (NACWO or NVS) recommends to the licence holder's designated signatory that the amendment be forwarded to the Home Office Inspector for authorisation.

Committee's investigation

- 4.8 The committee met with a number of staff who are directly involved with the AWERB process at different levels including NACWOs and Site Managers, the NVS, the PEL holder, a Research Scientist PPL holder and the Chair of the central AWERB.
- 4.9 The committee's aims broadly were to understand the AWERB process at Imperial and its contribution to promoting the 3Rs and raising animal welfare standards, in particular:
- a. The effectiveness of the local AWERB process in considering animal welfare issues and assessing costs and benefits of the proposed work.
 - b. The inter-relationship of the local and central AWERB process.
 - c. The frequency of retrospective reviews and their effectiveness in contributing to animal welfare improvements.
 - d. The involvement of NACWOs, NVS and other animal house staff in the AWERB process and their commitment within the process to animal welfare improvements.
 - e. The wider involvement of Imperial research staff in the AWERB and its ability to promote engagement and discussion on 3Rs and animal welfare issues and improvements.

Committee's observations and findings

AWERB process and staff involvement

- 4.10 The NACWOs play a key role in the local AWERB process, assessing and advising on PPL applications. Their continued input is vital to a successful AWERB process.
- 4.11 NACWOs meet regularly to discuss the 3Rs and to discuss animal welfare issues associated with licence applications. We recognised a high level of commitment and interest on the part of the NACWOs to the 3Rs. However, the structure and organisation of the AWERB process at Imperial did not provide the opportunities to build on this enthusiasm and bring it to bear on welfare standards and improvements.
- 4.12 It was clear from our investigation and conversations that given the volume of PPL applications Imperial considered an electronic process for the local AWERB to be most appropriate. However, an electronic discussion between a few participants does not necessarily provide a suitable forum or time for reflection, scientific challenge and discussion on the cost/benefit assessment and welfare improvements. Moreover, it does not engage the wider scientific community at Imperial in these discussions.
- 4.13 The central AWERB process brings together staff from the animal houses, NACWOs and senior management, along with scientists in order to review PPLs encompassing severe procedures, and to take the opportunity to consider welfare issues College-wide. While, to some extent, this should provide a valuable forum for exchanges of information and views on the 3Rs, it is inevitably limited by the frequency of the meetings. We noted that the minutes of these meetings are not made available to users. It was commented that the role of the central AWERB

and its activities were not as well known as they should be and that there were opportunities for its work and outputs to be more transparent.

- 4.14 A group of six scientists, small relative to the total numbers involved in animal research at Imperial, are members of the central AWERB committee and participate in discussions on welfare and scientific issues. The involvement of scientists at the local AWERB process is limited. Overall, the committee found that there was little active involvement of scientists through the AWERB process in the discussion of the 3Rs and the development of welfare improvements. One PPL holder commented that they did not believe there was much awareness of the AWERB process, and that most activity surrounding welfare issues happened directly between NACWOs and scientists.

Administration of the AWERB process

- 4.15 The NVS, as well as attending to her duties as NVS, administers the AWERB process. She is also the NTCO. As part of her duties administering the AWERB process, she is responsible for signing off the PPLs on behalf of the PEL holder before submission to the Home Office.
- 4.16 The committee noted the potential for conflict of interest between the duties of the NVS and the administration of the AWERB process.
- 4.17 The committee was also concerned at the wide range of responsibilities and the burden of work shouldered by one person. We concluded that there would be considerable advantages to the management and improvement of the AWERB process by separating the roles of the NVS and AWERB administration.

AWERB and the 3Rs

- 4.18 The committee noted a strong focus on delivering an AWERB process that was efficient and timely for the licensing of animal research. However, the role of the AWERB is much wider than the management and administration of licence applications. It includes a number of important elements that bear upon the 3Rs, particularly:
- a. Promoting awareness of animal welfare.
 - b. Provides a forum for the discussion and development of ethical advice to the PEL holder on all matters related to animal welfare, care and use at the establishment.
 - c. Considers standards of animal care and accommodation, including breeding stock, and the humane killing of animals.
 - d. Sets up and regularly reviews procedures and protocols, including management systems, for monitoring, reporting and following up on acquisition, welfare and proper use of animals at the establishment.
 - e. Promotes the development and uptake of the 3Rs and advises staff how to apply them.
 - f. Throughout the lifetime of projects, follows their development and outcome, including those requiring retrospective review, so that lessons learnt can be used to further apply the 3Rs.
- 4.19 The committee found that the AWERB process at Imperial was not best configured to undertake these elements of ethical and scientific review. Some of these elements are discussed from time to time at the central AWERB, but overall important elements of the AWERB process were not given sufficient attention.

- 4.20 We found that NACWOs are keen to promote best practice and research 3Rs and welfare improvements from diverse sources, and applaud their enthusiasm. CBS staff are also encouraged to attend seminars, courses and gather information from websites. However, concerns were raised by some of our interviewees of the ability of staff to engage with the 3Rs and to participate actively in the development of welfare improvements and new welfare practices. A reformed AWERB process will aid considerably in involving all staff in the 3Rs.
- 4.21 The local process operating via an electronic discussion and involving only a few individuals does not provide an effective forum for implementation of the 3Rs as part of the AWERB process. This includes review of procedures and protocols on a regular basis, including management systems, as well as the development and implementation of new approaches to welfare practices.
- 4.22 The committee reviewed the level of activity of PPL review and amendment at all the Imperial sites. We concluded that the numbers of licence applications did not by itself necessitate an electronic process for the local AWERB.
- 4.23 We did not find any clear process for the dissemination to the wider Imperial animal research community of 3Rs information and welfare improvements that might emerge from NACWO discussions or the local and central process.
- 4.24 There were no reviews undertaken of developments and outcomes of ongoing projects. Moreover, no retrospective reviews of PPLs had been undertaken for some time. Thus there was not the opportunity to assess welfare issues that may have arisen, to digest the lessons learnt and to implement necessary improvements in the 3Rs.
- 4.25 The committee concluded that the current structures and mechanisms for the AWERB within Imperial were not fit to foster an active programme in the 3Rs and welfare improvements in which all staff are engaged, and which is energetically disseminated to all involved in animal research at the College.

