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Education

2015/16

Animal Welfare

Overall report rating:

Significant assurance with minor
improvement opportunities

Imperial College London

February 2016

INTERNAL AUDIT

Contents

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Distribution

To (for action):	cc (for information):
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Maggie Dallman – Associate Provost	

Sponsor

James Stirling, Provost

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Section One

Executive summary

Conclusion

We reviewed the progress the College has made against recommendations raised 'Independent Investigation into Animal Research at Imperial College' (the Brown Report) and have concluded an assessment of **significant assurance with minor improvement opportunities (green-amber)**. We found that there had been substantial progress made since the Brown report, however, there was still room for further improvement to better embed the response to issues raised.

We reviewed the Brown report and tested a sample of recommendations from each area assessed; Animal and Welfare Review Body (AWERB), Operation of Central Biomedical Services (CBS), Training and competency assessment and Culture, leadership & management. We found that progress on the recommendations from the Brown report had been reported to the Home Office in February 2015, and at that time, the majority of recommendations had been resolved.

The College reformed its Central AWERB, and created two additional AWERB's for the local sites (Hammersmith and St. Marys/South Kensington). We found that the Central AWERB was chaired by the Associate Provost, an appropriate figure of authority to raise significant concerns to the Governance Board for Animal Research. We evidenced the minutes of these meetings being reported to the Governance Board for Animal Research, however we were informed that the minutes are not anonymised and published for all staff. We are aware that management are intending to publish redacted minutes on the CBS website once security issues have been resolved.

The CBS staff and Research staff have integrated to form a more coherent team of employees within the College, as was recommended by the Brown report. Events are now held in conjunction with the two bodies of staff to enhance their relations and widen CBS staff understanding of the research environment. We were informed that the level of staffing within the department has been consistently above the benchmark-required level of staff to cages. This has ensured that technical and research staff have had significant and adequate exposure to '*in vivo*' research. In addition, we found that the College has a policy in place for raising animal welfare concerns which is included the CBS users guide and displayed on posters throughout the College, however we have recommended that the policy is included in the College's Whistleblowing policy.

The College appointed a Named Training and Competency Officer (NTCO) during 2014, who is the head of CBS training. She is responsible for training both the College Staff Trainers and Assessors; who deliver the training programme to CBS and Research staff. Training and subsequent assessing occurs on a rolling three year basis to maintain the highest levels among CBS staff. Further, we found that the NTCO is responsible for the formulation and preparation of training courses; through which, best practice identified from AWERB meetings is incorporated.

During the change process, Deloitte were engaged as a 'Change Management partner', and a senior directorial position was created; Director of Bioservices. This position was filled in July 2015, and we found that the new Director sits on a number of committees and groups including the Management and Strategy Group. We evidenced the commitment to the Colleges three Animal Welfare priorities; the replacement, reduction and refinement of the use of animals in research (3R's). The importance of priorities has been communicated to staff via the creation of annual prizes for those staff members who show commitment to the 3R's within their work.

Background

The health and welfare of research animals is of high importance to Imperial ('the College'). Animal Welfare in the United Kingdom is overseen by the statutory regulator of animal research in the UK, the Home Office. The College holds an institutional Home Office licence to conduct research involving animals, and each researcher and technician who works with animals, as each new research project, require a separate Home Office licence. There are a number of statutory requirements which the College and staff must follow in order to maintain its licence. Compliance with regulations is monitored by regular unannounced inspections by the Home Office. Over 1,000 employees at College, at three separate sites, are currently involved in animal research. The College is a strong advocate of the 3Rs (replacement, refinement and reduction), and only uses animals in research programmes where it is absolutely essential.

In April 2013, following allegations about animal research published by the Sunday Times, the Home Office carried out an investigation of the College. In parallel, the College commissioned an independent review into the culture and approach to animal care and welfare at the College. The report was produced by an independent panel chaired by Professor Steve Brown, and in December 2013 produced the 'Brown Report'. The Brown Report's recommendations were intended to ensure that Imperial would in future set the highest standard of care in animal research nationally and internationally. The Report commented on the good standards of animal husbandry at the College, but also produced a series of recommendations requiring a substantial financial investment and cultural change.

