

CLIMATE Trial News

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Welcome to the fourth CLIMATE newsletter

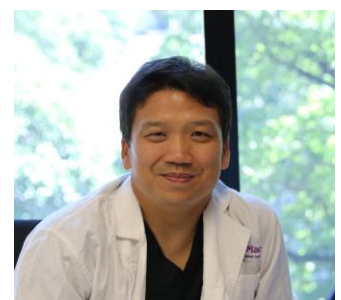
The recruitment goal is fast approaching for CLIMATE study with a total of 140 patients recruited to-date. We have a total of 12 sites open and running; thank you all for your hard work and your continued support towards this exciting study.

Study accrual:

Site	PI	Participants recruited
<i>Open for recruitment</i>		
Epworth Freemasons (VIC)	Ben Tran	46
Peter Mac (VIC)	Jeremy Lewin	36
Calvary Mater Newcastle (NSW)	James Lynam	8
Austin Hospital (VIC)	Andrew Weickhardt	11
Eastern Health Box Hill (VIC)	Lia Papadopoulos	4
Barwon Health Geelong (VIC)	David Campbell	4
Chris O'Brien Lifehouse (NSW)	Peter Grimison	9
Princess Alexandra Hospital (QLD)	Aaron Hansen	8
Sydney Adventist Hospital (NSW)	Gavin Marx	4
St Vincent's Hospital Sydney (NSW)	Ben Namdarian	2
Royal Brisbane and Women's Hospital (QLD)	Anna Kuchel	2
Te Whatu Ora Southern (NZ)	Orlaith Heron	6

Study Chair: Associate Professor Ben Tran

"We're nearly there everyone!!! 60 more patients and then we'll be ready to run the assay on all baseline samples! Let's get a final push to finish recruitment! Remember the six-week window post orchidectomy... Make sure all your urologists and their registrars are aware of the study!"



Please continue to screen potential participants who may be eligible for the study:

- Adults with clinical stage 1, testicular germ cell tumour (seminoma *and* non-seminoma)
- Orchidectomy within 6 weeks prior to consent (and baseline miRNA sample)
- Planned for active surveillance following orchidectomy (adjuvant therapy *not* permitted)
- No prior history of testicular cancer

Tips and Reminders

- Please discuss CLIMATE with your local surgical colleagues and MDTs.
- Make sure to register your patients on REDCap and iTestis as soon as they have consented.
- UNIVIDs are assigned by iTestis. Sample IDs are assigned by RedCap.
- Sample ID is prepopulated in RedCap and sequential. When getting close to using up all the IDs, get in touch for more IDs to be prepopulated.
- At routine visits where miRNA sampling is required, depending on your local set-up, your site may find it easier to collect any standard-of-care bloods at the same time and spare the participant >1 venepuncture.
- When completing sample log/manifest, please include UNIVIDs and sample IDs generated by RedCap to help with reconciliation.
- While recording cryovial locations in RedCap database, please record alphanumeric indexing numbers i.e. 1A, 1B.
- Please ensure that no data fields are missing in the forms marked as complete in RedCap database.
- Please track timepoints for your enrolled patients. Booking in the next review at each blood collection can help forward manage this.
- Protocol amendment V4 incorporates extension of follow up to allow collection of recurrence samples and data between 24months and 36months. Window period has been extended to 28 days from Month 9 onwards.
- If a patient has a recurrence within their next timepoint window, only a relapse sample is required. Use the relapse 'RL' labels and the next sequential kit for sample collection and enter this sample data in the relapse form in REDCap.
- Any protocol deviations need to be documented in a protocol deviation log.



Walk, Cycle, Swim, or go your own way... Do 111 Your Way throughout October to raise funds and awareness for the 111 Australian and NZ people diagnosed every day with Below the Belt cancers.

CLIMATE key contacts

- Clinical trial operations (WEHI) to Miku Kuba, E: CLIMATE@mh.org.au
- Coordinating PI: Ben Tran E: ben.tran@petermac.org
- Sponsor queries (payments, contracts) Archana Nair, E: trials@anzup.org.au
- Trial information: <https://anzup.org.au/clinical-trial/climate/>