Yorkhill Research Ethics Committee

Annual Report

2004/2005
Yorkhill Research Ethics Committee
Annual Report
April 2004 - March 2005

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4. Membership April 2004 - March 2005 -18-

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<tr>
<th>Proposal Number</th>
<th>Title</th>
<th>Authors</th>
<th>Department</th>
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</tr>
</thead>
<tbody>
<tr>
<td>P55/03</td>
<td>The effect of growth hormone treatment on growth and bone health in children with inflammatory bowel disease. (Re-submission)</td>
<td>Dr Ahmed</td>
<td>Department of Child Health</td>
<td>Approved with Amendments</td>
<td>01/04/2004</td>
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<tr>
<td>P62/03</td>
<td>Magnetic Resonance Imaging (MRI) and Ultrasound (US) in the early identification of disease progression in Juvenile Idiopathic Arthritis. (Re-submission)</td>
<td>Drs Kileen, Gardner-Medwin, Galea, Sturrock, Watt, Johnson</td>
<td>Department of Child Health</td>
<td>Approved with amendments</td>
<td>03/06/2004</td>
</tr>
<tr>
<td>P1/04</td>
<td>The Effect of Growth Hormone Treatment on Growth and Bone Health in Children with juvenile Idiopathic Arthritis (JIA). (Re-submission)</td>
<td>Dr Ahmed</td>
<td>Department of Child Health</td>
<td>Approved with amendments</td>
<td>01/04/2004</td>
</tr>
<tr>
<td>P11/04</td>
<td>Noise Levels within the Paediatric Intensive Care Unit at Yorkhill and Suggestions on Creating a Quieter Environment (Re-submission)</td>
<td>Sr Cafferty</td>
<td>Intensive Care Unit</td>
<td>Approved</td>
<td>06/05/2004</td>
</tr>
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<tr>
<td>P12/04</td>
<td>The Pathology of Epistaxis.</td>
<td>Dr Whymark</td>
<td>Surgical Directorate</td>
<td>Approved with amendments</td>
<td>01/04/2004</td>
</tr>
<tr>
<td>P13/04</td>
<td>The Microbiology of Epistaxis</td>
<td>Dr Whymark</td>
<td>Surgical Directorate</td>
<td>Approved with amendments</td>
<td>01/04/2004</td>
</tr>
<tr>
<td>P14/04</td>
<td>Pilot Study: Implementing Transitional Through Group Work.</td>
<td>Dr Ferguson</td>
<td>Department of Child Health</td>
<td>Approved</td>
<td>06/05/2004</td>
</tr>
<tr>
<td>P15/04a</td>
<td>Measured Versus Reported Parental Height.</td>
<td>Dr Donaldson</td>
<td>Department of Child Health</td>
<td>Approved with amendments</td>
<td>01/04/2004</td>
</tr>
<tr>
<td>P15/04b</td>
<td>Assessment of contrast sensitivity in infants and children with neurological impairment.</td>
<td>Drs Dutton, Brahnam</td>
<td>Department of Ophthalmology</td>
<td>Approved with amendments</td>
<td>06/05/2004</td>
</tr>
<tr>
<td>P16/04</td>
<td>04S0708/20 Bilingual issues in stammering intervention an exploratory study.</td>
<td>Drs Lickley, Murthy</td>
<td>Speech and Language Therapy Department</td>
<td>Approved</td>
<td>05/08/2004</td>
</tr>
<tr>
<td>P17/04</td>
<td>04S0708/21 Play therapy as an intervention in child psychiatry - does it make a difference to children's mental health.</td>
<td>Dr Kelly</td>
<td>Department of Child and Family Psychiatry</td>
<td>Approved</td>
<td>05/08/2004</td>
</tr>
<tr>
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<td>P18/04</td>
<td>04S0708/22 Children with developmental difficulties and sleep problems: parental attributions and treatment acceptability.</td>
<td>Drs Keenan, Wild, Espie</td>
<td>Fraser of Allander Unit</td>
<td>Approved with amendments</td>
<td>03/06/2004</td>
</tr>
<tr>
<td>P19/04</td>
<td>Assessment of literacy skills and usefulness of clinical letters in patients attending the genetics clinics.</td>
<td>Dr Longman</td>
<td>Department of Medical Genetics</td>
<td>Not approved</td>
<td>01/07/2004</td>
</tr>
<tr>
<td>P21/04</td>
<td>Friendship quality of looked after and accommodated children mediated by deficits in emotion recognition.</td>
<td>Miss Purves</td>
<td>Department of Psychology</td>
<td>Approved</td>
<td>01/07/2004</td>
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<tr>
<td>P22/04</td>
<td>Predictors of post operative psychological morbidity in children after minor elective surgery.</td>
<td>Ms MacLeod</td>
<td>Surgical Directorate</td>
<td>Approved with amendments</td>
<td>05/08/2004</td>
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<tr>
<td>P23/04</td>
<td>04/S0708/35 Heart rate and blood pressure variability in children post cardiac surgery.</td>
<td>Dr Patel</td>
<td>Surgical Directorate</td>
<td>Approved with amendments</td>
<td>05/08/2004</td>
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<td>P24/04</td>
<td>Mother's cognitions regarding intimate physical aspects of parenting: The development and preliminary psychometric evaluation of a self report measure for use with mothers who have a history of childhood sexual abuse.</td>
<td>Dr Smeddle</td>
<td>Department of Psychology</td>
<td>Approved with amendments</td>
<td>05/08/2004</td>
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<tr>
<td>P25/04</td>
<td>An investigation of very long term memory and accelerated forgetting in children with idiopathic generalised epilepsy.</td>
<td>Drs Davidson, Doris</td>
<td>Fraser of Allander Unit</td>
<td>Approved with amendments</td>
<td>05/08/2004</td>
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<tr>
<td>P26/04</td>
<td>Assessment of the effects of massage on movement and co-ordination of children and young people with CP.</td>
<td>Drs Gladden, Ross McGregor</td>
<td>Fraser of Allander Unit</td>
<td>Not Approved</td>
<td>01/09/2004</td>
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<tr>
<td>P27/04</td>
<td>Cerebral visual impairment a follow up audit.</td>
<td>Professor Dutton</td>
<td>Department of Ophthalmology</td>
<td>Approved with amendments</td>
<td>07/10/2004</td>
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<td>P28/04</td>
