

**Imperial College
London**

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**Action plan for world class
animal research**

Imperial College London – Action plan for world class animal research

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Acronyms

3Rs: Replacement, reduction and refinement of the use of animals in research
AAALAC: Association for Assessment and Accreditation of Laboratory Animal Care
ASPA: Animal Scientific Procedures Act
AWERB: Animal Welfare and Ethical Review Body
CBS: Central Biomedical Services [CBS provides infrastructure and support for animal research at Imperial]
HOLO: Home Office Liaison Officer
NACWO: Named Animal Care and Welfare Officer
NTCO: Named Training and Competency Officer
NIO: Named Information Officer
NVS: Named Veterinary Surgeon
PEL: Establishment licence
PIL: Personal licence
PPL: Project licence
QA: Quality assurance

Imperial College London – Action plan for world class animal research

1. Document purpose

This document sets out a series of actions to achieve Imperial's aim of being an international leader in animal research. It also itemises the College's progress and specific plans in response to the Brown Report's recommendations.

2. Overview

Imperial considers the use of animals in research to be essential for improving human and animal health and welfare.

Animals are only used in research when there is no alternative, and when their use is shown to be essential for creating new knowledge, making scientific and medical advances and developing new treatments. Imperial is committed to ensuring that all animals in its care are treated with full respect, and that all staff involved with this work act accordingly at all times.

The College is committed to the principle of the replacement, reduction and refinement of the use of animals in research (3Rs). The College has signed up to the National Centre for the 3Rs' Animal Research Reporting *In Vivo* Experiments (ARRIVE) guidelines that the College was involved in developing, and that aim to prevent unnecessary animal studies.

Imperial seeks to be open about animal research and the benefits it can bring. In October 2012 the College, along with 40 other organisations, signed a Declaration on Openness in Animal Research. Signatories have committed to developing a concordat setting out how they will be more open about the ways in which animals are used in scientific, medical and veterinary research in the UK.

On 10th December 2013, Imperial College London accepted in full the recommendations in the report from the independent investigation into animal research led by Professor Steve Brown. The Brown committee considered its overarching responsibility was to *'deliver where necessary recommendations for change that would ensure that Imperial was a leader, both within the UK and internationally, in the development and application of the 3Rs.'*

The Brown Report commended the high standards of animal husbandry and day to day animal care at Imperial, and noted an approach to delivering an Animal Welfare and Ethical Review Body (AWERB) process for the licensing of animal research that was efficient and timely. Additionally, the Brown Report found that animal experimentation at the College was supported by a committed and engaged animal house staff, which was willing to develop new approaches to animal welfare.

In order to continue to improve best practice in animal research, the Brown Report highlighted scope for improvement in several areas including the AWERB approach to the 3Rs. In addition to improvement activities already initiated during 2013, the College has taken further actions to implement the Brown recommendations. Furthermore, Imperial has begun a longer-term programme of change.

In implementing the Brown Report’s recommendations, the four key changes that Imperial will deliver are:

