



# Diabetes and Antenatal Milk Expressing (DAME) Trial

ACTRN12611000217909

## SAFETY COMMITTEE TERMS OF REFERENCE

The purpose of this document is to describe the roles and responsibilities of the Safety Committee for the DAME trial including the timing of meetings, methods of providing information to and from the Safety Committee, frequency and format of meetings and relationships with other committees.

### Aims

To safeguard the interests of trial participants by assessing the safety of participation, and to assist and advise the principal investigators so as to protect the credibility of the trial.

### Relationships

The Safety Committee reports to the DAME principal investigators. A Data Monitoring Committee will be reporting separately on recruitment progress and accruing data from the trial.

### Specific roles of the Safety Committee

- To review reports of serious adverse outcomes in both trial arms to identify possible contributing factors related to participation in the trial and any association with either trial arm
- To advise the principal investigators if the Safety Committee has concerns about the safety of participants that might require the trial's early termination

The adverse events that the Safety Committee will be required to report on are:

- Perinatal/infant outcomes
  - Fetal compromise associated with expressing as evidenced by:
    - a) any abnormality on any a CTG during/following expressing (within four hours); or
    - b) decreased fetal movements during/following expressing (within four hours) necessitating presentation to hospital for fetal monitoring and/or cessation of the intervention;
  - Moderate to severe encephalopathy with or without seizures;
  - Admission to NICU/NISC for respiratory support (defined as respiratory support greater than four hours);
  - Perinatal death.
- Maternal
  - Maternal hypoglycaemia within half an hour of expressing (defined by a blood glucose level less than 4 mmol/l or symptoms requiring treatment<sup>1</sup>)
  - Abdominal pain after antenatal expressing –within 4 hours
  - Vaginal bleeding after antenatal expressing –within 4 hours

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<sup>1</sup> Women will have received a list of symptoms of hypoglycaemia as part of their pregnancy care, and those defined by Diabetes Australia, Victoria are weakness, trembling or shaking, sweating, light headedness, headache, lack of concentration/behaviour change, dizziness, tearful/crying, Irritability, numbness around the lips and fingers, hunger.