

University of Cambridge

General Board Review of the University of Cambridge

Regulatory/Operational Framework Governing Animal Research

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1. Executive Summary

This Report considers whether the University of Cambridge's governance and operational frameworks and processes for the use of animals in science effectively and efficiently support the University's mission to pursue "...research at the highest international levels of excellence"¹. The Review Panel believes that all governance systems need regular care and maintenance and that whatever systems are in place the aim should be to seek continuous improvement. This Report sets out a series of recommendations for how the current frameworks, systems and outcomes can be improved without significantly increasing the resource requirements.

There are many elements of good practice to commend in the current governance systems and outcomes. The main areas where the Review Panel considers improvements should be made relate more to the structure, complexity and efficiency, rather than the effectiveness, of the current systems. The inefficiencies, inconsistencies, weaknesses, and residual risks within the current governance systems need to be addressed to make best provision for the success and sustainability of the University's biomedical research-base, and to plan, provide and operate the facilities and services required to host animal research of the highest quality.

The Review Panel's main conclusions are:

- The commitment to sound governance is clearly visible at the top of the University hierarchy with strong, active senior management support to promote compliance and high standards of science and animal welfare.
- This is reflected in the desire to work to high standards with the expected "culture of care" the Review Panel witnessed throughout the University; and is reinforced by the good working relationships observed within and between management, academic, research, technical, administrative, and other staff.
- The animal facilities are currently owned and operated either by the School of the Biological Sciences or the School of Clinical Medicine and are supported by the University Biomedical Support Service (UBSS) as three functional Management Groups. The Review Panel believes that this fragmented ownership and management model is largely responsible for the significant differences in the processes, practices, standards of care and use, and outcomes that can be found within and between the three UBSG Management Groups.
- There would be immediate benefits if a single new Directorate, based on UBSS, effectively owned, staffed and operated all of the animal facilities on behalf of the University; hosted the Animal Welfare and Ethical Review Body (AWERB); supported and assisted the Establishment Licence Holder (ELH), Named Persons and others with responsibilities under the Animals (Scientific Procedures) Act 1986 (ASPAs); and produced and acted on the management information required to develop unified structures, standards, processes and outcomes. Such a re-organisation would allow the current complex and distributed AWERB structures and processes to be re-balanced, streamlined, and made more efficient and effective. The Review Panel considers these structural changes to be an essential pre-requisite for the process and other changes required to improve standards and outputs.
- The ASPA Named Persons functions, other than that of Named Person Responsible for Compliance (NPRC), should be discharged by persons other than the ELH, and there is a need to improve the visibility, availability, and delivery of the Named Training and Competence Officer (NTCO) and Named Information Officer (NIO) functions.
- The lengthy lead times reported for obtaining project licence authorities and local study plans are incompatible with the need to ensure licence authorities keep pace with the needs of scientists working in competitive and rapidly evolving fields. From the management information currently available within the University it is impossible to know precisely how long these processes take in practice, and how inefficiencies, redundancies and unnecessary delays can be remedied. These anticipated delays and frustrations impact on the structure of the project licences and study plans, and have the potential to create, rather than eliminate, residual compliance risks.

Taking the information, analysis and opinion set out in this report as a whole, the Review Panel's principal recommendation is:

Recommendation 1: A new Directorate, based on UBSS, should effectively own, staff, manage and operate all of the animal facilities on behalf of the University. This Directorate should host the AWERB; support and assist the ELH, Named Persons and others with responsibilities under the ASPAs; and produce and act on the management information required to develop unified structures, standards, processes and outcomes. Such a re-organisation would allow the current complex and distributed AWERB structures and processes to be re-balanced, streamlined, and made more efficient and effective. The Review Panel considers these structural changes to be an essential pre-requisite for the process and other changes required to improve standards and outputs.

¹ <http://www.cam.ac.uk/about-the-university/how-the-university-and-colleges-work/the-universitys-mission-and-core-values>

2. Introduction

This independent Review of the governance of the production, care and use of animals for experimental and other scientific purposes was commissioned by the General Board of the University of Cambridge to:

- Enable the University to better understand its strengths and weaknesses.
- Make recommendations to strengthen as required the current governance systems and frameworks.
- Assist with planning governance systems consistent with future improvements to the facilities provided for animal research in the University.

The Review was conducted between March and August 2014. The Review Panel met with a wide range of University staff and representatives of the Home Office Inspectorate; attended meetings and all parts of the AWERB; was given access to relevant documentation; and visited a cross-section of the University animal facilities.

The Review was limited to the governance of Home Office ASPA licensed animal research, and in particular to compliance with the regulatory requirements and standards set by the Home Office as the regulator. The Review Panel considered whether the current governance systems are efficient and effective: efficient in the sense that they make the best use of the resources deployed without introducing unnecessary bureaucracy or delays; and effective in the sense that they promote compliance, high standards, and the required "*culture of care*", and that relevant risks are identified, eliminated or minimised, and properly managed.

The Review Panel considered whether the governance processes, standards and outcomes are consistent across the University; resilient yet responsive to the circumstances of individual cases; and capable of adapting to progress and change relating to science, animal welfare, the operation of the regulatory regimen, and the needs of those undertaking animal-based research at the University.

The Review Panel did not examine in detail the use of animals for research or teaching not requiring Home Office licences, and the review was not an audit of the University animal facilities or the ASPA licensed work conducted at the University. This Report does take account of reputational risk, but does not consider general management issues such as security, HR policies, or financial controls.

The Report comments on the management structures; the AWERB; Named Persons; animal accommodation, care and use; staffing, including training and competence; and considers whether the systems, processes and outcomes the Review Panel observed match those described in the supporting documentation.

The Report Panel makes two general recommendations that reflect the approach the Review Panel feels should be taken to ensure the efficiency and effectiveness of the governance systems.

Recommendation 2: The inefficiencies, inconsistencies, weaknesses, and residual risks within the current governance systems need to be addressed to make best provision for the success and sustainability of the University's biomedical research-base, and to provide the facilities and services required to host animal research of the highest quality.

Recommendation 3: Whatever governance frameworks and processes are developed and deployed to support and manage Home Office licensed research conducted at the University, their efficiency and effectiveness should be regularly reviewed with a view to their being continually improved.

3. Management Structures

The University of Cambridge:

- Is a large and complex organisation striving to undertake high quality research to the highest standards.
- Believes that animal use as part of basic and translational research programmes continues to be necessary to enable advances to be made that will provide new insights contributing to or enabling the development of new and improved healthcare strategies and technologies to help address unmet clinical needs.
- Is licensed under ASPA as a User, Breeding and Supplying establishment, with in excess of 150 project licences and almost 1,000 personal licence holders having primary availability at the University.
- Currently adopts a Schools-based approach to the planning, development, provision and operation of animal facilities.
- Endorses and implements the 3Rs of Replacement, Reduction, and Refinement.
- Understands the importance of regulatory compliance, seeks to implement and maintain processes to minimise the risk of non-compliance, and promotes the self-reporting and analysis of “near misses” and potential compliance issues to continuously improve its governance systems.
- Is a signatory to the Concordat promoting openness with respect to the use of animals for scientific purposes, and has endorsed the ARRIVE Guidelines and other third-party good practice documents.

The number of University animal facilities has reduced in recent years, and this trend is expected to continue as the University adjusts the number and nature of facilities to better match current and anticipated needs.

The animal facilities are currently owned and operated by the School of the Biological Sciences or the School of Clinical Medicine, with UBSS supporting three separate regional Management Groups, rather than being owned and operated by one entity on behalf of the University as a whole. The current complex AWERB framework and processes reflect the scale, breadth and nature of the animal research undertaken at the University, and the role the two Schools, UBSS, and the regional Management Groups play in the provision and operation of the animal facilities.

Figure 1 shows the main governance structures developed by the University to promote accountability and compliance, based on the main components of the AWERB as agreed with the Home Office.