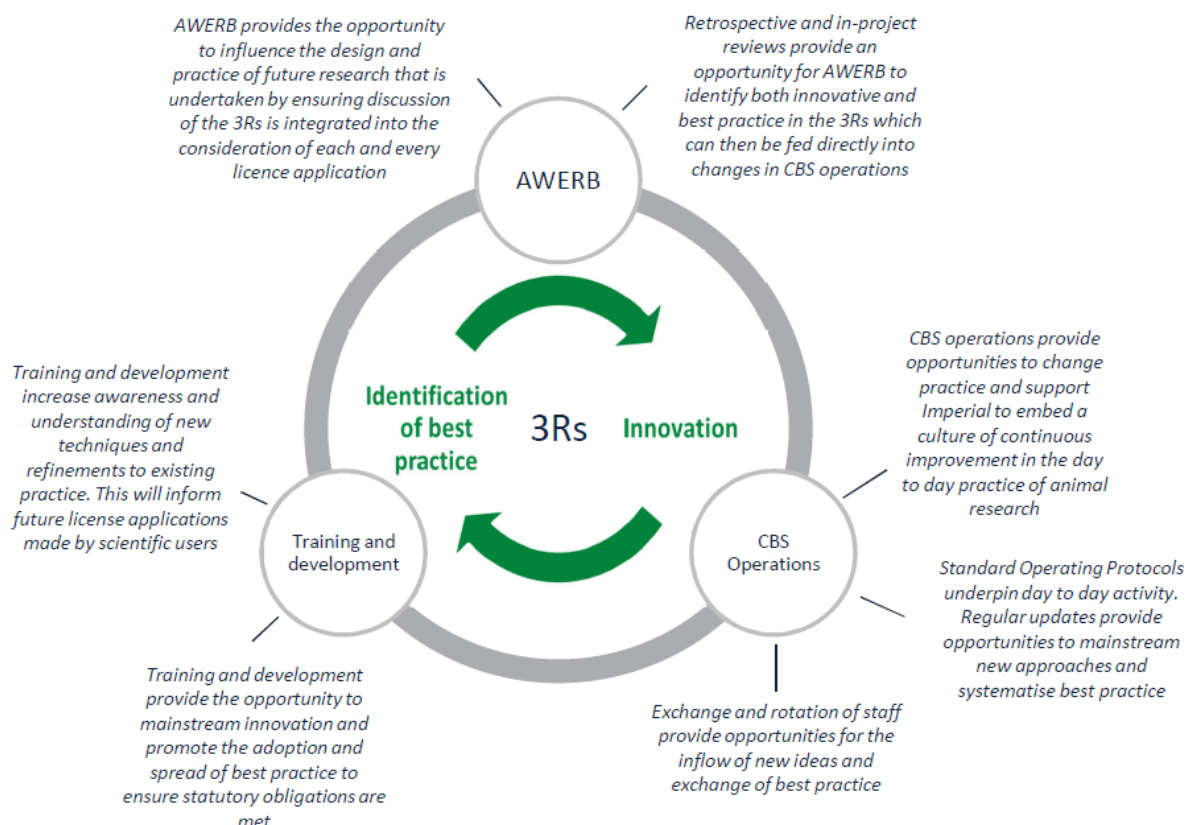
- recruitment of a Director of Bioservices to provide overall strategic leadership and direction;
- a cultural change programme to reach the highest standards of animal research, promoting full consideration of the 3Rs, and developing and implementing stronger links between researchers and Central Biomedical Services (CBS), supported by the recruitment of the Named Training and Competency Officer (NTCO) and other appropriate support staff;
- AWERB reform including revised structures and terms of reference particularly with respect to the 3Rs; and
- More effective internal and external communication.

This change programme will be supported by a new governance structure for animal research, encompassing a new leadership and management structure. It is underpinned by a set of design principles to ensure that strategic change and day to day operations are governed effectively.

The overall impact of these changes will enable Imperial to reach the highest standards in effective governance of animal research.

The College’s goal is to create a research environment that meets the highest international standards in terms of promulgation of the 3Rs, bringing in new ideas from the wider research community and creating a thought environment that stimulates best practice for animal research. This vision is summarised in Figure 1 below.

Figure 1 A vision for best practice and innovation for animal research at Imperial College London

