Therapeutic/Diagnostic Devices

**Additional Information required if not present in Protocol:**

Describe the nature of the device, including details of the design, composition, specification, mode of action and application of the device: Include whether of human or animal origin:

Is the device registered on the Australian Register of Therapeutic Goods (ARTG)

Yes No

Is the device being considered under the Clinical Trial Exemption (CTX) Scheme

Yes No

Is the device being considered under the Clinical Trial Notification (CTN) Scheme

Yes No

# Please provide documentary evidence for the above

**Signature from Biomedical Engineer (x5189) indicating approval from Biomedical Engineering Department, to be obtained before submission to HREC:**

Signature: ............................................................... Date: ………. / ……. / ………

Name & Position: …………………………………………………………….

Describe previous experiences relevant to the safety and efficacy of the device

Long-term follow-up – describe the intended procedures to ensure long-term follow-up of trial participants

**Please provide (tick if present)**

|  |  |
| --- | --- |
|  | Relevant correspondence with other regulatory authorities (includes statements of the commercial or investigational status of device overseas) |
|  | Relevant correspondence with other ethics committees |
|  | All information concerning previous product recalls |
|  | For devices of human or animal origin, provide evidence of compliance with Quarantine, where appropriate |