Figure 1. Existing Committee Reporting Lines and Membership

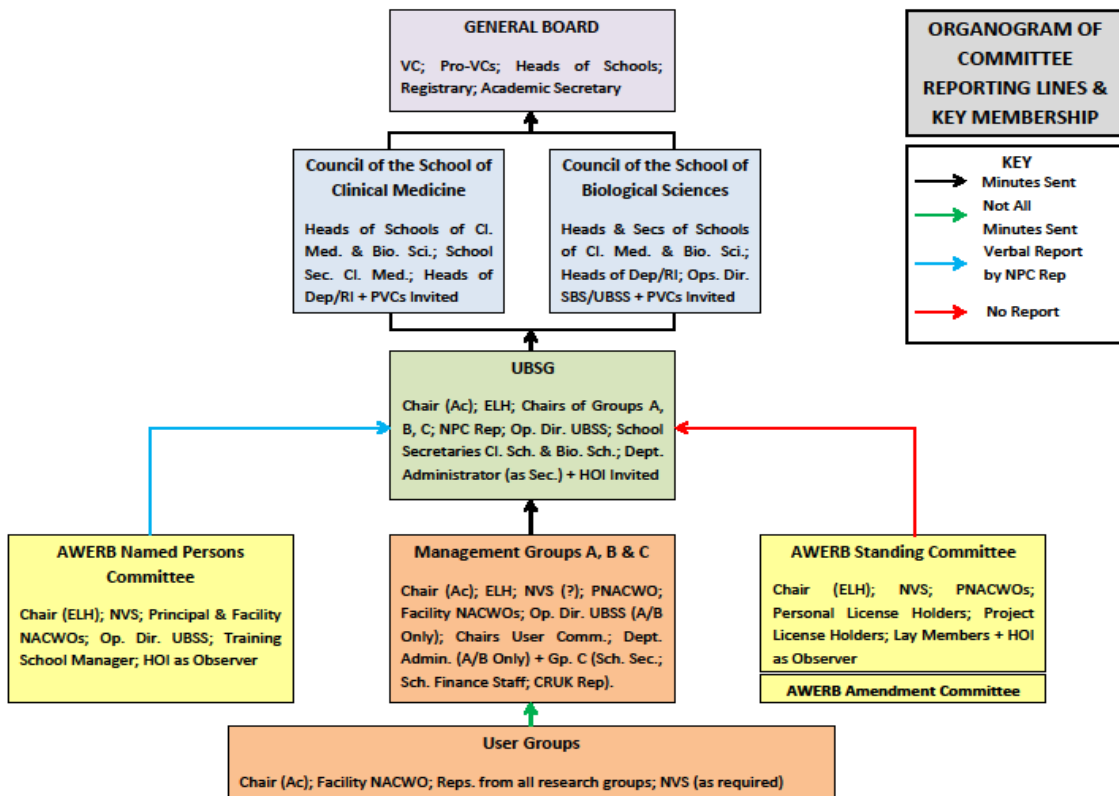
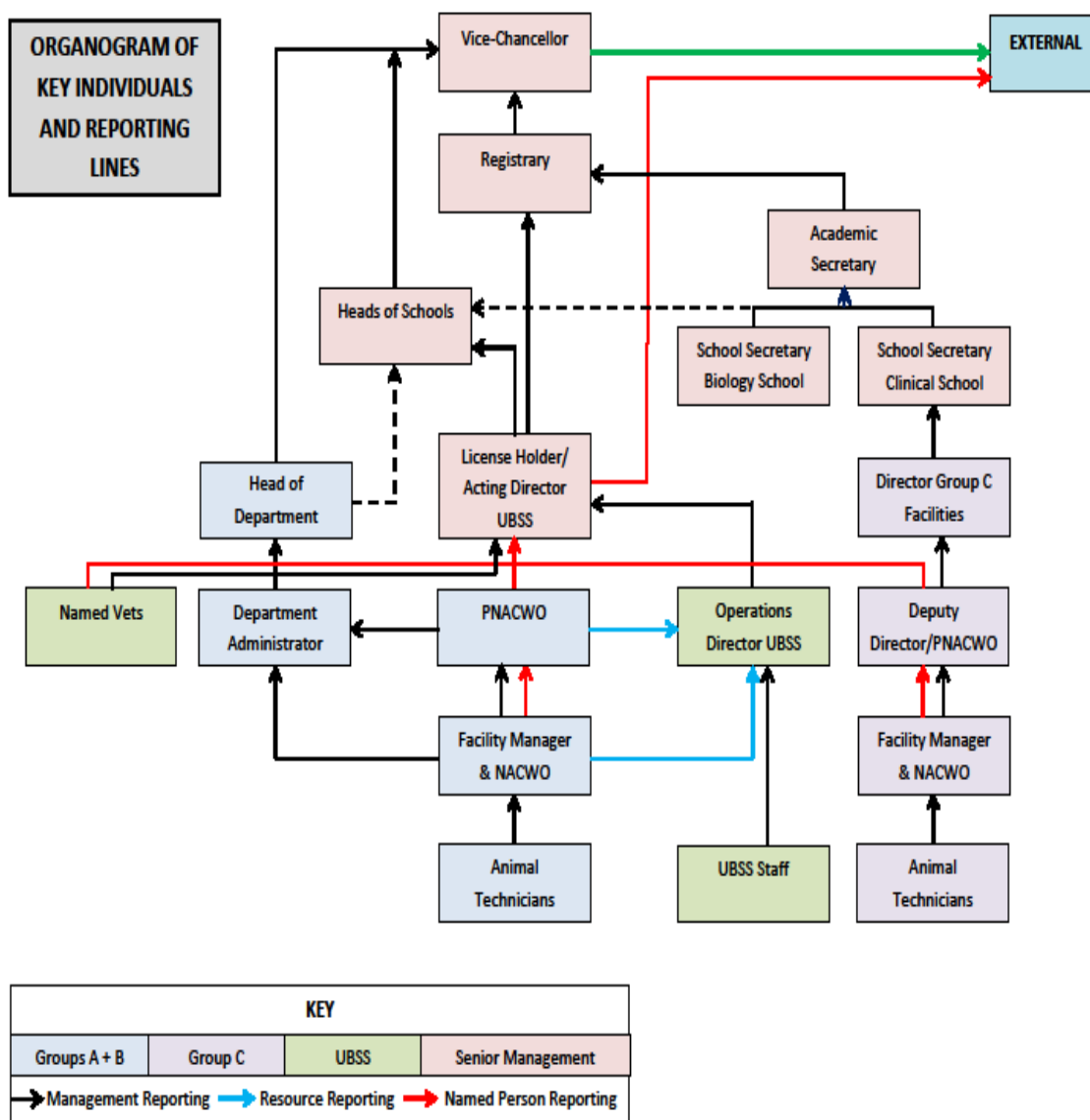


Figure 2 is shows the key individuals and reporting lines.

Figure 2: Key Individuals and Reporting Lines



3.1 University Biomedical Strategy Group (UBSG)

UBSG is an academic-led committee established in-part to monitor, oversee and co-ordinate the systems the ELH maintains to ensure compliance with the requirements of the Animals (Scientific Procedures) Act 1986 and the terms and conditions of licence authorities. The UBSG Chairman is appointed by the Council of the School of the Biological Sciences and the Council of the School of Clinical Medicine.

UBSG's role in supporting the ELH is currently manifest in its strategic management of the facilities, facility planning across the University, consideration of Management Group and Named Person Group outputs², and its interest in high-level finance issues.

Whilst UBSG has a role in the management of the animal facilities and compliance with University policies, its present priorities and activities are driven by strategic considerations of future requirements and the management of large scale projects.

² These inputs tend to be provided as verbal or short written reports rather than UBSG considering the full minutes and papers of these other meetings.

Taking account of its composition and other responsibilities, the Review Panel believes UBSG is well-placed to monitor, consider, and advise on governance issues; take a University-wide strategic interest in animal care and use; and consider the efficiency and effectiveness of the AWERB, and monitor and quality assure its outputs and outcomes, mindful that the AWERB must be free to offer independent advice. UBSG does not currently play a sufficiently active role in supporting the AWERB processes and quality assuring the AWERB outputs.

Recommendation 4: UBSG should monitor, consider, and advise on governance issues; take a University-wide strategic interest in animal care and use; and consider the efficiency and effectiveness of the AWERB, and monitor and quality assure its outputs and outcomes, mindful that the AWERB must be free to offer independent advice.

3.2 University Biomedical Support Service (UBSS)

The individual animal facilities within the University come under the authority of the School of the Biological Sciences and the School of Clinical Medicine. Operational management of the individual animal facilities (including staffing and financial management) is provided primarily by the two Schools and/or the individual Departments within the Schools.

The University Biomedical Support Service (UBSS) provides a range of services to those undertaking animal-based research at the University. The ELH's governance systems and the three UBSG Management Groups cut across the School and Departmental boundaries and aggregate the animal facilities into three functional UBSG Management Groups based on the location and operational and research needs of the individual animal facilities. Under the terms of the relevant University Ordinance UBSS is part of the School of the Biological Sciences: however the Review Panel believes that to avoid real, potential and perceived conflicts of interest it would be best if UBSS worked alongside the two Schools rather than being directly accountable to them.

The post of UBSS Director is currently vacant. The ELH³ is the interim Director of UBSS, and is supported by the UBSS Operations Director, currently a half-time post responsible for the day-to-day operation of the facilities and ensuring their resource requirements are met. The UBSS Operations Director is also currently the half-time Operations Director for the School of the Biological Sciences. The present UBSS Management structure does not include a Technical Director/Manager.

Both the interim UBSS Director and Operations Director chair, are members of, or attend the AWERB Named Person, Group-User, Group-Management and strategy committees. They are well-placed to know what is happening in practice, and exert influence and control and provide support as required.

The services provided by UBSS include assistance and support to users with compliance, administration, licensee and technician training, and animal welfare and the 3Rs⁴. UBSS also provides advice and support to the UBSG and the AWERB committees; supports the ELH, Named Persons and AWERB; operates systems for the governance of Home Office licensed animal research; and is responsible for implementing policies developed by UBSG and others to promote high standards of animal welfare and science.

Technical and other support staff involved in the production, care and use of protected animals are generally employed or line-managed within the School of the Biological Sciences or the School of Clinical Medicine. The main exceptions are small subsets of staff employed by UBSS: the Named Veterinary Surgeons, a pool of animal care staff⁵ available to assist in facilities in any of the three UBSG Management Groups (increasingly used in place of agency staff), those responsible for planning and coordinating licensee and technician training, and a small team of administrators who support the processing of Home Office licence applications and amendments.

3.3 Record Keeping

The record keeping systems differ across the Management Groups and between the facilities. Uniform University-wide IT-based record keeping facilities would simplify and standardise record keeping systems, and facilitate the use of the information recorded to generate management information, and manage personnel, projects and facilities.

Recommendation 5: Record keeping and management information systems should be standardised across all of the animal facilities.

³ As ELH he reports to the Registry and as interim Director of UBSS he reports to the Head of the School of the Biological Sciences.

⁴ Consideration is being given to capacity building with respect to experimental design.

⁵ Referred to below as the "UBSS bank-staff".

4. Animal Welfare and Ethical Review Body⁶

The University of Cambridge AWERB is required to provide independent ethical advice to the ELH; support to the Named Persons, licensees and others; and to promote humane animal production, care and use. Its component parts and outputs are key sources of advice and support on the 3Rs to those involved in animal production, care and use at the University.

