Document 1

Australian Animal Health Laboratory – Animal Ethics Committee (AAHL AEC)

AEC Number **1836**

ANNUAL PROGRESS REPORT – AEC 4

(Office Use Only)	File Number:	C2018/199
	Meeting Number:	2018/1

PROJECT DETAILS

1.1	Project title
Antibody-based prevention of cell-associated SHIV infection in macaques	
1.2	Science leader
s 22 [redacted]	
1.3	Principle Investigator
s 22 [redacted]	
1.4	Original approval date
Jan 2017	

OBJECTIVES

2.1	What were the objectives of this project stated in the original application? (Insert from original approved AEC 1 form question 2.1)

A vaccine against HIV requires understanding the mechanisms of viral transmission. Most assessments of transmission involve exposing macaques to free viruses using SIV or SHIV. Such challenges provide robust reproducible infections. Previous studies have shown that, using the free virus challenge system, broadly neutralizing antibodies against the outer coat of the virus (the Envelope) provide high levels of immunity.

s 47, s 47G(1)(a) [redacted]

s 47, s 47G(1)(a) [redacted]

PROGRESS	
3.1	Outline the progress that has been made to date? Refer to the objectives where possible.
We have successfully tested antibody regimens for protection cell-associated SHIV and treatment of SHIV in infected controls. We expect to complete the remaining groups during 2018.	
3.2	Have any problems been encountered that have interfered with the progress of the project?
s 47G(1)(a), s 47C [redacted]	
3.3	How is the project meeting the original objectives?
s 47, s 47G(1)(a) [redacted]	

ANIMAL USE	
4.1	How many animals of each species were originally approved?
24 Macaca nemestrina	
4.2	How many animals have been approved in subsequent AEC 6 modification requests?
6	
4.3	What was the total number of animals approved?
30	
4.4	How many animals have been used?
16	
4.5	How many animals are currently being held?
12	
CLINICAL SIGNS & HUMANE KILLING OUTCOMES	
5.1	How many animals have been humanely killed due to reaching the humane endpoint?
1 (An AEC6 was submitted for one animal)	
5.2	How many animals were humanely killed or culled as part of the experimental design?
3	
5.3	If animals were humanely killed due to reaching the humane endpoint, what were the clinical signs observed?
s 47G(1)(a), s 47C [redacted]	
5.4	How have the clinical signs described above correlated to the classification of clinical signs (mild, moderate or severe) described in table 14.4 of the original application?
s 47G(1)(a), s 47C [redacted]	
5.5	How many animals have been found dead during the experiment?
0	
5.6	What were the reasons for the deaths?
s 47G(1)(a), s 47C [redacted]	

WELFARE ISSUES	
6.1	Please provide a summary of the welfare of the animals during the experiment to date and whether it has been consistent with that anticipated in the project application.
s 47G(1)(a), s 47C [redacted]	
What improvements or problems in relation to animal welfare have been revealed during the experimentation? The following headings may act as guidelines.	
6.2	Husbandry, accommodation and diet.
s 47G(1)(a), s 47C [redacted]	
6.3	Expertise and equipment.
None needed	
6.4	Experimental procedures.
None needed	
6.5	Analgesia and humane killing.
s 47G(1)(a), s 47C [redacted]	
6.6	Other.

Document 2

From: s 22 [redacted]
To:
Subject: AEC 4 - Protocol 1836
Date: Wednesday, 18 April 2018 3:00:00 PM
Attachments: AEC 4 - 1836 24Jan18.docx

Dear s 22 [redacted]

This is to advise that the attached AEC 4 Annual Report for protocol ***1836*** *Antibody-based prevention of cell-associated SHIV infection in macaques* that you submitted to the February AEC meeting was **APPROVED** at the April AEC meeting

We had a large amount of paperwork for our February meeting so many reports had to be held over to our April meeting - we apologise for the delay.

Regards

s 22 [redacted]

Document 3

Australian Animal Health Laboratory – Animal Ethics Committee (AAHL AEC)

AEC Number **1836**

COMPLETION/DISCONTINUATION REPORT – AEC 5

(Office Use Only)	File Number:	
	Meeting Number:	

PROJECT DETAILS	
1.1	Project title
Antibody-based prevention of cell-associated SHIV infection in macaques	
1.2	Science leader
s 22 [redacted]	
1.3	Principle Investigator
s 22 [redacted]	
1.4	Original approval date
23 Jan 2017, amendment approved 14 Nov 2017	
1.5	Completion date
April 2019	
OBJECTIVES	
2.1	What were the objectives of this project stated in the original application? (Insert from original approved AEC 1 form question 2.1)
A vaccine against HIV requires understanding the mechanisms of viral transmission. Most assessments of transmission involve exposing macaques to free viruses using SIV or SHIV. Such challenges provide robust reproducible infections. Previous studies have shown that, using the free virus challenge system, broadly neutralizing antibodies against the outer coat of the virus (the Envelope) provide high levels of immunity.	

s 47, s 47G(1)(a) [redacted]

s 47, s 47G(1)(a) [redacted]

2.2	Please provide details on how the objectives were achieved, or why they were not fully achieved

s 47, s 47G(1)(a) [redacted]