Recommendations

- 4.26 The committee recommends a number of substantial improvements to the AWERB process. In summary, these include:
- a. A reformed local process, that involves standing committees meeting regularly and providing a forum for the robust review of projects and the cost/benefit assessment, as well as the development of ethical advice and new welfare practices.
 - b. A streamlined and better defined central process that provides an overarching view of animal research at Imperial and sets College-wide standards for the review and conduct of animal research.
 - c. The establishment of a separate senior appointment to administer the AWERB process.

The local AWERB process

- 4.27 We recommend the establishment of at least two standing local committees, one for South Kensington and St. Mary's, the other for Hammersmith. These committees would meet to assess project applications, including cost/benefit assessments, assess amendments, carry out reviews of welfare outcomes of ongoing projects, undertake retrospective reviews of PPLs, and develop and

oversee the implementation of the 3Rs and associated animal welfare improvements. The aim is to ensure greater ethical review of animal research, a more robust approach to the cost/benefit assessment and an active programme of 3Rs and welfare improvements driven by both scientists and animal house staff.

- 4.28 The committee concluded that each local AWERB should be chaired by a senior academic on the site and include one or more lay members; several scientists (including those active in animal research and where appropriate scientists who can bring additional relevant expertise to the discussion); the Director of CBS; the NVS; NACWOs and the Site Manager. The committees would meet every month on average.
- 4.29 We strongly recommend that the activities of each local AWERB fully engage the wider research community at Imperial. Scientists proposing new projects or amendments should attend the committee to discuss their proposals, and should be present at the committee during discussion of retrospective reviews and other assessments of ongoing work. Meetings should be publicised and staff who have specific skills or knowledge in the areas of discussion or assessment should be encouraged to attend and contribute. Anonymised minutes of meetings should be available to all staff at the College.

The central AWERB process

- 4.30 The committee recommends that the central AWERB undertakes an overarching role in setting and monitoring standards for animal research College-wide.
- 4.31 We envisage that the central AWERB will focus its activities in three areas:
- a. To set and review strategy in terms of animal research, the 3Rs and welfare improvements for the College as a whole.
 - b. Review the outputs and activities of the local committees, including the consideration of retrospective reviews.
 - c. Receive and consider PPL proposals involving severe protocols from the local committees.
- 4.32 The committee recommends that the membership of the central AWERB be reviewed, but include an element of overlap with the local AWERB to ensure joined up working. Importantly, the central committee and its role needs strong support from Imperial's senior team and we recommend that the central AWERB should be chaired by a senior academic, such as a Dean.
- 4.33 The committee considered that strengthening scientific participation at the central AWERB was critical to ensure wider engagement. Thus we recommend that an interview process is established to select scientists with the appropriate mix of skills and interests to serve the AWERB. Tenure would be limited to three years.
- 4.34 Meetings of the central AWERB should be publicised and anonymised minutes of the discussions and outcomes should be made available widely across the College.

Administration of the AWERB process

- 4.35 The committee concluded that the current roles undertaken by the NVS, including the administration of the AWERB, are separated and new appointments made to

cover AWERB and compliance and training areas. The NVS would focus their work on the veterinary and welfare elements of the role.

- 4.36 The committee recommends the appointment of a senior administrator for the AWERB process. This new appointment would also play an important role in establishing the new reformed AWERB process that we recommend.

Chapter 5: The Operation of the Central Biomedical Services

Committee's investigation

- 5.1 The committee met with a number of staff who are directly involved with the operation and use of the CBS facilities. Staff held roles at different levels and within different animal care teams, research groups and additional support areas. These included NACWOs and Site Managers, the NVS and dNVS, the PEL holder and Research Scientists (junior and senior) holding both project and personal licence authorities.
- 5.2 The committee's aims regarding the operation of CBS were to understand the day to day operation of the animal facilities at Imperial and how the activities undertaken contributed to promoting and raising animal welfare standards, in particular:
- a. Operational structure
 - staffing levels in relationship to activity
 - resource available for out of hours and weekend working
 - b. Operational standards
 - c. Communication and working practices
 - d. How concerns about animal welfare were managed and reported

Committee's observations and findings

Operational structure

- 5.3 The CBS animal facilities are currently based over three sites; South Kensington, Hammersmith and St Mary's. At the Hammersmith site, two separate units (H1 and H2) operate.
- 5.4 Each unit has a clear line management structure with technical and support staff reporting to a Chief Technician who reports to a Site Manager. The Site Managers report to the Director of CBS. Spans of control and tiers of management appeared appropriate.
- 5.5 The CBS operates a strict barrier system as one of the biosecurity measures employed. This necessitates a 48 hour quarantine period for staff who wish to move between facilities **and** between areas within the same facility. The policy includes senior facility managers and the NVS team.
- 5.6 The difficulties of moving between barriers restricted free flow of staff between and within facilities leading to decreased overall staffing flexibility and the possibility of imbalances in workloads.
- 5.7 The quarantine period of 48 hours limited availability of veterinary oversight. Therefore cameras were used to allow animals to be inspected by video link or from still images. If absolutely necessary a shower and change of clothes would be used before over-riding the 48 hour quarantine period. However it was reported that this was rarely required.

