Section 4. To be completed by the authority approving the conduct of the trial

Complete for all notifications. In cases where the Human Research Ethics Committee or Approving Authority for more than one site is the same, it is still necessary to submit a Trial Site Details Page for **each** site. The bodies approving the conduct of the trial at each site need to be declared individually. This requirement also still applies in cases where, for example, an Area Health Service or Hospitals Group may encompass several different institutions.

The Approving Authority must appoint a person to be responsible for giving approval on its behalf. The terms of approval for the conduct of the trial must be consistent with the Human Research Ethics Committee's (HREC) recommendations and these terms must be no less restrictive than the HREC advice.

Approving Authority name	Mater Health Services North Queensland Ltd		
Address	21-29 Fulham Rd, Pimlico. QLD, Australia		
		Post code:	4814

Approving authority certification

I, the undersigned

- am authorised to represent the body, organisation or institution at which the above mentioned clinical trial will be conducted and, having regard to the advice and approval of the trial protocol by the Human Research Ethics Committee responsible for monitoring the trial at this site, give approval for this trial to proceed;
- undertake that the use of the drug will comply with all relevant Commonwealth and State or Territory legislation; and
- undertake to comply with requests by an authorised officer, whether made before or after the start of a clinical trial, to give information about the conduct of the clinical trial and allow an authorised officer (regulation 2A of the Therapeutic Goods Regulations or regulation 10.1 of the Therapeutic Goods (Medical Devices) Regulations 2002) to do the things mentioned in regulation 12AC and regulation 12AB of the Therapeutic Goods Regulations or in regulation 7.4 of the Therapeutic Goods (Medical Devices) Regulations 2002.

Signature Phone 47274570	HREC Chairperson	Position	MX) no	Karen Gerrard	Name (Print)
	47274570	Phone	- HALAU		Signature
Date 27/5/2014 GENHAU WINGER 47251034	47251034	14 tax	GERMAN WYN	27/5/2014	Date