Home Office

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[redacted]

Our Ref FOI No. 4295
Date 9 October 2006

Dear [redacted]

## REQUEST FOR INFORMATION UNDER THE FREEDOM OF INFORMATION ACT 2000

I am writing further to our letter of 25th September 2006 in which [redacted] you asked to be provided with information relating to the Animals Scientific Procedures Inspectorate's (ASPI) cost benefit assessment of the project licence that we considered was referred to in an article in Scotland on Sunday on 4th September 2005 titled 'Winston unveils 'life saving' pig organ research'. We interpreted this to mean the disclosure of any relevant information held by the Home Office regarding ASPI's cost benefit assessment of this project, from initial informal approaches to present day monitoring of ongoing costs and benefits.

We have treated your request as a request for information under the Freedom of Information Act 2000 and have handled it accordingly. I am pleased to be able to inform you that we are now in a position to provide you with a substantive response.

However, before doing so I would like to take this opportunity to correct a factual error included in the information disclosed to you in November 2005 in which I indicated that the project licence in question was granted in February 2005. This information was incorrect. The licence was in fact granted in February 2003.

As stated in our previous correspondence, we do not hold some of the information you requested. Specifically, we do not hold

- the technical failure rate;
- whether the 'novel gene constructs' have been expressed on epithelium of transplanted material;
- whether the 'novel gene constructs' prevented HAR in the arterial model;
- transcriptions of primary data describing the adverse effects actually suffered by the animals used in this project, e.g. clinical signs and other notes made by researchers and technicians;
- progress reports on this project provided by the licensees;

In answer to the other specific areas identified in your request (detailed below) I can inform you of the following:

1. notes relating to the Home Office's consideration of whether to refer the application to an external assessor or the United Kingdom Xenotransplantation Interim Regulatory Authority, and any subsequent recommendations;

The application was subject to internal referral, and no notes exist with regard to consideration of a potential application for referral to an external assessor or the United Kingdom Xenotransplantation Interim Regulatory Authority.

2. whether the researchers have moved to the renal model and the results of any such procedures, including control procedures using unmodified kidneys;

We do not hold this information.

3. whether a separate project licence been sought to establish genetically altered pigs expressing the construct (from 'Plan of work' # 1);

No separate licence has been sought.

4. whether any unforeseen (in the project licence) complications causing adverse effects have occurred, including as immunosuppressive toxicity, circulatory problems or sepsis due to endothelial damage in the grafted kidney, side-effects of gene construct, cannulation;

Although we have access to the researcher's records on request, the Department holds little information relevant to this enquiry. See information disclosed from inspection reports.

5. whether protocol 19b7 includes transplantation and whether any animals experimented on under this or other procedures have suffered renal failure;

Protocol 19b7 does not include transplantation.

6. whether the 'reassurances' provided in relation to anaesthesia in protocol 19b8 have been fulfilled and the Inspectorate's scrutiny of this aspect of the licence;

No non-compliance issues have been found or reported. See details disclosed from inspection reports.

7. consideration by the applicant and the Home Office of non-animal methods to achieve objectives three and four, and the perceived justification for using animals for such objectives;

In the previous round of correspondence we provided all of the information from the licence that we believe may be disclosed. The attached ASPI assessment form indicates the headings against which the ASPI judgements of justification were made.

8. the sources of funding (Section 17) disclosed in the project licence.

We do hold information on the source of funding for this work. However, we consider this information to be exempt from disclosure by virtue of section 38 (health and safety) of the Freedom of Information Act 2000.