ANIMAL USE	
3.1	How many animals of each species were originally approved?
30	
3.2	How many animals have been approved in subsequent AEC 6 modification requests?
0	
3.3	What was the total number of animals approved?
30	
3.4	How many animals were used?
26	
3.5	If fewer animals were used than approved, please explain why?
We did not complete studies s 47, s 47G(1)(a) [redacted].	
CLINICAL SIGNS & HUMANE KILLING OUTCOMES	
4.1	How many animals were humanely killed due to reaching the *humane endpoint*?
0	
4.2	How many animals were humanely killed or culled as part of the experimental design?
25	
4.3	If animals were humanely killed due to reaching the *humane endpoint*, what were the clinical signs observed?
NA	
4.4	How did the clinical signs described above correlate to the classification of clinical signs (mild, moderate or severe) described in table 14.4 of the original application?
NA	
4.5	How many animals were found dead during the experiment?
1	
4.6	What were the reasons for the deaths?
s 47G(1)(a), s 47C [redacted]	
WELFARE ISSUES	
5.1	Please provide a summary of the welfare of the animals during the experiment and whether it has been consistent with that anticipated in the project application.
All animals remained healthy throughout their time at AAHL and their welfare was consistent with that anticipated in the project application. Animals gained weight appropriately. There were no adverse events related to any of the procedures. There were no instances of immunodeficiency or SHIV disease in the animals.	
What improvements or problems in relation to animal welfare have been revealed during the experimentation? The following headings may act as guidelines.	
5.2	Husbandry, accommodation and diet.
NA	
5.3	Expertise and equipment.

NA	
5.4	Experimental procedures.
See below	
5.5	Analgesia and euthanasia.
In consultation with AAHL staff and the AEC we evaluated reversible BDAK sedation rather than Ketamine alone during this protocol. We found this to work effectively and result in the animal waking up more quickly from sedation. We provided a verbal report to the full AEC on this in Dec 2018.	
5.6	Other.

s 47G(1)(a), s 47C

[redacted]

s 47G(1)(a), s 47C

[redacted]

5. An acknowledgement that under the Code, this work cannot be published.
I acknowledge the communications from s 22 and the AEC and that no publications will now be submitted on this work.

Document 4

Australian Animal Health Laboratory – Animal Ethics Committee (AAHL AEC)

AEC Number **1836**

COMPLETION/DISCONTINUATION REPORT – AEC 5

(Office Use Only)	File Number:	C2019/2047
	Meeting Number:	2019/4
PROJECT DETAILS		
1.1	Project title	
Antibody-based prevention of cell-associated SHIV infection in macaques		
1.2	Science leader	
s 22 [redacted]		
1.3	Principle Investigator	
s 22 [redacted]		
1.4	Original approval date	
23 Jan 2017, amendment approved 14 Nov 2017		
1.5	Completion date	
April 2019		
OBJECTIVES		
2.1	What were the objectives of this project stated in the original application? (Insert from original approved AEC 1 form question 2.1)	
A vaccine against HIV requires understanding the mechanisms of viral transmission. Most assessments of transmission involve exposing macaques to free viruses using SIV or SHIV. Such challenges provide robust reproducible infections. Previous studies have shown that, using the free virus challenge system, broadly neutralizing antibodies against the outer coat of the virus (the Envelope) provide high levels of immunity.		

s 47G(1)(a), s 47 [redacted]

s 47G(1)(a), s 47 [redacted]

2.2	Please provide details on how the objectives were achieved, or why they were not fully achieved.

s 47G(1)(a), s 47 [redacted]

ANIMAL USE	
3.1	How many animals of each species were originally approved?
24	
3.2	How many animals have been approved in subsequent AEC 6 modification requests?
6	
3.3	What was the total number of animals approved?
30	
3.4	How many animals were used?
26	
3.5	If fewer animals were used than approved, please explain why?
We did not complete studies s 47G(1)(a), s 47 [redacted].	
CLINICAL SIGNS & HUMANE KILLING OUTCOMES	
4.1	How many animals were humanely killed due to reaching the *humane endpoint*?
0	
4.2	How many animals were humanely killed or culled as part of the experimental design?
25	
4.3	If animals were humanely killed due to reaching the *humane endpoint*, what were the clinical signs observed?
NA	
4.4	How did the clinical signs described above correlate to the classification of clinical signs (mild, moderate or severe) described in table 14.4 of the original application?
NA	
4.5	How many animals were found dead during the experiment?
1	
4.6	What were the reasons for the deaths?
s 47G(1)(a), s 47C [redacted]	
WELFARE ISSUES	
5.1	Please provide a summary of the welfare of the animals during the experiment and whether it has been consistent with that anticipated in the project application.
All animals remained healthy throughout their time at AAHL and their welfare was consistent with that anticipated in the project application. Animals gained weight appropriately. There were no adverse events related to any of the procedures. There were no instances of immunodeficiency or SHIV disease in the animals.	
What improvements or problems in relation to animal welfare have been revealed during the experimentation? The following headings may act as guidelines.	
5.2	Husbandry, accommodation and diet.

In consultation with AAHL veterinary staff we reviewed our food-based enrichment activities and the diet of the animals. This resulted in an improvement in the behaviour of the animals.	
5.3	Expertise and equipment.
In consultation with AAHL veterinary staff we reviewed our animal training procedures, including clicker-based training for animals to enter the crush area of the cage. This resulted in an improvement of animal engagement and mental stimulation.	
5.4	Experimental procedures.
See below	
5.5	Analgesia and euthanasia.
In consultation with AAHL staff and the AEC we evaluated reversible BDAK sedation rather than Ketamine alone during this protocol. We found this to work effectively and result in the animal waking up more quickly from sedation. We provided a report to the AEC on this in Dec 2018.	
5.6	Other.

s 47G(1)(a), s 47C

[redacted]

s 47G(1)(a), s 47C

[redacted]

s 47G(1)(a), s 47C

[redacted]

s 47G(1)(a), s 47C

[redacted]

s 47G(1)(a), s 47C

[redacted]