The current AWERB reference document (October, 2013), as approved by the Home Office, describes and defines the University of Cambridge AWERB structures and functions. The AWERB functions as set out in the Home Office Guidance on the 1986 Act are delivered through a number of committees. The complexity of the current AWERB committee structure, see Figure 1, reflects the different functional roles and responsibilities assigned to the various committees; the roles played by the UBSG, Schools and UBSS in the provision, operation and management of the animal facilities; and the scale, nature and complexity of the animal research undertaken at the University. Some of the University staff the Review Panel spoke to were not familiar with the full details of the AWERB processes.

In order to fully appreciate how the AWERB functions are delivered the Review Panel attended meetings of all the component parts of the AWERB, reviewed past papers, and considered the committee inputs, processes, outputs and outcomes. The Review Panel notes that there has been some drift from the original terms of reference, and some divergence in the roles and operation, of some committees. Succession planning for key committee members is done well, but there are no induction packs or training for new Committee members.

Although standards across the University are generally high, the AWERB objective to harmonise and optimise standards of animal care and use across the University has not been achieved, and some of the current AWERB outputs and outcomes do not do justice to the amount of time taken and the resources deployed. The Review Panel believes a disproportionate amount of AWERB resource is devoted to consideration of project licence applications and amendments, and with respect to the 3Rs more time and resource should be devoted to Reduction and Replacement.

What was designed as a holistic means of delivering the required AWERB outcomes in places appears fragmented rather than seamless: there are some gaps, redundancies and inconsistencies in the way the AWERB functions are delivered across the University, and a lack of clarity about how and where the various committees' outputs are co-ordinated. The Review Panel notes that there is no formal governance committee, no committee with primary responsibility for identifying and promoting consistency and best practice with respect to the required AWERB outcomes, and no oversight committee monitoring and evaluating the effectiveness of the AWERB and its component parts mindful that the AWERB must offer independent advice.

The Review Panel believes that entrusting UBSG with ensuring the effectiveness of the AWERB process and committees, and making UBSG responsible for advising the ELH on the independence, efficiency and effectiveness of the AWERB, coupled to the other recommendations made in this Report, would both address these problems and enable the current AWERB systems to be simplified, streamlined, re-balanced, more clearly mapped onto the Home Office requirements and thus better suited to the needs of the University.

Recommendation 6: The current AWERB systems should be simplified, streamlined, re-balanced, and more clearly aligned to the requirements set out in the Home Office Guidance on the operation of the 1986 Act. The AWERB terms of reference and operating instructions should to be periodically reviewed and updated, and the key structures and functions reinforced and communicated to users and others. Induction packs should be supplied to new committee members.

Recommendation 7: UBSG should be responsible for advising the ELH on the independence, efficiency and effectiveness of the AWERB.

Recommendation 8: The AWERB should make provision for monitoring the efficiency and effectiveness of the governance systems, and the promotion of consistency and best practice with respect to the required AWERB outputs and outcomes.

4.1 The AWERB Standing Committee

The AWERB Standing Committee considers project licence applications before they are formally submitted to the Home Office, and undertakes interim and retrospective reviews of licensed work.

⁶ The Review Panel judged the AWERB against the provisions of the Home Office Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (March, 2014 edition).

Pending the appointment of a new chairman, the ELH is acting as interim Chairman. The Review Panel does not consider this to be best practice: the AWERB Standing Committee exists to provide impartial advice to the ELH. The appointment of a new chairman should be made without undue delay.

The Review Panel considers the interim and retrospective review of all project licences to represent good practice: however such reviews should be undertaken and feedback provided before existing project licence holders start to write new project licence applications. In practice interim reviews are often submitted to the Standing Committee at the same time as applications for replacement project licences.

The membership of the Standing Committee is broadly based, exceeds the minimum statutory requirements, and includes lay persons and a statistician. All of the scientists involved are leaders in their fields; all of the Named Persons involved have strong animal welfare credentials. The Committee would benefit from the involvement of someone knowledgeable about a wide range of biomedical research and testing, and/or a broad, expert knowledge of replacement alternatives.

The Committee meets sufficiently frequently to consider work items without imposing unreasonable delays. A risk-based approach has been devised to target resource to where it is best used – for example special consideration is given to those seeking secondary availability at the University, applications considered particularly sensitive, and procedures likely to cause higher levels of animal suffering. The Review Panel is unclear about how the risk-based system was developed and operates.

Applicants are invited and expected to attend the meetings at which their proposals are discussed, with a member of the Standing Committee acting as the lead reviewer of each work item.

In terms of reputation risk there are blind spots. The Standing Committee's current remit does not extend to consideration of University staff undertaking regulated procedures, or collaborating with scientists, abroad or at other ASPA licensed user establishments; those applying for project licences with primary availability at other ASPA licensed establishments; or work performed elsewhere during sabbaticals.

Recommendation 9: the ELH should not chair the AWERB Standing Committee. The appointment of a new chairman should be made without undue delay.

Recommendation 10: To manage the associated reputational risk the Standing Committee's current remit should extend to consideration of University staff undertaking regulated procedures, or collaborating with scientists, abroad or at other ASPA licensed user establishments; those applying for project licences with primary availability at other ASPA licensed establishments; or work performed elsewhere during sabbaticals.

4.1.1 Project Licences

The Review Panel examined a sample of current project licences, attended a meeting of the AWERB Standing Committee screening project licence applications, reviewed past papers, and met with current and past members of the Committee.

The processes currently involved in preparing a project licence application include initial in-house discussions, a dialogue with the Home Office inspector, further in-house consultations, ethical review within the AWERB, and then submission to and consideration by the Home Office. The precise sequence of events differs in different parts of the University. Although there are inconsistencies in what the Review Panel was told by users and Named Persons, it is clear that scientists and others anticipate and accept that the project licensing process currently takes in excess of 12 months. Indeed, the UBSS web-site acknowledges that *"...It normally takes 12 to 18 months from start to finish to write a project licence and receive approval from the Home Office..."*.

The Review Panel could not determine the true end-to-end processing times or where, how and why unnecessary delays are taking place – in part because each Management Group uses different record keeping and accounting systems to document and monitor progress, and the accounting systems used often fail to capture the preliminary interactions between project licence applicants and the Home Office Inspector. The University must devise and adopt a common approach to tracking the progress of project licence applications and amendments (beginning with the applicant's first interaction with the Home Office inspector, Named Persons, or AWERB) in order to understand and remedy any unnecessary delays.

Some delays appear to be within the control of the University, some are created by the applicants themselves, and others lie elsewhere. The reported lead times are challenging for those working in competitive and rapidly evolving

fields, particularly those who must have appropriate project licence authorities in place in order to finalise and release grant funding. Concerns about delays may also be a consideration when scientists are considering taking up appointments at the University.

As a result of anticipated delays (and some said on the instruction of the Home Office) the project licences examined by the Review Panel tend to include plans of work and procedural details purporting to set out full, immutable five-year programmes of work (to avoid the need for the licences to be amended). Although the adverse effects, endpoints and severity limits are specified, with so many options and procedural loops it is difficult for the Review Panel to know what combinations of the procedural options would not be compliant with the licence authorities; and, the Review Panel believes, in some cases the lack of detail on the nature, likelihood and intensity of adverse effects must make it difficult for the AWERB members and others to undertake a harm/benefit assessment based on the licensing documents alone.

For these reasons the Review Panel believes the structure and format of the current project licences authorities pose a compliance risk. This is not a criticism of the quality of the science or of the project licence holders: it results from the construction of the project licences. The lack of detail in some areas coupled with the numerous options set out in other sections creates residual compliance issues that necessitate supplementary downstream governance systems that themselves currently impose additional bureaucracy and delays. This is discussed further under "Study Plans" at 4.4.2.

The project licence pre-application systems should be streamlined in-part by developing a clearer understanding of what the Home Office expects and requires. The Review Panel consulted the Home Office Chief Inspector for advice on the order in which the various transactions should take place. The Review Panel was advised that after an initial consultation with the Home Office Inspector to identify any element of a project licence application likely to be contentious or require exceptional justification, applicants should take advice from the Named Persons, complete the AWERB processes, and then formally submit the AWERB and ELH endorsed project licence application to the Home Office for consideration. The Chief Inspector also advised that the Inspectorate would be prepared to run a capacity-building workshop at the University on how project licence applications should be constructed.

Recommendation 11: With respect to project licensing:

- The preferred means of completing the pre-application process should be optimised in line with the advice received from the Chief Inspector, and the Chief Inspector's offer to run a capacity-building workshop at the University on how project licence applications should be constructed should be accepted.
- The University should devise and adopt a common approach to tracking the progress of project licence applications and amendments (beginning with applicants' first interaction with the Home Office inspector, Named Persons, or AWERB).
- The information collected on the time taken for the different elements (from first consultation draft through to a licence being granted) should be used to identify the nature and cause of the delays and where they are occurring (e.g. with applicants, Named Persons, Home Office inspectors, individual Management Groups, AWERB committees). Inefficiencies with input from Named Persons and in the operation of the AWERB Standing and Amendment Committees should be identified and addressed.
- Evidence-based turn-around times should be established and published based on what is happening in practice.
- The aim should be to document, monitor and continuously improve the processes and outcomes.

4.1.2 Study Plans

The University expects and requires that local study plans are prepared using a standard template in advance of all licensed animal use. These document the purpose of each study, and the procedures, observations and endpoints to be applied. The process is clearly described at the UBSS intranet pages.

Study Plans are prepared by project licence holders in consultation with the NACWOs and NVSs. The project licence holder takes responsibility for ensuring the studies are compliant with the project licence authorities; the NACWO for the endpoints and actions to be taken being clearly stated; and the NACWO and NVS for being satisfied the potential animal welfare costs have been minimised.

In the context of governance, specifically ensuring the details of individual studies are as authorised by the relevant project licences and that everyone involved knows what is so be done and why, the best of the study plans seen by the Review Panel are excellent. However, others omit the purpose of the studies, and many describe studies encompassing a series of experiments with a number of optional procedural steps and endpoints.