The College accepted the recommendations in full, and in January 2014 produced its Action Plan for World Class Animal Research. Following this, a formal project called the Enhancing Bioservices Project (EBSP) commenced to implement the recommendations of Brown. The Home Office published the results of its investigation into the College in February 2014. 18 cases of potential non-compliance relating to 30 individuals were investigated. As a result of this, letters of reprimand and requirements for further training were sent to eight license holders. In the other cases, no evidence non-compliance was found. The Home Office report, more widely, identified a lack of awareness of the responsibilities of the duties of licensees and College was therefore issued with a 'Compliance Notice' pertaining to the overall Establishment Licence of the College.

Section One

Executive summary (cont.)

Since the College's Action Plan was published, progress has been made in a number of areas, including a new governance structure, improved ethical review processes, more effective communications, and better management of training. The work remains ongoing, though.

Animal research at the College is overseen by the Governance Board for Animal Research, chaired by the Dean of the Faculty of Medicine. There are two related committees within the College relating to; Animal Welfare; – the Animal Welfare and Ethical Review Body (AWERB) and the Central Biomedical Services Management and Strategy Committee (M&S Committee). The M&S Committee in turn oversees committees responsible for quality assurance, the 3Rs (replacement, refinement and reduction) and designated rooms that have been approved for use in animal research. There are further subgroups in place which oversee operational matters at the three campuses.

Objectives

Objective	Description of work to undertake
Objective One Monitoring arrangements	We reviewed the College's action plans and monitoring arrangements in place to address the recommendations from the Brown report. We selected a sample of recommendations from the Brown report to test the progress against actions agreed.

Areas of good practice

- ✓ The Local and Central AWERB's have been successfully reformed to afford them an independent position, aside from the College governance hierarchy;
- ✓ AWERB's are chaired by a Senior Academic;
- ✓ CBS staff have integrated with research staff by attending seminars, workshops and lab meetings as mixed groups;
- ✓ A NTCO has been appointed to ensure a systematic, site-wide process for assessment and training had been implemented;
- ✓ Change Management experts were engaged to assist the College with the implementation of the recommendations.;
- ✓ A systematic site-wide training system has been implemented with staff; and
- ✓ A Senior Directorial role, the Director of Bioservices, was introduced and recruited into. The senior management, including CBS director and NTCO, must report into the Director of Bioservices.

Areas for development

- We could not evidence the Action Plan being monitored at an operational level. **See Recommendation 1**
- We also raised two low priority recommendation surrounding the publication of Central an Local AWERB committee minutes as well as including the procedures for raising animal welfare concerns in the College's Whistleblowing policy.

Recommendations raised

We have raised the following recommendations (high priority represents the most urgent and high risk category):

	High	Medium	Low	Total
Made	-	1	2	3
Accepted	-	1	2	3

Acknowledgment

We thank the staff involved for their help in completing this review.

Section Two

Recommendations

This section summarises the recommendations that we have identified from our work. We have given each of our observations a risk rating as follows:

Priority rating for recommendations raised		
High Priority (one): a significant weakness in the system or process which is putting the College at serious risk of not achieving its strategic aims and objectives. In particular: significant adverse impact on reputation; non-compliance with key statutory requirements; or substantially raising the likelihood that any of your strategic risks will occur. Any recommendations in this category would require immediate attention.	Medium Priority (two): a potentially significant or medium level weakness in the system or process which could put the College at risk of not achieving its strategic aims and objectives. In particular, having the potential for adverse impact on your reputation or for raising the likelihood of strategic risks occurring.	Low Priority (three): recommendations which could improve the efficiency and/or effectiveness of the system or process but which are not vital to achieving the College's strategic aims and objectives. These are generally issues of good practice that we consider would achieve better outcomes.

