

# Tasman Oncology Research

## Local Services Offered:

Early Phase, Clinical trials site, Phase 1 unit, Bench research, Trial Patient Recruitment, Treatment of patients, Completion of study documentation as per ICH GCP and contract

Details: This PDF complements the information found in the CSV generated by this website with additional site information.

<b><u>Facility Details:</u></b>	
Please provide your Facility Website.	<a href="http://www.tasmanhealthcare.com.au/">http://www.tasmanhealthcare.com.au/</a>
Is your facility/organisation a Life Sciences Queensland (LSQ) Member?	No
Do you have Affiliated Research Sites or Satellite Sites/Clinics? <i>A Satellite Site is a secondary location where the investigator sees clinical trial subjects. Usually this is the same investigator who sees subjects at the primary site location.</i>	No
Provide the list of Sub-Therapeutic Areas for your Facility.	Rheumatology
Is your Facility affiliated with a government agency or part of a government funded health service?	No
Does your Clinical Trial site or Service undertake any recruitment?	Yes
<b><u>IRB/ERB/Ethics Committee:</u></b>	
Does your Facility perform HREC (IRB/ERB/Ethics) Committee submissions?	Yes
Does your Facility have a dedicated department or group to perform HREC (IRB/ERB/ETHICS) Committee submissions?	Yes
Does your Facility have other review boards that need to approve the study prior to HREC (IRB/ERB/Ethics) Committee submission? For example, scientific, radiation safety committees, or others	No
Are there any other steps that the Sponsor should be aware of for your IRB/ERB/Ethics Committee review and submission?	No
Does the HREC Committee require payment prior to the release of final approval documents?	No

Does the HREC require contract/budget approval prior to release of final approval documents?	No
<b><u>Consent:</u></b>	
Does your Facility have a written SOP/Policy/Procedure for Informed Consent?	Yes
Does your Facility have a written SOP/Policy/Procedure for Minor Assent for paediatric populations?	No
Does your Facility have a written SOP/Policy/Procedure for other vulnerable populations?	No
Does your Facility have access to translators and translation support for study conduct (e.g. consent, study- specific instruction)?	No
<b><u>Training:</u></b>	
Does your Facility have a training program for the research staff?	Yes
Does your Facility training course content include GCP?	Yes
If your facility uses external program course/s. Please provide the program course/s name.	
Do you have a process or program in place to retrain research staff when a protocol is amended?	Yes
Does the study staff that prepares or transports dangerous goods have training that meets the IATA International Air Transport Association (US) or other countries hazardous training requirements for shipping dangerous goods?	Yes
<b><u>Facility And Equipment:</u></b>	
<b><u>Facility Capabilities:</u></b>	
Can your Facility support in-patient admissions for research studies?	No
Can your Facility support patient visits on weekends?	No
Is your Facility capable of administering infusions?	Yes

Does your Clinical Trial Site have the capacity to conduct Clinical Trials involving GMOs?	Yes
If yes, which of the following? (chose all that apply)	DNA vaccines, Clinical trials involving other types of GMOs
Is your Facility adequately staffed to support studies with both blinded and unblinded Investigational Product?	Yes
Does your Facility have the ability to collect and store PK/PD specimens?	Yes
Does your Facility have the ability to collect PK/PD samples beyond normal business hours?	Yes
Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?	Yes
Does the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)?	Yes
<b><u>Equipment:</u></b>	
Does your Facility have an SOP or process that ensures routine calibration and maintenance of general equipment? Examples of general equipment include: scale, pulse oximeter, stadiometer, sphygmomanometer, etc.?	Yes
Does your Facility have the necessary equipment to treat medical emergencies (for example crash/code cart)?	Yes
<b><u>IT Capabilities:</u></b>	
Does your Facility have computers that are dedicated to research studies?	Yes
What type of computer operating system(s) does your institution use to support studies?	Windows (Windows XP, Windows 7, Windows 10, etc)
What browser does your facility use?	Chrome
Does your Facility limit or prohibit access and use of external web-based tools or sites for clinical research (E.g. web portals to submit documents to sponsors or CROs)?	No
Does the Facility have access to local IT support?	Yes
Please indicate all equipment that will be available to Monitors	Phone, Fax, Copy Machines, Internet Access

<b><u>Labs:</u></b>	
Local Lab Usage	No
Does your Facility use private laboratory services?	Yes
If you selected 'Yes' on the previous question, please specify here which services	Sullivan Nicolaidis Pathology
<b><u>IP Storage Details:</u></b>	
IP Recipient Name	Tasman Health Care Pharmacy
Is the Investigational Product Storage Room secured with controlled access?	Yes
Storage Room Backup Power	Yes
Does your Facility have the ability to manage on-site or off-site destruction of the Investigational Product?	Yes
Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate?	Yes
Does the Facility have the ability to handle radio-labelled Investigational Products?	Yes
Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?	Yes
Does your facility have a written SOP/Policy/Procedure for the destruction of Investigational Product?	Not Applicable
<b><u>Source Documents:</u></b>	
Does your Facility have secure storage for patient records?	Yes
<b><u>Electronic Medical Records (EMR) /Electronic Health Records (EHR):</u></b>	
What EMR/EHR system do you use?	In-house system
Please list any access limitations/requirements for the Electronic Medical Records	Medical records will be printed and provided to trial monitors as verified copies.