

Appendix 1: Requirements and Specifications

Tenderers must address each of the issues and requirements in this part of the RFT and submit a detailed description in each case which demonstrates how these issues and requirements will be dealt with / met and their approach to the proposed delivery of the Goods. A mere affirmative statement by the Tenderer that it can / will do so or a reiteration of the tender requirements is NOT sufficient in this regard.

Specifications for Service: Research Model of Chronic Tympanic Perforation

1. **Product Description:** Provision of research laboratory/veterinary services: to complete an *in vivo* assessment of chronic tympanic perforation repair in a chinchilla model.
 - Dr [REDACTED] research team and Biomedical Resource Center (BRC) veterinarians at the Medical College of Wisconsin (MCW) are available to support this study. Repairing procedure will be conducted by Ear/Nose/Throat (ENT) surgeons. Assessment of TMP repair will be done by ABR testing and endpoint histology which will be processed by RCSI.

2. **Product Requirement:** We require a research/veterinary laboratory experienced in or capable of establishing a chronic tympanic perforation model in a chinchilla model, that we be used to assess the regenerative potential of a collagen-based material developed in our lab.
 - Two of our ENT surgeons will perform procedure to establish chronic TMP in chinchillas and later perform treatment, Dr [REDACTED]. A team of research and veterinary laboratory personnel are available to provide assistance and supports during study duration.

3. **Product Specification:**
 - The tenderer must organise/already have in place, relevant Ethical Approval and associated documentation.
 - Approval has been obtained from the MCW Animal Use Application (AUA 7441). Approval letter attached.
 - Provider to supply all animals, as well as all bedding/housing materials, surgical instruments/consumables, pharmacologics/animal medicines and histology consumables required
 - Chinchilla vendor is Moulton Chinchilla Ranch. All animal supplies required for this study are order via MCW Biomedical Resource Center (BRC). Histology reagent is available from Kerschner lab. We will send fixed specimens back to RCSI.
 - Approximately 15 animals will be required
 - Correct
 - Chronic perforation will be induced for approximately 8 weeks
 - Correct
 - Subsequent assessment of our regenerative technology will take place over an additional 6 weeks
 - Correct
 - Standard clinical observations will be completed at regular intervals throughout the study, in addition to standard otic examinations and auditory brainstem response monitoring (standard ABR)
 - As stated in the approved protocol, attached AUA7441.
 - Histology to be completed on relevant tissues at study end (haematoxylin and eosin only)
 - **This is incorrect.** The agreement is for MCW to harvest, fix the bulla, and send those fixed tissues to RCSI for processing.

The experimental model will be similar to that reported by:

- (a) Weber et al., <https://pubmed.ncbi.nlm.nih.gov/16652074/>
- (b) Wieland et al., <https://pubmed.ncbi.nlm.nih.gov/20620631/>

- 4. **Required product capacity:** N/A
- 5. **Required Delivery time:** The full study will ideally be completed by June 2021.
- 6. **Required Backup & support facilities:** N/A
- 7. **Required Spare parts availability:** N/A
- 8. **Ancillaries required for product performance:** N/A. Costs provided in the quote should be wholly inclusive i.e. costs to be included for all materials as described above, in addition to surgical/veterinarian/research team personnel costs and any other necessary fees and charges.