<td>Adverse Drug reaction Study</td>
<td>Drs S Rodden, K Graham</td>
<td>Trust Wide (Nursing)</td>
<td>Approved with amendments</td>
<td>07/10/2004</td>
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<td>P29/04</td>
<td>The Management of finger injuries.</td>
<td>Dr Boyce</td>
<td>Accident &amp; Emergency Department</td>
<td>Approved with amendments</td>
<td>07/10/2004</td>
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<tr>
<td>P30/04</td>
<td>Genetic modifiers of cystic fibrosis.</td>
<td>Dr A Devenney</td>
<td>Medical Directorate</td>
<td>Approved with amendments</td>
<td>04/11/2004</td>
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<td>P31/04</td>
<td>Validation of the Flep scale.</td>
<td>Dr Zuberi</td>
<td>Fraser of Allander Unit</td>
<td>Approved with amendments</td>
<td>04/11/2004</td>
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<td>P32/04</td>
<td>04/S0708/68 Adult outcome in congenital hypothyroidism.</td>
<td>Dr Donaldson</td>
<td>Department of Child Health</td>
<td>Approved with amendments</td>
<td>02/12/2004</td>
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<td>P33/04</td>
<td>04/S0708/69 Effect on position on anatomy relevant to epidural anaesthesia. The effects of position of anatomical variables relevant to epidural anaesthesia using Magnetic Resonance Imaging.</td>
<td>Dr Kerryn Martin</td>
<td>Anaesthetics Directorate</td>
<td>Approved with amendments</td>
<td>02/12/2004</td>
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<tr>
<td>P34/04</td>
<td>04/S0708/70 Funding NHS in Glasgow: Queen Mother's Maternity Hospital Assessing the extent to which a funding crisis exists within the NHS in Glasgow: a case study of the Queen Mother’s Maternity Hospital.</td>
<td></td>
<td>Yorkhill Division</td>
<td>Study Withdrawn</td>
<td>02/12/2004</td>
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<td>P35/04</td>
<td>04/S0708/73 How collaborative is our working?</td>
<td>Mrs F Whyte</td>
<td>Nursing and Patients Services</td>
<td>Not approved Study Withdrawn</td>
<td>13/01/2005</td>
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<tr>
<td>P36/04</td>
<td>04/S0708/75 End Organ Effects of Paediatric Cardiopulmonary Bypass.</td>
<td>Dr T Vassalos</td>
<td>Surgical Directorate</td>
<td>Approved with amendments</td>
<td>13/01/2005</td>
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<td>P37/04</td>
<td>04/S0708/76 Hypermobility and Growing Pains: A Clinical Investigation.</td>
<td>Mr Azzopardi</td>
<td>Orthopaedic Surgery</td>
<td>Approved with amendments</td>
<td>13/01/2005</td>
</tr>
<tr>
<td>P1/05</td>
<td>05/S0708/6 Follow up of neck veins post percutaneous cannulation ECLS.</td>
<td>Ms C McGuire</td>
<td>Department of Diagnostic Imaging</td>
<td>Approved with amendments</td>
<td>03/02/2005</td>
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<tr>
<td>P2/05</td>
<td>05/S0708/8 A comparison of approaches for identifying communicative need.</td>
<td>Ms Y Allan</td>
<td>Speech and Language Therapy</td>
<td>Approved with amendments</td>
<td>03/02/2005</td>
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<td>P3/05</td>
<td>05/S0708/12 Heart rate variability in neonates on ECMO.</td>
<td>Dr L McGlone</td>
<td>Surgical Directorate/QMH</td>
<td>Approved with amendments</td>
<td>18/04/2005</td>
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<tr>
<td>P4/05</td>
<td>05/S0708/14 Pilot Study – measuring growth factors in urine of infants with haemangiomas.</td>
<td>Dr Mealyea</td>
<td>Medical Directorate</td>
<td>Approved with amendments</td>
<td>18/04/2005</td>
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<tr>
<td>Mc9/04</td>
<td>SSA MREC 00/2/73. (London) Whole Body Hypothermia for the Treatment of Perinatal Asphyxia.</td>
<td>Dr Simpson</td>
<td>Department of Haematology</td>
<td>No objection to study at this site</td>
<td>01/04/2004</td>
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<td>Mc10/04</td>
<td>SSA MREC 04/0/0006 (Scotland A) A Process Evaluation of Stakeholder Involvement in Diabetes Care Service Developments.</td>
<td>Dr McDonach</td>
<td>Medical Directorate</td>
<td>No objection to study at this site</td>
<td>01/04/2004</td>
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<tr>
<td>Mc11/04</td>
<td>SSA MREC 04/01/006. (South East) Inflammatory Bowel Disease: Collection of follow-up data.</td>
<td>Dr Roberts</td>
<td>Medical Directorate</td>
<td>No objection to study at this site</td>
<td>01/04/2004</td>
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<tr>
<td>Mc12/04</td>
<td>SSA MREC 01/9/53. (Wales) Medical Research Council Acute Myeloid Leukaemia 15 Trial (Trial Reference ISRCTN 17161961).</td>
<td>Dr Gibson</td>
<td>Department of Haematology</td>
<td>No objection to study at this site</td>
<td>01/04/2004</td>
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<tr>
<td>Mc13/04</td>
<td>SSA MREC 02/0/47 (Scotland) Scottish Register of children with Cerebral Palsy.</td>
<td>Dr Bonellie</td>
<td>Yorkhill Division</td>
<td>No objection to study at this site</td>
<td>01/04/2004</td>
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<tr>
<td>Mc14/04</td>
<td>SSA MREC North West 03/08/103 Cyclosporin C monitoring in paediatric renal transplant patients.</td>
<td>Dr Maxwell</td>
<td>Medical Directorate</td>
<td>No objection to study at this site</td>
<td>06/05/2004</td>
</tr>
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<td>Mc15/04</td>
<td>SSA MREC Trent Hyperfractionated accelerated radiotherapy (HART) with chemotherapy (Ciplatin CCNU, Vincristine) for non pineal supratentorial primitive neuroectodermal tumours.</td>
<td>Dr Ronghe</td>
<td>Department of Haematology</td>
<td>No objection to study at this site</td>
<td>06/05/2004</td>
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<tr>
