PROTOCOL No.4

EXPERTS PROTOCOL

1. Context for the Involvement of Experts

1.1 The work of the Inquiry is to provide insight into and understanding of the issues raised by the Revised Terms of Reference. In order to carry out that task it will need to be informed by independent expert opinion in a number of areas.

1.2 The Revised Terms of Reference calls for an investigation into why Adam Strain and Raychel Ferguson died. The Inquiry is also investigating the death of Claire Roberts. Additionally the Inquiry is investigating issues surrounding record-keeping in respect of the treatment of Conor Mitchell bearing in mind the introduction of the DHSSPS(NI) Guidelines on the Prevention of Hyponatraemia in Children in March 2002.

1.3 At the heart of the investigation into the deaths of Adam, Claire and Raychel lies the question of how the administration of intravenous fluids to these children was managed. In relation to Conor, what is primarily at issue is how the administration of the intravenous fluids was recorded.

1.4 However, those investigations will not of themselves provide a complete answer to the issues to be addressed by this Inquiry in the course of its work. The care and treatment provided to these children leads naturally to broader issues concerning medical education and training, as well as the procedures and structures for ensuring an effective flow of information to enable lessons to be learned from the deaths of children in hospital and adverse incidents.

1.5 Furthermore and as part of the consideration of any requirement for change, it will be important for the Inquiry to be able to establish the extent to which the deaths of these children form a pattern of outcome from treatment involving the administration of the intravenous fluids, as well as how the incidence of death in this way compares with that in the rest of the UK and other European countries.

1.6 In addition to the appointment of the Inquiry's Advisors to assist it with its work and the engagement of Expert Witnesses, the Inquiry will also commission a series of 'Background Papers' from Experts on areas of particular significance such as medical education and training.

1.7 Finally, and so that the Inquiry can have confidence in the quality and independence of the views of its Advisors on which it will rely, it will be necessary for those views to be subject to peer review.

2. Inquiry's Advisors

2.1 The Inquiry has appointed experts to act as Advisors so as to provide expert advice and guidance throughout the investigation.

2.2 The primary role of the Advisors is to assist the Inquiry in dealing with the evidence that the Inquiry is to assess in addressing the issues raised by the Revised Terms of Reference.

2.3 The assistance provided by the Advisors to the Inquiry is likely to be:

- 2.3.1 Helping to identify the evidence (mainly but not exclusively medical) that the Inquiry should call for and, if appropriate, the likely sources of such evidence
- 2.3.2 Helping to interpret and evaluate the evidence provided to the Inquiry, including providing an expert view on questions raised by the Inquiry
- 2.3.3 Helping to identify any other expertise that the Inquiry should appoint
- 2.3.4 Providing a Final Report
- 2.3.5 Assisting with the Seminars

2.4 The Advisors are not appointed by the Inquiry to advance any given 'line' of argument or to support any particular 'side'; rather their task is to assist in the process of inquiring.

3. Peer Reviewers

3.1 The Inquiry has appointed experts from outside the United Kingdom to provide peer review of the work of its Advisors.

3.2 The Peer Reviewers perform three main functions for the Inquiry:

- 3.2.1 Commenting upon the work of the Advisors and so help to ensure that the Inquiry receives independent, high quality advice
- 3.2.2 Providing an insight into issues such as the organisation of medical education and training and of hospital administration in other jurisdictions, to assist the Inquiry with the broader issues it has to address in providing recommendations
- 3.2.3 Assisting with the Seminars, including the formulation of Seminar topics and the identification of presenters and key invitees

4. Experts preparing Background Papers

4.1 The Inquiry has commissioned 'Background Papers' from experts who will carry out research and provide the results of that research in a

series of papers to be available to the Inquiry and for publication prior to the start of oral hearings. The Background Papers are not intended to make any given case; rather their function is to provide a factual context within which to receive and consider the evidence of the Witnesses.

4.2 It may be that the Background Papers will also provide, to a limited degree, the opinions of their authors and if so that will be clearly indicated including the material on which the opinion is based.

5. Expert Witnesses

5.1 From time to time, and depending on the needs of any individual case, the Inquiry may also appoint an Expert Witness to provide advice in a given area or on a particular issue and who may be required to give evidence.

5.2 Expert Witnesses are not engaged by the Inquiry to advance any given 'line' of argument or to support any particular 'side'; rather their task is to provide their opinion and to explain its basis during the Oral Hearings.