- 5.8 Separation of the facilities across different sites, buildings, floors and biosecurity levels, with offices on a different floor in H1, reduces the ability for senior facility management overview of the facilities.
- 5.9 The facilities house predominantly rodent species using Individual Ventilated Cage Units and handled within laminar flow cage changing stations.
- 5.10 A number of procedural areas, including operating theatres, are embedded within each facility. Additional designated areas outside the CBS enable procedures to be conducted on animals within laboratories of specific research groups.
- 5.11 While our investigation was proceeding, Imperial introduced a Quality Assurance (QA) programme to ensure delivery of high standards of compliance. Alongside the QA programme the College had already initiated a project to procure a new laboratory animal facility management software. In addition, it is proposed to seek Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) accreditation. The committee was informed that additional resources will be provided to meet the significant and sustained increase in workload that these changes will entail.

Operational standards

- 5.12 The facility visited (Hammersmith H1) was well equipped for both animal husbandry purposes and the conduct of basic experimental procedures including anaesthesia, surgery and recovery. The fabric of the building was to the required standard of finish, with evidence of recent refurbishment. Environmental control appeared to be according to Code of Practice standards.
- 5.13 Housekeeping and cleanliness of the animal holding/procedural areas and of the cages was to a high standard. The effort of the CBS staff to maintain these high standards was very much in evidence. Animal stocking densities appeared appropriate.
- 5.14 Cage labelling was clear and indicated the severity limit for the relevant protocol for the animals held.
- 5.15 In terms of staff to activity ratios, these appeared satisfactory for basic husbandry and welfare duties (checking cage inmates, feeding, watering and changing cages). However the relatively high cage numbers per technician, combined with a weekly cage change regimen, required the use of agency staff to ensure that all husbandry duties could be accomplished each week. Staffing levels are unsurprisingly exacerbated by staff recruitment and retention problems experienced within London. The potential high cage number to staff ratio was not recognised by more senior CBS staff or by the PEL holder.
- 5.16 This minimal staffing level was vulnerable to any unplanned absence for example, due to sickness particularly if this occurred when other staff were on annual leave.
- 5.17 The routine use of agency staff could impact on the number of available staff to cover the weekend rotas.
- 5.18 It was not clear that sufficient attention was given to supervision and oversight of the animals undergoing procedures in the theatre and procedural areas by comparison with the focus on ensuring that basic animal husbandry duties were completed. 'Intense workload' was reported by a member of the animal care staff.

- 5.19 It was also reported that more input by CBS staff into post-operative care was limited by demands of their current duties. More senior staff were expected to take responsibility for managing the section (floor) and oversee all staff and rooms in the section (including theatre and procedure rooms). Not all research staff/support teams were aware that such an overview was intended, perhaps because currently such oversight was rarely possible because of staffing levels.
- 5.20 Lack of oversight of the procedure rooms in which rodent surgery was conducted would also contribute to the reported difficulties in ensuring aseptic surgical standards were maintained.

Communication and working practices

- 5.21 The current working practice assigns responsibility to individual licence holders to monitor animals after surgery and make post-operative assessments. Advice on pre- and post-operative care was available from the dNVS.
- 5.22 It was clear from a number of interviews with research staff that duties that might typically be undertaken by animal technicians were carried out by research personnel. For example maintenance of a number of breeding colonies of transgenic animals were conducted by the separate transgenics support team.
- 5.23 The dedication of all the CBS staff to maintaining high standards of housekeeping and care was recognised by all committee members. However, the ability of animal care staff and named persons to extend their areas of expertise appeared limited by the staff resource available and the operational structure/culture. This constrains a clearly desired greater involvement and interaction of CBS staff with research colleagues.
- 5.24 Research colleagues identified that CBS staff were always busy (this was a common theme) and this appeared to be linked to a lack of confidence that experimental protocols could be implemented to the required standards by CBS staff.
- 5.25 The existence of a 'them and us' view (taken of each other, by both animal care staff and research colleagues) also did not appear to contribute to the recognition of the expertise of the animal care staff. Nor would this improve the confidence of animal care staff so that they felt able to challenge research staff on animal care and welfare issues. This could impact on the opportunities for maximising the implementation of the 3Rs to their fullest extent.
- 5.26 Communication about welfare issues appeared to rely heavily on emails since this was perceived as more likely to be successful than the use of the telephone or direct face to face meetings.
- 5.27 Email interaction may be contributing to the reduced level of personal interactions required for meaningful team working. Recently introduced lunchtime seminars are reported to be proving helpful in bringing people together. However, we were concerned that attendance would be difficult for CBS staff who were heavily committed to a high workload of animal care.
- 5.28 The depth of personal interaction of CBS staff with research colleagues appeared to vary, and seemed to be dependent upon the level of personnel in the hierarchy of CBS. Although it was reported that animal welfare issues were discussed at some research group laboratory meetings, CBS animal care staff were not

included. CBS staff attendance could be operationally difficult to achieve with current staffing levels but would benefit working relationships and animal care/experimental outcomes.