<td>Mc16/04</td>
<td>SSA MREC Scotland National investigation into related deaths in Scotland.</td>
<td>Dr Zador</td>
<td>Yorkhill Division</td>
<td>No objection to study at this site</td>
<td>06/05/2004</td>
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<tr>
<td>Mc17/04</td>
<td>SSA MREC Trent: A phase two open label study of clofarabine in paediatric patients with refractory relapsed acute lymphoblastic leukaemia.</td>
<td>Dr Gibson</td>
<td>Department of Haematology</td>
<td>No objection to study at this site</td>
<td>06/05/2004</td>
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<td>Mc18/04</td>
<td>SSA MREC Trent Phase II study of the combination of Castaplin &amp; Temozolomide in malignant gilal tumours in children and adolescents at diagnosis or in relapse.</td>
<td>Dr Ronghe</td>
<td>Department of Haematology</td>
<td>No objection to study at this site</td>
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<td>Mc19/04</td>
<td>SSA MREC Northern &amp; Yorkshire Metoclopramide in steroid refractory and transfusion dependent DBA: role of prolactin and steroids in erythroid response.</td>
<td>Dr Chalmers</td>
<td>Department of Haematology</td>
<td>No objection to study at this site</td>
<td>06/05/2004</td>
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<tr>
<td>Mc20/04</td>
<td>SSA MREC Northern &amp; Yorkshire NESTAC</td>
<td>Dr Kubba</td>
<td>Surgical Directorate</td>
<td>No objection to study at this site</td>
<td>01/07/2004</td>
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<tr>
<td>Mc21/04</td>
<td>SSA (PCT) Research exploring employers perceptions of supporting employees affected by cancer.</td>
<td>Mr Stewart</td>
<td>Department of Human Resources</td>
<td>No objection to study at this site</td>
<td>01/07/2004</td>
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<tr>
<td>Mc22/04</td>
<td>SSA MREC Scotland A survey of Scottish patients with gender dysphoria to ascertain social functioning; morbidity; treatment and service use.</td>
<td>Dr Wilson</td>
<td>Department of Psychology</td>
<td>No objection to study at this site</td>
<td>01/07/2004</td>
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<tr>
<td>Mc23/04</td>
<td>SSA MREC London Evaluation of the psycho social impact of mammographic surveillance services on women under 50 years with a family history of breast cancer.</td>
<td>Dr Davidson</td>
<td>Department of Medical Genetics</td>
<td>No objection to study at this site</td>
<td>01/07/2004</td>
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<td>Mc24/04 M31/04</td>
<td>SSA A randomised double blind, placebo controlled, multicentre, parallel group study of one year duration followed by 2 years of open label treatment to determine the safety and efficacy of orally administered 2.5 mg or 5.0 mg daily risedronate in children &gt;=4 to &lt;16 years old with osteogenesis imperfecta.</td>
<td>Dr F Ahmed</td>
<td>Department of Child Health</td>
<td>Withdrawn</td>
<td>05/08/2004</td>
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<tr>
<td>Mc31/04</td>
<td>SSA Re-submission: Mc24/04 MREC Trent</td>
<td>Dr F Ahmed</td>
<td>Department of Child Health</td>
<td>No objection to study at this site</td>
<td>01/09/2004</td>
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<tr>
<td>Mc25/04</td>
<td>SSA (Glasgow West) Hvidore Study group on childhood diabetes SSA</td>
<td>Dr K Robertson</td>
<td>Medical Directorate</td>
<td>No objection to study at this site</td>
<td>05/08/2004</td>
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<tr>
<td>Mc26/04</td>
<td>SSA MREC London An economic evaluation of a randomised controlled trial of whole body hypothermia for the treatment of perinatal asphyxial perinatal encephalopathy</td>
<td>Dr Henderson</td>
<td>Paediatric Department</td>
<td>No objection to study at this site</td>
<td>05/08/2004</td>
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<td>Mc27/04</td>
<td>SSA MREC Trent SSA 04/4/001: Lung Function in Wilms</td>
<td>Drs Miland, Ronghe</td>
<td>Department of Haematology</td>
<td>No objection to study at this site</td>
<td>01/09/2004</td>
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<tr>
<td>Mc28/04</td>
<td>MREC Trent SSA 03/4055 03/4/055: T-cell Lymphoma</td>
<td>Dr E Chalmers</td>
<td>Department of Haematology</td>
<td>No objection to study at this site</td>
<td>01/09/2004</td>
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<td>Mc29/04</td>
<td>MREC Glasgow SSA 04/S0703/13: STOPPIT study.</td>
<td>Dr K Hanretty</td>
<td>Directorate of Maternity and Obstetrics</td>
<td>No objection to study at this site</td>
<td>01/09/2004</td>
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<tr>
<td>Mc30/04</td>
<td>04/S0702/47: SSA Glasgow South The use of BMP for alveolar reconstruction.</td>
<td>Prof Ashraf Ayoub</td>
<td>Surgical Directorate</td>
<td>No objection to study at this site</td>
<td>01/09/2004</td>
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<tr>
<td>Mc32/04</td>
<td>SSA MREC Glasgow West A prospective observational study of acute renal failure in paediatric intensive care units.</td>
<td>Drs Slack, Ramage, Davidson</td>
<td>Renal Day Unit/ Medical Directorate</td>
<td>No objection to study at this site</td>
<td>01/09/2004</td>
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<tr>
<td>Mc33/04</td>
<td>MREC TRENT Co-operative multi centre study for children and adolescents with low grade glioma.</td>
<td>Dr M Ronghe</td>
<td>Department of Haematology</td>
<td>No objection to study at this site</td>
<td>07/10/2004</td>
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<td>Mc34/04</td>
<td>MREC Scotland. Re-active attachment disorder.</td>
<td>Dr H Minnis</td>
<td>Department of Child and Family Psychiatry</td>
<td>No objection to study at this site</td>