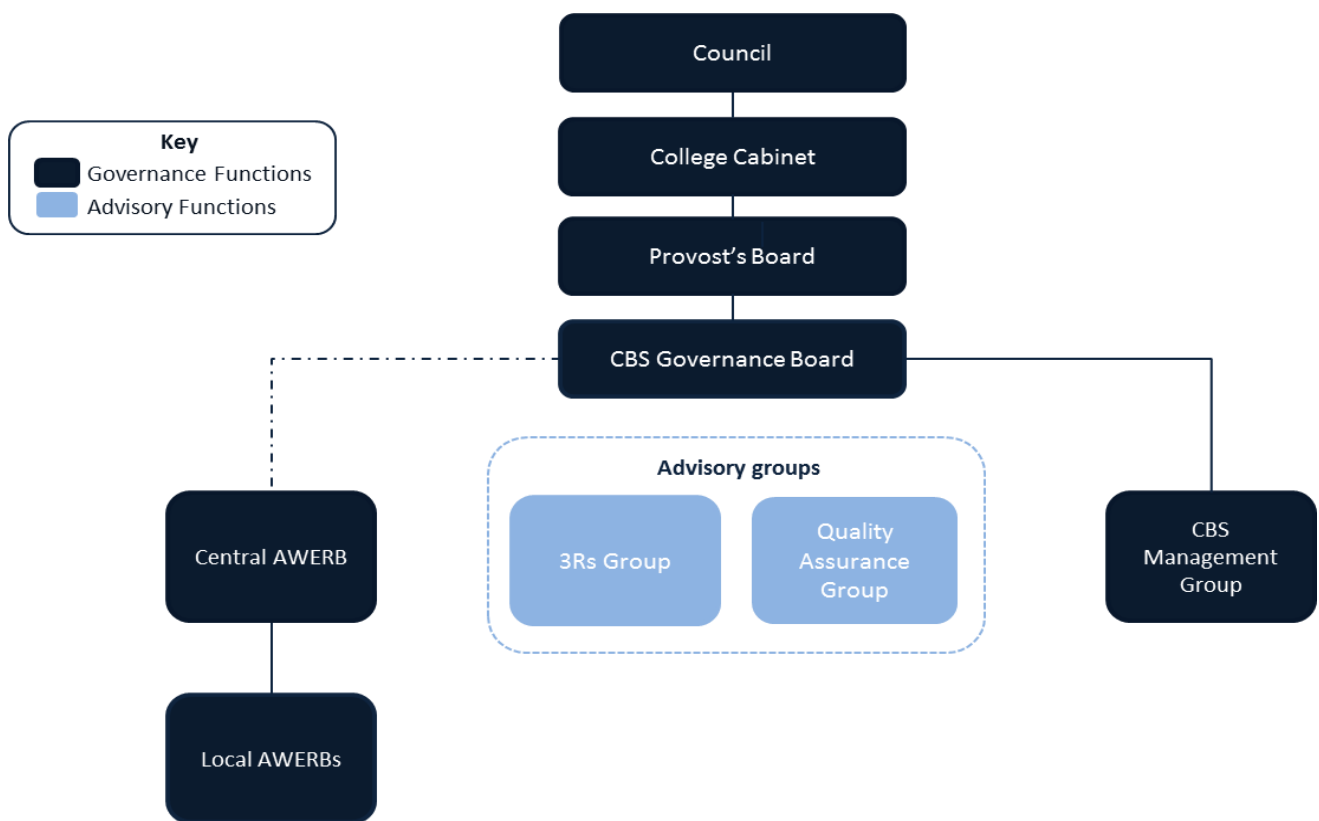


3. Architecture for change

A new governance structure is being developed for animal research at Imperial. The design of the new governance structure will provide the architecture in which to manage and deliver world class scientific research and promulgation of the 3Rs. The changes to the governance structure are significant and will create an effective framework for assuring regulatory compliance and promoting leadership in animal research, as set out in figure 2.

The new structure comprises a combination of oversight, decision-making and advisory functions. This will ensure that decisions made by AWERB will translate into management and operational delivery. Furthermore, this governance structure will foster cultural change and enhance communications for the benefit of best practice in animal research.

Figure 2 Proposed governance structure for animal research at Imperial College London



The new structure will be based on a set of design principles, which will guide governance of animal research at Imperial. The new structure will:

- continue to allow Imperial to discharge its statutory obligations and to develop and implement best practice in animal research;
- be underpinned by promulgation of the 3Rs;
- have clear accountabilities, and accountable owners with the necessary authority and credibility to undertake their roles in the governance process;
- be open and transparent especially with regards to decision-making, escalation routes through the governance hierarchy and relationships between governance functions;
- provide effective and efficient central oversight of multi-site operations;

- provide appropriate challenge at every level of the governance hierarchy to support rigorous assurance and decision-making; and
- have processes that are sustainable in the long term, with a supporting secretariat that is sized and resourced appropriately.

