Updated By: [redacted] @ 12-Dec-2016 09:13:02 PM

Application Form AE / Bio-Safety v3.02

General Information

Completion of Application

Research Type:

Select the purpose for this Application: * 1. Research

General:

Protocol Number:	001811
Project Title:	Mapping Gastrointestinal Bioelectrical Activity and Motility in Pigs
Responsible Investigator:	[redacted]
Department:	*Bioengineering Institute

Project Funding - Research:

?

1: Please indicate how the project is funded:

Public good or academic research:	100	%
Commercially funded contract:		%
=	100	%[must equal 100]

*2a: Has the proposed work been peer reviewed as part of a successful funding application?
Yes

Note: for NIH funding applications our Animal Welfare Assurance Renewal number is #A5014-01.

*2b: Is this project (partially) funded by Uniservices?
No

*2d: The following (other) granting body has allocated (additional) funds specifically for work covered by this proposal:
HRC, MedTech CoRE

*2e: The following (University of Auckland) colleague(s) - not named as personnel in this application - could provide local expert comment, if required:
Prof. Ian Bissett (Surgery)

Other:

* 3a: Will any Genetically Modified Organisms (animals, cells, bacteria etc.) be used during the manipulations described in this application?
No

Please indicate from which other bodies approvals or permits for this project are required:

?

- ☐ The University of Auckland - Biological Safety Committee
- ☐ The University of Auckland - Human Ethics Committee
- ☐ Another Animal Ethics Committee
- ☐ Department of Conservation
- ☐ Other (please specify)

Section A: UoA Personnel

Personnel - Review

(Add Personnel - Review
)

Personnel - Review

Name of UoA Personnel: [redacted]

RI	Start Date	End Date	Role	E-Mail:
☑	04-Oct-2016		PI	[redacted]

Certification Begin End
- - - Certifications

No response is required for Start Date, End Date and Certifications

*Qualifications: ?☐
PhD (Bioengineering)

Please confirm whether you have completed the following training modules:

Yes *Module 1 - Legislation

No *Module 2a - Handling, sexing and euthanasia of rodents

No *Module 2b - Handling, sexing and euthanasia of rabbits and guinea pigs

Please refer to the Animal Ethics website for details of how to register for these Module(s).

*Experience: ?☐
More than 10 years experience with animal studies including PI for multiple ethics applications conducting similar studies.

Categories of procedures to be performed:

☐ Manipulation

☑ Monitoring

☐ Euthanasia

Note: All personnel named in the application are required to sign the 'Details of Personnel' form. This can be downloaded here. Once all the personnel have read and signed this form, the document needs to be uploaded into 'Section G: Attachments'.

Note: To prevent any loss, please save your work regularly by clicking on the 'save' icon located at the top left corner of this application form!

Personnel - Review

Name of UoA Personnel: [redacted]

RI	Start Date	End Date	Role	E-Mail:
☐			Co-Inv	[redacted]

Certification Begin End
- - - Certifications

No response is required for Start Date, End Date and Certifications

*Qualifications: ?☐
MSc

Please confirm whether you have completed the following training modules:

No *Module 1 - Legislation

No *Module 2a - Handling, sexing and euthanasia of rodents

No *Module 2b - Handling, sexing and euthanasia of rabbits and guinea pigs

Please refer to the Animal Ethics website for details of how to register for these Module(s).

*Experience: ?☐
[redacted] is a new PhD student with limited experience in animal studies. He will be supervised by [redacted] who are members of the same research group. In addition, [redacted] will be present and supervise all studies.

Categories of procedures to be performed:

☐ Manipulation

☑ Monitoring

☐ Euthanasia

Note: All personnel named in the application are required to sign the 'Details of Personnel' form. This can be downloaded here. Once all the personnel have read and signed this form, the document needs to be uploaded into 'Section G: Attachments'.

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Personnel - Review

Name of UoA Personnel: [redacted]

RI	Start Date	End Date	Role	E-Mail:
☐			Co-Inv	[redacted]

Certification Begin End
- - - Certifications

No response is required for Start Date, End Date and Certifications

*Qualifications: ?☐
PhD Bioengineering

Please confirm whether you have completed the following training modules:

Yes *Module 1 - Legislation

No *Module 2a - Handling, sexing and euthanasia of rodents

No *Module 2b - Handling, sexing and euthanasia of rabbits and guinea pigs

Please refer to the Animal Ethics website for details of how to register for these Module(s).

*Experience: ?
Approximately 6 years experience conducting similar studies.

Categories of procedures to be performed:

☑ Manipulation

☑ Monitoring

☐ Euthanasia

Note: All personnel named in the application are required to sign the 'Details of Personnel' form. This can be downloaded here. Once all the personnel have read and signed this form, the document needs to be uploaded into 'Section G: Attachments'.

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Personnel - Review

Name of UoA Personnel: [redacted]

RI	Start Date	End Date	Role	E-Mail:
☐			Co-Inv	[redacted]

Certification Begin End
- - - Certifications

No response is required for Start Date, End Date and Certifications

*Qualifications: ?
PhD Bioengineering

Please confirm whether you have completed the following training modules:

Yes *Module 1 - Legislation

No *Module 2a - Handling, sexing and euthanasia of rodents

No *Module 2b - Handling, sexing and euthanasia of rabbits and guinea pigs

Please refer to the Animal Ethics website for details of how to register for these Module(s).

*Experience: ?
Approximately 6 years experience conducting similar studies.

Categories of procedures to be performed:

☐ Manipulation

☑ Monitoring

☐ Euthanasia

Note: All personnel named in the application are required to sign the 'Details of Personnel' form. This can be downloaded here. Once all the personnel have read and signed this form, the document needs to be uploaded into 'Section G: Attachments'.

Note: To prevent any loss, please save your work regularly by clicking on the 'save' icon located at the top left corner of this application form!

Personnel - Review

Name of UoA Personnel: [redacted]

RI	Start Date	End Date	Role	E-Mail:
☐			Co-Inv	[redacted]

Certification Begin End
- - - Certifications

No response is required for Start Date, End Date and Certifications

*Qualifications: ?
MBChB, Surgical Trainee.

Please confirm whether you have completed the following training modules:

Yes *Module 1 - Legislation

No *Module 2a - Handling, sexing and euthanasia of rodents

No *Module 2b - Handling, sexing and euthanasia of rabbits and guinea pigs

Please refer to the Animal Ethics website for details of how to register for these Module(s).

*Experience: ?
Gastrointestinal surgical trainee. Conducting PhD in surgery. Has had limited experience in animal studies. He will be supervised by [redacted] who are members of the same research group. In addition, [redacted] will be present and supervise all studies.

Categories of procedures to be performed:

☑ Manipulation

☑ Monitoring

☐ Euthanasia

Note: All personnel named in the application are required to sign the 'Details of Personnel' form. This can be downloaded here. Once all the personnel have read and signed this form, the document needs to be uploaded into 'Section G: Attachments'.