- 5.29 The NACWO position was undertaken at Advanced Technician level, Senior Animal Technician level, Chief Technician and Site Manager level, and several NACWOs were available at each site, ensuring that NACWO cover should be readily available throughout the working day and during weekend and Bank Holidays.

Animal welfare concerns

- 5.30 Documenting actions and monitoring issues with animals seemed to rely primarily upon email communication, although staff also commented that they would speak directly with research colleagues if the opportunity arose. The use of score sheets and the recording of quantitative data to allow more informed decisions to be made about animal welfare did not appear to be normal practice.
- 5.31 Assurances were given that the NACWOs had sufficient authority to ensure that avoidable animal welfare issues were resolved independently of NVS or licence holder input if an animal's welfare gave significant cause for concern. However, it appeared that the usual practice was to refer to the NVS and/or licence holder without the NACWOs maintaining a continued input into the process. It was not clear whether routine follow up of incidents by the NACWO was undertaken to ensure that the matter was dealt with appropriately. It was also unclear if the NACWOs decision making process was free from any additional pressures within the establishment. An earlier written response reported that the PIL or PPL holder decides if an animal has reached its humane endpoint with guidance from the NVS and NACWO.
- 5.32 The CBS had a long history of staff being promoted within the same facility. In some cases this may have led to a reduced recognition of the technical ability and authority of CBS staff by research colleagues.
- 5.33 NVS duties are divided between three dNVSs and the senior NVS. The amount of veterinary resource available should ensure that satisfactory levels of cover are in place. It was reported that an escalation process for welfare concerns was rarely used, but was available if there were differences of opinion between the PIL or PPL holder, NACWO and NVS. It was reported that there had never been cause to stop an experiment due to welfare concerns.
- 5.34 The dNVS appeared well aware of the need for the PPL holder to report to the Home Office Inspector any incident where the adverse effects of a protocol had been exceeded.
- 5.35 Discussions between the NVS (and dNVSs) and licence holders appeared to be a regular occurrence. The importance of giving due consideration to experimental requirements as documented in the PPL was recognised. It was less clear how the requirement to minimise potential suffering was implemented by refining research procedures.
- 5.36 Availability of PPL and PIL documents appeared not to be straightforward, with no guarantee that licence authorities could be checked easily by all concerned. This could lead to difficulties in acting upon licence requirements for safeguarding

welfare and applying humane endpoints along with associated compliance issues when procedures are being conducted.

- 5.37 The number of PPLs authorised for use across Imperial was given as the reason for the lack of PPL information available in rooms shared by different research colleagues. PPL information was available within the unit offices (distant to the animal holding areas) with only 19b protocols of those licences deemed appropriate by care staff, for example of higher severity, being available on the floor.
- 5.38 The knowledge of both research and CBS staff of the correct reporting process via Standard Condition 18 of the PPL was highly variable. The process did not appear to be actively driven by the CBS staff. The requirement to report had not previously been understood by all concerned and scientific colleagues were not aware of their legal obligations. The local Home Office Inspector has recently reminded staff of this requirement. Despite this, individuals questioned during the interview process were still not absolutely clear of their responsibilities.
- 5.39 Issues of compliance with CBS requirements in the past has resulted in the use of a penalty points system by which CBS and the College enforced standards, for example, penalties for breaching barrier rules. It was reported that this system has resulted in better compliance. The system had therefore been extended to animal welfare issues. It was reported that this was necessary to enforce standards. It was not clear that the use of such measures will deliver the required culture of care and compliance and could alienate research colleagues and CBS staff from each other. It is considered that this system, and the potential consequences of amassing penalties, could reduce the amount of self-reporting by staff of any welfare issues.
- 5.40 Escalation of welfare issues to the PEL holder appeared not to have been undertaken in the past and all had been dealt with in-house.

Recommendations

- 5.41 The committee recommends a number of significant changes to the operation of the CBS.

The operational structure

- 5.42 The committee recommends that staffing levels are increased to allow significantly expanded involvement of animal care staff and named person involvement with the *in vivo* research programmes at Imperial. Furthermore, the committee considers that this involvement must not be limited to basic animal husbandry duties. Involvement should extend to active oversight of experimental areas and procedures including peri-operative care and humane killing.
- 5.43 The staff resource available for out of hours and weekend working must provide sufficient time for an independent overview of the welfare of animals housed in the facilities and the time required to deal fully with any welfare issues when problems arise.
- 5.44 A staffing policy should be developed that reduces the reliance upon agency staff. This is essential in order to develop the required level of in-house expertise and the flexibility required for appropriate weekend cover.

- 5.45 The further development of the technical competencies of CBS staff to enable them to undertake licensed procedures should be actively promoted. This should improve both the service provided by CBS and the professional standing of CBS staff with clear benefits to both animal welfare and the scientific quality of *in vivo* studies.
- 5.46 The current barrier systems and 48 hour quarantine periods should be reassessed to determine whether they are still appropriate and fit for purpose. Modifying these systems would increase the flexibility of limited staff resource but it is recognised that this flexibility has to be balanced with biosecurity concerns.
- 5.47 A thorough assessment of the CBS staff resource required to support the introduction and subsequent maintenance of the laboratory animal facility management software and the AAALAC accreditation process should be undertaken before implementation of these initiatives.