The technical and animal care staff the Review Panel spoke to find these documents useful and informative. Some project licence holders expressed concern at the time taken to agree the final text with the NACWOs and NVSs, citing instances where the process took several weeks to complete. As a result some project licence holders now prepare study plans covering several experiments, rather than a single experiment. Ideally a study plan would cover a single experiment, with each single-experiment study plan drafted and approved in a matter of days.

The Review Panel visited one facility with links to the University where detailed and specific single-experiment study plans are routinely drafted and finalised within 48 hours, and sees no reason why this could not be done almost in real-time in all University facilities – e.g. at regular drop-in surgeries with the NACWO and NVS.

The University should develop management information systems to determine the time taken to prepare and agree study plans, and deal with any unnecessary delays.

Recommendation 12: With respect to Study Plans the University should develop management information systems to track the time taken to prepare and agree study plans, and deal with any inefficiencies and unnecessary delays. Each study plan should cover a single experiment, and should typically be drafted and approved/rejected within 48 hours.

4.2 The AWERB Amendment Committee

Operating as a virtual committee, the Amendment Committee is capable of dealing without undue delay with requests for amendments to project licence authorities, with the NVSs, NACWOs and pNACWOs identifying any amendment request justifying referral to the AWERB Standing Committee.

The Review Panel notes the absence of clear written guidance, and records of policy and precedent, on what is to be referred to the Standing Committee.

Recommendation 13: The AWERB Amendment Committee should be provided with clear written guidance on what is to be referred to the AWERB Standing Committee, and a record should be maintained of policy and precedent.

4.3 UBSG Group Management Committees/User Committees

Within the UBSG Management Groups three separate regional Management groups and a number of User groups play a role in operational compliance, and standard setting in the facilities; and provide representation and information to inform discussion and decision making at UBSG. The effectiveness of these committees is currently dependent on a small number of key individuals

These UBSG Management Group-based committees facilitate UBSS' operational support to the facilities, and implementation of policies determined by UBSG and the ELH. Their remit includes standards of animal accommodation, care, and use – in some cases including the use of animals not regulated by ASPA.

With representatives from the administrative, scientific, technical staff and Named Persons these committees are well placed to look critically at compliance and the 3Rs - including animal breeding, minimising surpluses, and tissue sharing. They take a local perspective, focusing on the more immediate needs of the individual UBSG Management Group rather than the needs of the University as a whole, and there are currently limited opportunities for the lessons learned and good practices developed within the individual UBSG Management and User Groups to be shared with the others. There has been some drift in the composition and functions of these committees – with some issues relating to the 3Rs and compliance now being seen more as matters for the AWERB Named Persons Committee even though this does not have representatives from the research staff. In addition there is a great deal of business common to the three UBSG Management Group Committees that might be dealt with more efficiently elsewhere.

Not all of the Management and User group meetings the Review Panel observed were well attended or, in our view, had the right mix of people present. Not all attendees consult with those they notionally represent before or after the meetings. In general, users were not active enough on User Committees.

User Committees should place greater emphasis on the support the University can give to users – such as addressing the limitations and shortcomings of the current facilities, and contributing to the planning of the modernisation programme. More users should know what is going on – and be prepared to contribute or participate.

The Review Panel spoke to some licensees who were not fully familiar with the structure, functions and outputs of these committees – or where and how to raise issues relevant to their own areas of responsibility or programmes of work.

Recommendation 14: Communication within and between three UBSG Management Groups should be improved. User Committees should place greater emphasis on the support the University can give to users – such as addressing the limitations and shortcomings of the current facilities, and contributing to the planning of the modernisation programme. More users should know what is going on – and be prepared to contribute or participate.

4.4 AWERB Named Persons Committee

The AWERB Named Persons Committee is well attended and provides a forum for discussion of facility management, good practice, promotion of the 3Rs, and training. It brings together the ELH (who is also currently the NTCO and NIO), the NVSs, NACWOs, and pNACWOs from each of the animal facilities within all three UBSG Management Groups.

In considering animal production, care and use, this Committee acts as a forum for discussion of the 3Rs and compliance issues, and agrees or endorses University policies and third party guidelines relating to animal care and use. However, some of these functions, for example compliance and endorsement of policy, would be better referred to AWERB committees which have appropriate user representation.

Although this committee is ideally placed to promote and ensure effective communication within and between the three UBSG Management Groups and the two Schools, the Review Panel did not see this happening in practice.

4.5 The 3Rs

The 3Rs are a standing item on the agenda on all UBSG Management Group, User and Named Persons meetings. The UBSS intranet pages act as a central repository for reference material on the 3Rs, particularly refinement. Although the University has adopted or endorsed a number of policies and third-party guidelines for humane animal research, these have not been sufficiently clearly communicated to all staff, and the AWERB has not reviewed whether they are used in practice.

During the course of the Review two members of University staff received awards from external organisations for replacement and refinement initiatives.

4.5.1 Replacement

Replacement is considered by individual scientists, within the AWERB licence review process, and by the Home Office in its assessment of project licence applications and amendments.

The Review Panel found no instances where relevant replacement alternatives were not being used, and did find examples where replacement methods have been introduced which reduced or eliminated some classes of animal use without compromising the scientific objectives.

Nevertheless the Review Panel believes that the University could do more to reinforce its commitment to progress with replacement. For example:

- A critical overview of progress with replacement should form a visible component of the University project licence interim and retrospective review.
- Appointing someone with a broad knowledge of a wide range of replacement alternatives to the AWERB Standing Committee would reduce the risk of relevant replacement alternatives being overlooked.
- The NIO should pro-actively research and advise on progress with, and the availability of, relevant replacement methods.

4.5.2 Reduction

Consideration of the main elements of study design and animal production, care and use that underpin reduction form part of the licensee training programmes delivered by the University.

Most of the project licence holders the Review Panel spoke with seemed familiar with the approaches which should be taken to optimise study design. Although it is not currently offered as a central service by UBSS a number of scientists have access to statistical advice.

The Review Panel considers that there would be merit in advice and capacity building on study design being offered as a central service by UBSS during project licence and quinquennial training⁷, at project licence review, and to project licence applicants and holders.

Within the individual animal facilities and within each UBSG Management Group efforts are made to minimise over-breeding and facilitate the sharing of tissues. The Named Persons Committee could play a greater role in coordinating these activities between the Management Groups.

A University database of genetically altered animals has been developed to optimise their production and breeding within the University: the University should seek to share this information with the existing international databases, and the NIO should draw users' attention to the international and other third party databases.

There may be scope for reduction, refinement, and minimising administrative burdens by obtaining a small number of generic project licences to co-ordinate the production and breeding of genetically altered animals as a service to users rather than the large number of project licences which currently authorise this.

4.5.3 Refinement

The University's culture, structure and processes appear to the Review Panel to make particularly good provision for the promotion, development and adoption of refinement options. But there is room for improvement.

Although minimum severity protocols have been developed or adopted by the University for a number of common procedures (e.g. the production and breeding of genetically modified animals), they are not used by all project licence applicants, or they have been amended by others for reasons that are not explained in the licence documents. The Review Panel believes that the current set of minimum severity protocols should be periodically reviewed, updated and expanded as required with input from the Named Persons and users; that additional minimum severity protocols are developed or adopted when a need is identified; that the Named Persons draw project licence applicants' and the Standing Committee's attention to these as new applications are prepared and evaluated; and that the optimised protocols are made more accessible on the UBSS intranet.

Similar provision could be made to provide, maintain, publicise and monitor the uptake of other refinement resources such as recommended limit volumes for dosing and sampling, Standard Operating Procedures for common regulated procedures, recording of clinical signs and coding of actual severity, and anaesthetic and analgesic regimens.

The maintenance of registers of personal licensees deemed competent to undertake aseptic surgery is good practice.

The University invested considerable resource in advance of the introduction of the Home Office requirement to record the actual level of suffering experienced by animals undergoing regulated procedures, including the actual severity to be assigned to procedure-related deaths. The University has not as yet reviewed record keeping systems to evaluate if this is being done consistently in practice.

Recommendation 15: With respect to the 3Rs:

- Replacement: the University should do more to reinforce its commitment to progress with replacement. For example: critical review of progress with replacement should form a visible component of the University project licence interim and retrospective review; appointing someone with a broad knowledge of a wide range of replacement alternatives to the project AWERB Standing Committee would reduce the risk of relevant replacement alternatives being overlooked; and the NIO should pro-actively research and advise on progress with, and the availability of, relevant replacement methods.
- Reduction: advice and capacity building on study design should be offered as a central service by UBSS during project licence and quinquennial training, at project licence review, and to project licence applicants and holders; and there may be scope for reduction, refinement, and minimising administrative burdens by obtaining a small number of generic project licences for the production and breeding of genetically altered animals as a service to users rather than the large number of project licences which currently authorise this.
- Refinement: the current set of minimum severity protocols should be periodically reviewed, updated and expanded as required with input from the Named Persons and users; additional minimum severity protocols should be developed or adopted when a need is identified; the Named Persons should draw

⁷ All licensees are encouraged to undertake refresher training every five years as part of their CPD. This training is delivered by the UBSS Training School. It reprises important elements of the Modular training and trends and important developments that have taken place over the last five years.

project licence applicants' and the Standing Committee's attention to these as new applications are prepared and evaluated; and the optimised protocols are made more accessible on the UBSS intranet. Similar provision should be made for the development, maintenance, and promotion of other resources such as recommended limit volumes for dosing and sampling, SOPs for common regulated procedures, recording of clinical signs, and anaesthetic and analgesic regimens.