<td>07/10/2004</td>
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<tr>
<td>Mc35/04</td>
<td>Primary Care Committee Glasgow. Patient parent satisfaction with psychiatric services.</td>
<td>Dr H Minnis</td>
<td>Department of Child and Family Psychiatry</td>
<td>No objection to study at this site</td>
<td>07/10/2004</td>
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<tr>
<td>Mc37/04</td>
<td>SSA MREC Scotland B Qualitative study of parental perspectives of a novel, dietetic-led behavioural programme and standard dietetic care for the treatment of obesity.</td>
<td>Dr J Reilly</td>
<td>Department of Human Nutrition</td>
<td>No objection to study at this site</td>
<td>04/11/2004</td>
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<tr>
<td>Mc38/04</td>
<td>SSA MREC Trent Protocol for the treatment of extracranial germ cell tumours in children and adolescents.</td>
<td>Dr M Ronghe</td>
<td>Department of Haematology</td>
<td>No objection to study at this site</td>
<td>04/11/2004</td>
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<tr>
<td>Mc39/04</td>
<td>SSA MREC Trent Rare tumours in childhood and adolescence.</td>
<td>Dr M Ronghe</td>
<td>Department of Haematology</td>
<td>No objection to study at this site</td>
<td>04/11/2004</td>
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<tr>
<td>Mc40/04</td>
<td>MREC Trent SSA 04/mre04/79. EURAMOS treatment strategies in resectable osteosarcoma.</td>
<td>Dr M Ronghe</td>
<td>Department of Haematology</td>
<td>No objection to study at this site</td>
<td>02/12/2004</td>
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<td>Proposal Number</td>
<td>Title</td>
<td>Authors</td>
<td>Department</td>
<td>Decision</td>
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<td>Mc41/04</td>
<td>SSA 04/S0708/74 Brighton B MREC: 04/Q1907/56 The efficacy of dexamethasone in mechanically ventilated children with lower respiratory tract infection caused by respiratory syncytial virus.</td>
<td>Dr J Scarth</td>
<td>Paediatric Intensive Care Unit</td>
<td>No objection to study at this site</td>
<td>13/01/2005</td>
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<tr>
<td>Mc1/05</td>
<td>SSA 05/S0708/5 [05/MRE04/2 Trent MREC] A national protocol for collecting and banking childhood cancer samples for research (2005 BS01, formerly 1998 BS05).</td>
<td>Dr M Ronghe</td>
<td>Department of Haematology</td>
<td>No objection to study at this site</td>
<td>03/02/2005</td>
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<tr>
<td>Mc2/05</td>
<td>SSA MREC Trent 05/S0708/4 LNESG2 Study.</td>
<td>Dr M Ronghe</td>
<td>Department of Haematology</td>
<td>No objection to study at this site</td>
<td>03/02/2005</td>
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<td>Mc3/05</td>
<td>[SSA MREC North West 99/8/63] Treatment of recurrent central nervous system primitive neuroectodermal tumours (PNETs) in children and adolescents – a strategy including the use of high dose Thiotepa and high dose Carboplatin.</td>
<td>Dr M Ronghe</td>
<td>Department of Haematology</td>
<td>No objection to study at this site</td>
<td>03/02/2005</td>
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<tr>
<td>Proposal Number</td>
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<td>Mc4/05</td>
<td>SSA 05/S0708/2 [MREC South West 04/6/028] Twin birth study.</td>
<td>Dr A Cameron</td>
<td>Directorate of Maternity and Obstetrics</td>
<td>No objection to study at this site</td>
<td>03/02/2005</td>
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<tr>
<td>Mc05/05</td>
<td>SSA 05/S0708/7 (Glasgow South) Transobturator vaginal tape in the management of urinary incontinence.</td>
<td>Dr L Macara</td>
<td>Directorate of Maternity and Obstetrics</td>
<td>No objection to study at this site</td>
<td>03/02/2005</td>
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<tr>
<td>Mc06/05</td>
<td>SSA 05/S0708/3 [Thames Valley MREC 05/MRE12/6] Qualitative study of children’s perspectives of a novel dietetic led behavioural programme and standard dietetic care for the treatment of childhood obesity.</td>
<td>Dr J Reilly</td>
<td>Department of Human Nutrition</td>
<td>No objection to study at this site</td>
<td>03/02/2005</td>
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<td>Mc7/05</td>
<td>SSA 05/S0708/77 [West Glasgow Ethics:05/S0703/1] Scoping Study – ethical and practical concerns regarding changes to human tissue legislation.</td>
<td>Professor S McLean</td>
<td>Yorkhill Division</td>
<td>No objection to study at this site</td>
<td>03/02/2005</td>
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<tr>
<td>Mc8/05</td>
<td>SSA 05/S0708/72 [GOS LREC 04/0508/34] UK Cystinosis Registry.</td>
<td>Dr J Beattie</td>
<td>Medical Directorate/ Renal Unit</td>
<td>No objection to study at this site</td>
<td>03/02/2005</td>
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<td>Proposal Number</td>
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<tr>
<td>Mc9/05</td>
<td>SSA MREC Scotland 10/26 Predictors of disease relapse in childhood arthritis.</td>
<td>Dr O Kileen</td>
<td>Department of Child Health</td>
<td>No objection to study at this site</td>
<td>03/03/2005</td>
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<td>Mc10/05</td>
<td>SSA MREC Trent Hepatocellular carcinoma (SIOPEL 5)</td>
<td>Dr M Ronghe</td>
<td>Department of Haematology</td>
<td>No objection to study at this site</td>
<td>03/03/2005</td>
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<td>Mc11/05</td>
<td>SSA Oxfordshire MREC Evaluation of a school based mental health service.</td>
<td>Dr Fazel</td>
<td>Community Child Health</td>
<td>No objection to study at this site</td>
<td>03/03/2005</td>
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## Attendance Yorkhill Research Ethics Committee