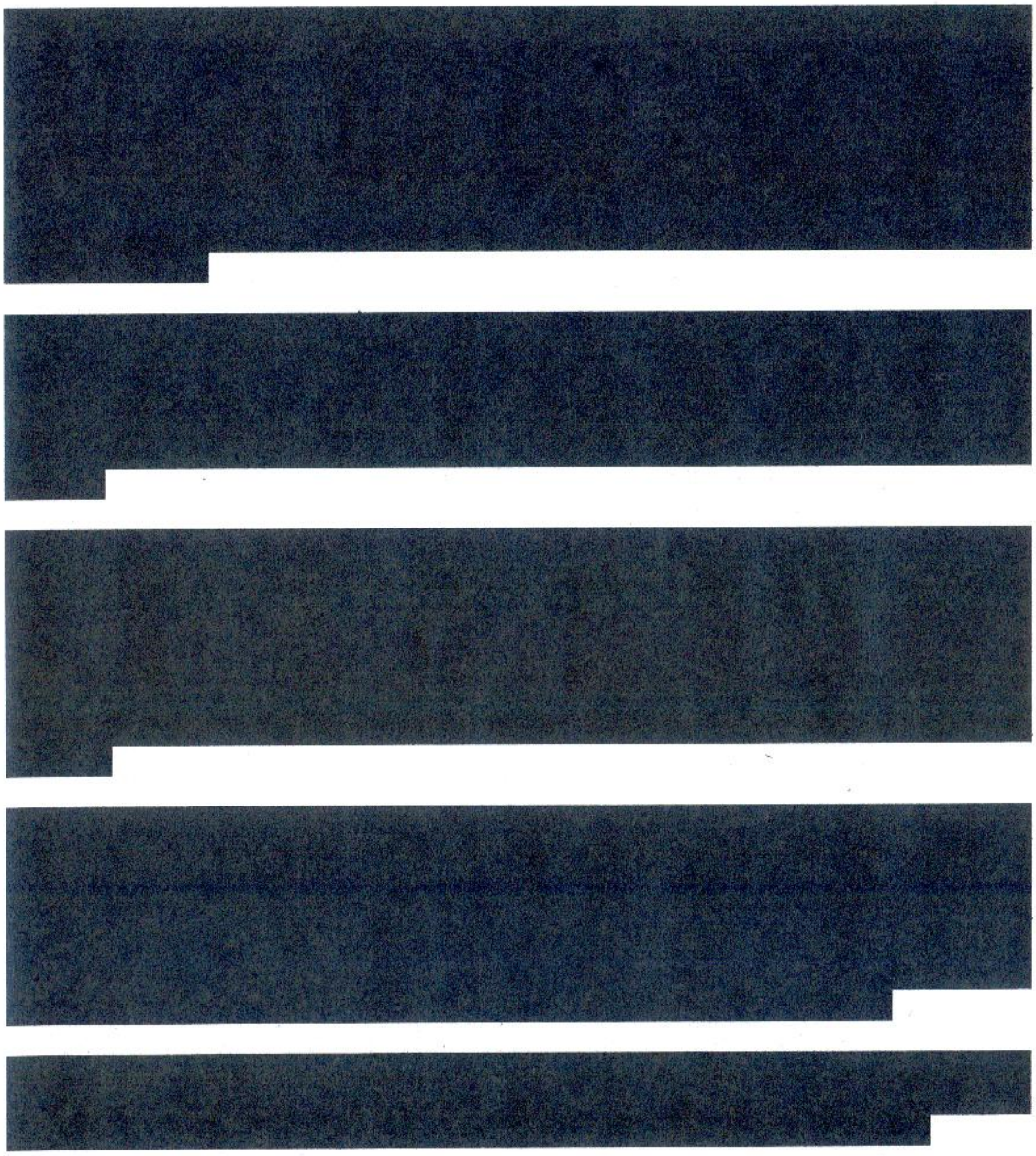
I am pleased to be able to disclose the attached documents in redacted form with this letter to you.

- **Annex A** -All relevant information from the file minute sheet for the project licence in question which formed part of the cost-benefit assessment;

- **Annex B** - A copy of the project licence assessment form from the file held by the Department;
- **Annex C** – Relevant information from the ASPI visit (inspection) reports.

In interpreting this information you need to be aware that the Inspectorate cost-benefit assessment is a professional judgement that follows the principles set out in the document entitled "Cost/Benefit Assessment – A Note by the Chief Inspector" published as part of the APC review of the operation of the Animals (Scientific Procedures) Act 1986 in the APC Annual Report for 1997 (pp50-59), a copy of which can be found at http://www.apc.gov.uk/reference/ar97.pdf. The full extent of the considerations is not recorded, only information for other inspectors and officials with good understanding of the arguments. In addition inspection reports focus on positive reporting – highlighting exceptions and making little mention of the routine.

These documents have been provided with the information outside the scope of your request or exempt from disclosure redacted. It is after careful consideration that we have concluded that the redacted information in these documents is exempt from disclosure by virtue of sections 38 (heath and safety) and 40 (personal information) under the Freedom of Information Act 2000.



I should also point out that disclosure under the Freedom of Information Act is essentially

disclosure to the public at large and that in keeping with the spirit and effect of the Freedom of Information Act, all information is assumed to be releasable to the public unless exempt. The department therefore, will be simultaneously publishing the information you requested in the Home Office FOI disclosure log on the Home Office website, together with any related information that will provide a key to its wider context.

If you are dissatisfied with this response you may request an independent internal review of our handling of your request by submitting your complaint to:

Information Policy Team
Information and Record Management Service
Home Office
4th Floor, Seacole Building
2 Marsham Street
London
SW1P 4DF

During the independent review the department's handling of your information request will be reassessed by staff who were not involved in providing you with this response. Should you remain dissatisfied after this internal review, you will have a right of complaint to the Information Commissioner as established by section 50 of the Freedom of Information Act.

I hope that you find this information of interest, and would like to assure you that you have been supplied with all the disclosable information that the Home Office holds. Where information has been withheld, I can also assure you that we have considered the application of exemptions with great care in this case and that the Home Office always seeks to disclose as much information as it is able to.

Yours sincerely

[redacted]
**Animals Scientific Procedures Division**