5. Named Persons

5.1 The Establishment Licence Holder

The ELH represents the establishment's governing body and is responsible for: providing leadership, ensuring compliance, ensuring the 3Rs are applied as fully as possible, ensuring the establishment is suitably staffed, establishing and maintaining an AWERB, the performance and conduct of the Named Persons, identifying and when necessary avoiding of conflicts of interest, ensuring protected animals have appropriate care and accommodation, countersigning project licence applications, record-keeping and ensuring appropriate identification of animals, maintaining a register of those competent (initially under supervision) to kill protected animals.

The University of Cambridge ELH is:

- A University Director.
- Interim Director of UBSS.
- The Named Compliance Officer (NCO), NTCO, and NIO.

The ELH chairs or attends the meetings of the AWERB committees, contributes to the University licensee training programmes, and makes periodic visits to the animal facilities. Although visits to the individual animal facilities are relatively infrequent, he is highly visible within the AWERB processes, has regular interactions with the Named Persons, and was considered accessible and approachable by all of those the Review Panel spoke to.

The Review Panel believes that the ELH should be at least a Director within the University hierarchy, that the current ELH has a clear understanding of the legal requirements and his roles and responsibility, and that the provisions set out at 3.13.1 of the Home Office Guidance relating to the roles and responsibilities of the ELH are met.

Nevertheless, there is room for improvement.

- The ELH is not by training a laboratory animal scientist. The current UBSS management structure does not include a senior Technical Director/Manager with this competence to act on his behalf to direct, evaluate and co-ordinate the operational activities of, and manage, the Named Persons.
- Although the Review Panel considers that the NVSs and NACWOs have sufficient status and delegated authority to discharge their statutory functions, we did encounter instances where Named Persons offered conflicting advice, or where their advice was questioned or not taken. In view of the potential animal welfare costs, and the reputational risks regardless of whether or not animal welfare is at risk, there is a need to ensure that the advice relating to animal welfare offered by the Named Persons is taken, or that any exceptions are justified and promptly brought to the attention of the AWERB. A UBSS Technical Director/Manager would be well placed to prevent, manage or quickly resolve these conflicts.
- The ELH does not currently maintain a risk register relating his roles, responsibilities, and governance systems. There is merit in developing and maintaining such a resource, and ensuring that senior management understands and endorses the risk appetite and residual risks that such a document would make transparent.
- Compliance with a number of the conditions of issue on the Establishment Licence is effectively delegated to the pNACWOs, NAWCOs, NVSs and parts of the AWERB framework. This delegation is documented in job descriptions, and the reference document defining the AWERB structure and functions. For completeness a separate document should be prepared and maintained describing how compliance with each condition on the Establishment Licence is achieved, showing where the delegated authority resides and how the outcomes are monitored.

5.2 Named Person Responsible for Compliance (NPRC)

The ELH is also the NPRC: the Review Panel believes this is right and proper.

5.3 Named Information Officer (NIO)

The NIO is responsible for ensuring that those dealing with animals have access to any information they need about the types of animal they are using. The ELH is also currently the NIO: this responsibility will shortly be delegated to a new NIO appointment being made within UBSS.

5.4 Named Training and Competence Officer (NTCO)

The NTCO is responsible for ensuring that those dealing with animals are adequately educated, trained and supervised until they are competent and that appropriate further training continues.

The ELH is currently also the NTCO. The Review Panel feels this role would be better placed within the UBSS Training School or with a UBSS Technical Director/Manager.

5.5 Named Veterinary Surgeon (NVS)

Three veterinary surgeons, direct employees of the University within UBSS, provide the NVS services to three defined areas of the University estate, with the distribution of veterinary responsibilities cutting across School, Departmental, and UBSG Management Group boundaries.

The range of veterinary services and support provided satisfies the provisions set out in the Home Office Guidance on the operation of the 1986 Act, and the NVS Guidance produced by the Royal College of Veterinary Surgeons – with the main activities and outputs relating to animal welfare, support to scientists, and promoting compliance and high standards.

The Review Panel is concerned that the three veterinary surgeons are subject to little active management direction and oversight, and that the NVS service provided in different facilities reflects the different views and interests of three individuals with different working practices with respect to the support offered to project licence applicants and others rather than forming a seamless corporate service.

The NVSs need more active direction, leadership and management to provide a more corporate and consistent service. This management function could be provided by a UBSS Technical Director/Manager.

5.6 Named Animal Care and Welfare Officer (NACWO)

The NACWOs are responsible for overseeing the welfare and care of the animals.

The NACWOs named on the Establishment Licence are all experienced animal care staff employed in-part to supply the full range of NACWO duties set out in the Home Office Guidance on the 1986 Act. The NACWOs report to the three UBSG Management Group pNACWOs (who are themselves also the NACWOs for some of the animal facilities).

The three pNACWOs are effectively the regional technical services managers for the animal facilities within each of the three UBSG Management Groups. They play a central role in the AWERB, particularly with respect to communication, compliance and governance. Two are currently employed by Departments within the School of the Biological Sciences, and the third by the School of Clinical Medicine.

The pNACWOs (including those who are unit NACWOs) are listed as contact points on some project licences. Although in no case did the Review Panel find any actual conflicts of interest, the Review Panel believes that to minimise reputational risk and perceived conflicts of interest this is best avoided.

The Review Panel notes that three pNACWOs, like the NVSs, are subject to little active technical management oversight. Although the pNACWOs have a central role in ensuring consistency and the flow of information up, down and across the UBSG Management Groups, the Review Panel observed different standards and practices in each of the Management Groups and in the different facilities. Like the NVSs, the different services the three pNACWOs provide reflect in-part the different views and interests of the three individuals rather than forming a seamless, consistent, corporate service.

The Review Panel believes a UBSS Technical Director/Manager should lead and manage this resource, and provide the direction and co-ordination required to ensure consistency within and between the facilities managed by the pNACWOs for the three UBSG Management Groups.

Recommendation 16: With respect to the Named Persons:

- ELH: the ELH should maintain the NPRC responsibility, but no other Named Person role; the ELH should be supported by a Technical Director/Manager working within UBSS at the same level as a full-time Operations Director; the ELH should develop and maintain a risk register relating to the ELH role and responsibilities; and should document how compliance with each condition on the Establishment licence is achieved, where the delegated authority resides, and how the outcomes are monitored.
- NTCO: the NTCO role should be placed within the UBSS Training School or with a UBSS Technical Director/Manager.
- NVS and NACWO: the NVSs and pNACWOs require more active direction, leadership and management to provide a more corporate service. This could be provided by a UBSS Technical Director/Manager.
- Named Persons should not be listed as Contact Persons on project licences.

6. Animal Accommodation, Care and Use

6.1 The Animal Facilities

The individual animal facilities are currently owned and operated by the School of the Biological Sciences or the School of Clinical Medicine. Each School has a large degree of autonomy in terms of its activities and management processes, and this is reflected in the differences in standards and practices the Review Panel observed in the different facilities.

The animal facilities are at various sites in and around Cambridge, with the operational management function provided primarily by three UBSG Management Group Committees. These UBSG Management Groups to some extent cut across the ownership of the facilities by the two Schools.

Ideally the standards, processes, practices, IT systems and documentation within the Schools and three UBSG Management Groups would be consistent and harmonised. This is not currently the case.

Different facilities (and different areas within some of the facilities) operate to different microbiological health statuses. The NVSs and NACWOs, and pNACWOs have devised biosecurity protocols to maintain appropriate health statuses in the individual facilities⁸. Appropriate measures seem to be in place to allow for the safe introduction and re-derivation of animals of unknown or lower health status. Although recent health screens suggest these measures are generally effective, the Review Panel is aware that the biosecurity protocols are not always complied with, and that alternative arrangements can be made for "special cases".

Although it is not strictly a governance issue, the Review Panel believes that the University needs a strategic plan to define and move towards a more unified, defined microbiological status.

Most of the facilities are small- or medium-sized by today's standards and were constructed, and have been refurbished or adapted, at various times. In most cases their layout reflects the intended use at the time they were constructed rather than being ideally suited to their current use. Many holding rooms now house individually ventilated caging systems for mice: although there are no animal welfare concerns, the size and shape of some of the holding rooms are not ideal for this purpose. The condition of the fabric and surface finishes varies from facility to facility, and will require regular care and maintenance and periodic refurbishment. The current fabric and the environmental conditions in the facilities visited by the Review Panel seemed fit for purpose and in compliance with the standards expected by the Home Office.

The surgery and general procedure areas visited by the Review Panel were fit for purpose, but the Review Panel did see some areas used for non-invasive procedures (e.g. behavioural testing) where the facilities provided are only border-line adequate. In discussion with the Review Panel two project licence holders described the specialist areas they had been given access to as *"good, but not perfect"*.

The performance of regulated procedures within the main facilities, rather than in designated procedure rooms outside the main facilities, is strongly encouraged. This is good practice.

The Review Panel was told of one example where the transportation or transfer of animals between facilities to best match supply and demand for animal holding space had the potential to delay, or jeopardise the quality of, the scientific findings. It is not clear to the Review Panel where and how such issues, which in this case involved two separate UBSG Management Groups, are identified, considered and resolved within the current AWERB committee structures.

The Review Panel also heard of new researchers being appointed before their likely need for space, specialist facilities and equipment had been defined, and the means of satisfying them identified or agreed. Whilst such appointments will remain the responsibility of the Schools and Departments, a means should be found to ensure these issues are identified and addressed before appointments are finalised.

The Review Panel understands the challenges of meeting current and anticipating future requirements for high-quality animal facilities. Because of the Schools-based approach some of the current facilities are operating close to their maximum operating capacity, whilst others (providing accommodation for the same species and similar classes of work, albeit not always operating to the same microbiological status) seem to be chronically under-occupied. The Review Panel believes that to make the best use of University resources, better manage the facilities, improve the

⁸ They have not however offered strategic advice on the University's future needs.

way the needs of the research groups are met, and plan for the future all of the animal facilities should be centrally managed and staffed.