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<td>Mrs B Reid</td>
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<td>Dr Gardner Medwin</td>
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Key

CP  Chair Present
VC P  Vice Chair Present
SP  Secretary Present
MP  Member Present
Apols Apologies
NM  New Member
Yorkhill Research Ethics Committee

Membership

April 2004 - March 2005

Mrs B Reid   Lay Representative, Chair
Mr S O'Toole  Consultant Surgeon, Vice Chairman
Dr H R Davidson Consultant, Medical Genetics, Secretary
Dr G Bell     Consultant Anaesthetist
Mr J Beresford Lay representative
Dr J Brennand Consultant Obstetrician
Dr J Gardner Medwin Consultant Rheumatologist
Mr J Hughes   Lay representative
Mr J Martin   Lay representative
Dr H Maxwell  Consultant Paediatric Nephrologist
Dr E McLellan General Practitioner
Mr A McMillan Lay representative
Mrs L Powls   Nursing/Midwifery
Mr J Wallace  Director of Pharmacy
Constitution for Yorkhill Local Research Ethics Committees

Terms of Reference

Local Research Ethics Committees (LRECs -referred to herein) are appointed by Greater Glasgow NHS Board through the auspices of the NHS Greater Glasgow Research Ethics Governance Committee to examine independently all proposals for research which are to be undertaken within the Board's geographical boundaries, within the NHS and involving human subjects.

This research will involve:

Patients and users of the NHS. This includes all potential research participants recruited by virtue of the patient or user's past or present treatment by, or use of, the NHS. It includes NHS patients treated under contracts with private sector institutions.

Individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined above.

Access to data, organs or other bodily material of past and present NHS patients. Fetal material and IVF involving NHS patients. The recently dead in NHS premises.

The use of, or potential access to, NHS premises or facilities.

NHS staff recruited as research participants by virtue of their professional role.

All LRECs within the geographical boundary of Greater Glasgow NHS Board shall be responsible to and report to the NHS Greater Glasgow Research Ethics Governance Committee. This Committee's objective is to oversee all of the Board's responsibilities for the establishment, support, training and monitoring of all NHS LRECs within NHS Greater Glasgow.

The Role of Local Research Ethics Committees

LRECs are the committees convened to provide the independent advice to participants, researchers, funders, sponsors, employers, care organizations and professionals on the extent to which proposals for research studies comply with recognised ethical standards. LRECs are responsible for acting primarily in the interest of potential research participants, but they should also take into account the interests, needs and safety of researchers who are trying to undertake research of good quality. However, the goals of research and researchers, whilst important, should always be secondary to the dignity, rights, safety and well-being of the research participants.

LRECs also need to take into consideration the principle of justice. This requires that the benefits and burdens of research be distributed fairly among all groups and classes in society, taking into account in particular age, gender, economic status, culture and ethnic considerations. In this context the contribution of previous research participants should also be recalled.

LRECs should provide independent, competent and timely review of the ethics of proposed studies. Although operating within the Governance Framework determined by SEHD, in their decision- making LRECs need to have independence from political, institutional, profession-related or market influences. They need similarly to demonstrate competence and efficiency in their work, and to avoid unnecessary delay.
In common with all those involved in research in the NHS, LRECs should have due regard for the requirements of relevant regulatory agencies and of applicable laws. It is not for the LREC to provide specific interpretation of regulations or laws, but it may indicate in its advice to the researcher and host institution where it believes further consideration needs to be given to such matters.

Membership

LRECs shall comprise fifteen Members, drawn from both sexes and from a wide range of age, seniority and experience. The membership shall include:

Up to six medical and appropriate scientific staff which should include one Member with relevant methodological and ethical expertise in research nominated by the local hospital medical advisory structure so as to reasonably reflect the spread of clinical services within the hospital or NHS Trust; One Member with expertise in social science methods including statistics relevant to research; one nursing representative nominated by the Senior Nursing Officer for the hospital; one pharmacist nominated by the Hospital, Pharmacy Manager or equivalent; One General Practitioner nominated by the General Practitioner Subcommittee of the Area Medical Committee;

Five lay persons appointed by Greater Glasgow NHS Board following invitation of nominations from local organisations including the Greater Glasgow Health Council, voluntary bodies, religious bodies and trade unions and/or by public advertisement. Lay representatives must constitute one third of the membership of the Committee. At least half of the lay members should be unconnected professionally with health care and be neither an employee of, nor advisor to, any NHS body.

A LREC shall have the power to co-opt or invite attendance of any person whom it considers to be of assistance in its deliberations. Co-opted persons will not have voting rights.

Terms of Office

The term of office of Members of LRECs shall be four years, with half of the Members retiring every two years. Terms of appointment may be renewed, but not more than, two four year terms of office may be served consecutively.

Any Member of a LREC who retires or leaves the employment of the NHS Trust concerned will at that point retire from the Committee of which he/she is a Member.

Chairman and Vice Chairman

Chairman and Vice Chairman of a LREC shall be appointed by the Greater Glasgow NHS Board on recommendations from the NHS Greater Glasgow Research Ethics Governance Committee. Where the appointed Chair is a clinician, where possible the appointed Vice Chair should be a lay person and vice- versa.