6. Criteria for Appointing Experts

6.1 The criteria for appointing Experts (whether as Advisors or Expert Witnesses) and the Peer Reviewers are:

6.1.1 An established and high level of competence in their particular field
6.1.2 Independence from any of the Interested Parties
6.1.3 Willingness and ability to commit the amount of time necessary to consider evidence, attend meetings and hearings as appropriate, provide reports and make themselves available to the Inquiry as required

6.2 None of the experts will be appointed from within Northern Ireland, save for those providing Background Papers where local knowledge is considered to be an asset. In the case of the Peer Reviewers, the Inquiry has looked to the USA, Canada and Australia to obtain a breadth of views on the issues involved in its work.

7. Forms of Assistance
Inquiry's Advisors

7.1 The Advisors have been and will be asked to provide the Inquiry with a range of forms of assistance as the circumstances and evidence require. Typically it has and is likely to involve:

- *Helping to identify the evidence*

  The Advisors will be provided with copies of the documentary evidence received by the Inquiry and will be asked to identify further documents for which the Inquiry might call.

  The Advisors will also be provided with the lists of persons from whom Witness Statements have been requested together with the Witness Statements and will be asked to assist with the identification of: (i) any additional persons from whom Witness Statements should be sought together with the areas which they should address, (ii) follow up evidence from the witnesses and, (iii) witnesses who should attend to give evidence at the Oral Hearings.

  In addition and as part of their consideration of the documents and the Witness Statements, the Advisors will be invited to identify any other areas of expertise from which the Inquiry might usefully engage an Expert Witness.

- *Helping to interpret and evaluate the evidence*

  In order to assist the Inquiry with the Oral Hearings, the Advisors will provide Preliminary Reports, assessing and evaluating the evidence that they have considered and giving their initial view on its import.

  Where the Advisors provide a Report which the Inquiry considers is potentially critical of a witness' evidence, then that witness will be advised of the criticism and will be afforded an opportunity of dealing with it during the Oral Hearings.

  The Advisors will attend the Oral Hearings, or such part of them as is considered appropriate having regard to their area of expertise, and will assist in developing lines of inquiry, formulating questions for the witnesses and responding to questions from the Chairman and or Counsel to the Inquiry.

- *Assisting in disseminating the Inquiry's preliminary findings*

  At the conclusion of the Oral Hearings and so as to assist the Inquiry in formulating its recommendations, the Advisors will provide their Final Reports. Those Reports will assess and evaluate the totality of the written and oral evidence together with all the expert opinion that they have seen, heard and considered and will give their concluded view on its import in respect of the issues raised by the Revised Terms of Reference.

  After the Oral Hearings, the Inquiry will convene special seminars, and may hold open meetings, to discuss various possible recommendations on issues such as: (i) education and training, (ii)

record keeping and maintenance of statistics, (iii) communication of information and lessons learned, together with other topics of relevance to the Inquiry. The Advisors may be asked to assist in the planning and the conduct of these events.

Peer Reviewers

7.2 The forms of assistance that the Peer Reviewers will provide to the Inquiry are:

- *Commenting upon the work of the Inquiry's Advisors*

  The Peer Reviewers will receive all the Background Papers, written comments and Preliminary and Final Reports of the Advisors and will produce their own reports on the relevant issues. For that purpose they will receive all the documentary evidence and will have access to the transcript of the Oral Hearings and will also be given all the Reports and Statements produced in the course of the Inquiry's work.

- *Providing an insight into the broader issues*

  The Peer Reviewers will be asked to comment in writing, within their areas of expertise, upon the broader issues of concern to the Inquiry such as: (i) medical education and training, (ii) hospital procedures relating to critical and adverse incidents, (iii) record keeping and maintenance of statistics, (iv) lines of responsibility and communication generally within the health service in relation to the dissemination of information on adverse and critical incidents to ensure that lessons are learned from them.

  The Peer Reviewers may be asked to support their comments by reference to documents and published literature. If appropriate and feasible they may be asked to provide copies of such material.

  The Peer Reviewers will provide a Final Report. Those Reports will assess and evaluate the totality of the written and oral evidence together with all the expert opinion which they have seen and considered and will give their concluded view on its import in respect of the issues raised by the Terms of Reference.