CBS Governance Board

The CBS Governance Board will have overall accountability for, and oversight of, animal research at the College.

It will have representation from senior animal researchers from Imperial as well as external representatives. The members of the board will represent best international practice in animal research and the 3Rs. The Board will be chaired by a senior academic from the Faculty of Medicine.

The CBS Governance Board will:

- assure that the governance of animal research has the appropriate levels of dialogue between the AWERB and CBS management;
- assure that, through external peer appraisal, that the College sustains best international practice;
- oversee and advise the formulation and review of Imperial's policies on the use of animals in scientific research;
- oversee key leadership and management changes; and
- communicate as appropriate with wider Imperial governance systems and external stakeholders.

The Establishment Licence holder will be a member of the CBS Governance Board and will be responsible for putting in place robust systems for complying with the Animal Scientific Procedures Act 1986 (ASPA), and the terms and conditions of the establishment licence, project licences and personal licences held at the establishment. This includes making animal research at the establishment follow the principles of the 3Rs, employing staff to maintain a high standard of husbandry and care, putting in place a strong programme for educating and training staff, and maintaining an effective AWERB.

Quality Assurance Group and 3Rs Group

The governance structure includes two advisory groups: the Quality Assurance (QA) Group and the 3Rs Group. There will be effective communication between these groups, and with the CBS Governance Board and the central AWERB. The QA and 3Rs groups will each be led by a senior academic, who will champion the groups' respective strategic goals and values. The champions will have leadership capability and be of sufficient standing to influence peers in the wider research community. Both groups will be supported by a full-time administrator.

The role of the 3Rs Group is to take examples of innovation and best practice in animal research and promulgate these widely such that they can be effectively integrated into the operational management of CBS. This includes the translation of best practice to replace, reduce and refine the use of animals in research into operational procedures and standards.

The QA Group is an existing internal project group that will advise on how world class animal research developments can be integrated into the operational management of CBS. Its role is to:

- provide a mechanism for ensuring compliance with applicable animal care and use, policies, guidelines and laws;
- promote effective and constructive communication and education for all members of the animal research community;
- ensure that the College is compliant with internationally recognised standards;
- review existing on-site and on-line training programmes and make recommendations as appropriate;
- develop an internal inspection process to review animal care and welfare activities; and
- ensure effective record keeping for the establishment.

The work of this group to date has included: the delivery of regular project licence (PPL) forums; communications, including new web-pages, visual aids, and student engagement; training and development initiatives; and changes to operational structures and standards, including working towards the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) accreditation, and a review of existing training records. These actions undertaken by the QA Group support and promote the implementation of many of the Brown Report's recommendations.

4. The Animal Welfare Ethical Review Body

The College is implementing wholesale reform of the AWERB, which will allow the College to reach the highest standards in the governance of animal research.

The Brown Report noted the College's strong focus on delivering an AWERB process that is efficient and timely for the licensing of animal research. Imperial now intends to build on this to create an AWERB with a more strategic oversight role for upholding the 3Rs.

The key features of the AWERB reform include:

- providing the mechanisms for the translation of lessons learned from ethical review into best practice, especially in relation to the 3Rs;
- providing a structure which enables formal face to face review of all licence applications; and
- recruitment of a full-time senior administrator to support the AWERB process, to allow the Named Veterinary Surgeon (NVS) to focus fully on the leadership of veterinary services.

Through reform of the AWERB processes as suggested by the Brown Report with the creation of local AWERBs, the College will improve its licence application process through greater involvement of researchers, vets and Named Animal Care and Welfare Officers (NACWOs) in discussion of licenses. This will enable greater ethical review of animal research and an active programme of 3Rs and welfare improvements driven by both researchers and CBS staff.

Central AWERB

A review of the remit and membership of the central AWERB is being undertaken. The changes proposed by the Brown Report will be implemented in order to optimise the way in which the AWERB discharges its terms of reference.

