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RCH HUMAN RESEARCH ETHICS COMMITTEE APPROVAL

HREC REF. No:	**33169 A**
PROJECT TITLE:	Risk/ benefit evaluation of fluid bolus therapy in the treatment of febrile children with cardiovascular compromise in the Paediatric Emergency Department
DOCUMENTS APPROVED:	PGIS v9 dated 28 October 2013 PIS v6 dated 28 October 2013 Flyer v3 dated 27 November 2013
APPROVED PROTOCOL:	Protocol v7 dated 27 November 2013
PRINCIPAL INVESTIGATOR:	Elliot Long
DATE OF ORIGINAL APPROVAL:	**29 November 2013**
DURATION:	60 months
DATE OF APPROVAL EXPIRY:	**29 November 2018**

SIGNED: .....
COMMITTEE REPRESENTATIVE

29th November 2013

APPROVED SUBJECT TO THE FOLLOWING CONDITIONS:

ALL PROJECTS

1. Must comply with the Investigator's Responsibilities in Research Procedure and other Campus Research Policies and Procedures
2. Any proposed change in the protocol or approved documents or the addition of documents must be submitted to the Human Research Ethics Committee (HREC) for approval prior to implementation, including:
   - flyers, brochures, advertising material
   - Increase in recruitment target
3. The Principal Investigator must notify Research Development & Ethics of:
   - Any serious adverse effects of the study on participants and steps taken to deal with them.
   - Any unforeseen events (e.g. protocol violations or complaints).
   - Investigators withdrawing from or joining the project.
4. A progress report must be submitted annually and at the conclusion of the project.
5. RCH HREC approval must remain current for the entire duration of the project. If the project is not completed in the allocated time a renewal request must be submitted to the Research Development & Ethics. Investigators undertaking projects without current HREC approval risk their indemnity, funding and publication rights.

CLINICAL TRIALS

6. Must comply with Good Clinical Practice (GCP)
7. Must report all internal (occurring in RCH participants) Serious Adverse Events (SAE) to the sponsor and the RCH HREC within 72 hours of occurrence.
8. Must report all Suspected Unexpected Serious Adverse Reactions (SUSARS) to the Therapeutic Goods Administration (TGA) (for sponsored studies the sponsor may take this responsibility).