

## 1<sup>st</sup> Birthdays

Our first Protect Me baby's have reached an exciting milestone in July, turning One! The Protect Me team wishes to congratulate all 6 families that celebrated a first Birthday last month.

August in 2019 also kept us busy, with all 3 August babies deciding to share their Birthday. We send each of them well wishes for a Happy Birthday.

## ITSEA & Bayley's

A year has come around quickly, which means that in just 12 months neurodevelopmental follow-up will begin. The planned follow up being in the form of the ITSEA questionnaire and the Bayley's assessment. Both are important tools for assessing and formulating the primary outcome for the trial, which is neurodevelopmental outcomes of all baby's involved in Protect Me.

Watch this space, though as we change to Bayley's IV assessment ahead of beginning our neurodevelopmental follow-up.

The team is in the process of ensuring these assessments are easily accessible to all our participant's.

## Progress Summary

Currently Monash is the only active recruiting site:

- 28 Woman recruited
- 1 Withdrawn
- 23 MRI's Completed
- 4 MRI Incomplete
- 23 GMA's (TCA) Complete
- 4 GMA's (TCA) Incomplete
- 0 GMA's (TCA) Upcoming
- 18 GMA's (3 Month TCA) Complete
- 3 GMA's (3 Month TCA) Incomplete
- 4 GMA's (3 Month TCA) Upcoming
- 1 Currently Pregnant

## COVID-19

Since the beginning of the pandemic the Protect Me Team have been ensuring all aspects of the trial limit any risk from COVID for both patients and staff.

With many appointments moving to Telehealth format initial mention of the trial has often been reliant on our colleagues during their consultation. We are truly grateful for your support with the trial by doing so. Gaining permission to make contact through this process has enabled us to offer participation to all women who meet eligibility criteria. The structure of antenatal trial follow-up has always been tailored to routine antenatal appointments, thus ensuring participants are not required to have any additional hospital attendance.

Our thoughts during these challenging times are with our front line colleagues and our families that are already facing a complex pregnancy and postnatal period.

## Branching out

Protect Me will be expanding to another possible 15 sites throughout Australia & New Zealand. Excitingly we will be welcoming on board Sunshine Hospital and multiple Hospitals across New Zealand soon, as they are in the final processes of setting up.

We welcomed on board The Mercy Hospital for Women in March, however Covid-19 has had a major impact on recruitment there. We remain hopeful to see the first Mercy participant in the near future. Our thoughts are with the team at the Mercy as they continue to keep mother's and babies safe during this time.

We appreciate the time and effort taken by all involved, enabling other Hospital's to be a part of this important research. Refer to the table below for further details as to where you might see PROTECT Me coming soon.

Site	Ethics	Governance/ CTRA	Enrolled participants	Withdra wn	Term corrected MRI	Term corrected GMA	3 month GMA	Baileys III	ITSEA
Monash Health, VIC	✓	✓	28	1	23	23	18		
Mercy Hospital for Women, VIC	✓	✓							
Sunshine Hospital, VIC									
The Royal Women's Hospital, VIC									
Royal Hobart Hospital, TAS									
Royal Prince Alfred Hospital, NSW									
John Hunter Hospital, NSW									
Mater Hospital Brisbane, QLD									
Townsville Hospital, QLD									
King Edward Memorial Hospital, WA									
Women's and Children's Hospital, SA									
Auckland City Hospital, Auckland New Zealand									
Middlemore Hospital, Auckland, New Zealand									
Christchurch Hospital, Christchurch, New Zealand									
Palmerston North Hospital, Palmerston North, New Zealand									
Wellington Hospital, Wellington, New Zealand									

## Trial Team Updates

We wish Harriet Dinning, one of our trial coordinators, all the best as she heads off on maternity leave. We look forward to meeting the latest member of the PROTECT Me team, alight a well grown member, in the weeks ahead.

We welcome Hildegard Mostman's to the team. Hildegard will join the team to assist with ethics and trial administration, particularly as we expand to many other participating sites.

Likewise, we wish Veronica Abruzzo well as she takes on an expanded role with the Murdoch Children's Research Institute.

Ebony LaPosta, a clinical midwife, will be joining the trial team at Monash Health and we are thrilled to have her join the team.

With these changes to the trial team, we remain highly committed to supporting other sites in joining the trial and the contacts for the team remain unchanged on [scs-protectme@monash.edu](mailto:scs-protectme@monash.edu)

## Follow us online



Trial Information can be found on the Monash University MHTP Clinical trials Site <https://mhtp-clin-trials.med.monash.edu/>



Protect Me information and updates are also visible on IMPACT (Interdisciplinary Maternal Perinatal Australian Collaborative Trials Network) website.

<https://impact.psanz.com.au/clinical-trials/the-protect-me-trial/>

Updates will also be available in the Monash Woman's Clinical Trials Network Recruitment Update Newsletter



You can continue to follow us on Twitter @ProtectMeTrial

*thank you*