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ETHICS IN HUMAN RESEARCH COMMITTEE APPROVAL

EHRC REF. No:	**24105 A**
PROJECT TITLE:	Neuromuscular apparatus and the control of smooth muscle motility in children with constipation: Examination of archived specimens.. Refer study 23081B,
Documents approved:	P/GIS&Consent v2 dated 21 Oct 2004, PIS&Consent v2 dated 21 Oct 2004
Approved Protocol:	Protocol within Mod 1 submitted 31 Aug 2004,
INVESTIGATOR(S):	J Hutson, B Southwell, P Farmer, S King, A Harrington, J Sutcliffe
DATE OF ORIGINAL APPROVAL:	**28 October 2004**
DURATION:	24 months
DATE OF APPROVAL EXPIRY:	28 October 2006

SIGNED: 1.11.104
COMMITTEE REPRESENTATIVE

APPROVED SUBJECT TO THE FOLLOWING CONDITIONS:

ALL PROJECTS

1. Any proposed change in protocol, or any approved documents, or the addition of any documents (including flyers, brochures, advertising material etc) and the reasons for that change or addition, together with an indication of ethical implications (if any), must be submitted to the Ethics in Human Research Committee for Approval prior to implementation.
2. The Principal Investigator must notify the Secretary of the Ethics in Human Research Committee of:
   - Actual starting date of project.
   - Any adverse effects of the study on participants and steps taken to deal with them.
   - Any unforeseen events.
   - Investigators withdrawing from or joining the project.
3. A progress report must be submitted annually and at the conclusion of the project, with special emphasis on ethical matters.
   Please note that it is the investigator's responsibility to ensure that the RCH EHRC approval remains current for the entire duration of the project. Investigator's undertaking projects without current EHRC approval put at risk their indemnity, grant and publication rights.

DRUG TRIALS

4. The investigators must maintain all records relating to the study for a period of 23 years.
5. The investigator(s) must report to the Sponsor and the Ethics in Human Research Committee within 24 hours of becoming aware of any serious adverse event experienced by any subject during the trial.
6. The investigators must ensure that all externally sponsored Clinical Drug Studies have insurance coverage that is current for the entirety of the study.