The central AWERB is an independent body that will focus its activity in four key areas. These are to:

1. set and review strategy in terms of animal research, 3Rs, and animal welfare improvements;
2. review the outputs and activities of the local AWERBs, including consideration of retrospective reviews;
3. receive and consider project licence (PPL) proposals involving severe protocols from the local AWERBs; and
4. ensure continued and retrospective review of project licences and practices.

A senior academic will be appointed to chair the central AWERB. The Chair will be supported by a lay Vice-Chair. A full-time senior administrator will be appointed to manage and provide a secretariat to the AWERB. This will produce an AWERB process that is resourced appropriately to achieve its objectives and desired impacts in a timely and efficient manner.

Local AWERBs

The new governance structure establishes standing committees for local AWERBs which will be site-based. These will provide a forum for project review, cost/benefit assessment and development of 3Rs. The role of the local AWERB will be to provide greater ethical review of animal research and an active programme of 3Rs and welfare improvements driven by both researchers and CBS staff. The local AWERBs will also consider all proposals for new licences and significant modifications face to face at their meetings. The Brown Report recognised the importance of the NACWO role in the local AWERB process and the high level of commitment and interest on their part to the 3Rs. Our vision is for local AWERB to provide an effective forum for interactions between researchers, CBS staff, NACWOs and vets through appropriate composition of the standing committees.

5. Operation of Central Biomedical Services

Imperial is fully committed to the highest standards of design, planning and delivery of animal research. The Brown Report highlighted that a high quality of husbandry was evident and staff responsible for the day to day care of animals were committed to animal welfare.

In order to maintain world-leading capabilities in animal research, Imperial recognises the requirement for continuous improvement. As such, the College has committed additional resources to augment the management and staffing of CBS, and broaden the training and development offering. This will promote continued compliance and ongoing improvements.

The changes to AWERB and the wider governance structure described in the previous section will support this by providing oversight at senior levels.

Strategic leadership and senior management

A new appointment will be made for a Director of Bioservices. The post holder will provide overall strategic leadership and direction and will be the accountable officer for the operations of animal research.

The Director of Bioservices will be supported by a senior leadership team. This will include the Director of Central Biomedical Services (responsible for all operational aspects of CBS); NVS; Home Office Liaison Officer (HOLO) and the Named Information Officer (NIO). This leadership team will also include new positions: a full-time Named Training and Competency Officer and a full-time AWERB Administrator. In addition, a project management team will be recruited and mobilised to ensure that dedicated resource and appropriate capability is in place to implement a defined programme of change. The recruitment process has commenced for all new positions.

Staffing

Imperial is committed to the ongoing professional development of all staff and to creating an environment in which they can perform at the highest level. The College will increase its staffing levels to improve capacity for staff to be involved with the *in vivo* research programmes. The College will seek to identify best practice in terms of staffing and will configure its resources accordingly to allow for greater independent overview of animal welfare out of hours and during weekends, as recommended in the Brown Report.

These changes will enable the development of technical competencies and the wider capabilities of CBS staff, and will facilitate enhanced communications. This should improve both the service provided by CBS, and the professional standing of CBS staff. This will deliver benefits to both animal welfare and the scientific quality of *in vivo* studies.

By investing in staff and further supporting their ongoing professional development, the College will be recognised as an employer of choice in the wider animal research community.

Reporting animal welfare concerns

The College has established an escalation protocol to clearly delineate roles, responsibilities and actions to be taken by staff at each level of the reporting chain. The protocol is widely displayed in all working areas, and awareness of the escalation process is reinforced through regular communications and staff engagement. The escalation process reinforces the wider role of the NACWO and the mandatory requirement for the establishment licence (PEL) holder to be included in the reporting of serious incidents.

Communications and working practices

Stronger links between researchers and CBS staff will be critical to the development of an efficient and effective service that actively promotes a 'culture of care'.

The changes to the governance structure will enhance the communications between researchers and CBS staff and improve cross-College understanding of research projects.