Experts providing Background Papers

7.3 The experts from whom Background Papers are commissioned will carry out independent research on their respective topics and provide the Inquiry with a properly referenced paper for consideration by the Inquiry and publication on its website. The Background Papers that have so far been identified are:

- *Education, training and continuing professional development in respect of doctors and nurses in Northern Ireland, the rest of the United Kingdom and the Republic of Ireland*

- *Systems of procedures and practices in the United Kingdom for recording, reporting and disseminating information of unexpected deaths (involving Hospitals, Trusts, Area Boards, Department of Health, Chief Medical Officer)*

- *Systems of procedures and practices in the United Kingdom for reporting and disseminating information on the outcomes or lessons to be learned from Coroner's Inquests on deaths in hospital (involving Hospitals, Trusts, Area Boards, Department of Health and Chief Medical Officer)*

- *Adverse incidents, near misses and dissemination of information in respect of them*

- *Comparison of statistics of child hospital deaths in Northern Ireland from hyponatraemia or fluid overload with such deaths in the rest of the United Kingdom and Western Europe*

- *Quality of Northern Ireland statistical information on child hospital deaths from hyponatraemia or fluid overload as compared with those for the rest of the United Kingdom and Western Europe*

Expert Witnesses

7.4 Those engaged as Expert Witnesses will be asked to provide their opinion on specific issues with a view, if appropriate, to being called to explain their opinion and its basis during the relevant Oral Hearings .

7.5 The Expert Witnesses will also be required to attend relevant parts of the Oral Hearings so as to appraise themselves of the evidence being given and the matters in issue.

8. List of Inquiry's Advisors and Peer Reviewers

The following have and/or are providing assistance to the Inquiry as Advisors and Peer Reviewers:

Inquiry's Advisors:

Dr. Harvey Marcovitch
MA(Cantab & Oxon) MB BChir FRCP(Lond) FRCPCH (hon) DCH DObstRCOG
Area of expertise: Paediatrics

Harvey Marcovitch was a full time NHS consultant paediatrician from 1977 to 2001, latterly in Oxfordshire where he was also honorary senior clinical lecturer at the University of Oxford. From 1994 to 2002 he was editor of Europe's leading paediatric scientific journal, Archives of Disease in Childhood and is now editor in chief of Clinical Risk, a bimonthly journal dealing with patient safety, medical law and clinical risks, published by the Royal Society of Medicine Press Ltd. He is also associate editor of the British Medical Journal. Since 2001 he has been an Associate of the General Medical Council and chairs many of its Fitness to Practice hearings.

He has been chairman of the Committee on Publication Ethics (an organization of some 6000 editors of learned journals worldwide) and was on the board of the UK Research Integrity Office, for whom he remains an adviser.

From 1985 to date he has acted as an expert witness for claimants and defendants in clinical negligence cases and is a member of the Expert Witness Institute. He was awarded honorary fellowship of the Royal College of Paediatrics & Child Health in 2006, having previously held various offices since its foundation, including honorary editor and adviser on external relations.

Ms. Carol Williams
BA(Hons) MSc RGN RSCN
Area of expertise: Paediatric Intensive Care Nursing

Carol Williams is an independent healthcare consultant who has recently worked in healthcare regulation. Between March 1985 and January 2006 she worked in Paediatric Critical Care at Guy's & St Thomas' NHS Foundation Trust, London. Her most recent post was Consultant Nurse in Paediatric Intensive Care, but she has managed Children's Critical Care & worked as a lecturer on both undergraduate and masters nursing programmes. She has provided expert witness evidence in the Brompton & Harefield Hospitals and Bristol Royal Infirmary Inquiries.

As Chair of the Royal College of Nursing and Paediatric & Neonatal Intensive Care Forum, Carol provided written and verbal evidence to a House of Commons Select Committee on Child Health and contributed to the development of the National Service Framework for Paediatric Intensive Care Co-ordinating Group and for a Department of Health Team benchmarking national paediatric intensive care standards.

Grenville Kershaw
BA (Hons) FHSM CCMI
Area of expertise: NHS Management

Gren Kershaw has worked in the UK National Health Service for over 36 years. He has held a number of senior managerial positions in different Health Organisations in England and Wales, covering acute, community and

mental health services. For the last 16 years until December 2008, he was the Chief Executive of Conwy & Denbighshire NHS Trust in North Wales.

Gren Kershaw has a long standing interest in quality & safety in health care. He has been responsible for the Welsh Risk Pool, which manages clinical negligence claims in Wales. He was a project board member for the introduction of the National Reporting and Learning System for the National Patient Safety Agency. More recently he led the successful “Safer Patients Initiative” in his own organisation and was a core team member of the "Patient Safety First" campaign in England. He continues to advise on leadership in the “1000 lives” campaign in Wales.

In addition to regular teaching on leadership, Gren Kershaw provides induction training on patient safety to new NHS Non-Executive Board Directors, through the Appointments Commission in England.