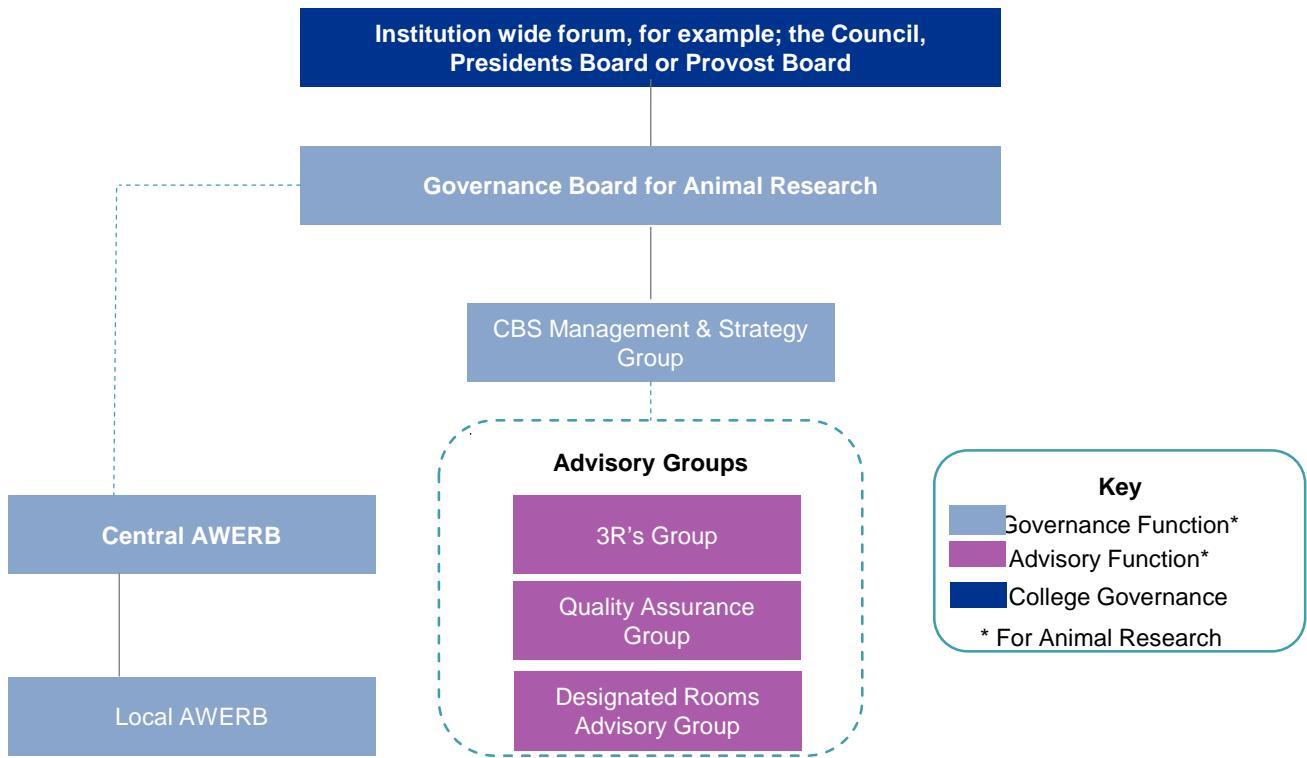
#	Risk	Recommendation	Management response, executive and deadline
1	● (Two)	<p>Monitoring & Action Plan</p> <p>We reviewed both the Management & Strategy group and Central AWERB meeting minutes and found that there was a lack of specific monitoring discussion surrounding the progression of the College toward the implementation of the Brown report recommendations. However, we did evidence that an assessment of progress against the Brown Report was produced and submitted to the Home Office.</p> <p>We recommend that the Management & Strategy Committee include a standing Agenda point to review progress against the outstanding college action plan on a twice annual basis.</p>	<p>Accepted</p> <p>A progress update on the implementation of the College's Action Plan for Animal Research will be included twice a year on the agenda of the CBS Management & Strategy Committee. This committee reports to the Governance Board which in turn reports to Provost's Board.</p> <p>The recommendations itemised in the Action Plan will be tabulated and the progress against each action will be discussed and reviewed.</p> <p>Due date: Immediately</p> <p>Responsible Officers: Director of Bioservices</p>
2	● (Three)	<p>Animal Welfare Concerns</p> <p>We found that the College does have a policy for raising animal welfare concerns which is included on posters throughout the College CBS facilities and within the CBS user guide. However, they do not included in the College's overall Whistleblowing policy.</p> <p>We recommend that the procedures for raising Animal Concerns are accurately detailed within College's the Whistleblowing policy.</p>	<p>Accepted</p> <p>The current Animal Welfare Concerns policy will be reviewed, expanded and linked to the College's overall Whistleblowing policy.</p> <p>Due date: Summer 2016</p> <p>Responsible Officers: CBS Director</p>
3	● (Three)	<p>Minutes of the AWERB's</p> <p>We identified that the minutes for the AWERB's are available to staff, upon request. This is in contrast to the recommendations made by the Brown report, which suggested that the minutes should be 'anonymised and publicised to the wider college'.</p> <p>We recommend that the AWERB minutes are anonymised and subsequently published on the AWERB page of the intranet portal, once security issues have been resolved.</p>	<p>Accepted</p> <p>Once the security issues regarding the CBS website are resolved, redacted minutes (which are currently available to the CBS community on request as well as to the CBS Management and Strategy Committee and the Governance Board) will be made available to the CBS community via the website.</p> <p>Due date: Q2 2016</p> <p>Responsible Officers: CBS Director (re security) AWERB administrator (re making redacted minutes available online)</p>