Note: To prevent any loss, please save your work regularly by clicking on the 'save' icon located at the top left corner of this application form!

Personnel - Review

Name of UoA Personnel: [redacted]

RI	Start Date	End Date	Role	E-Mail:
☐				[redacted]

Certification Begin End
- - - Certifications

No response is required for Start Date, End Date and Certifications

*Qualifications: ?☐
Certificate in Veterinary Nursing;
Certificate in Laboratory Animal Science

Please confirm whether you have completed the following training modules:

Yes *Module 1 - Legislation

Yes *Module 2a - Handling, sexing and euthanasia of rodents

Yes *Module 2b - Handling, sexing and euthanasia of rabbits and guinea pigs

*Experience: ?☐
[redacted] is an experienced animal technician, with extensive knowledge in manipulations, monitoring, and euthanasia of animals.

Categories of procedures to be performed:

☑ Manipulation

☑ Monitoring

☑ Euthanasia

Note: All personnel named in the application are required to sign the 'Details of Personnel' form. This can be downloaded here. Once all the personnel have read and signed this form, the document needs to be uploaded into 'Section G: Attachments'.

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Personnel - Review

Name of UoA Personnel: [redacted]

RI	Start Date	End Date	Role	E-Mail:
☐			Co-Inv	[redacted]

Certification Begin End
- - - Certifications

No response is required for Start Date, End Date and Certifications

*Qualifications: ?☐
FRACS, PhD Surgery

Please confirm whether you have completed the following training modules:

Yes *Module 1 - Legislation

No *Module 2a - Handling, sexing and euthanasia of rodents

No *Module 2b - Handling, sexing and euthanasia of rabbits and guinea pigs

Please refer to the Animal Ethics website for details of how to register for these Module(s).

*Experience: ?☐
Approximately 6 years experience conducting similar studies. Trained in general surgery.

Categories of procedures to be performed:

☑ Manipulation

☑ Monitoring

☐ Euthanasia

Note: All personnel named in the application are required to sign the 'Details of Personnel' form. This can be downloaded here. Once all the personnel have read and signed this form, the document needs to be uploaded into 'Section G: Attachments'.

Note: To prevent any loss, please save your work regularly by clicking on the 'save' icon located at the top left corner of this application form!

Personnel - Review

Name of UoA Personnel: [redacted]

RI	Start Date	End Date	Role	E-Mail:
☐			Co-Inv	[redacted]

Certification Begin End
- - - Certifications

No response is required for Start Date, End Date and Certifications

*Qualifications: ?☐
PhD Bioengineering

Please confirm whether you have completed the following training modules:

Yes *Module 1 - Legislation

No *Module 2a - Handling, sexing and euthanasia of rodents

Yes *Module 2b - Handling, sexing and euthanasia of rabbits and guinea pigs

Please refer to the Animal Ethics website for details of how to register for these Module(s).

*Experience: ?☐
Approximately 6 years experience with animal studies.

Categories of procedures to be performed:

☑ Manipulation

☑ Monitoring

☐ Euthanasia

Note: All personnel named in the application are required to sign the 'Details of Personnel' form. This can be downloaded here. Once all the personnel have read and signed this form, the document needs to be uploaded into 'Section G: Attachments'.

Note: To prevent any loss, please save your work regularly by clicking on the 'save' icon located at the top left corner of this application form!

Section A: non-UoA Personnel

UoA Personnel not found in the HR List or addition of non UoA Personnel:

First & Last Name:	Email:	Role:	Qualifications:	Experience:	#Man	#Mon	#Eut	*Mod 1	*Mod 2a	*Mod 2b
[redacted]		Co-Inv	PhD	Limited	☐	☑	☐	No	No	No

Section B: Description

B.1: Protocol Number:
001811

*B.2: Project Title:
Mapping Gastrointestinal Bioelectrical Activity and Motility in Pigs

* B.3: Lay Summary: ?

The digestive tract includes the stomach, small and large intestine. Each of these organs has electrical activity that coordinates the contractions of the digestive tract necessary for the digestion of food. If this electrical activity becomes uncoordinated it can lead to clinical disorders such as indigestion and vomiting. We seek to improve the understanding of normal and abnormal electrical activity in the intact digestive tract by recording and modulating this electrical activity. Our ultimate aim is to improve the treatment of human digestive disorders.

*B.4: Describe why animals are needed for this project: ?

We have made encouraging gains to our understanding of gastrointestinal bioelectrical activity as part of previous studies conducted in pigs. However, our current understanding of gastrointestinal electrophysiology remains relatively limited. In our proposed studies we will continue to refine our understanding of normal and abnormal activity in the stomach and small intestine. We will also begin to apply and adapt our experimental techniques to the large intestine.

We are primarily interested in whole organ function. Therefore, the information that can be obtained from cell and tissue cultures are known to not reliably reflect whole organ activity. We have already developed, and continue to, develop sophisticated mathematical models of gastrointestinal electrical activity. However, these models require appropriate validation from experimental data. The knowledge we gain from these studies will also be used to improve mathematical models, thereby reducing the number of animal studies required in the future.

In the long-term, the information we obtain from these studies will be used to inform and improve treatment of human functional gastrointestinal disorders. Therefore, the potential scientific and clinical benefits from this work outweigh any ethical concerns on animal welfare.

*B.5: Describe how the experimental findings will be used, promoted or published at the conclusion of the study: ?

The findings will be presented at local and international conferences and will be published in peer-reviewed scientific journals. Work conducted as part of this ethics application will be incorporated into two PhD theses.

*B.6a: Are the experiments an extension of previous animal studies from your laboratory?
Yes

*B.6b: Please provide the AEC reference number of the previously approved study:
001459

*B.6c: Has an End of Approval report of the previous study been submitted to the AEC yet?
No

*B.6d: Please provide a short report, or references to any publication, in which the study has been reported:
Our previous ethics application (001459) completes in Feb 2017. We had no adverse advents to report. We have published a number of articles (and a number are currently in press). This ethics application will replace ethics application 001459.

A novel retractable laparoscopic device for mapping gastrointestinal slow wave propagation patterns. Berry R, Paskaranandavadivel N, Du P, Trew ML, O'Grady G, Windsor JA, Cheng LK. Surgical Endoscopy. 2016; Epub ahead of print. PMID: 27129554

Time Delay Mapping of High-Resolution Gastric Slow Wave Activity. Paskaranandavadivel N, O'Grady G, Cheng L. IEEE transactions on bio-medical engineering. 2016; PubMed PMID: 27071158

Multi-channel wireless mapping of gastrointestinal serosal slow wave propagation. Paskaranandavadivel N, Wang R, Sathar S, O'Grady G, Cheng LK, Farajidavar A. Neurogastroenterology and motility : the official journal of the European Gastrointestinal Motility Society. 2015; 27(4):580-5. NIHMSID: NIHMS653242 PubMed PMID: 25599978 PMCID: PMC4380526

*B.7a: Do these experiments repeat work performed by you or others?
No

Section C: Animal Use

Species and Strains to be used:
IMPORTANT: Please click on the yellow '+' icon to add a species or strain. Fill out the details for each species and/or strain.