This will take place within the new AWERB structures, and will be reinforced by activities initiated by the QA Group including:

- lunchtime seminars to discuss and promote stronger links between CBS staff and research groups;
- PPL (project licence) fora to increase interaction between PPL holders and personal licence (PIL) holders, and between PPL holders and other members of the animal research community;
- organisational development courses for CBS staff; and
- providing CBS staff with the capacity to attend departmental research seminars.

These initiatives will foster a culture of openness, trust and respect where teams of researchers and support staff work together.

6. Training and competency assessment

Imperial is committed to ensuring that all those working with animals possess the necessary skills and satisfy their responsibilities under ASPA. Additionally, the QA Group has initiated a series of actions including targeted refresher training, online learning platforms, and lecture based training.

The College's vision is to develop a broader training and development programme that provides the opportunity to mainstream innovation and promote the adoption and spread of best practice in animal research.

Imperial will meet these commitments by:

- providing high-quality training for those requiring project or personal licences under ASPA. This is available through our modular training programme, together with opportunities for refresher courses to enable them to update their skills;
- investing in and harnessing technology to support the delivery and recording of compliance with the mandatory training through the implementation of the A-tune software package. This provides immediate information to supervisors and research leaders about existing training and competencies thereby highlighting appropriate future provision needs. This system will standardise the capture of training and competency details of all members of staff and will enable validation of ongoing compliance;
- ensuring that those working under ASPA are aware of their roles and responsibilities.
- organising regular seminars on matters related to the 3Rs;
- encouraging a team approach to animal work that fosters good communication and collaboration between all those involved in the care and welfare of animals;
- working with leading research organisations to provide further opportunities for staff development through a work exchange programme; and
- increasing awareness and understanding of new techniques and refinements, to support a continuous improvement culture in the laboratory environment.

The management of training and assessment will be under the direction of the new full-time NTCO and will be facilitated by Imperial's investment in the A-tune animal management software. Opportunities to broaden the programme of training and development will be

identified by the 3Rs Group and the QA Group. This will enable Imperial to reach the highest standards of animal research and promulgation of the 3Rs.

7. Culture, leadership, and management

Within this action plan, Imperial has set out a number of commitments that will create a research environment that is recognised as being of the highest international standards in terms of promulgation of the 3Rs, bringing in new ideas from the wider research community, and creating a thought environment that stimulates best practice for animal research. This will require and create a change in culture in the short, medium, and longer term. The practice of animal research at Imperial will be defined by a culture of openness, trust and respect where teams of researchers and support staff work together.

Imperial is committed to a working culture within the practice of animal research that reflects the world class quality of research undertaken at the College. This will be achieved through:

- incorporating a questioning approach to animal research and the 3Rs;
- continually searching for opportunities for innovation and development of best practice;
- promoting debate, peer challenge and dialogue between all staff, including at the AWERB level and through our advisory groups; and
- creating new solutions in animal research of relevance to both Imperial and the international research community.

The wholesale reform of the governance process will play an important role in driving culture change, increasing the dialogue between the AWERB and the local AWERBs.

Specifically, AWERB provides the opportunity to influence the design and practice of future research by ensuring that discussion around the 3Rs is integrated into the consideration of each and every licence application. How this is done will play an important part in achieving cultural change: the face to face discussion of all licence applications will increase the visibility of those undertaking and supporting research, build relationships, and create a community where there is more contact between individuals. The retrospective and in-project reviews will also help to identify both innovation and best practice in the 3Rs which can then be fed directly into CBS operations.

The governance structure includes two advisory groups – the QA Group and the 3Rs Group. Each will be led by an academic champion. In the case of the 3Rs group this individual will be recognised as a leader in the 3Rs and of appropriate standing to influence peers within the academic community. The investment in dedicated project management support demonstrates our commitment to focussing on increased promulgation of 3Rs activity. There will be a clear expectation that each and every individual member of the boards and groups within the governance structure will be an advocate for the 3Rs. Our commitment to the 3Rs will be demonstrated by:

- the way individual research projects are appraised;
- the innovative methods that researchers have developed to replace, reduce and refine the use of animals in research; and

- the advocacy for improving research standards by improving professional standards across the animal research community.

