NON-TECHNICAL SUMMARY (NTS)

Project Title	Detecting bladder volume and pressure from sacral nerve signals in sheep
Key Words	bladder, sacral nerves, neuroprosthesis, sheep
Expected duration of the project	3 year(s) 0 months

Purpose of the project (as in ASPA section 5C(3))

Purpose	
No	(a) basic research;
	(b) translational or applied research with one of the following aims:
Yes	(i) avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality, or their effects, in man, animals or plants;
Yes	(ii) assessment, detection, regulation or modification of physiological conditions in man, animals or plants;
No	(iii) improvement of the welfare of animals or of the production conditions for animals reared for agricultural purposes.
No	(c) development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feedstuffs or any other substances or products, with one of the aims mentioned in paragraph (b);
No	(d) protection of the natural environment in the interests of the health or welfare of man or animals;
No	(e) research aimed at preserving the species of animal subjected to regulated procedures as part of the programme of work;
No	(f) higher education or training for the acquisition, maintenance or improvement of vocational skills;
No	(g) forensic inquiries.

Describe the aims and objectives of the project (e.g. the scientific unknowns or scientific/clinical needs being addressed):

Accidents in people can cause damage to the spinal cord. This causes paralysis and incontinence for which there is no cure. In this project, we aim to develop a new treatment for urinary incontinence. To do this, we plan to design an intelligent implant able to monitor the bladder, for use in man. This has never been done.

Our objectives are:

1. to place in surgery a biocompatible implant on the nerves controlling the bladder;
2. to analyse, during surgery, electrical signals from the nerves controlling the bladder;
3. to continue recording electrical signals with the implant in awake animals during their normal activities.

Altogether, the project will deliver a new implant and surgical protocols for bladder control.

What are the potential benefits likely to derive from this project (how science could be advanced or humans or animals could benefit from the project)?

This project could benefit people or animals (such as companion dogs) that have sustained damage to the spinal cord. In the United Kingdom, around 50,000 people live with spinal cord injury, with about 1,000 new cases every year. This cost annually approximately £1 billion, which is 1% of the total NHS budget. Worldwide, spinal cord injury affects about 2.5 million people with approximately 130,000 new cases each year. This new treatment will offer affected humans a method to better manage urinary incontinence, instead of using drugs or bladder catheterisation that currently reduce life expectancy. We will also describe a new surgical technique for this implant with less adverse effects for people. For the scientific community, our results will advance knowledge in: (i) the design and surgical implantation of implants for nerves; (ii) nerve signal processing techniques. It will be applicable to other medical conditions and to radar and sonar systems.

What types and approximate numbers of animals do you expect to use and over what period of time?

We plan to use a maximum of 16 sheep over 3 years.

In the context of what you propose to do to the animals, what are the expected adverse effects and the likely/expected levels of severity? What will happen to the animals at the end?

All the surgical procedures are of moderate severity and will be conducted under general anaesthesia. From past experience, pain after the surgeries we propose to do will be mild and transient and can easily be controlled with drugs routinely used for animals. All possible adverse effects we might see are anticipated to be transient and controllable with routine veterinary care and medication. None of the procedures done in awake animals will be invasive, for example, none of these involve breaching the skin.

Application of the 3Rs

Replacement

State why you need to use animals and why you cannot use non-protected animal alternatives

Replacement

We need to use animals to test our implant because there is no other alternative that model the live urinary and nervous system. We need to do some recordings from a live animal, which size is comparable to humans. This is to allow future use in human patients.

Reduction

Explain how you will ensure the use of minimum numbers of animals

Reduction

We will minimise the number of sheep by using one animal at a time and analysing data before going to the next animal. We will also use animals over long periods of time using non-invasive tests to obtain a maximum of 'real-life' data without having to rely on biopsies or post-mortem evaluation only.

Refinement

Explain the choice of animals and why the animal model(s) you will use are the most refined, having regard to the objectives. Explain the general measures you will take to minimise welfare costs (harms) to the animals.

Refinement

We are using sheep because their nervous system better mimics that of humans (compared to rats for example). This allows more straightforward application of our treatment to humans or other large animals. We will minimise welfare costs by using totally implantable and biocompatible systems and allow sheep regular access to grazing during the study period. Sheep will be able to express their natural behaviour throughout the project and methods of assessing our implant will remain non-invasive on awake animals.