Dr. Peter Booker
MB BS(Lond), FFARCS(Lond), MD (Liverpool)
Area of expertise: Paediatric Anaesthesia

Peter Booker was appointed as a consultant paediatric anaesthetist in January 1982 at the Royal Liverpool Children’s Hospital (Alder Hey). He was a Senior Lecturer in paediatric anaesthesia at the University of Liverpool from 1992 - 2005. He retired from his NHS post at the end of August 2010.

He was an examiner for the Royal College of Anaesthetists from 1994 -2005. He had a particular interest in paediatric cardiac anaesthesia and most of his research and publications reflected that interest. He was heavily involved in postgraduate education and organised, for many years, a revision course for trainee anaesthetists about to take their final specialist examination.

Ms. Mary Whitty
BA(Hons)
Area of expertise: Health Service Management

Until 2002 Mary Whitty was the Chief Executive of Brent and Harrow Health Authority in North West London. She joined the National Health Service as a management trainee in 1973 and retired in 2002, having had extensive experience of managing hospital, community and family practitioner health services in London.

From 2002 until 2004 she was a member of the Department of Health Inquiry into the handling by the NHS of allegations regarding the conduct of Clifford Ayling, who practised as a hospital doctor and GP in Kent. Since 2002 she has also worked part-time for the Human Fertility and Embryology Authority and the Health Protection Agency.

Mary Whitty retired from the Panel through ill-health in 2010 and has been replaced by Grenville Kershaw whose details are above.

Peer Reviewers:

Professor Allen Arieff
BA (Michigan) BS (Illinois) MD (North Western) MS (North Western) FACP
Area of expertise: Internal Medicine/Nephrology

Allen Arieff has been a Professor of Medicine at the University of California Medical School at San Francisco for over 25 years. He has done extensive research on the effects of fluid and electrolyte disorders on the brain. This has resulted in 66 invited lectures at international meetings, with over 180 critically reviewed publications, including 10 textbooks on fluid, electrolyte and acid-base disorders and a dozen citation classics.

He has been a consultant to the Food & Drug Administration (USA), the National institutes of Health (USA), Office of the Surgeon General (Canada), Environmental Protection Agency (Norway), Attorney General and Public Defenders Offices (California, USA) and multiple industrial and pharmaceutical companies.

He has served as an expert witness for multiple state courts (USA) in homicide cases, and to both the State and Federal Court System (USA) in many cases of medical malpractice. He has been on the editorial board or review board for over 25 critically reviewed publications. He has over 10 publications in the paediatric literature about fluid & electrolyte disorders and has described two new syndromes leading to brain damage in children.

Dr Desmond Bohn
MB BCh FFARCS, MRCP, FRCPC
Area of expertise: Paediatric Anaesthesia and Paediatric Critical Care Medicine

Desmond Bohn is the chief of the Department of Critical Care Medicine at The Hospital for Sick Children in Toronto and Professor of Anaesthesia and Paediatrics at the University of Toronto. He did his undergraduate medical training at University College Dublin graduating in 1969 and postgraduate training in anaesthesia in Bristol between 1971 and 1975. He joined the staff of the critical care unit at The Hospital for Sick Children, Toronto in 1980 where he has been in full time practice in paediatric critical care medicine. He has authored peer reviewed publications and book chapters on fluid therapy and acute hyponatraemia. He has also been a member of the Paediatric Death Review Committee of the Office of the Chief Coroner of Ontario since 1991. This committee provides peer review for the investigation of deaths in children that are referred to the coroner's office.

Dr. Sharon Kinney
Cardiothoracic Cert., Paed ICU Cert., BN (La Trobe), MN (Deakin), PhD (UniMelb)

Area of expertise: Paediatric Intensive and Critical Care Nursing

Sharon Kinney has worked for many years in paediatric and/or critical care areas in New Zealand, England and Australia. She was a clinical educator and coordinator of the Paediatric Intensive Care Nursing Course at the Royal Children's Hospital, Melbourne from 1988-1997. From 1997-2004 she was a lecturer at the University of Melbourne coordinating the postgraduate nursing programme in paediatric critical care. Between 2004 and 2009 her clinical and research work involved examining life threatening events of hospitalised children (including hyponatraemia) in order to better understand, and ultimately improve, the management of seriously ill children on the wards. She currently holds teaching and research positions with the Royal Children's Hospital and the University of Melbourne. Her research interests include paediatric resuscitation, paediatric critical care nursing, and improving the safety and quality of care for hospitalised children.