Townsville University Hospital - James Cook University (Oncology)

Local Services Offered:

Clinical trials site, 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.

Facility Details:	
Please provide your Facility Webs	https://www.townsville.health.qld.gov.au/
What Department is your Trial	Medcial Services
Site? (Queensland Health HHS-	
See List of Services and Levels-	
Clinical Services Capability	
Framework)	
Is your facility/organisation a Life	No
Sciences Queensland (LSQ)	
Member?	
Do you have Affiliated Research	Yes
Sites or Satellite Sites/Clinics? 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.	
Please provide other facility	Other Townsville HHS facilities
Provide the list of Sub-	Hemic and Lymphatic Diseases
Therapeutic Areas for your	
Facility.	
Does your Clinical Trial site	Yes
undertake any patient	
IRB/ERB/Ethics Committee	2:
Does your Facility perform	No
HREC (IRB/ERB/Ethics)	
Committee	
Does your Facility have a	No
dedicated department or group to	
perform HREC	
(IRB/ERB/ETHICS) Committee	
HREC Committee Name.	Townsville HHS HREC
What is the meeting frequency of	Two meetings per week in NMA
your Local IRB/ERB/Ethics	
Committee?	
Does the HREC Committee	Yes
require payment prior to the	
release of final approval	

Consent:	
Does your Facility have a written	Yes
SOP/Policy/Procedure for	
Informed Consent?	
Does your Facility have a written	Yes
SOP/Policy/Procedure for Minor	
Assent for paediatric populations?	
Does your Facility have a written	Yes
SOP/Policy/Procedure for Other	
vulnerable populations?	
Does your Facility have access to	Yes
translators and translation support	
for study conduct (e.g. consent,	
study-specific instruction)?	
,	
Training	
Training:	04
Does your Facility have a training	Utner
program for the research staff?	**
Does your Facility training course	Yes
content include GCP?	
If your facility uses external	Caledonian; ARCS; Syneos online
program course/s. Please provide	
the program course/s name.	
Do you have a process or	Yes
program in place to retrain	
research staff when a protocol is	
Does the study staff that prepares	Yes
or transports dangerous goods	
have training that meets the IATA	
International Air Transport	
Association (US) or other	
countries hazardous training	
requirements for shipping	
Facility And Equipment:	
Facility Capabilities:	
Can your Facility support in-	Yes
patient admissions for research	
Can your Facility support patient	Yes
visits on weekends?	
Is your Facility capable of	Yes
administering infusions?	
Is your Facility adequately staffed	Yes
to support studies with both	
blinded and unblinded	
Investigational Product?	
Does your Facility have the	Yes
ability to collect and store PK/PD	100
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Does your Facility have the	Yes
ability to collect PK/PD samples	
beyond normal business hours?	
Does your Facility typically allow	Yes
the collection of	
Pharmacogenomic (PGX)	
samples for research purposes?	
Does the Facility have storage	Yes
space for Study-Related materials	
(e.g. Lab Kits, Patient Materials,	
(e.g. Euo Kits, i attent iviaterials,	
Equipment:	
Does your Facility have the	Yes
necessary equipment to treat	
medical emergencies (for example	
crash/code cart)?	
,	V
Does your Facility have an SOP	Yes
or process that ensures routine	
calibration and maintenance of	
general equipment? Examples of	
general equipment include: scale,	
pulse oximeter, stadiometer,	
sphygmomanometer, etc.?	
IT Capabilities:	
Does your Facility have	No
computers that are dedicated to	
research studies?	
What browser does your facility	Edge
use?	Euge
	Yes
Does the Facility have access to	res
local IT support?	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\
Does your Facility limit or	Yes
prohibit access and use of	
external web-based tools or sites	
for clinical research (E.g. web	
portals to submit documents to	
What type of computer operating	Windows
system(s) does your institution	
use to support studies?	
Labs:	
Is your Facility using a local	Yes
pathology lab?	
Please provide the Local Lab	Pathology Queensland-Townsville Hospital
-	
IP Storage Details:	
IP Recipient Name	Townsville University Hospital Pharmacy
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Do so the Investigational Draduct	Yes
Does the Investigational Product	Yes
Storage Room have back-up	
power?	77
Is the Investigational Product	Yes
Storage Room secured with controlled access?	
Is the Investigational Product	Yes
Storage Area securely	
Does your Facility have the	Yes
ability to manage on-site or off-	
site destruction of the	
Investigational Product?	
Does your facility have a written	Yes
SOP/Policy/Procedure for the	
destruction of Investigational	
Product?	
Does your Facility have the	Yes
ability to manage on-site or off-	
site destruction of controlled	
substances when appropriate?	
Does the Facility have the ability	Yes
to handle radio-labelled	
Investigational Products?	
Do you provide your Satellite	Yes
Site(s) with a dedicated inventory	
of Investigational Product?	
Does your Facility have a written	Yes
SOP/Policy/Procedure to ensure	
that Investigational Product is	
appropriately maintained during	
transportation to Satellite Site(s)?	
Source Documents:	
Does your Facility have patient	Yes
record archiving on-site?	
Does your Facility have secure	Yes
storage for patient records?	
storage for patient records:	
Electronic Medical Records (FM	 R /Electronic Health Records (EHR):
Do you have Electronic Health	EXTENSION PROBLEM RECORDS (ETITY).
Records (EHR)/ Electronic	
Medical Records (EMR)?	
The second (Elvin).	