Operational standards

- 5.48 The committee recognises that staff resources will be constrained even after an increase in staffing levels. It is therefore critical that staff are aware of the need to focus attention on those animals and areas that are considered likely to require additional support and oversight. This will require that increased direction is given to animal care staff so that this can be achieved without detracting from the high standards of care and husbandry observed in the animal holding areas.
- 5.49 Specifically it is recommended that:
- a. CBS animal care staff formally monitor all theatre and procedure areas at least once daily (but more frequently for complex procedures).
 - b. CBS staff should contribute to the supervision and competency records of licence holders.
 - c. CBS staff must enter their observations of animals undergoing procedures on the animal record sheets and note any action taken. This must be linked with a robust mechanism to ensure all recommendations and requests made to PPL and PIL holders are implemented rapidly and effectively.
- 5.50 This overview must be undertaken in the form of collegiate working and not seen as a purely policing undertaking by CBS. The roles of the NACWO, NVS and NTCO within this process must be clearly stated and included in the new working arrangements.

Communication and working practices

- 5.51 We recommend the development and implementation of stronger links between scientific users of the facility and CBS staff that will be critical to the development of an efficient and effective service that actively promotes a 'culture of care'. It is particularly important that greater efforts are made to integrate the role and activity of CBS staff into the broader *in vivo* research activities of the College and we make a number of recommendations in this area.
- 5.52 A strategic plan for CBS development that includes a clear service level agreement, coupled with a statement of capacity, capabilities and types of technical support that can be provided should be developed.

- 5.53 Building on this strategic plan, work currently undertaken by research staff at Imperial that would ordinarily be undertaken by the equivalent of CBS staff in other establishments should be identified, and a programme implemented to involve CBS staff in these activities.
- 5.54 CBS and research staff should increase the frequency of face to face interactions and phone conversations and reduce the current reliance on email contact. CBS staff at all levels should be encouraged to attend research group meetings to improve communications and understanding of particular research projects. Furthermore, our recommendations on the AWERB process (see Chapter 4), specifically the implementation of active local AWERB committees involving CBS staff, NACWOs, NVS and scientists also provide an important forum for interactions between scientists and CBS staff.

How concerns about animal welfare were managed and reported

- 5.55 We recommend the introduction of standardised documentation to monitor animals during experimental protocols (or if stock animals give cause for concern). The information should be collated regularly and systematically reviewed by the animal care staff, the NACWOs and NVS team and research staff. The information obtained should be used to inform animal care staff and research staff of specific welfare issues and to develop appropriate humane endpoints that can be applied without any undue delay.
- 5.56 All PPLs, including 19b protocols, adverse effects and humane endpoints should be readily available at the level of the holding room or theatre post-operative area/procedural area. The use of pdf versions available via laptops or tablets would be helpful in this respect.
- 5.57 The existing policy regarding action to be taken in the event of animal welfare concerns should be more robustly implemented and more clearly communicated. The advice of the named persons must be actively sought, taken and followed. Importantly the NACWOs must ensure that appropriate action is taken once advice is given, that this is fully documented and that the Home Office have been notified by the PPL holder when appropriate.
- 5.58 A clear route for escalation of animal welfare concerns via the lay or other members of the AWERB should be implemented and communicated.
- 5.59 The role of the NVS and NACWO in improving standards and implementing the 3Rs, and the expectations of the Home Office upon the holders of these posts, must be understood by the research community and supported by the AWERB. A means of effectively communicating the roles and responsibilities of the NACWO and NVS to the research community at Imperial must be developed.
- 5.60 The understanding and willingness of staff, including licence holders and animal care staff, to undertake the 'self-reporting' process correctly must be actively managed in a sympathetic manner that encourages correct action being taken. The use of the 'penalty points system' to achieve this should be re-examined.
- 5.61 The inclusion of the PEL holder in the reporting of serious cases which may result in infringements must be a mandatory requirement.

Chapter 6: Training and competency assessment

Background

- 6.1 The committee considers that provision of effective training, supervision and competency assessment is central to the successful operation of a research animal facility and to the implementation of the 3Rs (particularly refinement). Assessment of competency, to ensure this training is translated into conduct of procedures to appropriately high standards is equally important, and is a legal requirement under UK legislation. If appropriately high standards in this area are not attained this can lead to failures to maintain good animal welfare and to conduct good quality *in vivo* research.

Committee's investigation

- 6.2 The committee met with a number of key personnel with responsibilities for delivery of training, or having oversight of assessment of training and competency. We also discussed this area with the majority of the staff that we interviewed. Because of time constraints, we did not attend any of the Home Office training courses offered by Imperial.

Committee's observations and findings

- 6.3 It was reported that staff are provided with a general induction to the animal facilities provided by CBS staff; an additional induction was provided for staff working in specific areas of the facilities. Home Office modular training courses were provided by Imperial at the South Kensington site.
- 6.4 There was very little evidence of informal or formal sharing of ideas and practices between staff, and between units. A series of seminars for all staff had recently been organised to provide additional continued training and development, however there seemed relatively little integration of these seminars within the broader framework of technician and research worker training and competency assessment.
- 6.5 It was clear that many academic staff were unaware of the various animal welfare and laboratory animal science-based meetings that were available to the research community. Those that were aware of these did not seem enthusiastic about attending. Knowledge of the National Centre for the Replacement, Refinement and Reduction of Animals in Research's website and other resources that could assist with training and competency appeared very limited.
- 6.6 The provision for training, supervision and competency assessment appeared *ad hoc*. Training and supervision of staff undertaking procedures was deemed (appropriately) to be the responsibility of PPL holders. Advice was available from the NVS and NACWO on request but there was no systematic approach for ensuring that their input and oversight was included. Competency assessment was undertaken by PPL holders, but again there appeared to be no systematic approach for assessing new and experienced licensees, including input from the NVS, NACWOs or other CBS staff. Regular assessment of experienced licence holders is important to ensure best practice is maintained.