Species:	Strain:	Usage:	Tot. No. req'd for Project	Sex:	Age Range:	Weight Range:
1k - Pigs	white cross-breed	Manipulation	24	Female	<1 year	35-50kg

Please justify species selection:

For each of the species and strains listed, please explain why you need to use this specific species and strain of animal i.e. explain why this animal is appropriate on scientific, technical, humanitarian and/or educational grounds for the procedures proposed.
Our group has significant experience with conducting equivalent studies in pigs and humans. Pigs have similar anatomy and size to humans and are therefore a good model for our studies, prior to translating our techniques to human studies. The continued use of this model means we will not need to perform additional studies to define normal baseline activity.

If your response to this question exceeds 4000 characters (including spaces), please (a) write "Refer to attachment" in the field above and (b) upload a word document of your response in 'Section G: Attachments'.

AFM Approval

* If the animals are being obtained from, or are being housed in an animal facility, has the facility manager confirmed in writing that the proposal can be accommodated within the resources of the facility?
Before submitting this application, please obtain confirmation from the facility manager, as this is a requirement of the AEC. The AEC will not approve an application unless written confirmation has been received. Please upload the written confirmation into section G.

Yes

Animal Usage Statistics

Species section(Add Species section)

Species section

1k - Pigs

Note: Admin use only! Please ignore the fields above.

* 1. Please select the Usage Type for this Species: Manipulation

2. Source of Animals:	Number:
Breeding Unit	
Commercial	24
Farm	
Born during project	
Captured	
Imported into NZ	
Public sources	
TOTAL:	* 24

5. Re-Use:	Number:
No prior use	
Previously used	

6. Grading:	Number:
No impact - A	
Little impact - B	24
Moderate impact - C	
High impact - D	
Very high impact - E	

3. Status of animals:	Number
Normal/Conventional	24
SPF/germ free	
Diseased	
Transgenic/Chimera	
Protected Species	
Unborn/prehatched*	
Other	

7. Alive:	Number:
Retained [by institution]	
Returned [to owner]	
Released [to the wild]	
Disposed [to works or rehomed]	
Total Alive:	* 0

4. Purpose:	Number:
Teaching	
Species conservation	
Environmental management	
Animal husbandry	
Basic biological research	
Medical research	24
Veterinary research	
Testing	
Production of biological agents	
Development of alternatives	
Other	

8. Dead:	Number:
Total Dead	* 24

9. Total manipulated/used:	* 24

Notes:

* The Animal Welfare Act (1999) describes pre-natal stages as 'any mammalian foetus, or any avian or reptilian pre-hatched young, that is in the last half of its period of gestation or development; the definition includes any marsupial pouch young'. This means that the mothers and young are required to be added as separate groups in Table 3. The young will have the status 'Unborn/prehatched' box, and the mothers whichever status is appropriate with reference from the AWA to the stages which are specifically excluded e.g. larval stages.

IMPORTANT:

Note: To prevent any loss, please save your work regularly by clicking on the 'save' icon located at the top left corner of this application form!

Section D: Scientific description of the project

*D.1: The aim of the experiments: ?❐

These studies aim to:
1. Develop and validate new flexible and suction based electrodes for recording gastrointestinal bioelectrical activity in pigs.
2. Develop and validate new electrode platforms for recording gastric electrical activity from the mucosal surface of the gastrointestinal tract.
3. Modulate gastrointestinal bioelectrical activity by an external stimulator or ablation techniques.
4. Obtain manometric (pressure) measurements from the gastrointestinal tract to determine flow patterns.

* D.2: The design of the experiments: (max 4000 characters) ?❐

Pigs (35-50 kg) will delivered to the [redacted] at the Grafton campus of the University of Auckland on the morning of the study. On rare occasions 2 pigs may delivered, and 1 of the pigs may be housed overnight.

The studies will be conducted in the [redacted] Anaesthesia will be induced and maintained as per SOP914.

The following interventions will be carried out on the fully anesthetised animals. A midline incision will be made along the abdomen, exposing the gastrointestinal tract.

(i) Electrode platforms will be placed on/attached to the surface of the stomach/intestine and connected to an electrophysiological mapping system (e.g., Biosemi ActiveTwo, Amsterdam, Netherlands).

(ii) Electrodes from bioelectrical stimulator (e.g., a DS8000 World Precision Instruments, Sanasota, FL, USA) will be inserted into the wall of the stomach/intestine or in close proximity to nerves (e.g., sacral nerve, vagal nerve) and the stimulated with small bioelectrical charges, following a predetermined duration and frequency protocol.

(iii) Radio-frequency ablation techniques will be applied to the surface of the gastrointestinal tract to create lesions or functional blocks in the tissue.

(iv) A pressure sensing catheter (e.g. a high-resolution fibre-optic based) catheter may be inserted into the gastrointestinal tract to sense pressure.

(v) Endoscopic guidance may be used to assist with visualisation of the gastrointestinal tract.

Electrical signals from each electrode will be recorded. The spatial location of “activation times” from each electrode will be determined by sharp deflections in the signal traces. By combining this information from an array of electrodes an “activation map” can provide information about the propagation patterns of the electrical activity. In addition, information such as frequency, velocity and amplitude can also be characterised. We will aim to record information from the stomach, small intestine and large intestine with n=8 animals dedicated to each organ (total n=24). In some cases, we will be able to be to record from multiple organs of the same animal, however, from experience, prolonged studies (due to anaesthesia, cooling and handling) can result in unreliable electrical recordings.

On completion of the study, the animal will be euthanized while under anaesthesia.

Note: If required, please attach any supplementary information on the experimental design, including any tables, flowcharts, pictures, etc which would assist the AEC in assessing this application, and upload to Section G.

*D.3a: Will the animals be captured in the wild?
No

Manipulation:

* D.4a: Please describe the following for each surgical or non-surgical manipulation that the animals will undergo: i.e. drug in drinking water, injection or dietary supplementation (max 4000 characters) : ?❐

(Manipulation 1) Following laparotomy, the bio-electrical activity will be recorded from the wall of the gastrointestinal system via electrodes placed or attached to the surface of the musculature.

(Manipulation 2) Electrical stimulation may be injected into the gastrointestinal wall to “entrain” or control the underlying bio-electrical activity.

(Manipulation 3) Abalation techniques may be used to create lesions (or functional blocks) in the gastrointestinal tissue.

(Manipulation 4) Pressure sensing catheters may be placed within the gastrointestinal tract to detect contractions of the musculature.

(Manipulation 5) An endoscope or camera may be

placed within the gastrointestinal tract to aid in visualisation.

* D.4b: The extent and duration of the manipulation(s): ?
Each study (surgery and manipulation is expected to last approximately 4-5 hours). Animals will be anaesthetised for the entire procedure and the gastrointestinal tract used for in-vivo studies of bioelectrical activity as above. Animals will be euthanized at the completion of the study while still under anaesthesia.

