Cairns Hospital - Clinical Research Unit

Location:

-16.9124 - 145.76831

Local Services Offered:

Clinical trials site, Satellite Site, Completion of study documentation as per ICH GCP and contract

Details: In addition to the information contained within csv generated by this website, this PDF provides additional site information

LSQ Member	Yes
Sub-Therapeutic areas	Data Collection/ Lead site/
	Experienced with Teletrial as both
	primary and satellite site
Does your Clinical Trial Site have the capacity	No
to conduct Clinical Trials involving GMOs?	
Oil AMI (I D I C')	V
Other Affiliated Research Sites	Yes
Other facility details	We are part of the Northern Cluster
	for teletrials. We are also a Satelitte
	site for Princess Alexandra Hospital
	(Brisbane)
Is your Facility affiliated with a government	No
agency or part of a government funded health	
service?	
Are there any notable factors relating to your	ATSI population
Patient Population (e	
Does your Facility perform HREC	Yes
(IRB/ERB/Ethics) Committee submissions?	
Does your Facility have a dedicated department	No
or group to perform HREC	
(IRB/ERB/ETHICS) Committee submissions?	
Any Additional Process	No
Details of other steps for HREC	We use Metro South HREC if there
(IRB/ERB/Ethics)Committee review and	is a site in the Health Service. We
submission	tend to use Metro North HREC
	currently
Does your Clinical Trial site or Service	Yes
undertake any recruitment?	
What percentage of Clinical trials undertaken	
on your site do you meet or exceed the	100%
recruitment target?	
Has your Clinical Trial site been audited?	Yes

Audit Type	FDA (Food Drug Administration),
	CRO (Clinical Research
	Organisation), Sponsor
Has your Clinical Trial Site or Service been	Yes
accredited?	
If your Clinical Trial Site or Service has been	NATA
accredited, please select all relevant types	
Does the HREC Committee require payment	No
prior to the release of final approval	
documents?	
Does the HREC require contract/budget	No
approval prior to release of final approval	
documents?	
Does your Facility have other review boards	
that need to approve the study prior to HREC	
,	No
example, scientific, radiation safety committees,	
or others	
Local Lab Usage	Yes
Lab Name	Pathology Queensland- Cairns
Does your Facility use private laboratory	Yes
services?	
If you selected 'Yes' on the previous question,	Sullivan and Nicolaides and QML
please specify here which services	
Does your Facility have a written	Yes
SOP/Policy/Procedure for Informed Consent?	
D	N
Does your Facility have a written	No
SOP/Policy/Procedure for Other vulnerable	
populations?	N.
Does your Facility have a written	No
SOP/Policy/Procedure for Other vulnerable populations?	
	No
Does your Facility have access to translators	INO
and translation support for study conduct (e.g. consent, study-specific instruction)?	
consent, study-specific instruction):	
Does the study staff that prepares or transports	Yes
dangerous goods have training that meets the	
IATA International Air Transport Association	
(US) or other countries hazardous training	
requirements for shipping dangerous goods?	
Does the course content include GCP?	Yes
	I .

Do you have a manage on ma amon in along to	Yes
Do you have a process or program in place to	res
retrain research staff when a protocol is amended?	

Does your Facility have a training program for	Yes
the research staff?	
Can your Facility support patient visits on	No
weekends?	
Can your Facility support in-patient admissions	No
for research studies?	
Does the Facility have storage space for Study-	Yes
Related materials (e.g. Lab Kits, Patient	
Materials, etc.)?	
Does your Facility have the ability to collect	Yes
and store PK/PD specimens?	
Does your Facility have the ability to collect	Yes
PK/PD samples beyond normal business hours?	
Does your Facility typically allow the collection	Ves
of Pharmacogenomic (PGX) samples for	1 03
research purposes?	
1 1	Yes
Does your Facility have an SOP or process that ensures routine calibration and maintenance of	i es
general equipment? Examples of general	
equipment include: scale, pulse oximeter,	
stadiometer, sphygmomanometer, etc.?	
D	***
Does your Facility have the necessary	Yes
equipment to treat medical emergencies (for	
example crash/code cart)?	
Does your Facility have computers that are	Yes
dedicated to research studies?	
What type of computer operating system(s)	Windows (Windows XP, Windows
does your institution use to support studies?	7, Windows 10, etc)
Internet Browser	Internet Explorer, Firefox, Chrome
Does your Facility limit or prohibit access and	No
use of external web-based tools or sites for	
clinical research (E.g. web portals to submit	
documents to sponsors or CROs)?	
·	
Does the Facility have access to local IT	Yes
support?	
IP Recipient Name	Thennarasu Dharmalingam
IP Storage Location Name	Cairns Hospital Pharmacy
Is the Investigational Product Storage Room	Yes
secured with controlled access?	
secured with controlled access:	

Storage Room Backup Power	Yes
Does your Facility have the ability to manage	Yes
on-site or off-site destruction of controlled	
substances when appropriate?	
Does your Facility have the ability to manage	Yes
on-site or off-site destruction of the	
Investigational Product?	
Do you provide your Satellite Site(s) with a	Yes
dedicated inventory of Investigational Product?	
Does your facility have a written	Yes
SOP/Policy/Procedure for the destruction of	
Investigational Product?	
Is your Facility capable of administering	Yes
infusions?	
Is your Facility adequately staffed to support	Yes
studies with both blinded and unblinded	
Investigational Product?	
Does your Facility have the ability to manage	Yes
on-site or off-site destruction of controlled	
substances when appropriate?	
Does the Facility have the ability to handle	No
radio-labelled Investigational Products?	
Location Information	No
Secure Storage Records	Grace Management, Toohey Street,
	Portsmith, Cairns Queensland 4870
	Australia
Do you have Electronic Health Records (EHR)/	Yes
Electronic Medical Records (EMR)?	
EMR/EHR systems	Other
Location of Monitor	Can monitor at primary and satellite
	sites
Please list any access limitations/requirements	Read only
for the Electronic Medical Records	
Please list any access limitations/requirements	Fax, Copy Machines
for the Electronic Medical Records	
EDC Systems	Mosiaq