Appendix A

Animal Welfare and Ethical Review Board

Testing of the Operation of Central Biomedical Services

We reviewed the Animal Welfare and Ethical Review Board (AWERB), which received a total of 4 recommendations as a result of the publication of the 'Independent Investigation into Animal Research at Imperial College London'. Following the recommendations, the College restructured its governance around animal research to the below;



Findings

Through review of the 'Terms of Reference' documents for both of the Local Animal Welfare and Ethical Review Body (AWERB), St. Marys/South Kensington and Hammersmith, and the Central AWERB, the minutes of their respective meetings during 2014 and 2015, we found;

- ✓ The AWERB committee's have both been reformed through a process of focussing their attention on the 3R's (the Replacement, Reduction and Refinement of animals in research). We evidenced that the new hierarchical structure saw the AWERB committees sit independently away from the main governance structure, providing them an impartial opinion;
- ✓ The Central AWERB is chaired by the Associate Provost, giving a heightened authority and purpose to the actions arising from the meetings. This also ensures that actions arising from the Local AWERBs are reported upward to the Central AWERB, and further upward again to the CBS Governance Board.
- ✓ The Advisory groups liaise with the CBS M&S group and the Central AWERB to aid the sharing of 'best practice procedures' from across the research unit, alongside the promotion of effective communication and compliance.
- The AWERB committee's had increased their communication with wider staff by allowing staff to request the minutes, and also reporting the minutes to the Governance Board for Animal Research. However, the minutes have not been anonymised and publicised widely across the college as was recommended by the Brown report. **See Recommendation 3**
- The Action Plan created in response to the Brown report was not found to be monitored through any management group or committee. **See Recommendation 1**

Appendix B

Operation of Central Biomedical Services

Testing of the Operation of Central Biomedical Services

We reviewed the four areas within Operation of Central Biomedical Services (CBS), which received a total of 14 recommendations as a result of the publication of the 'Independent Investigation into Animal Research at Imperial College London'. We assessed 6 of the recommendations and found the following;

