

ACTA Trial of the Year Consumer Involvement Award



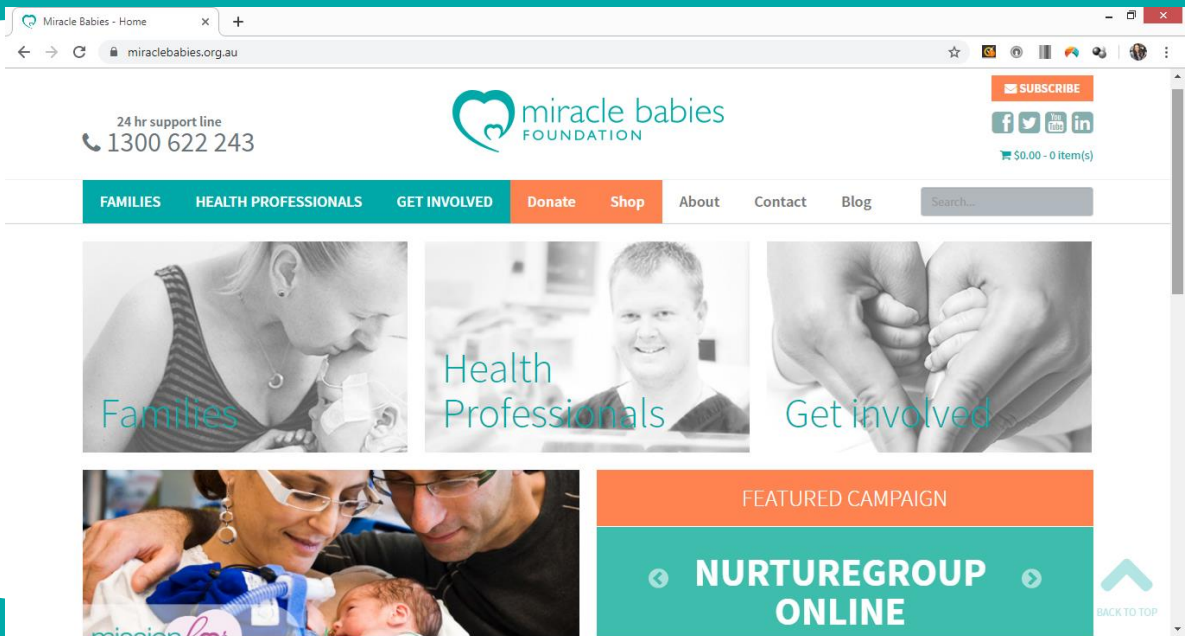
Melinda Cruz



The
ALPHA
Collaboration

my boys





the beginning of our consumer rep journey

Why the need for
parent involvement
in trials?



what's been achieved so far

- AI and CI on numerous trials
- coauthored 10 medical publications
- international presentations in Italy, Germany, US, Canada & NZ
- engagement of neonatal families for information and data
- committee positions including PSANZ, ANZNN and Australian Red Cross Blood Service Milk Bank
- winner of the ACTA Consumer Involvement Award



TORPIDO 30/60

1,470 babies <29 weeks gestation

Test initial oxygen concentration
of 30% or 60%

Improves survival without disability



TORPIDO 30/60

Consent during delivery is a challenge

Optimum initial oxygen concentration for preterm infants unknown for over 30 years

Restricting enrolment to prior consent excludes the sickest and those born as emergencies.

Deferring consent until after randomization can result in post-randomization exclusion bias

Guided by NHMRC National Statement on Ethical Conduct of Research - waiver of consent was sought



TORPIDO 30/60

Open session to the Hunter and New England Human Research Ethics Committee :

- Parents in shock find it difficult to make acute decisions about research
- Knowing their babies' treatment has not been validated causes distress
- Parents preferred knowing that the 'without prior consent' study their baby is in was approved by HRECs
- Evidence that participating in Phase III trials is associated with better outcomes and survival, compared to usual care



TORPIDO 30/60

What is important to parents :

That their feelings are considered, and that the opt out for secondary outcomes and follow up outcomes will be respected

That their experience is contributing to something larger, the improvement of medical care for all babies



TORPIDO 30/60

“This is a question that hasn’t been answered for 30 years...

on treatments that are already happening”



TORPIDO 30/60

Hunter and New England HREC
voted unanimously to allow the
waiver of consent



Where to from here?





The **ALPHA** Collaboration

Advancing
Large, collectively
Prioritized trials for
Health outcomes
Assessment worldwide

AIMS

The ALPHA Collaboration is a global initiative promoting a network-of-networks to embed large, simple trials of between 5,000 and 50,000 or more participants in routine care.

"Ten times larger and faster, at one tenth the cost"



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We plan to engage thousands of parents and former patients alongside other stakeholders in international prioritization exercises to identify key questions for future RCTs to improve disability-free survival.

"Ten times larger and faster, at one tenth the cost"





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Let's make this one of the first questions
parents and patients want to ask us:

"Are there any trials we can join?"

"Ten times larger and faster, at one tenth the cost"



consumer reps / parent voice

The requests:

- o Panels / Committees
- o On research as investigators
- o Reviewing documents
such as policies, strategies, brochures etc
- o Presentations / Keynotes / Talks
- o Access to NICU / SCN families for data collection
eg online surveys, focus groups



View Insights

Liked by melindacruz_ and others

miraclebabiesfoundation *QUICK SURVEY*****

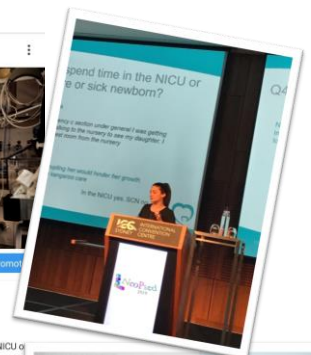
Are you a parent to a baby that has been cared for in NICU or SCN? We want to hear from you.

Click here to complete this short 6 minute survey and have your say on being separated from your baby during their time in a Neonatal Intensive Care Unit/Special Care Nursery: <https://www.surveymonkey.com/r/V8HKG6X>

IN BIO or visit <https://www.surveymonkey.com/r/V8HKG6X>

Thank you! Your feedback is important and will help other families just like your own.

#miraclebabies #prematurebabies #sicknewborns #nicu #survey



consumer reps / parent voice

Development of :

- o Application / Induction / Training process for parents
- o Online request form for health professionals requesting consumers
- o Working Toolkit and secretariat support for consumers
- o Guidelines for parents and health professionals
- o Process on documenting time and outcomes/impact



same goal – *better, healthier families*

Grow consumer involvement

Raise the awareness of trials

*Trials that are ten times larger and faster,
at one tenth the cost*

Embed trials into routine care

Parents asking “are there any trials we can join?”