6.2 Working Practices

Based on the facilities, practices and outcomes observed the Review Panel is generally satisfied that systems are in place to ensure that:

- The environment, housing, and husbandry systems make appropriate provision for animal health and well-being.
- The fabric, installations, equipment and environment of the approved areas meet the current Home Office requirements.
- The health and well-being of all protected animals and the environmental conditions are demonstrably checked at least daily by a competent person.
- A range of measures are in place to identify and remedy avoidable pain, suffering, distress.
- Appropriate quarantine, acclimatisation and re-derivation facilities are provided.
- Systems are in place to ensure animals are appropriately identified and cages and enclosures appropriately labelled.
- Appropriate records are kept of the source, use and disposal of animals⁹.
- A register is maintained of individuals trained and competent to kill animals by methods listed on Schedule 1 to the 1986 Act.

Live animal use is almost exclusively within the main animal facilities. The University policy for the movement of animals between facilities is under review.

In a number of the facilities the more routine regulated procedures are performed by highly skilled, licensed technical staff: the Review Panel considers this to be good practice, and would strongly encourage it as a means of ensuring regulated procedures are conducted to high standards.

There are differences in how standard procedures are performed within and between the different UBSG Management Groups and in the different animal facilities within each Management Group: for both care and husbandry procedures and basic regulated procedures. The Review Panel believes that high standards would be best achieved and maintained, training and competence assessment facilitated, and the movement of staff and animals between facilities simplified, by inviting the pNACWOs, NACWOs and NVSs to work with users to develop, implement, and maintain University-wide Standard Operating Procedures for these tasks.

The University has endorsed and promotes the use of the "*LASA Guiding Principles for Preparing for Undertaking Aseptic Surgery*". These Guidelines were known to, and followed by, most, but not all, users. The Review Panel notes that at least one of the animal facilities maintains a register of personal licensees deemed competent to perform aseptic surgery. Although the assessment criteria were not transparent, the Review Panel considers this register to be good practice and a useful governance tool.

Training in Schedule 1 methods for humane killing of protected animals is provided jointly by the UBSS training school and Named Persons. Although registers of competent persons are in place at each facility the Review Panel did not find documented standards against which competence is assessed. Copies of Schedule 1 are displayed where the killing is performed, and the equipment used was appropriate and well-maintained. The University intranet system that makes reference materials available to those involved in animal care and use still in places displays a version of Schedule 1 which has now been superseded.

Recommendation 17: With respect to facilities and working practices:

- The ownership, staffing and management of the animal facilities should be centralised.
- To ensure regulated procedures are conducted to high standards the more routine regulated procedures should be performed by highly skilled, licensed technical staff.
- The needs of new researchers for space, specialist facilities and equipment should be identified and addressed before appointments are finalised.
- The pNACWOs, NACWOs and NVSs should work with users to develop, implement, and maintain University-wide Standard Operating Procedures for husbandry and standard regulated procedures.

⁹ The Review Panel notes that different record keeping systems are used in different facilities.

7. Staffing

7.1 University Staff

All of those undertaking animal research at the University, and those involved in the production and care of the animals, have University contracts - including those funded by third-parties such as the Research Councils.

The Review Panel spoke to a cross-section of University staff, including ASPA Named Persons and personal and project licence holders. Everyone we spoke to was clear about their roles and responsibilities.

The Review Panel is satisfied that systems are in place to ensure that there are enough trained and competent staff available as required to maintain high standards of animal care and use; and, although the current documentation is imperfect, that those involved in animal, production care and use are adequately trained or appropriately supervised until they are deemed competent.

The Review Panel was impressed by the professionalism and dedication of the animal care staff, and noted that in many facilities standards are at times maintained by discretionary effort on their part – evidenced by instances where staff shortages were addressed by voluntary unpaid overtime rather than the use of agency or UBSS bank-staff.

The Review Panel believes the current system whereby animal units are regarded as School or Departmental facilities has significant drawbacks with respect to staffing:

- Individual staff often train and work only in one facility.
- Some are only trained to work with a limited range of animal types.
- Promotion prospects within any single facility are limited.
- Other local employers who can offer more flexible or desirable terms and conditions also require skilled animal care staff, making retention and external recruitment of middle and senior grade animal care staff difficult.
- When promoted posts are filled by internal candidates, those promoted often need further training and support to become fully effective.
- New, external appointments are typically to the lower technical grades.

The UBSS bank-staff are deployed and redeployed as necessary to provide additional staff to the different facilities as required. pNACWOs and NACWOs consider this to be a valuable service, but commented that for short-term attachments these staff often worked under supervision or in support of existing staff. One member of the UBSS bank-staff commented that it took time to adjust to the different working practices and standards within the different University facilities.

7.2 Controls on Visiting Workers and Retired Staff

The governance systems recognise and seek to make proper provision for the risks associated with, and needs of, visiting workers and those not otherwise fully supported by the standard governance systems.

7.3 Induction of New Staff

The processes for inducting new staff seem sound – albeit with different options and processes for technicians and academics, and the details of the induction processes differing across the three UBSS Management Groups.

7.4 Training and Competence

The University recognises the importance of all staff involved in the planning, conduct, analysis, reporting and review of animal-based research being trained and competent, undertaking appropriate continued professional development, and being subject to periodic re-assessment of competence.

However, for the assessment of technical competence different documentation is used at different sites – and there are no common, written standards for determining the competence of individuals.

7.4.1 The UBSS Training School

Licensee modular training and IAT technician training are provided by the UBSS Training School. The training is delivered by a surprisingly small team of University staff including the ELH, NVSSs, NACWOs and pNACWOs.

The Review Panel feels that the UBSS Training School is a potentially valuable asset that is capable of doing better. Most of the imperfections result not from a lack of commitment on the part of the staff who currently organise or provide the training, but from a lack of active oversight and direction of the training school by UBSS senior management and the AWERB. Consideration should be given to embedding a curriculum and steering committee within the AWERB to direct, benchmark, and quality assure training and assessment – and this should be done before the training and assessment systems are aligned to the new UK training requirements.

There would be merit in the NTCO and NIO functions residing within the Training School.

7.4.2 Licensee Training

The University's licensee training programmes have been independently accredited as meeting the requirements of the current Home Office licensee training Modules 1-5. The UBSS training co-ordinator liaises with the accrediting body, but has not benchmarked the local courses or assessment systems against those provided by other establishments. A gap analysis was recently completed at the request of the accrediting body to determine how the training and assessment tools need to be restructured to meet the revised requirements set out in the current edition of the Home Office Guidance on the Operation of the 1986 Act.

Training sessions are held regularly and take the form of small group teaching. The numbers attending each session are limited by the size of the teaching room and as a result at times demand for licensee training can exceed supply.

There is provision for overseas visitors to study the theoretical components of some of the Modules on-line, with the assessment of understanding and competence taking place after the trainees arrive in at the University. Making more use of this system, coupled to web-casts of the lectures and an IT tool to allow on-line interaction with the tutors, could reduce the waiting times for places on training courses during times of peak demand.

The delivery of a number of the training Modules was observed during the Review. In one case a Review Panel member observed a presenter over-emphasising the information relevant to the assessment. The course materials available at the UBSS intranet site and the PowerPoint presentations are in places inconsistent (for example, handouts and slides providing different information), in places out of date (e.g. referencing superseded editions of reference documents), and are in various formats. They do not have a professional, corporate style, feel or format. The training materials do not list or promote the full range of policies and good practice documents the University has developed or endorsed with respect to animal care and use.

The Review Panel would commend the teaching and reference materials relating to elements of experimental design, and health and safety. The content of these elements is of a particularly high-quality, and the presentation of the factual content generally excellent.

The theory assessment schemes used for Modules 1-3, although endorsed by an accrediting body, are not particularly challenging. Use could be made of TurningPoint (or an equivalent technology) to confirm and reinforce understanding of key concepts and as part of the assessment system.

The practical skills assessment (for example, animal handling and surgery) are undertaken by the pNACWOS/NACWOS and NVSs – but there is no documented standard or framework which sets out the pass/fail criteria.

7.4.3 Technician Training

The technician training provided by the UBSS Training School follows the IAT syllabus for IAT Levels 2 and 3, and technical staff have also received support to undertake a foundation degree in animal technology.

7.4.4 Continued Professional Development (CPD)

CPD is encouraged, including in-house training to up-skill technical staff for promoted posts. Available in-house training includes management skills, financial management, and IT skills.

A non-accredited quinquennial training course has been introduced as CPD for existing Home Office licensees. The Review Panel considers both the concept and the current content to represent good practice. However, although described to the Review Panel as "a requirement", attendance is not mandatory and there is no formal assessment of the attendees.

A proposal which would enable UBSS to provide training and support to up-skill users in statistics and other elements of experimental design is under consideration. The Review Panel considers this would be a useful additional resource.

7.4.5 Documentation of Training and Competence

The current record keeping systems are paper-based. The data and training records for the technical staff seen by the Review Panel were robust, those for the scientists less so. For the scientists the records related to regulated procedures, and not animal care and handling. The paper systems make provision for four levels of competence from direct supervision to trainer/supervisor status. As noted elsewhere there is a lack of documented standards for assessing and determining technical competence. The Review Panel also noted that a number of staff were deemed to have progressed rapidly through the levels of competence.

Provision is made for the periodic reassessment of competence of staff, including newly appointed staff, again with different systems in place in different parts of the University.

A University-wide training/competence IT package is being commissioned to replace the paper-based system, and this will provide an opportunity to remedy some of the shortcomings discussed above.