The term of office of the Chair and Vice Chair will be four years with the option to serve for another four years.

Administrative Arrangements

Each LREC shall have an administrator/secretary who may be a Member of the Committee. The Division should continue to appoint the administrator/secretary, whose appointment to the post will be confined by the NHS Greater Glasgow Research Ethics Governance Committee. Where a Member of the Committee acts as administrator/secretary, appropriate administrative support shall be provided, if requested, by Board/Trust management. Local arrangements for the administrator/secretary to be delegated the authority to sign correspondence on behalf of the Chairman should stand.
**Legal Liability**

Greater Glasgow NHS Board will take full responsibility for Members' actions in the course of the proper performance of their duties as Members of a LREC other than those involving bad faith, wilful default or gross negligence; the Board should be notified if any action or claim is threatened or made in any such event. Members of the Committee should be ready to assist the Board as required.

**Procedures**

The LREC shall act in accordance with the Constitution and the Standard Operating Procedures.

All LRECs shall devise and maintain written standing operating procedures to be amended and updated as necessary and be approved by the NHS Greater Glasgow Research Ethics Governance Committee. In preparing or amending the SOPs, the LREC shall use their best endeavours to ensure that they are (a) in line with the Governance Arrangements for Research Ethics Committees and (b) are ICH/GCP compliant.

The LRECs should always be able to demonstrate that they have acted reasonably in reaching their decisions.

All LRECs shall furnish the NHS Greater Glasgow Research Ethics Governance Committee with an annual report and inform the Committee of any matters or issues of concern pertinent to the proper functioning of LRECs.

**Submissions and Approvals**

All applications shall be submitted to the administrator/secretary of the LRECs in writing using the appropriate documentation.

The LREC may receive and review applications referred to it by NHS Greater Glasgow Research Ethics Governance Committee or by another local LREC.

**Administration of LRECs**

All LRECs shall consider every correctly completed application at its next available meeting provided the application is received not less than ten working days before that meeting.

The administrator/secretary will circulate all completed applications and associated documents, together with an agenda, one week in advance of the meeting of the LREC.

**Meetings**

All LRECs should meet monthly on pre-arranged dates with all submissions for ethical approval being submitted beforehand and circulated to Members one week in advance of the meeting. The principal investigator should normally be given the opportunity to attend the meeting.

For meetings at which research ethical review is undertaken, a quorum shall consist of seven Members. It shall include the Chair and/or Vice Chair, at least one "expert" Member with the relevant clinical and/or methodological expertise, one lay Member as defined and at least one other Member who is independent of the institution or specific location where the research is to take place.

An unanimous decision is required of those present at the meeting in respect of ethical approval for proposed research projects.
All Members of LRECs shall be required to attend two-thirds of their meetings within a yearly cycle. The Committee may, unless it is satisfied that Member’s absence was due to illness or other reasonable cause, declare their seat on the Committee to be vacant and, thereupon, a casual vacancy shall be declared. LREC meetings will normally be held in private.

**Decisions**

The administrator/secretary shall notify applicants in writing of the decision of the LREC within one week of the meeting in which the project was considered. Any projects which have not been approved shall have the reasons clearly stated.

**Records**

The administrator/secretary shall prepare and maintain Minutes of all meetings and shall retain a copy of all applications received, together with any relevant correspondence. Information and documents relating to research projects shall be treated as highly confidential. The administrator/secretary shall maintain a register of all applications received. The LREC should retain all relevant records for a period of at least 10 years after completion of the trial and be able to produce these if required to do so.

**Monitoring**

All LRECs shall request an annual update of approved projects and shall require any changes or amendments to the studies to be referred to the LREC for approval. The LREC shall also require to be informed of any projects which are abandoned with the reasons given.

W Marshall/2003
Consent Sheet template

Name of Study

initial box

1. I confirm that I have read and understood the information sheet dated ( ) for the above study and have had the opportunity to ask questions

2. I understand that my /my child's participation is voluntary and that I am free to withdraw at any time without giving any reason, without my child's medical care or legal rights being affected

3. (If appropriate) I understand that sections of any of my child's medical notes may be looked at by responsible individuals from (company name or from regulatory authorities where it is relevant to my taking part in research.) I give permission for these individuals to have access to my records

4. I agree to take part in the above study

_________________________________  ____________________  __________________________
Name of patient     Date   Signature

_________________________________  ____________________  __________________________
Name of person taking consent     Date   Signature
(if different from researcher)

_________________________________  ____________________  __________________________
Witness     Date   Signature

Date

Version Number

1 for patient/staff ,   1 for researcher,   1 to be kept in hospital notes
Consent Sheet template for a Child

‘Title’

initial box

1. I know what this study is about and can ask questions about it

2. I know that I do not have to take part in this study or if I join it I can still change my mind and no one will mind.

3. (If appropriate) I know that my medical notes will be looked at and I agree to this

4. I agree to take part in the above study

___________________________ ____________ __________________________
Name of patient    Date   Signature

___________________________ ____________ __________________________
Name of person taking consent (if different from researcher) Date   Signature

_________________________  ______________________________________
Witness     Date   Signature

Date

Version Number
1 for patient, 1 for researcher, 1 to be kept in hospital notes
The guidance which follows applies primarily to multi-centre pharmaceutical studies and encompasses the ICH Good Clinical Practice guidelines. However, the principles and much of the content will be of use to researchers writing information sheets in their particular fields, for studies involving patient/member of staff members of staff, patient/member of staff volunteers, healthy volunteers and staff volunteers. You will find it helpful to refer also to other guidelines produced for writing patient/member of staff information sheets.