* D.4c: The extent to which the animals may experience pain or distress during or after any of the manipulations, and which signs may be seen: ?
The animals may experience some initial mild discomfort during the administration of the anaesthetic. However, after this the animal will be fully anesthetised for the remainder of the experiment.

* D.4d: Please explain why this extent of pain or distress is unavoidable:
The distress during the administration of anaesthetic will be minimised by handling the pigs in a gentle, calm and quiet manner. A short period of discomfort is tolerated well and allows a smooth transition to surgical anaesthesia.

* D.4e: Describe the pain management plan that has been developed for the alleviation of pain: ?
There is no analgesia provided for the pigs in these acute terminal studies. The animals will experience brief pain and distress during induction of anaesthesia and remain under surgical depth of anaesthesia until euthanasia on completion of our study. Depth of anaesthesia will be confirmed with palpebral reflexes and surgery will not be initiated until it is ensured that the animals are in a deep anaesthetic state.

* D.4f: Detail the post manipulation care and/or any special housing needs:
N/A

* D.4g: Explain the monitoring procedures and contingencies that will be in place to detect and limit signs of pain or distress: ?
A surgery record and welfare monitoring sheet will be used. Vital signs such as temperature, heart rate, blood pressure, and end-tidal CO2 measurements will be monitored and recorded on the surgery record throughout the studies. The study will be terminated should any adverse events be encountered.

* D.4h: Describe the humane endpoints that will be applied if applicable i.e. specific clinical signs being shown by an animal that will require its immediate euthanasia. ?
As this is an acute study, the animals will be euthanised at the completion of the study. Humane endpoints relate solely to the period under anaesthesia. Pigs will be routinely monitored throughout the study and details documented on the Monitoring Sheet. Anaesthesia is known to cause dose dependent respiratory and cardiovascular depression and routine monitoring of the depth or plane of anaesthesia is essential. Respiration rate will be maintained via the ventilator and heart rate, blood pressure, ECG and palpebral reflexes observed. If there is any question that the pig cannot be maintained under a satisfactory plane of surgical anaesthesia, it will be euthanased immediately.

In addition, if IV access cannot be obtained or maintained, or intubation and ventilation cannot be achieved or maintained, or haemorrhage occurs that cannot be easily controlled, then immediate euthanasia will be performed. These decisions will be taken in close consultation with our experienced animal anaesthetic technician.

* D.5a: Will the animals undergo any new manipulations not described in previous applications you have submitted to the Committee?
No

*D.6a: Will neuromuscular blockade be used?
No

* D.7a: Will the animals be killed at any stage during the experiment?
Yes

D.7b: Please select the technique/s used: ?

☑ Anaesthetic overdose	☐ Blunt trauma	☐ Captive Bolt
☐ Cervical dislocation	☐ Decapitation	☐ Exsanguination
☐ Injection	☐ Pithing	☐ Poisoning
☐ Sharp trauma	☐ Snap traps	☐ Chilling in ice water
☐ Intracardiac injection of potassium citrate	☐ CO2	☐ Other

Methods of euthanasia should be selected with reference to the ANZCAART Guidelines. A copy of this is also available on the Animal Ethics web page. If a prescription drug is to be used, please state that "animals will be euthanized as per the IDAO", complete an IDAO form and attach it to 'Section G: Attachments'.

* D.8: For the animals that are killed for tissue collection only, have other researchers that may be interested in the other tissues been notified?

Yes

* D.9: Describe any other animal welfare or ethical implications of this project:
N/A

*D.10: Describe why the nominated number of animals is needed: ?❐
The planned experiments are largely technical in nature, being focused on novel medical devices, and pre-clinical validation studies. Biological variability therefore is not formally factored into our primary outcomes, and formal power calculations are therefore not necessary to determine the number of animals needed. This strategy allows us to keep our animal requirement low. We are experienced in large-animal bioengineering studies, and generally 5-8 animals have proved sufficient to achieve publication of our technical work to date (refer to passed publications). In addition, multiple experiments will be conducted in each pig (depending on the specific aims), meaning that we are able to be particularly efficient with our overall animal burden for this proposal. This means that with only a relatively small number of animals are needed to achieve several experimental outcomes. Our estimate based on these factors is that 24 animals will be sufficient altogether to meet the current goals, although if the goals are met sooner, then we will use fewer animals.

D.11: Detail where the experiments will be conducted:

	Building:	Room Number:
a. before experimentation	[redacted]	[redacted]
b. during manipulation		
c. after manipulation		
d. disposal		

* D.12: Estimated period of housing per animal: ?❐
Animals and will be delivered on the morning of the study and will be euthanized at the end of the acute study. Housing will therefore not be required.

On some occasions, when studies are scheduled for consecutive days, two pigs will be delivered and one pig may be housed overnight in [redacted] Floor pens. When housing of a pig is required, it will be conducted in accordance with the SOP835 which has been approved for the [redacted] large animal area.

D.13: Describe how this study has taken into account the purpose of the Animal Welfare Act 1999 to promote the principles of Refinement, Reduction and Replacement that govern the use of animals in research, testing and teaching (the 3 R's). In particular, describe the extent to which you have:

(i) assessed the possibility of using non-sentient or non-living alternatives in the project; and
(ii) replaced animals as subjects with suitable non-sentient or non-living alternatives where possible; and
(iii) identify the sources you have used to make the assessment under (i), and the methods you have used to consider any replacement under (ii) - e.g. Animal Welfare Information Centre, www.nc3rs.org.uk or internet search engines.

*a. Refinement: ?❐
These refined studies comprise the welfare, anaesthesia and monitoring techniques well established by the experienced staff in the large animal facility. These will be monitored and maintained until euthanasia occurs on completion of the study.

Our mapping approaches are already well validated, having been refined already by our group in previous work in the same acute weaner pig model. In addition, any new techniques to be introduced or applied will be first extensively tested in a benchtop setting prior to application in experimental animal studies, allowing prior refinement of methods. These approaches allow us to keep experimental failures to a minimum, ensuring high animal use efficiency.

*b. Reduction: ?❐
The number of animals proposed for this study are necessary to refine and adapt our existing slow wave mapping techniques. We will reduce the total number of animals used by combining different studies in each animal (e.g., small intestine/colon/stomach in conjunction different electrode platforms).

In addition, our group are world leaders of the 'Virtual Gut' project, involving the development of mathematical 'in-silico' models of physiology. This strategy has successfully enabled major reductions in our animal numbers in multiple experimental series. The current work will contribute to the further development and refinement of these models, which we will continue to publish freely, meaning that our group is making a substantive progressive global contribution to reducing animal model research in gut motility through this work.

*c. Replacement: ?❐

As above, our group are world leaders in the replacement of animal models for research in gut motility, having introduced and published multiple in-silico models from our previous pig work. However, there remains a justified need to use animals where experimental data is lacking or where new techniques must be validated in animals prior to clinical applications (in human subjects). For the present aims, we have reviewed the possible role of in-silico modelling, and find that the proposed number of in-vivo animal studies are necessary and further replacement is not possible.

