**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: Karen McCardie or Nurse Unit Manager

Fax for notices: +61 (0) 2 9382 5170 Phone for notices: +61 (0) 2 9382 5191

**eCTN details (Approving Authority Details):**

Name of Approving Authority South Eastern Sydney Local Health District

Approving Authority Contact Officer: 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) -20oC freezer temperature monitored with alarm -80oC freezer temperature monitored with essential power, and back to base alarm ECG machine

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

Clinical Research Associates performing source data verification using Mosaiq 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.OBrien@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

Offsite archiving: Iron Mountain Australia Group Pty Ltd Tel 61 1300 476 668 website: www.IronMtn.com.au/Home