Potential recruits to your research study must be given sufficient information to allow them to decide whether or not they want to take part. An Information Sheet should contain information under the headings given below where appropriate, and in the order specified. It should be written in simple, non-technical terms and be easily understood by a lay person. Use short words, sentences and paragraphs. 'The readability' of any text can be roughly estimated by the application of standard formulae. Checks on readability are provided in most word processing packages.

Consumers for Ethics in Research (CERES) publish a leaflet entitled 'Medical Research and You'. This leaflet gives more information about medical research and looks at some questions you may want to ask. A copy may be obtained from CERES, PO Box 1365, London N16 0BW.

Use headed paper of the hospital/institution where the research is being carried out. Patient/member of staff Information Sheets submitted to an MREC should be headed simply 'Hospital/Institution/GP Practice headed paper'. If you are a local researcher for an MREC approved study, the Patient/member of staff Information Sheet should be printed on local hospital/surgery paper with local contact names and telephone numbers before it is submitted to the LREC. Unheaded paper is not acceptable.

1. Study title

Is the title self explanatory to a lay person? If not, a simplified title should be included.

2. Invitation paragraph

This should explain that the patient/member of staff is being asked to take part in a research study. The following is a suitable example:

'You are being invited to take part in a study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.'
3. **What is the purpose of the study?**

The background and aim of the study should be given here. Also mention the duration of the study.

4. **Why have I been chosen?**

You should explain how the patient/member of staff was chosen and how many other patient/members of staff will be studied.

5. **Do I have to take part?**

You should explain that taking part in the research is entirely voluntary. You could use the following paragraph:

_No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive._

6. **What will happen to me if I take part?**

You should say how long the patient/member of staff will be involved in the research, how long the research will last (if this is different), how often they will need to visit a clinic (if this is appropriate) and how long these visits will be. You should explain if the patient/member of staff will need to visit the GP (or clinic) more often than for his/her usual treatment and if travel expenses are available. What exactly will happen e.g. blood tests, x-rays, (over and above those involved in standard diagnosis and treatment.) Whenever possible you should draw a simple flowchart or plan indicating what will happen at each visit. What are the patient/member of staff’s responsibilities? Set down clearly what you expect of them.

You should set out simply the research methods you intend to use - the following simple definitions may help:

**Randomised Trial:**

_Sometimes because we do not know which way of treating patient/member of staff is best, we need to make comparisons. People will be put into groups and then compared. The groups are selected by a computer which has no information about the individual - i.e. by chance. Patient/member of staff in members of staff in each group then have a different treatment and these are compared._

You should tell the patient/member of staff what chance they have of getting the study drug/treatment e.g. a one in four chance.

**Blind trial:**

_In a blind study you will not know which treatment group you are in. If the study is a double blind trial, neither you nor your doctor will know which treatment group you are (although, if your doctor needs to find out he/she can do so)._
Cross-over trial:

In a cross-over study the groups each have the different treatments in turn. There may be a break between treatments so that the first drugs are cleared from your body before you start the new treatment.

Placebo:

A placebo is a dummy treatment such as a pill which looks like the real thing but is not. It contains no active ingredient.

7. What do I have to do?

Are there any lifestyle restrictions? You should tell the patient/members of staff if there are any dietary restrictions. Can the patient/members of staff drive?, drink?, take part in sport? Can the patient/members of staff continue to take their regular medication? Should the patient/members of staff refrain from giving blood? What happens if the patient/members of staff becomes pregnant?

Explain (if appropriate) that the patient/members of staff should take the medication regularly.

8. What is the drug or procedure that is being tested?

You should include a short description of the drug or device and give the stage of development.

You should also state the dosage of the drug and method of administration. Patient/members of staff entered into drug studies should be given a card (similar to a credit card) with details of the study they are in. They should be asked to carry it at all times.

9. What are the alternatives for diagnosis or treatment?

For therapeutic research the patient/members of staff should be told what other treatments are available.

10. What are the side effects of taking part?

For any new drug or procedure you should explain to the patient/members of staff the possible side effects. If they suffer these or any other symptoms they should report them next time you meet. You should also give them a contact name and number to phone if they become in any way concerned. The name and number of the person to contact in the event of an emergency (if that is different) should also be given.

The known side effects should be listed in terms the patient/members of staff will clearly understand (e.g. ‘damage to the heart’ rather than ‘cardiotoxicity’; ‘abnormalities or liver tests’ rather than ‘raised liver enzymes’). For any relatively new drug it should be explained that there may be unknown side effects.

11. What are the possible disadvantages and risks of taking part?

For studies where there could be harm to an unborn child if the patient/members of staff were pregnant or became pregnant during the study, the following (or similar) should be said:

'It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not therefore take part in this study, neither should women who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy.
Women who could become pregnant must use an effective contraceptive during the course of this study. Any woman who finds that she has become pregnant while taking part in the study should immediately tell her research doctor.

Use the pregnancy statement carefully. In certain circumstances (e.g. terminal illness) it would be inappropriate and insensitive to bring up pregnancy.

There should also be an appropriate warning and advice for men if the treatment could damage sperm which might therefore lead to a risk of a damaged fetus.

If future insurance status e.g. for life insurance or private medical insurance, could be affected by taking part this should be stated (if e.g. high blood pressure is detected). If the patient/member of staff s/members of staff have private medical insurance you should ask them to check with the company before agreeing to take part in the trial. They will need to do this to ensure that their participation will not affect their medical insurance.

You should state what happens if you find a condition of which the patient/member of staff was unaware. Is it treatable? What are you going to do with this information? What might be uncovered?

12. What are the possible benefits of taking part?

Where there is no intended clinical benefit to the patient/member of staff from taking part in the study this should be stated clearly.

It is important not to exaggerate the possible benefits to the particular patient/member of staff during the course of the study, e.g. by saying they will be given extra attention. This could be seen as coercive. It would be reasonable to say something similar to:

'We hope that both (all) the treatments will help you. However, this cannot be guaranteed. The information we get from this study may help us to treat future patient/member of staff s/members of staff with (name of condition) better.'