[
We have investigated alternatives to the use of animals (including human volunteers, tissues and cell lines). We searched the databases: pubmed, google scholar and www.nc3rs.org.uk using the terms "alternative slow wave gastrointestinal model". From the search results, no viable alternatives were detected.

As part of our research, we have previously (and will continue to) translate our techniques to human volunteers once our methods and techniques have first been refined and deemed safe in an animal model.
]

Section E: Brief Synopsis of current work

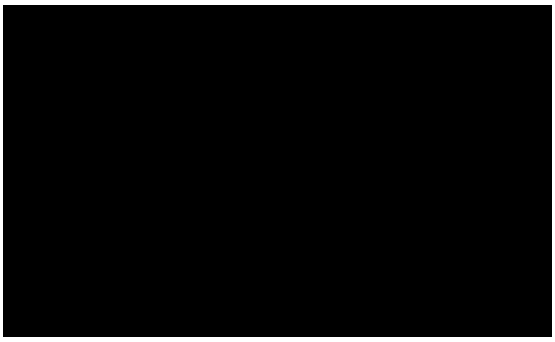
Please list all current University of Auckland Animal Ethics Committee approved protocols. Please detail the species and number of animals used/manipulated/observed for each, to date. Then add a one or two sentence summary of scientific progress to date.

AEC Number:001459

Species & No. of animals approved
Pig (24)

Species & No. of animals used
Pig (22)

Summary of progress to date
We have made good progress to date and had not had any adverse advents. A number of publications have been published based upon this work (see selected references below) and one PhD thesis has been submitted for examination. Additional publications are currently being prepared for publication.



AEC Number:001458

Species & No. of animals approved
Rabbit (12)

Species & No. of animals used
Rabbit (7)

Summary of progress to date
We have made good progress to date and had not had any adverse advents. One publication is currently being prepared. Further, followup studies are being planned.

AEC Number:

Species & No. of animals approved

Species & No. of animals used

Summary of progress to date

AEC Number:

Species & No. of animals approved

Species & No. of animals used

Summary of progress to date

AEC Number:

Species & No. of animals used

Species & No. of animals used

Summary of progress to date

Section F: References

List a reasonable number of references (5 - 10), either by the investigators or others that the committee would find helpful in assessing your application:
(In date order)

Egbuji, J.U., O'Grady, G., Du, P., Cheng, L.K., Lammers, W.J., Windsor, J.A. & Pullan, A.J., 2010. Origin, propagation and regional characteristics of porcine gastric slow wave activity determined by high-resolution mapping. Neurogastroenterol. Motil., 22(10), pp.e292–300.

O'Grady, G., Du, P., Lammers, W.J., Egbuji, J.U., Mithraratne, P., Chen, J.D., Cheng, L.K., Windsor, J.A. & Pullan, A.J., 2010. High-resolution entrainment mapping of gastric pacing: a new analytical tool. Am. J. Physiol. Gastrointest. Liver Physiol., 298(2), pp.G314–21.

Paskaranandavadivel, N., Wang, R., Sathar, S., O'Grady, G., Chen, Y. & Farajidavar, A., 2015. Multi-channel wireless mapping of gastrointestinal serosal slow wave propagation. Neurogastroenterol. Motil., 27(4), pp.580–5.

Berry R, Paskaranandavadivel N, Du P, Trew ML, O'Grady G, Windsor JA, Cheng LK. A novel retractable laparoscopic device for mapping gastrointestinal slow wave propagation patterns. Surgical Endoscopy. 2016; Epub ahead of print. PMID: 27129554

Paskaranandavadivel N, O'Grady G, Cheng L. Time Delay Mapping of High-Resolution Gastric Slow Wave Activity. IEEE transactions on bio-medical engineering. 2016; PubMed PMID: 27071158

Section G: Attachments

Document Name:	Document Version:	In reference to Question No.?	
Signed ro55	1	Section A	
Surgery Monitoring Sheet	1	D.4g	
Animal Facility Manager Letter	1	Section C	
SOP835	1	D12	

SOP914	1	D2	
IDAO 914-2	1	D2	
Memo addressing questions and comments	1		

Feedback

Please help us to improve this system by providing feedback on your experience with creating this eForm application: include all your positive and negative experiences as well as what improvements you would like to see in using this application.
Animal usage statistics were unable to be entered (due to browser scripting errors). We tried different computers and browsers without success.

The way personnel are selected was very time consuming - it took 5-10 minutes to add each person as I was on a slow internet connection. I would suggest there is a way of hiding all the people who have left the university. It might be a good idea to group people from within a department (rather than searching by name alone).

I was unable to the email address of the non-UOA person as their email address was too long for the box!
Email address is: [redacted]

*Is this Application now complete and ready for submission?
Yes

Appendix 1

EForm Name: AE and Bio-Safety Form v3.02

Page:

Section: **Section G: Attachments**
Please list all attachments appended in support of this application:

Question:

File Name: 201610110923.pdf

Animal Ethics Application - Details of Personnel

Ref No: 001811

Every person named in the Personnel section of this application (other than the RI and HoD) shall complete and sign the following declaration:

1. I have read the University of Auckland Code of Ethical Conduct available at www.auckland.ac.nz/ae.
2. I have read this application and approve the approach to the study, with particular reference to the ethics of experimentation and the welfare of the animals being used.
3. I agree that I will not deviate from the conditions in the approved application.
4. I have read and agree to abide by the University of Auckland Institutional Operating Plan for the Direct Management of Animals.
5. I have read and I agree to abide by any Institutional Drug Administration Orders (IDAOs) linked to this ethics approval.
6. In accordance with Part 6, Section 80, Paragraph 2 of the Animal Welfare Act 1999, I will ensure that:
   (i) in relation to animals used in research, testing, and teaching, all reasonable steps are taken to ensure that the physical, health, and behavioural needs of those animals are met in accordance with both good practice and scientific knowledge;
   (ii) where animals used in research, testing, and teaching are ill or injured, they receive, where practicable, treatment that alleviates any unreasonable or unnecessary pain or distress;
   (iii) where, because of the nature of the research, testing or teaching, the needs referred to in subparagraph (i) cannot be fully met or the treatment referred to in subparagraph (ii) cannot be provided, any degree of pain or distress is reduced to the minimum possible in the circumstances.

	Personnel	Signature	Date	Contact No.
1.	[redacted]	[redacted]	5/10/16	[redacted]
2.			5/10/16	
3.			5/10/16	
4.			5/10/16	
5.			5/10/16	
6.			5/10/16	
7.			5/10/16	

Please nominate two of these named individuals who may be contacted 24 hours 7 days if any animal health or welfare issues arise outside the normal working hours of the facility in which you will carry out the manipulations in this protocol.

