Requirements-Applications for medical trials of cannabis and cannabinoids

Component of trial	Specification	Requirements
Growing of Indian hemp	Application for licence under Section 52 to grow a Prohibited Plant	Application to include: 1. Specification of certified variety and limits of content of THC and total cannabinoid 2. National police check of applicant and directors of company 3. Police approval of growing site
Processing	Collaborative agreement with exempted public institution - Section 55	Written evidence of contract or agreement with institution must be lodged with department
Human trials	Name of chief medical investigator	Notification in writing to be given.
	Collaborative agreement with exempted public institution - Section 55	Written evidence of contract or agreement with institution must be lodged with department
	Trial protocol	Submission of trial protocol including details of: 1. clinical trial design, 2. participant and staff numbers and resources, and 3. confirmation that legal requirements such as indemnity and informed consent are met.
	Compliance with National Health and Medical Research Council's (NHMRC): 1. *National statement on ethical conduct in human research 2009* 2. *Australian code for the responsible conduct of research*	1. Written approval of human research ethics committee 2. Written evidence of compliance
	Compliance with Therapeutic Goods Administration's (TGA) *Note for guidance on good clinical practice (CMP/ICH/135/95)*	Written evidence of compliance
	Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) with TGA	Written evidence of notification or exemption.

It is recommended that applicants review "Australian Clinical Trials" at:
http://www.australianclinicaltrials.gov.au/home

Queries should be directed to:

Chief Pharmacist
Pharmaceutical Services Branch
Department of Health and Human Services
GPO Box 125
Hobart TAS 7001

Department of Health and Human Services **July 2014**