There is investment in new roles within Imperial's staffing model for animal research. The new role of the Director of Bioservices will be accountable for all aspects of animal research at Imperial, including the accountability to drive forward the programme of change to create a research environment that is recognised as being of the highest international standard.

The culture change will be reflected and reinforced through 'ways of working' at Imperial. CBS operations provide opportunities to change practice and support the College to embed a culture of continuous improvement in the day to day practice of animal research. Standard operating protocols (SOPs) underpin day to day activity. Regular updates to SOPs provide opportunities to mainstream new approaches and systematise best practice. The QA Group has introduced an exchange programme with a major industrial research organisation. Initiatives such as these will provide opportunities for the inflow of ideas and exchange of best practice. The advisory groups will continue to explore opportunities for the exchange and rotation of staff both within and outwith Imperial.

The cultural changes driven by the governance structure and the commitment to continuous improvement in the operations of CBS are underpinned by Imperial's commitments to training and development. The College is committed to the ongoing professional development of all staff and to creating an environment in which they can perform at the highest level. Accountability for this will rest with the NTCO and will be supported through our investment in A-tune software which will help them to monitor and identify training requirements. As well as meeting mandatory requirements, training and development provide opportunities to mainstream innovation and promote the adoption and spread of best practice. They also represent an opportunity to increase awareness and understanding of new techniques and refinements to existing practice. This will inform future licence applications made by researchers.

8. Managing progress

Imperial will develop a vision statement and action plan for the 3Rs, aiming to achieve the highest international standards in animal research and to be a world leader in developing ideas and best practice.

The action plan commits to changes in governance, training and development and CBS operations with significant investment in new posts and technology to underpin training and development. The cornerstones of the action plan are AWERB, training and development and CBS operations. The commitments set out in this document should each reinforce and drive sustainable and continuous cultural change. The CBS Governance Board will have overall accountability for this and will report on progress within the next 12 months.

9. Summary tables

The tables that follow provide a summary of the recommendations made in the Brown report and set out our progress to date and ongoing actions to deliver the recommendations

Table 1 – The Animal Welfare Ethical Review Body

Summary of recommendations contained in the Brown Report	Progress to date	Ongoing actions
<ul style="list-style-type: none"> • Reform of the local AWERB review process including enhanced engagement and communications. • Reform of central AWERB to more effectively deliver terms of reference. • AWERB leadership reform. • Appointment of senior administrator to instigate and manage the reformed process. 	<ul style="list-style-type: none"> • A new governance structure has been developed for animal research at the College including a fit for purpose local AWERB process and changes to the central AWERB. • PPL forums have been established to increase interaction between PPL holders and PILs holders, and between PPL holders and other members of the animal research community. • Imperial’s senior team have increased engagement with the central AWERB chair outside of meetings and changes to membership have enabled more senior stakeholders to attend (e.g. Chair of the QA Group). 	<ul style="list-style-type: none"> • We will establish at least two standing committees for local AWERB which will meet regularly. This will provide an improved forum for project review, cost/benefit assessment and development of 3Rs that will enable greater engagement between the NVS, NACWOs and researchers. • The central AWERB will effectively demonstrate its strategic role in animal research, 3Rs and welfare improvements, and have an oversight role of local AWERB. • Central AWERB will be a key part of the new governance structure. • A senior administrator will be appointed to support the AWERB process.