If the work proposed in this application will take place in the [redacted] FM&HS, only these two investigators (*please provide Access card numbers) will be granted 24/7 access to the [redacted] The others will receive access from 0800 until 1800, 7 days a week.

Name:	Mobile No:	Work No:	Home No:	*Access Card No:
[redacted]		[redacted]		

Appendix 2

EForm Name: AE and Bio-Safety Form v3.02

Page:

Section: **Section G: Attachments**
Please list all attachments appended in support of this application:

Question:

File Name: Pig Surgery Record.doc

Mapping Gastrointestinal Bioelectrical Activity and Motility in Pigs

AEC approval – 001811
Responsible Investigator – [redacted]
Auckland Bioengineering Institute

Pig # -	**IDAO #** - SOP914/2
Surgery Date -	Zoletil dosage – 10mg/kg
Breed -	Zoletil dose -
Gender -	Route of administration - IM neck/leg
Weight at surgery -	

Surgery Procedure	Time	Comment
Induction of Anaesthesia		
Intubation		
I.V Fluids start		
Surgery start		
Experiment complete		

Time	Temp.	Iso. %	O2 L	Resp.Rate	Tidal Vol.	CO2	BP	Comment

Comments:

Appendix 3

EForm Name: AE and Bio-Safety Form v3.02

Page:

Section: **Section G: Attachments**

Please list all attachments appended in support of this application:

Question:

File Name: animalfacility.jpg

THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND HEALTH SCIENCES

[redacted]
Faculty of Medical and Health Sciences,
The University of Auckland,
Grafton, Auckland

Dear Researcher/AEC Secretary,

This is to confirm that the [redacted] is a
to supply the following animals:

Species: Pig

Sex: Female

Age and or weight: 35 – 55kg

Total number: 24

This is to confirm that the [redacted] can house the following animals:

Number: 24

Duration: Overnight if required

Type of housing: Floor pens

As detailed in the Ethics application for

Responsible Investigator Name: [redacted]

Department / Institution: ABI

Ethics Project Title (section B2 of application): Mapping Gastrointestinal Bioelectrical Activity and Motility in Pigs

[redacted] Manager

Name: [redacted]

Signature: [redacted]

Date: 11/10/16

Appendix 4

EForm Name: AE and Bio-Safety Form v3.02

Page:

Section: **Section G: Attachments**
Please list all attachments appended in support of this application:

Question:

File Name: SOP 914 v2 Apr2015.docx

UNIVERSITY OF AUCKLAND [redacted] STANDARD OPERATING PROCEDURE	Effective From : 1/4/2015 Review date: 31/3/2017 AEC Ref: SOP914

Title: Anaesthesia and Euthanasia of Sheep and Pigs in the [redacted] and MRI.		
	Print name	Signed
[redacted] Authorised	[redacted] (Business Manager)	[redacted]

Table of Contents

1. Purpose

The procedures in this SOP describe the methods to be used by University of Auckland staff for the induction and maintenance of anaesthesia and for the euthanasia of sheep and pigs used for research and teaching purposes under AEC approvals.

2. Definitions

2.1 [redacted]
2.2 MRI – Magnetic Resonance Imaging.
2.3 AWO – Animal Welfare Officer.

3. Responsibility

3.1 The procedures shall only be carried out by University of Auckland animal technicians who have been trained in the handling of large animals (Module 2c), in the use of injectable and inhalation anaesthetics and drugs used for euthanasia, and who have been signed off as competent in their training file.
3.2 All members of staff engaged in this procedure must comply with this SOP and any related SOPs and documentation.

4. Equipment

4.1 Appropriate PPE
4.2 Isoflurane anaesthetic machine and scavenging system
4.3 Ventillator and/or re-breathing bag
4.4 Oxygen cylinder and portable anaesthetic machine for anaesthesia in the MRI
4.5 Anaesthetic monitoring system.
4.6 Operating table.
4.7 Laryngoscope.

5. Procedures

5.1 Pre-anaesthetic checks.

Pre-anaesthetic checks of equipment shall be carried out prior to the induction of anaesthesia in sheep or pigs.

These checks shall include the following:

- Check that there is an adequate supply of oxygen and that it is properly attached to the anaesthetic machine.
- For anaesthetics in the MRI unit, a cylinder of oxygen is required. Check that it contains an adequate amount of oxygen.
- Check that the flowmeters are functioning correctly by opening the cylinder valves and opening the needle valves that control the flow of gas through the flowmeters. The bobbins should rotate when gas is flowing. The gas flow rate is measured from the top of the bobbin.
- Turn off the gas flow using the needle valve and check that the bobbin sinks smoothly back to zero, and is not sticking and giving a false high gas flow rate.
- Check that the emergency oxygen switch on the machine is functioning correctly.
- If an anaesthetic circuit with valves is to be used, open them fully and check that they are operating correctly.
- Check that the Isoflurane vaporizer has been filled, that the bungs are in the correct place and that the control dial moves smoothly over the entire range of possible settings.
- Check that the connection tube is correctly fitted to the proper port with the correct connection fitting.
- Check that when the vaporizer is turned off, no anaesthetic odour can be detected when the oxygen flowmeter is turned on.
- Attach the circuit which will be used to the anaesthetic machine, turn on the oxygen supply and check the circuit for leaks by occluding the patient end of the tubing and fully closing any valves.
- Open the valves to check they are not sticking.
- Ensure the scavenging tubing is connected to and the system turned on.

A simple pre-use check list for anaesthetic machines is attached to every machine in the [redacted] This must be signed off by the [redacted] anaesthetist prior to using the machine.

After completion of the anaesthesia, the machine shall be shut down as follows:

- Turn the vapouriser and the flow meter to their “OFF” positions.
- Disconnect the oxygen supply.
- Turn off the scavenging unit and disconnect it from the outlet.

Other equipment to be used during the procedure shall also be checked and prepared in advance of administering the anaesthetic.

Monitoring equipment, when used, should be switched on, allowed a period to stabilize if necessary, and its functions checked.

Monitoring alarm limits should be reset from the default settings and then fine-tuned when the individual animal is connected.

6.2 Induction of anaesthesia

6.2.1 Sheep.

The sheep shall be starved of food overnight prior to the surgery, but water shall be available at all times.

In order to reduce the amount of stress to an individual sheep in a pen, it should first be transferred into a small catch pen. This will reduce the area for avoidance and reduce the need to chase the animal. The smaller the catch pen, the easier it will be to catch the sheep.

Once the sheep is in the catch pen, the animal handler shall manoeuvre it into a corner, using his/her arms or a portable gate to form a visual barrier.

The handler shall always approach sheep calmly and slowly initially, in order to minimise stress, but catching or handling should always be done with quick, confident, robust movements.

The sheep can then be backed into a corner of the pen and straddled. The handler must keep a hand under the jaw to control the sheep's movements. The sheep can then walked from the pen into a small wheeled transport box and taken to prep room for anaesthesia.

Sheep that are in metabolic crates shall be removed from them as safely as possible.