Recommendation 18: With respect to staffing, training and competence:

- The provision, appointment, line-management and career development of animal care staff should be centralised.
- The UBSS training school should host the NTCO and NIO functions, and should be supported and directed by a curriculum and steering group within the AWERB.
- The training materials should be consistent, in a corporate format and continuously updated; and should promote the full range of policies and good practice documents the University has developed or endorsed with respect to animal care and use.
- More use should be made of E-learning with on-line interaction with the tutors to reduce the waiting times for places on training courses during times of peak demand.
- The means by which technical competence is determined should be documented and standardised.

8. Communications

8.1 Effective Communication

Effective communication within large, complex organisations is challenging. In the context of this Review there is an unmet need for effective communication within each UBSG Management Group, between the UBSG Management Groups, and between the UBSG Management and User Groups and the Schools of the Biological Sciences and School of Clinical Medicine.

On paper the current governance systems and AWERB framework make proper provision for effective communication within and between these groups. In practice, the information flow is not taking place as intended. In some cases the issues seem to be with the way the processes are being operated and maintained, but in a few cases, as in any organisation, communication bottlenecks may be more to do with individuals than the structures and processes.

The Review Panel has identified some examples of good practice which it would commend:

- The system of “*tea-talks*” whereby research groups brief technical and animal care staff on the rationale for, and findings emerging from, the animal research they undertake is welcomed by research and technical staff alike. These talks should also provide a forum for the technical and animal care staff to brief the users on the skills and services that they can provide.
- There are generally sound systems in place for staff to raise and escalate concerns relating to animal welfare and compliance.
- There is a good flow of information from technical staff to scientists relating to problems encountered in practice. However, the Review Panel would question the need for, and length of, the seemingly ever-growing routine copy-lists of persons to whom this information is sent.
- There are plans for an ELH Newsletter.

The Review Panel has identified elements of communication where things could be done better. Many of these are set out in detail in other parts of this Report. In addition:

- The AWERB sub-committee minutes should be more informative and more accessible.
- The UBSG and the AWERB committees have, over time, endorsed a number of “University policies”, and third-party guidance, relating to animal care and use – these do not seem to have been recorded centrally, are not known to all users, are not promoted during the in-house training, and are not acknowledged or reflected in some of the current project licence authorities. For example, the University has endorsed and promotes the use of the UK National Centre for the 3Rs Animal Research Reporting *In Vivo* Experiments (ARRIVE) Guidelines. Not all users are aware of the Guidelines, or the University’s endorsement of them; and a review of recent publications of animal studies done at the University or by University staff in collaboration with others found that the Guidelines were not being consistently applied.
- Users and management need to work together to make better provision for exchanging information which, although not relevant to compliance, should be considered within the AWERB in view of the potential reputational risks.
- In some parts of the University staff are encouraged or required to communicate with the Home Office inspectors only through the Named Persons. All staff should be able to contact the inspector directly. The Review Panel also considers it a matter of regret that incoming communications from the Home Office Inspector to the ELH are sometimes routed through third-parties.
- External communications are sometimes handled by individuals who have limited operational information about the licensed facilities and research. As the University fulfils its commitment to openness and transparency about the use of animals for experimental and other scientific purposes, care needs to be taken to ensure that the University’s public statements are evidence-based and reflect what is happening in practice.

8.2 UBSS Intranet

The UBSS Intranet serves a repository for essential reference material and links to other information resources. That said, finding relevant information is not intuitive, and a more systematic approach is needed to ensure the information provided is comprehensive and up-to-date.

Navigating the site to find relevant information is not intuitive, but it does contain a number of documents including reference materials, AWERB minutes, licensing details, and standard templates including:

- Monthly reports to AWERB committees from NVSs and NACWOs: the Review Panels recommends similar report forms be developed for NPRC, NTCO and NIO.
- Personal Licence holder supervision log.
- Submissions to AWERB relating to ASPA non-regulated animal use for experimental and other scientific purposes.
- Project licence amendment and interim/retrospective review forms.
- Clinical signs/severity charts. However the Review Panel did see different versions in use in different animal facilities, and the reference document provides no guidance on how to assess severity when several signs are present.
- Study plan proformas.
- Unexpected death report forms.

The main issues needing attention are making this resource more user-friendly and intuitive, and maintaining and updating the content. This should be the responsibility of the NIO.

Recommendation 19: With respect to Communications:

- AWERB committee minutes should be more informative and more accessible.
- Templates should be developed for all Named Persons to supply informative monthly reports to the ELH and others.
- The “University policies” and the University-endorsed third-party guidance relating to animal care and use should be recorded centrally, made known to all users, promoted during the in-house training, and acknowledged or reflected in project licence documents.
- Users and management need to work together to make better provision for identifying and exchanging information which, although not relevant to compliance, should be considered within the AWERB in view of the potential reputational risks.
- All staff should have the contact details of the Home Office inspector.
- The UBSS intranet should be made more user-friendly and intuitive, and the content properly maintained and updated. This should be the responsibility of the NIO.

9. Recommendations

Principal Recommendation:

Recommendation 1: A new Directorate, based on UBSS, should effectively own, staff, manage and operate all of the animal facilities on behalf of the University. This Directorate should host the AWERB; support and assist the ELH, Named Persons and others with responsibilities under the ASPA; and produce and act on the management information required to develop unified structures, standards, processes and outcomes. Such a re-organisation would allow the current complex and distributed AWERB structures and processes to be re-balanced, streamlined, and made more efficient and effective. The Review Panel considers these structural changes to be an essential pre-requisite for the process and other changes required to improve standards and outputs.

General

Recommendation 2: The inefficiencies, inconsistencies, weaknesses, and residual risks within the current governance systems need to be addressed to make best provision for the success and sustainability of the University's biomedical research-base, and to provide the facilities and services required to host animal research of the highest quality.

Recommendation 3: Whatever governance frameworks and processes are developed and deployed to support and manage Home Office licensed research conducted at the University, their efficiency and effectiveness should be regularly reviewed with a view to their being continually improved.

Management Structures

Recommendation 4: UBSG should monitor, consider, and advise on governance issues; take a University-wide strategic interest in animal care and use; and consider the efficiency and effectiveness of the AWERB, and monitor and quality assure its outputs and outcomes, mindful that the AWERB must be free to offer independent advice.

Recommendation 5: Record keeping and management information systems should be standardised across all of the animal facilities.

Animal Welfare and Ethical Review Body

Recommendation 6: The current AWERB systems should be simplified, streamlined, re-balanced, and more clearly aligned to the requirements set out in the Home Office Guidance on the operation of the 1986 Act. The AWERB terms of reference and operating instructions should to be periodically reviewed and updated, and the key structures and functions reinforced and communicated to users and others. Induction packs should be supplied to new committee members.

Recommendation 7: UBSG should be responsible for advising the ELH on the independence, efficiency and effectiveness of the AWERB.

Recommendation 8: The AWERB should make provision for monitoring the efficiency and effectiveness of the governance systems, and the promotion of consistency and best practice with respect to the required AWERB outputs and outcomes.

Recommendation 9: The ELH should not chair the AWERB Standing Committee. The appointment of a new chairman should be made without undue delay.

Recommendation 10: To manage the associated reputational risk the Standing Committee's current remit should extend to consideration of University staff undertaking regulated procedures, or collaborating with scientists, abroad or at other ASPA licensed user establishments; those applying for project licences with primary availability at other ASPA licensed establishments; or work performed elsewhere during sabbaticals.

Recommendation 11: With respect to project licensing:

- The preferred means of completing the pre-application process should be optimised in line with the advice received from the Chief Inspector, and the Chief Inspector's offer to run a capacity-building workshop at the University on how project licence applications should be constructed should be accepted.
- The University should devise and adopt a common approach to tracking the progress of project licence applications and amendments (beginning with applicants' first interaction with the Home Office inspector, Named Persons, or AWERB).
- The information collected on the time taken for the different elements (from first consultation draft through to a licence being granted) should be used to identify the nature and cause of the delays and where they are occurring (e.g. with applicants, Named Persons, Home Office inspectors, individual Management Groups, AWERB committees). Inefficiencies with input from Named Persons and in the operation of the AWERB Standing and Amendment Committees should be identified and addressed.
- Evidence-based turn-around times should be established and published based on what is happening in practice.
- The aim should be to document, monitor and continuously improve the processes and outcomes.

Recommendation 12: With respect to Study Plans the University should develop management information systems to track the time taken to prepare and agree study plans, and deal with any inefficiencies and unnecessary delays. Each study plan should cover a single experiment, and should typically be drafted and approved/rejected within 48 hours.

Recommendation 13: The AWERB Amendment Committee should be provided with clear written guidance on what is to be referred to the AWERB Standing Committee, and a record should be maintained of policy and precedent.

Recommendation 14: Communication within and between three UBSG Management Groups should be improved. User Committees should place greater emphasis on the support the University can give to users – such as addressing the limitations and shortcomings of the current facilities, and contributing to the planning of the modernisation programme. More users should know what is going on – and be prepared to contribute or participate.

Recommendation 15: With respect to the 3Rs:

- Replacement: the University should do more to reinforce its commitment to progress with replacement. For example: critical review of progress with replacement should form a visible component of the University project licence interim and retrospective review; appointing someone with a broad knowledge of a wide range of replacement alternatives to the project AWERB Standing Committee would reduce the risk of relevant replacement alternatives being overlooked; and the NIO should pro-actively research and advise on progress with, and the availability of, relevant replacement methods.
- Reduction: advice and capacity building on study design should be offered as a central service by UBSS during project licence and quinquennial training, at project licence review, and to project licence applicants and holders; and there may be scope for reduction, refinement, and minimising administrative burdens by obtaining a small number of generic project licences for the production and breeding of genetically altered animals as a service to users rather than the large number of project licences which currently authorise this.
- Refinement: the current set of minimum severity protocols should be periodically reviewed, updated and expanded as required with input from the Named Persons and users; additional minimum severity protocols should be developed or adopted when a need is identified; the Named Persons should draw project licence applicants' and the Standing Committee's attention to these as new applications are prepared and evaluated; and the optimised protocols are made more accessible on the UBSS intranet. Similar provision should be made for the production, maintenance, and publicising of other resources such as recommended limit volumes for dosing and sampling, SOPs for common regulated procedures, recording of clinical signs, and anaesthetic and analgesic regimens.

