

ANIMAL WELFARE & ETHICAL REVIEW BODY

Minutes: 1:30pm, 20th June 2023, Online meeting

	Items.	AWERB Outcome
1	Attendance: Apologies from lay – comments sent.	
2	Minutes of the last meeting.	
2.1	Under review by last meetings/ reviewers.	Ongoing
3	Matters arising from the notes of previous meeting (23 rd May 2023)	
3.1	3.1 Generation of communal SOPs for audit preparation progressing	Ongoing.
3.2	3.2 Governance routes for commercial work carried out under service PPLs.	Ongoing.
3.3	3.3 University of Bristol 3Rs award.	Ongoing.
3.4	3.4 AWERB to discuss how to engage with the student union about animal research.	Ongoing.
3.5	3.5 Collaborative ASU/researcher nesting enrichment study	Ongoing.
3.6	3.6 Streamlining process for VIN owner follow-up contact.	Ongoing.
3.7	3.7 Establishment of UK-wide association of veterinary research reviewers.	Ongoing.
3.8	3.8 Standardised wording for grant applications and publications	Ongoing.
3.9	3.9 Zebrafish GAA Passport	Ongoing.
3.10	3.10 Ethical approval and governance routes involved with the use of animals overseas	Ongoing.
3.11	4.5 Facilitation of working group of decapod researchers	Ongoing

<p>4</p> <p>4.1</p> <p>4.2</p> <p>4.3</p> <p>4.4</p>	<p>Chair's Report</p> <p>Animal Issues Team proposal (name to be confirmed) - supported by Management Board and ELH.</p> <p>The Vice Chancellor met with students. AWERB will review ASC report when issued and take on any relevant recommendations.</p> <p>Recent FOI request – directed them to the published animal numbers and severity information on the website.</p> <p>AWERB Chair animal unit visit – staff very welcoming and knowledgeable animals obviously well cared for.</p>	<p>Terms of Reference to be developed.</p> <p>Chair to pass this positive feedback to the ELH.</p>
<p>5</p> <p>5.1</p>	<p>Project Licences – New Applications.</p> <p>PPL.1Jun23</p> <p>Aim: To evaluate ways of enhancing the protection of the heart of children during cardiac bypass surgery. About 1% of babies are born with a defective heart and some of these may have to undergo heart surgery to correct the defect, often whilst they are still very young. During surgery, it is often necessary to stop the heart temporarily to enable the surgeon to repair the defect. During this period, the blood supply to the baby's vital organs is maintained by coronary bypass. Despite this while the heart is stopped, and in the period immediately after it is restarted, the heart can sustain damage that can permanently restrict its function. The techniques currently used to limit this damage are based on those developed for adult patients however, these are less effective in children. Therefore, there is a need to develop more effective ways of protecting the heart of children's during heart surgery.</p> <p>Benefits: The primary output of the study will be new data relating to the mechanisms by which infant heart tissues sustain damage during coronary bypass surgery. In addition, the study will produce data relevant to the assessment of interventions aimed at minimising heart tissue injury during surgery.</p> <p>Harms: Pigs, coronary bypass under terminal anaesthesia (non-recovery), minor heart defect induced under anaesthesia with recovery (moderate), split approximately 50/50.</p> <p>Discussion:</p> <ul style="list-style-type: none"> • Continuation of work under previous PPL • Neuromuscular blockade process • Statistics – group size and effect size • Animal experience • Use of both or single sexes 	<p>Approved subject to discussions between applicant and AWERB Statistician</p>

5.2	<ul style="list-style-type: none"> • Adverse effects, experimental stop point and contingency plan • Pilot study • Flow of steps within protocols • Sufficiently up to date training record 	
	<p>PPL.2Jun23</p> <p>Aim: The aim of this project is to assess the potential of delivering drugs to the central nervous system (CNS) using natural fluid drainage pathways and to facilitate the development of the technology needed to achieve this.</p> <p>Benefits: Diseases of the central nervous system are a major cause of suffering and death. There is a lack of effective treatments for many diseases of the CNS. A major obstacle to the treatment of diseases of the CNS is the difficulty in achieving therapeutic drug concentrations required locally. Most drugs used in the treatment of diseases are prevented from entering the CNS by the blood brain barrier. As a result, the development of effective treatments for brain tumours and neurogenerative diseases such as dementia, Parkinson's, Alzheimer's and Motor Neurone Disease had been severely limited. Therefore, there is an urgent need to develop drug delivery systems that can overcome the limitations imposed by the blood brain barrier in order to address the unmet clinical need of patients.</p> <p>Harms: Pigs, sheep, surgery. Imaging, largely moderate procedures.</p> <p>Discussion:</p> <ul style="list-style-type: none"> • EDA flow diagram • Use of both sexes • Quality of product, how this is assured • Humane endpoints, definition of toxicity/toxic effects, monitoring, eg around cMax of drug administration • Controls in drug delivery work; tissue bank • Animal numbers in protocols versus overall • Post-operative accommodation and monitoring including Pig grimace scale development • Pre-study AWERB approval form • Statistics – determination of n number. • Sufficiently up-to-date training record. 	<p>Approved subject to discussions between applicant and AWERB Statistician</p>

6	Project Licences – Amendments. (None)	
7	Mid Term Reviews	
7.1.	MTR.1Jun23 Fewer animals used than expected due to COVID. Results of crossover study expected by end 2024, potentially ambitious. Initial work has contributed to a human trial.	Approved
8.	Final Reviews	
8.1	Final.1Jun23 Animal numbers discussion. Explanation of refined technique at another establishment due to availability of specialist equipment, lower number of mice needed to visualise the effect.	Approved
8.2	Final.2Jun23 Fewer animals used than predicted, largely due to COVID pandemic. Improved environmental enrichment results in fewer signs of depression. Research group now has grant to continue this work pending future AWERB approval.	Approved
10	Report on Non-Regulated Projects UIN and VIN applications.	
10.1	Non-Regulated Projects – UINs Reviewed: UIN.1, UIN.2 AWERB approved: AWERB approved pending clarifications: UIN.1, UIN.2 AWERB did not yet approved:	Secretary to inform
10.1.1	UINs to note: UIN.1 – Consideration of differing variables across the study. Inclusion of previous human participation experience. Confirmation of durability of device and consideration given to long-term use with risks of ingestion. Consideration to quality assurance and regulatory product approval.	

	UIN.2 - Inclusion of exclusionary criteria and drug licencing details.	
10.2	<p>Non-Regulated Projects – VINs.</p> <p>Reviewed: VIN.1-3 AWERB approved: VIN.1 - 3 AWERB approved pending clarifications: AWERB not yet approved:</p>	Secretary to inform
10.2.1	VINs to note: Potential clarification to be produced regarding UIN and VIN application criteria.	
11	Non-Regulated Projects - UIN and VIN amendments	
11.1	UINAmend.1 Extension to longitudinal cat veterinary study - approved	
12	AWERB Hub. (None)	
13	Any Other Business.	
13.1	<p>Location of external links to University of Bristol Animal Research website from main University website.</p> <ul style="list-style-type: none"> - AWERB agreed in the interests of openness, with the tag Animal Research. 	
13.2	<p>Slido comments at recent All Staff Livestream</p> <ul style="list-style-type: none"> - Discussion of ideas for openness. 	
13.3	Recent PPL application granted with no comments or changes required - HOI contacted applicant personally to compliment them on their application.	
14.	<p>Dates of Next Meetings (Online until further notice but twice yearly in person): 18th July 2023</p>	