- 6.7 An option to utilise senior animal technicians to assess competency of performance of more routine procedures such as blood sampling was available but not frequently requested. We believe that there is a considerable cadre of highly competent and skilled staff working within CBS, and we were confident that such staff could provide effective supervision and assessment of less experienced individuals.
- 6.8 It was recognised by CBS senior managers that more resources may need to be made available for the new NTCO role that currently is undertaken in its entirety by the NVS. We comment elsewhere on the various and substantive duties that are currently undertaken by the NVS.
- 6.9 In conclusion, training must be continually updated so that it introduces and shares best practice from within and outside the organisation. The committee recognises that attempts to achieve this are being made by some staff, but the provision of training is seriously under-resourced. As a leading academic institution, with a national and international reputation for research excellence, we consider that Imperial should be aspiring to and working towards the highest standards of animal welfare. Implementation of the following recommendations should contribute significantly to translating these aspirations into effective implementation of best practice in all aspects of the College's research programmes.

Recommendations

- 6.10 The committee recommends a significant increase in the resources allocated to training and competency assessment. This must be linked to a systematic, site wide review to develop mechanisms for dissemination and implementation of best practice.
- 6.11 A senior NTCO should be appointed, since this role has too great a workload to be undertaken by the NVS.
- 6.12 Implementation of training and dissemination of best practice must be linked to a systematic, College-wide, regular process for assessing competency. This must include assessment of trainers to ensure continued delivery of best practice.
- 6.13 A forum should be developed that will assist with this process, so that progress in training, assessment of competency and sharing of best practice is regularly assessed both within and across animal facilities. This process could fall within the remit of the reformed local AWERB with College-wide oversight from the central AWERB.
- 6.14 A more structured mechanism should be developed for identifying refinements in research procedures developed both within and outside the Institution. These refinements should then be incorporated into training programmes and competency assessments.
- 6.15 The CBS should consider using the general expertise available in the Imperial's Staff Development Unit to assist with implementation of these recommendations.

Chapter 7: Culture, leadership and management

Background

Cultures and communities of people

- 7.1 There are at least four communities of people involved in animal work at the Hammersmith site of Imperial: the CBS staff, the academic staff, the veterinary staff and specialist facilities such as the unit providing transgenic mouse and rat services in the MRC Clinical Sciences Centre. Within these communities there are several sub-communities; for example, some staff have moved from CBS into research support positions in academic teams.
- 7.2 To ensure the highest standards of animal welfare and science, a culture of openness, trust and respect where teams of scientists and support staff work together is needed. Universities across the country and beyond struggle to achieve harmony between those with academic positions, and those with professional or technical posts. This is a common issue across all disciplines. Problems around understanding and respect for others' skills, commitment and experience are hard to address, but the need is perhaps greatest when the welfare of animals and the success of the science is at stake.

Current leadership and management structures

- 7.3 CBS is headed by a Director and Deputy Director, who have overall responsibility for operations across the various facilities. Each campus is managed day to day by a Site Manager; the Deputy Director is Site Manager for facilities at the South Kensington Campus. The Director reports to the Chair of the CBS Management and Strategy Group, currently Dean of the Faculty of Medicine (the Dean of Faculty of Natural Sciences is Deputy Chair). The Management and Strategy Group have overall responsibility for strategy, policy and finances in CBS and report to the Provost Board (a senior College executive committee).
- 7.4 CBS is staffed by individuals with very defined posts in a straightforward hierarchy: Junior Technician, Technician, Advanced Technician, Senior Technician, Chief Technician, Site Manager. There are good opportunities to progress through the hierarchy and we found that career prospects are good for able staff. Many senior posts are held by long-term employees who have progressed through the system.
- 7.5 Each CBS site has an Operations Committee that is chaired by a senior academic. This committee focuses on monitoring the operational performance of work in the animal facility and planning operational changes and infrastructure developments. Each Operations Committee reports to the CBS Management and Strategy Group.
- 7.6 CBS holds senior Management meetings every four weeks, which involve the Site Managers, NVS/NTCO, NIO, HOLO, Finance Manager and Health and Safety representative. PPL holders or other interested scientists are not involved, except that there are occasional presentations from researchers.
- 7.7 As we discuss in detail elsewhere (see Chapter 5, Operations) CBS delivers a basic service; users provide research staff to carry out most functions above simple husbandry work. CBS staff are keen and able to provide more services.

- 7.8 The PEL holder is the Registrar and College Secretary, who sits on the CBS Management and Strategy Group, and the central AWERB.
- 7.9 The NVS has responsibility for a team of three dNVs. The NVS also runs the AWERB process and is NTCO. CBS veterinary services meet monthly to discuss operational issues.
- 7.10 The central and local AWERB processes run in parallel to these management structures. We discuss in detail elsewhere (see Chapter 4) the AWERB process.

Committee's investigation

- 7.11 The aim of the committee was to investigate how both the culture of work along with the existing management structures contributed to standards of animal care and the development and implementation of the 3Rs. In particular, we considered three interlinked questions:
- a. The interactions and relationship between the diverse groups who are involved in animal research at Imperial, and how they contribute to a culture of care.
 - b. Are the current management structures fit for purpose in delivering change and improvements in the 3Rs.
 - c. Do the appropriate structures exist to ensure the development of active champions in safeguarding the highest standards of animal welfare.

