The Royal Children's Hospital Melbourne
50 Flemington Road
Parkville Victoria 3052 Australia
TELEPHONE +61 3 9345 5522
www.rch.org.au

The Royal Children's Hospital Melbourne

RCH HUMAN RESEARCH ETHICS COMMITTEE APPROVAL

HREC REF. No:	**34005 A**
PROJECT TITLE:	Development of an e-Parenting Intervention Targeting Behavioural Problems for Children with Leukaemia : A Pilot Study
DOCUMENTS APPROVED:	PGIS & CF v2 dated 28 Mar 2014 Parent Baseline Survey v2 dated 28 Mar 2014 Control Survey Time 2 v2 dated 28 Mar 2014 Intervention Survey ¿ Time 2 v2 dated 28 Mar 2014 Control Survey ¿ Time 3 v2 dated 28 Mar 2014 Intervention Survey ¿ Time 3 v2 dated 28 Mar 2014
APPROVED PROTOCOL:	Protocol v3 dated 14 Apr 2014
PRINCIPAL INVESTIGATOR:	Lauren Williams
DATE OF ORIGINAL APPROVAL:	**17 April 2014**
DURATION:	24 months
DATE OF APPROVAL EXPIRY:	**17 April 2016**

SIGNED: _____ ..... 17th April 2014
COMMITTEE REPRESENTATIVE

APPROVED SUBJECT TO THE FOLLOWING CONDITIONS:

ALL PROJECTS

1. The study must not commence until all Research Agreements have been executed (if applicable)
2. Must comply with the Investigator's Responsibilities in Research Procedure and other Campus Research Policies and Procedures
3. 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
4. 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.
5. A progress report must be submitted annually and at the conclusion of the project.
6. 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

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