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January 27th 2023 **Ref. 01.23**

Dr Dan Lyons
Policy Consultant
Irish Anti-Vivisection Society

By Email

RE: FOI Request

Dear Dr. Lyons,

I refer to your recent FOI Request which sought:

I am writing to make a an FoI request. Please disclose all information relating to the tender issued on 18th January 2021 for the supply of Service – In vivo study: Chinchilla model (tympanic membrane). (see attached document)

In particular, focussing on the issues of greatest public interest, we request you disclose information relating to any consideration of non-animal research methods prior to the publication of the tender, and information relating to any laboratory which carried out the research, the regulatory assessment of any proposed project, and the results of any subsequent procedures carried out on animals under this tender.

I have made a decision to part-grant your request today. Personal identities have been redacted pursuant to S. 32(1)(b) as there is a reasonable expectation that disclosure of this information may endanger the life or safety of a person.

Please see the attached documents.

In addition, and outside the FOI process as this comprises information, not records, you are asked to note the following:

1. **Consideration given to non-animal research methods prior to publication of tender**

Researchers in the Royal College of Surgeons in Ireland (RCSI) perform an extensive array of in vitro testing on any technology under development s prior to advancing to evaluation in animal models. As a first step, tests are performed to assess the chemical composition, degradation characteristics, internal microarchitecture, swelling characteristics and mechanical properties of the device. These initial experiments provide an insight as to how the device might operate in a biological environment and allow refinement of the device should one or more of its properties be determined to be sub-optimal. Thereafter, 3D in vitro cell studies are performed which allow assessment of the cytotoxicity of the device. Furthermore, biochemical assays are performed to determine DNA content and extracellular matrix deposition as well as using histology to visualise the interaction between the cells

and the device. This in vitro culture analysis ensures that the device is optimised in every way possible prior to being considered for evaluation in vivo.

2. The use of animal models

All in vivo research carried out by RCSI researchers is done so under the 3Rs principle. In addition to the extensive testing described in the previous section, animal models are required as no other approach (eg: computational models or 3D in vitro culture) can replicate the physiological healing response of living tissue or the immunological response of the host to the implanted device. The ultimate aim is to translate this medical device to the clinic which will necessitate regulatory approval prior to human use. Both the Food and Drug Administration (FDA) and the European Medical Agency (EMA) require preclinical evaluation to allow Investigational New Drug (IND)/ Investigational Device Exemption (IDE) approvals in order to facilitate testing in humans. This means that a medical device must undergo a series of robust tests and experiments using accurate and reliable animal models as per the needs of the focused indication and regulatory guidelines.

3. The chinchilla as a model for tympanic membrane repair

This research is focussed on developing a medical device for the repair of damaged tympanic membranes. This technology has the potential to be used in 5 million patients globally p.a. The gold standard animal model for ear indications such as otitis media is the chinchilla. However, the expertise to perform such a specialised model does not exist within Ireland. Therefore, the study was performed in an international centre of excellence which has extensive experience in refining this model over many years and ensuring that the minimum number of animals are used.

4. Results of the study

Prior to performing any experiments on live animals, ethical approval was obtained from the local ethics committee. Bilateral tympanic membrane perforations (TMP) in chinchillas were monitored with otoscopy for 8 weeks. At 8 weeks, intervention began and TMPs were assigned to either a treatment group or a control group. Animals were euthanized 6 weeks post-intervention. Otoscopic imaging and auditory brain response (ABR) were conducted at baseline, 8 weeks post-TMP and 6 weeks post-intervention. All TMPs were then evaluated at 6 weeks post-intervention and bullae underwent histologic evaluation. The technology under investigation is the subject of a patent filing and results cannot be disclosed at this time as this would jeopardize their translation to clinical use. In time, the study results will be published in scientific journals and used for regulatory purposes to progress to human trials.

Right to Review

You have the right to a review of this decision. If you wish to do so, please submit a request for review by email within 4 weeks of the date of this notification to foi@rcsi.ie The making of a late appeal may be permitted in some circumstances. The appeal will involve a complete reconsideration of the matter by a more senior member of the staff of RCSI and the decision on your case will be made within 3 weeks of receipt of your letter. Please note that a fee of €30 must accompany any such request for review.

Yours sincerely,

Sent by email hence has no signature

Dónall King
FOI Officer