To induce the anaesthesia, one person shall restrain the animal, while another administers the anaesthetic by intravenous injection in the jugular or cephalic veins.

The area chosen for the injection site may now be clipped and swabbed with alcohol.

The anaesthetic can now be administered as per the attached IDAO.

6.2.2. Pigs

Pigs shall be starved of food overnight prior to the surgery.

The pig shall be caught and immobilised for ease of injection.

To catch the pig, ensure the handling area is large enough to perform the task safely, but small enough to restrict the pig's movement, e.g. at the end of a passage way, in a small pen or in a handling crate.

If a handling crate is not being used, apply gentle pressure with pig board or a leg to the hind-quarters and flank of the pig to keep it still.

Pigs can also be restrained with ropes or a wire loop around its snout (ie around the upper jaw, behind the incisor teeth. However, these methods of restraint cause a greater degree of stress to the pig, and should be avoided whenever possible.

Once the pig is immobilised, the site for the intramuscular injection is swabbed with alcohol. This site may be either the middle third of the side of the neck, or the rear part of the thigh.

The injection of anaesthetic is now given as per the attached IDAO.

6.3 Intubation and administration of inhalation anaesthesia in sheep and pigs.

Following induction, and once the animal has lost its palpebral reflex; it can be lifted onto the operating table in the supine position and strapped down, if necessary.

Using a speculum, the anaesthetist shall then identify the animal's larynx, and pass an endotracheal tube of the appropriate size. The cuff of the endotracheal tube shall then be inflated.

The endotracheal tube shall be immediately connected to the anaesthetic machine, and Isoflurane delivered according to the IDAO.

Any monitoring equipment, if being used, shall also be connected at this time.

6.4 Maintenance and monitoring of anaesthesia.

The depth of anaesthesia shall be monitored at regular intervals, but at a minimum of every five minutes, throughout the surgical procedure.

Anaesthetic depth may be monitored by:
1. Palpebral reflex
2. Respiration rate
3. Heart rate
4. Mucous membrane colour
5. Blood pressure
6. capnograph/pulse oximeter

The percentage of Isoflurane being delivered may be adjusted if required, as per the IDAO.

Appropriate fluid therapy shall be administered to all anaesthetised animals

6.5 Recovery.

If recovery surgery is being performed, the Isoflurane shall be turned off at the completion of surgery so that the animal is breathing oxygen only.

When the animal is breathing on its own, and the breathing is stable, it may be disconnected from the anaesthetic machine.

When the animal begins to chew, the cuff on the endotracheal tube shall be deflated, the tube gently removed, and the animal placed in sternal recumbency.

Regular monitoring shall continue until the animal is standing, and food and water can be offered to it.

6.6 Euthanasia.

If the surgery is non-recovery, the animal shall be euthanized by the intravenous or intra-cardiac injection of Pentobarbitone, as per the accompanying IDAO, unless an alternative method is used

under an AEC approval. Any method of euthanasia shall be completed while the animal is still fully anaesthetised.

The following signs of death shall be confirmed before the animal is removed from the operating table:

1. Cessation of respiration and heartbeat.
2. Lack of a pulse.
3. Fully dilated pupils.
4. Lack of palpebral reflex.

Appendix 5

EForm Name: AE and Bio-Safety Form v3.02

Page:

Section: **Section G: Attachments**
Please list all attachments appended in support of this application:

Question:

File Name: SOP 914 v2 Apr2015.docx

UNIVERSITY OF AUCKLAND [redacted] STANDARD OPERATING PROCEDURE	Effective From : 1/4/2015 Review date: 31/3/2017 AEC Ref: SOP914

Title: Anaesthesia and Euthanasia of Sheep and Pigs in the [redacted] and MRI.		
	Print name	Signed
[redacted] Authorised	[redacted] (Business Manager)	[redacted]

Table of Contents

1. Purpose

The procedures in this SOP describe the methods to be used by University of Auckland staff for the induction and maintenance of anaesthesia and for the euthanasia of sheep and pigs used for research and teaching purposes under AEC approvals.

2. Definitions

2.1 [redacted]
2.2 MRI – Magnetic Resonance Imaging.
2.3 AWO – Animal Welfare Officer.

3. Responsibility

3.1 The procedures shall only be carried out by University of Auckland animal technicians who have been trained in the handling of large animals (Module 2c), in the use of injectable and inhalation anaesthetics and drugs used for euthanasia, and who have been signed off as competent in their training file.
3.2 All members of staff engaged in this procedure must comply with this SOP and any related SOPs and documentation.

4. Equipment

4.1 Appropriate PPE
4.2 Isoflurane anaesthetic machine and scavenging system
4.3 Ventillator and/or re-breathing bag
4.4 Oxygen cylinder and portable anaesthetic machine for anaesthesia in the MRI
4.5 Anaesthetic monitoring system.
4.6 Operating table.
4.7 Laryngoscope.

5. Procedures

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- Check that the flowmeters are functioning correctly by opening the cylinder valves and opening the needle valves that control the flow of gas through the flowmeters. The bobbins should rotate when gas is flowing. The gas flow rate is measured from the top of the bobbin.
- Turn off the gas flow using the needle valve and check that the bobbin sinks smoothly back to zero, and is not sticking and giving a false high gas flow rate.
- Check that the emergency oxygen switch on the machine is functioning correctly.
- If an anaesthetic circuit with valves is to be used, open them fully and check that they are operating correctly.
- Check that the Isoflurane vaporizer has been filled, that the bungs are in the correct place and that the control dial moves smoothly over the entire range of possible settings.
- Check that the connection tube is correctly fitted to the proper port with the correct connection fitting.
- Check that when the vaporizer is turned off, no anaesthetic odour can be detected when the oxygen flowmeter is turned on.
- Attach the circuit which will be used to the anaesthetic machine, turn on the oxygen supply and check the circuit for leaks by occluding the patient end of the tubing and fully closing any valves.
- Open the valves to check they are not sticking.
- Ensure the scavenging tubing is connected to and the system turned on.

A simple pre-use check list for anaesthetic machines is attached to every machine in the VJU. This must be signed off by the [redacted] anaesthetist prior to using the machine.

After completion of the anaesthesia, the machine shall be shut down as follows:

- Turn the vapouriser and the flow meter to their “OFF” positions.
- Disconnect the oxygen supply.
- Turn off the scavenging unit and disconnect it from the outlet.

Other equipment to be used during the procedure shall also be checked and prepared in advance of administering the anaesthetic.

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Monitoring alarm limits should be reset from the default settings and then fine-tuned when the individual animal is connected.

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The handler shall always approach sheep calmly and slowly initially, in order to minimise stress, but catching or handling should always be done with quick, confident, robust movements.

The sheep can then be backed into a corner of the pen and straddled. The handler must keep a hand under the jaw to control the sheep's movements. The sheep can then walked from the pen into a small wheeled transport box and taken to prep room for anaesthesia.

Sheep that are in metabolic crates shall be removed from them as safely as possible.

