Insurance for Human Research Studies - Declaration for Approval – ALL SECTIONS MUST BE COMPLETED

Ethics Approval Number:					
1.	**Ethics Approval** Which institution/s granted ethics approval?				
	Clinical Trial Administrator Who is administering the funding for the clinical trial?				
	Funding (if applicable) Who is funding the trial?				
	Is there an agreement in place between the collaborators for this Clinical Trial? Please include a copy.	Yes ☐ No ☐			
	Clinical Trial Title & Description Provide the trial name and a brief description (short paragraph).				
2.	**UQ Role** What is UQ's role in the clinical trial? e.g. Sponsor, principal Investigator, principal local investigator for an overseas trial (responsible for all Australian sites), Investigator (for own site only), funder only, supplier of products only, researcher only (no volunteer contract)				
3.	**School / Department:** Which School /Institute is involved in the trial?				
4.	**Principal Investigator:** Principal Investigator's Details.	**Name:**		**Position:**	
		Email:		**Phone:**	
5.	**Sponsor** (if applicable): What is the name of sponsor, their insurer and policy limits?				
6.	**Indemnity:** Is an indemnity provided by the sponsor?	Yes ☐ No ☐ Not Applicable ☐			
7.	**Granting Body** (if applicable): Who is the granting body for the non-sponsored trial?				
8.	**Phase of Clinical Trial:** At what phase is the clinical trial? (Phase I, II, III or IV)				
9.	**Target Participant Numbers:** What is the number of participants anticipated to be involved in the trial during the next 12 months?				
	UQ Responsibility: Of the number of participants anticipated to be involved in the trial during the next 12 months, how many will UQ be responsible for?				
10.	**Target Participants For Whole Trial Period:** What is the number of participants anticipated being involved in the whole trial?				
	UQ Responsibility: Of the number of participants anticipated to be involved in the whole trial, how many will UQ be responsible for?				
11.	**Number of UQ Sites:** What is the total number of UQ clinical trial sites?				
	Overseas Sites: What is the total number of UQ clinical trial sites overseas? Please include locations (city, country).				

	For overseas sites, have you determined and complied with any local requirements? If you are collaborating with an overseas local entity, please attach the Indemnity and Insurance clause from that contract. Please note: It is your responsibility to make sure you are not in breach of local country laws when conducting a trial in that country including Insurance requirements. Breaches of such laws could result in legal action against you and the University and criminal action against you , which may include incarceration.	
12.	**Invasive Nature of Trial:** Provide details of any invasive procedures to be used during the trial.	
13.	**Start Date:** What is the start date of the trial?	
14.	**End Date:** What is the expected end date of the trial? Please note: Insurance cover will only be in place **until this date**. Any trial amendments require UQ Ethics approval and notification to insurancerenewals@uq.edu.au	
15.	**Name of Drug**	
16.	**Dosage of Drug**	
17.	**Trial - Full Description:** (including references to risk events)	
18.	**CTN/CTX trials:** Is the trial a CTN or CTX trial? Clinical trials conducted using "unapproved therapeutic goods" in Australia, that is, goods which have not been evaluated by the TGA for quality, safety and efficacy and entered into the Australian Register of Therapeutic Goods (ARTG) for general marketing, are required to make use of the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) schemes. The definition of an unapproved good can encompass many aspects of a product. These include formulation, dose form, name, indications, directions for use and container. Hence simply because a product *is* entered onto the ARTG, this may not necessarily mean that the product intended for use in a clinical trial does not need an exemption via the CTN or CTX schemes in order to be lawfully supplied. The indication may be quite different, or dosage higher than that approved for marketing, or the product may be sourced from a foreign market, for example.	Yes ☐ No ☐

I declare this document is true and correct to the best of my knowledge:

_____ _____

Signature - Principal Investigator **Date**