Committee's observations and findings

- 7.12 The committee found that the management of CBS is very process-focused. In our discussions, we recognised a strong emphasis on procedural issues and compliance to the detriment of delivering change and improvements in the 3Rs. Imperial have recently established a QA process to assess the quality of operations surrounding animal experimentation. While this is certainly important, the committee was surprised that the Chair of the central AWERB did not seem aware of this development. It will be particularly important that the goal of the QA process in underpinning improvements in the 3Rs, is developed with broad consultation and implemented effectively.
- 7.13 There is a desire from the CBS management and staff to provide more services. We were impressed with the dedication of CBS staff and their appetite to bring their skills and commitment to work both for the science at Imperial and improvements in the 3Rs and animal welfare. We discuss these issues more fully in Chapter 5.
- 7.14 There is an excellent culture of promotion and opportunities for progression within the CBS. As we discuss above, CBS is process driven and there do not seem to be many mechanisms for the inflow of new ideas or new challenges. In some cases there appeared to be some complacency; standards of husbandry were good but there was no one challenging assumptions or responsible for bringing in new ideas. Moreover, outside of the local and central AWERB, at which time and opportunities are limited, there are not appropriate fora for teams that include academics and CBS staff to engage in substantive discussions, assess and plan joint projects and to drive forward significant improvements and change in the 3Rs. We discuss this issue further in Chapter 4 on the AWERB process where we also

highlight the absence of fora for the wider discussion and implementation of the 3Rs across the various communities involved with animal experimentation.

- 7.15 We found that the respect that CBS staff receive from academic colleagues is not as universal as it should be. These issues are clearly person and team dependent; some CBS staff are well integrated into academic teams and respected for their ideas on husbandry and animal welfare in general, and for their considerable skills, but a high level of respect is not as prevalent as it could be. Overall, we found that a culture of whole teams working together to ensure the highest standards of welfare and implementation of the 3Rs, which will lead to better science, was lacking.
- 7.16 Some academics keep up to date with developments in the 3Rs, and have those issues regularly on agendas for team meetings. This is not however the norm, and again there was some complacency with the current standards of welfare and implementation of the 3Rs overall.

Recommendations

Strategic leadership – developing a vision and action plan

- 7.17 There is a need for strategic leadership around the implementation of the 3Rs, with a senior team given responsibility for driving change and empowered to do so. This team needs to comprise senior academics and senior CBS staff working together to promote the 3Rs, so that change can be owned by the two communities. The senior academics chosen for these roles need time for this commitment (and so may need to be relieved from other duties). At least some need to be current animal users, and to demonstrate passion for the implementation of the 3Rs.
- 7.18 In the first instance, the team should collaboratively develop a vision statement and action plan around the 3Rs which aims to set the highest international standards in the 3Rs and to be a world leader in developing and applying new ideas in this area, commensurate with Imperial's world-leading reputation for scientific research.
- 7.19 The development of the vision statement and action plan must be collaborative and collegial, involving all staff, to ensure cross-institution ownership. The team would benefit from input from experts in change management and we recommend that scientists with the appropriate expertise in other parts of Imperial are approached with the aim of helping design a collaborative process for the development plan. Consideration of the language used around the 3Rs could be helpful; changing the discourse from compliance and quality assurance to aiming for the highest standards and leading innovation will be more inspiring.

Senior management

- 7.20 We now turn our attention to the senior management team. We recommend key changes to the management structure. In so doing, we recognise the importance of appointing champions from within the academic and CBS staff at all levels, and giving these champions different responsibilities; for example, bringing in new ideas and innovations from outside sources.

- 7.21 As we discuss elsewhere, we concluded that the responsibilities placed on the NVS to head the veterinary service, run the AWERB process and act as the NTCO are unsustainable. Given the breadth of responsibilities across these diverse areas, the current arrangements are not conducive to these functions receiving the attention required. As discussed in Chapter 4 and Chapter 6, we recommend the appointment of two additional senior administrative appointments to run the AWERB process, and to undertake the duties of the NTCO. We also recommend that the NVS focuses their role on the management of veterinary services and championing their work, across diverse fora, such as the reformed local AWERB process, delivering as a key veterinary role high animal welfare standards and the development of the 3Rs.
- 7.22 We recommend the creation of a new Directorial role with overall responsibility for the delivery of bioservices at Imperial. The Director of CBS, the head of the NVS service, the NTCO, Head of the AWERB process, the NIO and HOLO would all report to the new appointee. This individual should be tasked with developing strategy across Imperial, have the vision to identify areas for change and have the authority to enact and manage this change. Furthermore, this individual should, as a priority, bring researchers, PPL holders and CBS staff into the decision making processes. A key role for this appointment would be to champion the highest standards of animal research at Imperial and to ensure an integrated, joined-up approach to the development of the 3Rs. The committee would strongly recommend an external appointment.
- 7.23 The new Director would be a member of the newly constituted central AWERB, working with the central AWERB on strategic developments and review of progress in the 3Rs and animal welfare. The new appointee would co-chair the CBS Management and Strategy Group along with the Dean of the Faculty of Medical Sciences. Together, they would be the senior champions for change and developments surrounding the 3Rs.