Area reviewed	Recommendations raised in areas	KPMG Commentary
Operation of CBS - Operational Structures	<ul style="list-style-type: none"> • Increase staffing levels to enable increased involvement of animal care staff with <i>in vivo</i> research programmes at Imperial. • Review the current barrier system with a view to enhancing flexibility of staff working. 	Through discussion with the Associate Provost, and with the Director of CBS, we found that staffing levels had been monitored correctly to ensure that the college were continually above the required benchmark for technical staffing levels.
Operation of CBS - Communication and Working practices	<ul style="list-style-type: none"> • Improve efforts to integrate the role and activities of CBS staff into the broader <i>in vivo</i> research activities of Imperial, including: developing strategic plan for CBS development, identifying work ordinarily undertaken by research staff usually undertaken by animal care staff in other establishments, and develop programmes to involve CBS staff in those activities. 	We found that ICL have made significant efforts to integrate the role of CBS staff with that of their research staff. This includes the attendance of CBS and research staff at joint workshops, the inclusion of CBS staff in research lab meetings and the completion of seminars, which are recorded and subsequently published to wider staff on a central portal.
Operation of CBS - Reporting animal welfare concerns	<ul style="list-style-type: none"> • Introduce standardised documentation to monitor animals during experimental protocols; the outputs systematically reviewed by CBS staff. • Implement an unambiguous policy for action in the event of animal welfare concerns, emphasising the responsibility of NACWO's, particularly their role in ensuring appropriate action is taken throughout the process and documented. • Communicate the key roles of NVS and NACWO's in the 3R's to the research community at Imperial, and institute a clear route for escalation of animal welfare concerns, via the AWERB. 	<p>We reviewed the central CBS website and found that standardised documentation is held for the monitoring of Animal Welfare. We noted that Health tracker cards are issued for animals undertaking procedures, which allows staff to monitor their wellbeing.</p> <p>Within the CBS website, guidance documents which inform staff of the processes that they are required to complete in the monitoring of Animal Welfare. It also informs staff of the numerous signs that an Animals Welfare may have been compromised and they are subsequently in distress. We also found that an Action Tracker document is held within the CBS department, which records any Animal Welfare concerns and ensures that the animals are monitored until their ailment is cured.</p> <p>We evidenced that the College provide an Animal Welfare concerns flyer with regard to raising concerns with Animal Welfare. However, it is not included in the College's overall whistleblowing policy See Recommendation 2</p> <p>We evidenced the role of the NVS and NACWO's being discussed through the annual report that was produced in January 2015. The report was published in response to the Brown report, ensuring communication of the College' commitment to 3R's and the roles of the NACWO's and NVS with regard to the 3R's.</p>

Appendix C

Training and competency assessment

Testing of Training and Competency assessment

We reviewed the Training and Competency assessment section, which received a total of 6 recommendations as a result of the publication of the 'Independent Investigation into Animal Research at Imperial College London'. We assessed 4 of the recommendations and found the following;

Area reviewed	Recommendations raised in areas	KPMG Commentary
Training and competency assessment	<ul style="list-style-type: none">• Appoint a Named Training Competency Officer (NTCO)	We were informed that the College has recruited a NTCO who began employment in September 2014. The NTCO is the head of CBS training and is responsible for training the trainers and assessors who pass along training and information to the staff. We reviewed the job description for position that was recruited into and we subsequently found that the role had the sufficient responsibilities for a NTCO role attached.
Training and competency assessment	<ul style="list-style-type: none">• Implement a systematic, site-wide process for assessing competency including an assessment of trainers	Staff and researchers holding licenses, must be re-assessed on a three year basis. This ensures that each of the staff members have the relevant skills necessary to maintain their licence and thus, a high standard of care at the College. The Training programme is currently still in the implementation processes, with the NTCO, trainers and assessors meeting on a regular basis to discuss the requirements of training, incorporating best practice and requests generated from the local and central AWERB meetings. The NTCO was included within the process of implementing the A-Tune system, which is used to record the progress of individuals throughout their various training courses.
Training and competency assessment	<ul style="list-style-type: none">• Develop a forum for assessment both within and across animal facilities of progress in training and competency assessment, potentially as part of the reformed AWERB process.	The NTCO attends training courses to view the content currently being taught and how receptive the audience are to it. This is used in conjunction with the AWERB suggestions to improve course content and provide the staff with information that they desire.
Training and competency assessment	<ul style="list-style-type: none">• Develop improved mechanisms for identifying refinements in research procedures, and incorporating them into training programmes and competency assessments.	The NTCO is responsible for the formulation and preparation of compliance training for the licence holders. In order to maintain these standards, they incorporate best practice identified from the local AWERB's into the training courses, to afford the insight to the wider members of CBS staff and researchers.