To induce the anaesthesia, one person shall restrain the animal, while another administers the anaesthetic by intravenous injection in the jugular or cephalic veins.

The area chosen for the injection site may now be clipped and swabbed with alcohol.

The anaesthetic can now be administered as per the attached IDAO.

6.2.2. Pigs

Pigs shall be starved of food overnight prior to the surgery.

The pig shall be caught and immobilised for ease of injection.

To catch the pig, ensure the handling area is large enough to perform the task safely, but small enough to restrict the pig's movement, e.g. at the end of a passage way, in a small pen or in a handling crate.

If a handling crate is not being used, apply gentle pressure with pig board or a leg to the hind-quarters and flank of the pig to keep it still.

Pigs can also be restrained with ropes or a wire loop around its snout (ie around the upper jaw, behind the incisor teeth. However, these methods of restraint cause a greater degree of stress to the pig, and should be avoided whenever possible.

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The endotracheal tube shall be immediately connected to the anaesthetic machine, and Isoflurane delivered according to the IDAO.

Any monitoring equipment, if being used, shall also be connected at this time.

6.4 Maintenance and monitoring of anaesthesia.

The depth of anaesthesia shall be monitored at regular intervals, but at a minimum of every five minutes, throughout the surgical procedure.

Anaesthetic depth may be monitored by:
1. Palpebral reflex
2. Respiration rate
3. Heart rate
4. Mucous membrane colour
5. Blood pressure
6. capnograph/pulse oximeter

The percentage of Isoflurane being delivered may be adjusted if required, as per the IDAO.

Appropriate fluid therapy shall be administered to all anaesthetised animals

6.5 Recovery.

If recovery surgery is being performed, the Isoflurane shall be turned off at the completion of surgery so that the animal is breathing oxygen only.

When the animal is breathing on its own, and the breathing is stable, it may be disconnected from the anaesthetic machine.

When the animal begins to chew, the cuff on the endotracheal tube shall be deflated, the tube gently removed, and the animal placed in sternal recumbency.

Regular monitoring shall continue until the animal is standing, and food and water can be offered to it.

6.6 Euthanasia.

If the surgery is non-recovery, the animal shall be euthanized by the intravenous or intra-cardiac injection of Pentobarbitone, as per the accompanying IDAO, unless an alternative method is used

under an AEC approval. Any method of euthanasia shall be completed while the animal is still fully anaesthetised.

The following signs of death shall be confirmed before the animal is removed from the operating table:

1. Cessation of respiration and heartbeat.
2. Lack of a pulse.
3. Fully dilated pupils.
4. Lack of palpebral reflex.

Appendix 6

EForm Name: AE and Bio-Safety Form v3.02

Page:

Section: **Section G: Attachments**
Please list all attachments appended in support of this application:

Question:

File Name: IDAO-914-2.pdf

Institutional Drug Administration Order

This form applies to use of AEC approved prescription medicines (human or animal) and/or medicines for the direct management of the animals, such as anaesthetics, analgesics and prophylactic antibiotics.

AEC OFFICE USE ONLY	
IDAO no.	SOP 914/2
Replaces IDAO no.	SOP 914/1
AEC approval commencement date	1/4/2014
AEC/IDAO approval end date	1/4/2017
Cancellation date if replaced	
Replaced by IDAO no.	

Reason for issue of IDAO (excessive detail is not required or expected)
Summary of aim of trial:
SOP 914: Anaesthesia, euthanasia and prophylactic treatment of sheep and pigs in the [redacted]

ANIMALS	
Species/Breed	Sheep and pigs
Gender	Male and Female
Age	Any
Weight	Any
Method of identification	Ear tags
Number	200 per year
Reproductive status	Not important

For details of Medicines, Administration, Effects and Outcomes and Disposal, please refer to the following Medicines Operating Procedures:

MOP 0027 Isoflurane MOP 0035 Alfaxan MOP 0042 Pentobarbitone MOP 0045 Xylazine MOP 0049 Propofol MOP-0069 Zoletil MOP 0072 Ketoprofen MOP 0073 Oxytetra LA MOP ~~0074~~ 0075 Adrenaline [redacted]	In the following combinations: Anaesthesia: Sheep: Alfaxan or Propofol with or without isoflurane Pigs: Zoletil with isoflurane Adrenaline as required Euthanasia: Sheep and pigs: Pentobarbitone or isoflurane overdose; Xylazine with Pentobarbitone Prophylactic antibiotics: Oxytetra LA

VET COMMENTS	
If the issuing veterinarian has any specific comments regarding this usage please enter here	

FOOD SAFETY	
Will products from these animals enter the food chain of any other animal (i.e. human or animal)?	No

Does use of the medicine pose any threat to agricultural security?	No
If the answer to either of the above questions is 'yes', please provide details	

STORAGE	
Where will the medicine be stored?	VJU 504-B07 and 504-B09

PERSONNEL			
Name	Skill/Qualification	Position	Signature*
[redacted]	Cert Anim Sci & Tech	Team Leader	[redacted]
		Technician	
	Cert Anim Sci & Tech	Senior Technical Officer	

*Signature confirms acceptance of this statement: "I have read, and agree to abide by, the University of Auckland Institutional Operating Plan for the Direct management of Animals".

Authorisation by prescribing veterinarian:

Date:...1/4/2014.....

Signed:... [redacted]

Name: [redacted]

Appendix 7

EForm Name: AE and Bio-Safety Form v3.02

Page:

Section: **Section G: Attachments**
Please list all attachments appended in support of this application:

Question:

File Name: Memo_Ethics_001811.txt

Memo addressing questions and comments on ethics application 001811
12 Dec 2016
[redacted]

1. Please explain why you are only using female pigs.

We have chosen to exclusively use female pigs primarily due to their anatomy.
The anatomy of male pigs, makes more difficult to create a lower mid-line laparotomy.
This can make it difficult to access the colon and parts of the small intestine.

2. Please contact the AEC Administrator to register [redacted] for Module 1.

This has been done.

3. Please better clarify who will carry out which particular procedures.

As stated in the application, manipulation of the animal will be conducted by named investigators who have appropriate training and have experiences with animal studies: [redacted] . All of these investigators may perform any of the named manipulations.

Monitoring will be performed by all investigators.

Euthanasia will be performed by [redacted] at the conclusion of each study.

4. D:4e â€“ Please remove the statement about analgesic, as these are terminal studies.

This has been removed.

5. D:13 â€“ Please provide the sources (including databases, search terms, and references) you have used to investigate potential alternatives to animal use, as required by the recent changes to the Animal Welfare Act.

The following paragraphs have been added:

We have investigated alternatives to the use of animals (including human volunteers, tissues and cell lines). We searched the databases: pubmed, google scholar and www.nc3rs.org.uk using the terms "alternative slow wave gastrointestinal model". From the search results, no viable alternatives were detected.

As part of our research, we have previously (and will continue to) translate our techniques to human volunteers once our methods and techniques have first been refined and deemed safe in an animal model.