Further improving the culture of the 3Rs

- 7.24 As we discuss in Chapter 5, the reward and recognition structures around the 3Rs should be reviewed. The penalty points system that is currently in place might not be as motivational as a system that rewarded improvement and innovation, rather than castigating failure. For example, an annual Imperial prize for a team's commitment to the 3Rs or the implementation of new developments or innovations in the 3Rs could be founded. The prize should take into account the whole team's input (including academic and CBS staff).
- 7.25 We discuss in Chapter 4 the contribution of the reformed AWERB process in providing a forum for scientists and CBS staff to discuss the 3Rs. We encourage Imperial to consider other fora, such as focused workshops to discuss specific topics, where 3Rs issues are considered by teams of academics and CBS staff working together on projects. Attendance at these fora should be mandatory for relevant staff. The aim would be to promote sharing of ideas and empower everyone to contribute (in contrast to a lecture series or similar). They would start with the premise that welfare and promotion of the 3Rs was the whole team's responsibility, with individuals having a remit for taking forward specific areas. Training staff in facilitation skills to run these meetings (or bringing in externals with this expertise) could be beneficial.

- 7.26 Other universities have suffered from ‘two tribes’ issues between academic and support staff. Initiatives that bring staff from these communities together, both socially and professionally, will be beneficial. For example, forming teams of individuals drawn from both communities with a common goal can promote cross working.
- 7.27 As we discuss in Chapter 5, CBS staff have skills that are currently underused, and we recommend that the involvement of CBS staff in research programmes be enhanced. We recognise that exploring an enhanced role for CBS staff, and empowering them to do more, would help with improving the culture. They will be seen less as staff who are just responsible for husbandry and more as part of the project team.
- 7.28 A culture that empowers staff to challenge others, including those who appear to be in a position of power (such as Principal Investigators) is needed. Imperial will recognise that this is not possible to achieve overnight. However, a strategy that includes an articulation of what success looks like and a clear action plan with measurable objectives will allow the organisation to chart progress.
- 7.29 It is important to ensure that existing mechanisms for whistle-blowing include reference to animal welfare concerns and that this inclusion is clearly communicated and widely understood throughout the College.

Chapter 8: Conclusions

- 8.1 The committee has undertaken a broad investigation into the approaches to animal care and welfare at Imperial. We make a number of recommendations for significant improvements in operations, management, training and ethical review that will enhance standards at the College, and allow them to aspire to and set goals which are world leading in the field of animal research. In so doing the committee recognise that certain strands and themes emerge that cut across the various areas that we discuss and which are important to recognise and reflect on both at Imperial and more widely across UK institutions carrying out experimental studies on animals.
- 8.2 First, we identify the importance of cross-institution teamwork between the diverse groups that undertake animal care and carry out animal research. The organisational, operational and scientific complexity of animal welfare and the implementation of the 3Rs demands a multi-disciplinary approach bringing together various institutional groups from animal facility staff to scientists amongst others. Promoting synergistic interactions between these groups will underpin a dynamic environment in which new approaches to the development of the 3Rs can flourish. Central to this is the role of the AWERB which provides a key forum to bring expertise and ideas together to consider the costs and benefits of ongoing research, to devise new approaches to the 3Rs, to instigate pilot studies, to review project outcomes and overall to drive the science of the 3Rs.
- 8.3 Second, and related to this theme, we identify the importance of leading and managing the complex operational and scientific aspects of animal care and the 3Rs, from the AWERB to training, to the assessment of welfare improvements, to the championing of new approaches. Fostering a collaborative and collegial environment with dynamic and committed leadership is as important for the study and promotion of the 3Rs as it is for the development and success of a world class university department, for example. Indeed, providing a world-class infrastructure in the 3Rs is a vital underpinning to delivering the best science.
- 8.4 Third, we recognise the importance of ensuring that highly skilled and committed staff within animal facilities are not only fully involved within the wider institutional team but also have the opportunity to take an increasing role in carrying out complex procedures within the *in vivo* research programmes. These opportunities are not always fully realised. Yet there are potentially significant gains to be had for animal welfare in standards of quality control, competency and continuity by fostering and utilising a cadre of highly trained staff within the animal facility. Moreover, there will be a commensurate and vital improvement in the validity and robustness of the scientific findings that emerge.

Annex 1: Membership of the committee

Professor Steve Brown (Chair)
Director, Medical Research Council's Mammalian Genetics Unit
MRC Harwell

Professor Paul Flecknell
Director, Research Animal Facilities
University of Newcastle

Professor Ian Jackson
Head of Medical and Developmental Genetics, Institute of Genetics and Molecular
Medicine
University of Edinburgh

Dr Maggie Leggett
Head, Centre for Public Engagement
University of Bristol

Dr Vicky Robinson
Chief Executive
National Centre for the Replacement, Refinement and Reduction of Animals in
Research

Mr Neil Yates
Director of the Biosupport Unit
University of Nottingham

Annex 2: Terms of reference for the committee

1. The committee will investigate and assess the culture and approach to animal care and welfare at Imperial College London, including areas such as:
 - Management
 - Operational procedures
 - Reporting structures
 - Supervisory practices
 - Training
 - Compliance monitoring
 - Ethical review

The committee's investigations will take into account, but not be limited by, the Home Office's investigations and Imperial's consideration of the incidents alleged by BUAV.

2. The committee will conduct interviews, visit facilities and explore with stakeholders involved with animal research at Imperial the approach to the design, implementation and local regulation of animal research. In so doing, the committee will aim to identify areas of best practice and any areas that fall short of best practice.
3. The committee, where appropriate, may enlist additional expertise to support its deliberations and investigations.
4. The committee will provide a report to the College, elaborating any areas where practice falls short of standards considered to be at the forefront of animal research and animal welfare standards in the UK. The report will deliver, where appropriate, detailed recommendations for improvements across relevant structures and practices involved in animal research at the College. The committee's recommendations may also encompass advice on areas of priority to address, as well as potential structures and solutions for improvements.