Table 2 – Operation of Central Biomedical Services

Summary of recommendations contained in the Brown Report	Progress to date	Ongoing actions
<ul style="list-style-type: none"> • Improvements to operational structures including optimisation of staffing arrangements, and promotion of technical development of CBS staff. • Improvements to operational standards. • Improvements to communications and working practices including stronger links and integration between researchers and CBS staff and promotion of a ‘culture of care’. • Improvements to processes for reporting animal welfare concerns. 	<ul style="list-style-type: none"> • An exercise has been initiated to establish best practice for staffing arrangements and working practices. • Two new roles have been identified and job descriptions produced for i) implementation of animal management software and for ii) managing the AAALAC accreditation process. • Workshops have been run to promote attendance of CBS staff at research group meetings and create stronger links between researchers and CBS staff • Budget committed for QA processes • A website has been created to increase transparency and availability of all information about animal research and ethics at Imperial (www.imperial.ac.uk/research/animal-research). • Guidance on supervision and competency recording for all PILs is available to relevant staff. • A review of standard operating procedures has been undertaken and these are being updated on an ongoing basis. Spot checks are also being conducted to ensure effective implementation. • A number of improvements have been made to processes for reporting animal welfare concerns including re-enforcement of the escalation process. • An exchange programme for sharing of best practice has been arranged with an industrial research collaborator • Updated posters are now on display at all CBS sites to create visible reminders of roles and responsibilities. 	<ul style="list-style-type: none"> • Staffing arrangements will be reviewed in light of benchmarks of best practice. • Committed a budget to resource expanded activity recommended in the Brown Report. New roles have been identified and the recruitment process has commenced. • A cultural change programme will be implemented to develop stronger links between researchers and CBS staff.

Table 3 – Training and competency assessment

Summary of recommendations contained in the Brown Report	Progress to date	Ongoing actions
<ul style="list-style-type: none"> • Increased resources for training and competency assessment. • Implementation of site-wide processes for assessing competency. • Improved mechanisms for identifying refinements in research procedures. • Appointment of a senior NTCO. 	<ul style="list-style-type: none"> • Resources have been increased for implementing best practice in systems, people and processes. • The Quality Assurance group has already undertaken initial review and identified and completed a number of actions in this area (See section 4). • Imperial has provided additional staff resource including identification of an NTCO role. The recruitment process for this role has commenced. • Learning platforms have been developed including end of course examinations on Home Office best practice and a refresher for licence holders on roles and responsibilities. Targeted refresher training has been undertaken to update staff and students in specific areas. • A mentoring programme for sharing of best practice has been arranged with an industrial research collaborator. 	<ul style="list-style-type: none"> • Animal management software will be fully implemented. This will provide a platform for capturing training and competency of staff. • The new governance structure will provide assurance that there is an improved process for assessing levels and sharing best practice. • The 3Rs group will provide assurance that there are mechanisms for identifying refinements in research procedures and this will be incorporated into training programmes and competency assessments. • Resources have been identified to enable long term benefits to be accrued.

Table 4 – Culture, leadership and management

Summary of recommendations contained in the Brown Report	Progress to date	Ongoing actions
<ul style="list-style-type: none"> • Creation of a strategic leadership team responsible for driving change regarding implementation of 3Rs. • Establish new directorial role with overall responsibility for delivery of bioservices. • Appoint champions within academic staff and CBS at all levels. • Improve the culture of the 3Rs. 	<ul style="list-style-type: none"> • Imperial is already committed to the 3Rs. See (www.imperial.ac.uk/research/animal-research/alternatives). • Imperial has signed the Declaration on Openness on Animal Research and will continue our commitment to this. See (www.imperial.ac.uk/research/animal-research/openness). • A proposed governance structure has been developed including a CBS Governance Board which will form the strategic leadership team responsible for driving change regarding the 3Rs. This board will be supported two advisory groups including a group specifically focusing on a new 3Rs programme across the College. • The recruitment process for a Director of Bioservices position has commenced. This position will be responsible for all CBS activity. • Initial concept is being developed for a course in 3Rs for graduate students. • Imperial have already established a number of initiatives to support the promulgation of the 3Rs. For example, there will be an annual prize for commitment to the 3Rs. 	<ul style="list-style-type: none"> • A CBS Governance Board will provide strategic leadership for driving change regarding the 3Rs. • A vision statement and action plan for the 3Rs is being developed. • A continuous programme of change will be implemented across the College to consider and implement further initiatives to improve the culture of the 3Rs. • We are developing advocacy to improve the culture of the 3Rs within the governance structure.