Named Persons

Recommendation 16: With respect to the Named Persons:

- ELH: the ELH should maintain the NPRC responsibility, but no other Named Person role; the ELH should be supported by a Technical Director/Manager working within UBSS; the ELH should develop and maintain a risk register relating to the ELH role and responsibilities; and should document how compliance with each condition on the Establishment licence is achieved, where the delegated authority resides, and how the outcomes are monitored.
- NTCO: the NTCO role should be placed within the UBSS Training School or with a UBSS Technical Director/Manager.
- NVS and NACWO: the NVSs and pNACWOs require more active direction, leadership and management to provide a more corporate service. This could be provided by a UBSS Technical Director/Manager.
- Named Persons should not be listed as Contact Persons on project licence.
- In view of the potential animal welfare costs, and the reputational risks regardless of whether or not animal welfare is at risk, there is a need to ensure that the advice relating to animal welfare offered by the Named Persons is taken, or that any exceptions are justified and promptly brought to the attention of the AWERB. A UBSS Technical Director/Manager would be well placed to prevent, manage or quickly resolve these conflicts.

Animal Accommodation, Care and Use

Recommendation 17: With respect to facilities and working practices:

- The ownership, staffing and management of the animal facilities should be centralised.
- To ensure regulated procedures are conducted to high standards the more routine regulated procedures should be performed by a small number of highly skilled, licensed technical staff.
- The needs of new researchers for space, specialist facilities and equipment should be identified and addressed before appointments are finalised.
- The pNACWOs, NACWOs and NVSs should work with users to develop, implement, and maintain University-wide Standard Operating Procedures for husbandry and standard regulated procedures.

Staffing

Recommendation 18: With respect to staffing, training and competence:

- The provision, appointment, line-management and career development of animal care staff should be centralised.
- The UBSS training school should host the NTCO and NIO functions, and should be supported and directed by a curriculum and steering group within the AWERB.
- The training materials should be consistent, in a corporate format, and continuously updated; and should promote the full range of policies and good practice documents the University has developed or endorsed with respect to animal care and use.
- More use should be made of E-learning with on-line interaction with the tutors to reduce the waiting times for places on training courses during times of peak demand.
- The means by which technical competence is determined should be documented and standardised.

Communications

Recommendation 19: With respect to communications:

- AWERB committee minutes should be more informative and more accessible.
- Templates should be developed for all Named Persons to supply informative monthly reports to the ELH and others.
- The "University policies" and the University-endorsed third-party guidance relating to animal care and use should be recorded centrally, made known to all users, promoted during the in-house training, and acknowledged or reflected in project licence documents.
- Users and management need to work together to make better provision for identifying and exchanging information which, although not relevant to compliance, should be considered within the AWERB in view of the potential reputational risks.
- All staff should have the contact details of the Home Office inspector.
- The UBSS intranet should be made more user-friendly and intuitive, and the content properly maintained and updated. This should be the responsibility of the NIO.

Annex A: Abbreviations

3Rs	Replacing, Reducing, and Refining the use of animals for scientific purposes
AWERB	Animal Welfare and Ethical Review Body
ASPA	Animals (Scientific Procedures) Act 1986
ELH	Establishment Licence Holder
NACWO	Named Animal Care and Welfare Officer
NCO	Named Compliance Officer
NIO	Named Information Officer
NTCO	Named Training and Competence Officer
NVS	Named Veterinary Surgeon
pNACWO	Principal Named Animal Care and Welfare Officer
UBSG	University Biomedical Strategy Group
UBSS	University Biomedical Support Service

Annex B An Alternative Structure

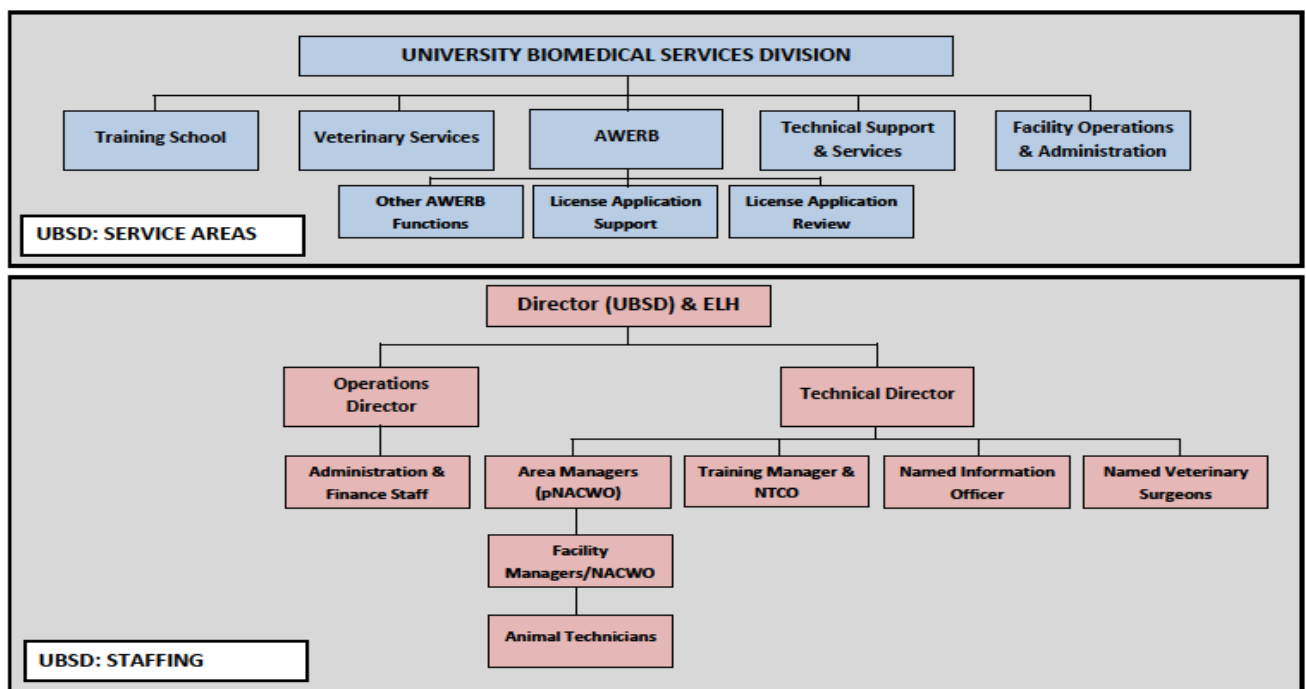
The Review Panel has recommended that the University of Cambridge animal facilities should effectively be owned and operated as corporate resources by a Directorate based on UBSS, rather than the current system whereby the individual animal facilities are under the authority of either the School of the Biological Sciences or the School of Clinical Medicine and part-managed by UBSS as three Management Groups. For convenience this new Directorate is referred to below as the University Biomedical Services Directorate (UBSD).

Although the fine detail of how this would impact on existing management structures and the AWERB frameworks is beyond the scope of this Review, and recognising that it is for the University to decide whether and how this recommendation is put into effect, the Review Panel would offer some additional comments on how such a framework could be structured to best meet the needs of the University and support high quality research and high standards of animal accommodation and care.

The Review Panel envisions UBSD as owning and operating the AWERB framework, veterinary services, staffing, other technical and support services, facilities operations and administration, and the training school.

The Review Panel suggests that the current ELH is also the Director of a newly formed UBSD, supported by a full-time Operational Director and Technical Director of an equivalent grade who would work together to run UBSD on a day-to-day basis. The Operational Director would have oversight of all administration, HR, and finance functions for all facilities including overseeing capital projects: the Technical Director would advise the ELH/Director on technical matters and take the lead on the provision and management of veterinary services, technical staff, non-administrative AWERB functions, and the training school (including the NIO and NTCO). Table 1 illustrates one possible structure.

Table 1



There are a number of sensitivities relating to the resulting cultural changes and structures and processes, not least ensuring that there is strong representation and effective input into at the top-level committee from the School of the Biological Sciences and the School of Clinical Medicine.

The Review Panel believes three issues merit special attention.

- Although the two Schools would in effect be pooling their resources and surrendering control of the facilities and staff to UBSD for the common good, the Schools must nevertheless be empowered to ensure that proper provision is made for the current and future needs and interests of the research groups within the Schools.

- In addition, as the AWERB is a source of independent advice the arrangements made to monitor its efficiency and effectiveness must be done in such a way that its independence is not threatened or compromised.
- In our view the restructuring can be achieved without dispensing with the services of, or inappropriately redeploying, any current post-holder. If that is also the view of the University then it should be communicated to staff at an early stage.

We envision that the current USBG would evolve to assume the role of a University Biomedical Services Strategy Committee (UBSSC), still chaired by a senior academic who is also a past or present user, and would become the overarching strategic and governance committee for UBSD; that the need for three separate animal facility management groups would be reviewed with a view to forming a single management committee to oversee management and operational issues (e.g. finance, staffing, occupancy, maintenance etc); that the AWERB committees would be more focused yet take a broader more strategic perspective; and an appropriate range of active user committees would continue to deal with local issues and feed into the operational, AWERB, and strategy committees. The Named Persons committee would be charged with playing a central role in setting standards, ensuring consistency, and communication.

Table 2 is one outline of what the structures and relationships might be.

Table 2

