

Clinical Trial Research Agreement Information (Site Details):

Institution: South Eastern Sydney Local Health District

Name: (Principal Investigator)

Address: Prince of Wales Hospital, Barker ST Randwick, NSW, 2031, Australia

ABN: 70 442 041 439

Contact for notices: Christie Norris

Fax for notices: +61 (0) 2 93822588

Phone for notices: +61 (0) 2 93822466

eCTN details (Approving Authority Details):

Name of Approving Authority	South Eastern Sydney Local Health District
Approving Authority Contact Officer	Mr Tobi Wilson
Position	General Manager, Prince of Wales, Sydney and Sydney Eye Hospitals and Health Services
Contact Phone	0293823587
Contact Email	SESLHD-RSO@health.nsw.gov.au

Trial Unit Equipment

Centrifuge (refrigerated)

-20°C freezer temperature monitored with alarm

-80°C freezer temperature monitored with essential power, and back to base alarm

ECG machine

Electronic Medical Record Mosaicq™

The Oncology Trials Unit utilises an electronic Medical Record (Mosaicq™). This has been assessed to comply with the FDA code 21 CFR part 11.

Clinical Research Associates performing source data verification using Mosaicq will be given personalised username and password to access read only patient data. It is to be noted that the trial unit monitors patient access of CRAs on a regular basis to ensure compliance and patient privacy.

CRA facilities for monitoring visits

Hot desks available, with computer for access to electronic medical records.

All attempts will be made to accommodate monitoring visits within two weeks of first patient on study. Otherwise CRA's need to book monitoring visits at least 4 weeks in advance.

Pharmacy

Joanne O'Brien. Senior Pharmacist – Clinical Trials

Prince of Wales Hospital, Pharmacy Department, High Street, Randwick NSW 2031

Phone: (02) 9382 2333, Fax: (02) 9382 2345, email; Joanne.O'Brien@health.nsw.gov.au

Drug delivery:

Pharmacy Department, Level 2 via Loading Dock 3, Prince of Wales Hospital High Street, Randwick NSW 2031

Lab:

South Eastern Area Laboratory Services (SEALS), Randwick Campus, Level 4 Campus Centre, High Street, Randwick NSW 2031 Australia.

Radiology:

Nuclear Medicine, Level 2, Campus Centre, Prince of Wales Hospital, Barker Street,
Randwick NSW 2031 Australia

Wales CT, Medical Imaging Department, Level 0, Campus Centre, Prince of Wales Hospital,
Barker Street, Randwick NSW 2031 Australia

Offsite archiving:

Government Records Repository, 143 O'Connell St, Kingswood NSW 2747
Ph 02 96731788 Fax 02 88055306 e-mail grr.nsw@records.nsw.gov.au