Appendix D

Culture, leadership and management

Testing of the culture, leadership and management

We reviewed the three areas within Culture, leadership and management, which received a total of 8 recommendations as a result of the publication of the 'Independent Investigation into Animal Research at Imperial College London'. We assessed 6 of the recommendations and found the following;

Area reviewed	Recommendations raised in areas	KPMG Commentary
Culture, leadership and management – Strategic leadership	<ul style="list-style-type: none"> Develop a vision statement and action plan for the 3R's, aiming to set the highest international standards and to be a world leader in developing ideas and practice in this area. This should be a collaborative project involving the senior team working with Imperial staff. 	<p>Through discussion with a member of Senior Management, we were informed that the 3R's are implemented into the Animal Welfare policy, which is held through the ICL website. Upon reviewing this policy, we found that the AWERB was referenced and the 3R's specifically discussed.</p>
Culture, leadership and management – Strategic leadership	<ul style="list-style-type: none"> Enlist help from experts in change management to foster a collegial and collaborative process and cross-institution ownership. 	<p>We found that Deloitte were engaged by the College in order to assist with the implementation of the Brown report recommendations. This provided the College an independent opinion regarding the implementation of the recommendations.</p>
Culture, leadership and management – Senior Management	<ul style="list-style-type: none"> Create a new senior directorial role with overall responsibility for the delivery of Bioservices at Imperial. The CBS director, NVS, head of AWERB, NTCO, NIO and HOLO would all report to the new appointee. 	<p>We evidenced that a senior directorial role was created and given the title; Director of Bioservices. We found that this role was recruited into in July 2015, and she was in the position at the time of the audit (November 2015). Through review of the job description of the director, we found that she sits on numerous committees including Management and Strategy Group. As a result of the committees that she co-chairs and chairs, numerous senior managers including; the CBS director, NVS, and NTCO report into her.</p>
Culture, leadership and management – Senior Management	<ul style="list-style-type: none"> The new director would be tasked with developing strategy across Imperial, and co-chair the CBS Management and Strategy Group. 	<p>We reviewed the minutes for the Management and Strategy Group and found that each meeting was chaired.</p>
Culture, leadership and management – Improving the culture of the 3R's	<ul style="list-style-type: none"> Consider establishing an annual Imperial prize for a teams commitment to the 3R's, or the implementation of new developments or new innovations supporting the 3R's. The prize would reflect the whole team's commitment and contribution. 	<p>The College has established four employee awards for their commitment to the 3R's. Each award represents a different aspect of the 3R's including CBS staff, researchers, lifetime achievement and communication. The prizes reflect teams working on the same project showing continued commitment.</p>
Culture, leadership and management – Improving the culture of the 3R's	<ul style="list-style-type: none"> Develop initiatives that bring together academic and support staff both socially and professionally. 	<p>The 3R culture has been expressed through the number of seminars and workshops that are held jointly between the CBS staff and the research staff. We confirmed with Senior Management that these joint events had brought the two groups of staff together.</p>

Appendix E

Staff involvement and documents reviewed

We undertook interviews in November 2015 with key staff members to inform this work, including:

Staff member	Title
James Stilling	Provost
Marina Botto	Director of Bioservices
Mandy Thorpe	Director of Central Biomedical Services
Maggie Dallman	Associate Provost

During our testing, we reviewed the following documents:

- Independent Investigation into Animal Research at Imperial College London;
- Action Plan for World Class Animal Research;
- Terms of Reference for AWERB's;
- Meeting minutes for Local and Central AWERB;
- CBS Seminar documentation and register;
- Animal Welfare tracker and related guidance;
- Annual Report 2014;
- NTCO and Director of Biomedical Services job descriptions;
- Example training forms;
- Animal Welfare policy; and
- Animal Welfare awards publication.