13. What if new information becomes available?

If additional information becomes available during the course of the research you will need to tell the patient/member of staff about this. You could use the following:

'Sometimes during the course of a research project, new information becomes available about the treatment/drug that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to continue in the study you will be asked to sign an updated consent form.

Also, on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue.'
14. **What happens when the research study stops?**

If the treatment will not be available after the research finishes this should be explained to the patient/member of staff. You should also explain to them what treatment will be available instead. Occasionally the company sponsoring the research, may stop it. If this is the case the reasons should be explained to the patient/member of staff.

15. **What if something goes wrong?**

Your should inform patient/member of staff/s/members of staff how complaints will be handled and what redress may be available. Is there a procedure in place? You will need to distinguish between complaints from patient/member of staff/s/members of staff as to their treatment by members of staff (doctors, nurses etc.) and something serious happening during or following their participation in the study i.e. a reportable serious adverse event.

Where there are no Association of the British Pharmaceutical Industry (ABPI) or other no-fault compensation arrangements, and the study carries risk of physical or significant psychological harm, the following (or similar) should be said:

'*If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms may be available to you.*'

Where there are ABPI or other no-fault compensation arrangements the following (or similar) should be included:

'*Compensation for any injury caused by taking part in this study will be in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI). Broadly speaking the ABPI guidelines recommend that 'the sponsor', without legal commitment, should compensate you without you having to prove that it is at fault. This applies in cases where it is likely that such injury results from giving any new drug or any other procedure carried out in accordance with the protocol for the study. 'The sponsor' will not compensate you where such injury results from any procedure carried out which is not in accordance with the protocol for the study. Your right at law to claim compensation for injury where you can prove negligence is not affected. Copies of these guidelines are available on request.'*

16. **Will my taking part in this study be kept confidential?**

You will need to obtain the patient/member of staff's permission to allow restricted access to their medical records and to the information collected about them in the course of the study. You should explain that all information collected about them will be kept strictly confidential. A suggested form of words for drug company sponsored research is:

'*If you consent to take part in the research any of your medical records may be inspected by the company sponsoring (and/or the company organising) the research for purposes of analysing the results. They may also be looked at by people from the company and from regulatory authorities to check that the study is being carried out correctly. Your name, however, will not be disclosed outside the hospital/GP surgery.'*
or for other research:-

'All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital/surgery will have your name and address removed so that you cannot be recognised from it.'

You should always bear in mind that you as the researcher are responsible for ensuring that when collecting data, you are not contravening the legal or regulatory requirements in any part of the UK. This is not the responsibility of the REC.

You should explain that for studies not being conducted by a GP, the patient/member of staff's own GP will be notified of their participation in the trial. This should include other medical practitioners not involved in the research who may be treating the patient/member of staff. You should seek the patient/member of staff's agreement to this. In some instances agreement from the patient/member of staff that their GP can be informed is a precondition of entering the trial.

17. What will happen to the results of the research study?

You should be able to tell the patient/member of staff what will happen to the results of the research. When are the results likely to be published? Where can they obtain a copy of the published results? Will they be told which arm of the study they were in? You might add that they will not be identified in any report/publication.

18. Who is organising and funding the research?

The answer should include the organisation or company sponsoring or funding the research (e.g. Medical Research Council, Pharmaceutical Company, charity, academic institution).

The patient/member of staff should be told whether the doctor conducting the research is being paid for including and looking after the patient/member of staff in the study. This means payment other than that to cover necessary expenses such as laboratory tests arranged locally by the researcher, or the costs of a research nurse. You could say: -

'The sponsors of this study will pay (name of hospital department or research fund) for including you in this study' or

'Your doctor will be paid for including you in this study.'

19. Who has reviewed the study?

(GMC recommendation for medical staff)

You may wish to give the name of the Research Ethics Committee(s) which reviewed the study (you do not however have to list the members of the Committee).
20. **Contact for Further Information**

You should give the patient/member of staff a contact point for further information. This can be your name or that of another doctor/nurse involved in the study.

Remember to thank your patient/member of staff for reading the information sheet.

The patient/member of staff information sheet should be dated and given a version number.

The **Patient/member of staff Information Sheet** should state that the patient/member of staff will be given a copy of the information sheet and a signed consent form to keep.

**Version 7 2005**
NOTES ON INFORMATION SHEETS FOR CHILDREN AND YOUNG PEOPLE

The guidance which follows applies primarily to multi-centre pharmaceutical studies. These notes are meant to give you ideas about what is important when producing patient information for children and young people. They are not intended to be totally comprehensive. Please use the information to help develop your own information sheets relevant to your own study. Information sheets should always be accompanied by verbal explanation/demonstration of procedures wherever possible. All available information, including about future stages, should be given at the outset.

It is recommended that information sheets are produced for the following age ranges, which reflect cognitive stages of development:

- Parents/guardians (to be referred to as 'person with parental responsibility')
- Children 8 years and under
- Children 8-12 years
- Young people 12-16 years
- Young people 18 and over (16 in Scotland) would have the same information as parents/guardians, but worded to be aimed directly at them, because they can consent for themselves.

Because there may be a discrepancy between the biological age, reading age and study group age of children in any given population, it may be appropriate to alter the age groups. In addition discretion should be sued in deciding which information sheet to give. For example it might be appropriate for a mature and bright 11 year old to have the 12-16 age group information, whereas a poorly 14 year old (or even a distressed parent) may appreciate the simpler information in the 8-12 age group.

For REC approval it will be necessary to clearly identify which information is aimed at which group. However to avoid children thinking they might have the 'wrong' information sheet, age groups should be discreetly displayed in the final version given to patients, e.g. in a footer.

Information sheets should be no longer than 3 pages; the style and language should be appropriate for the child's level of understanding, and easy to read.

Consent/assent

Consent will need to be given and a consent form signed by parents or those with legal responsibility for the child, but children should also have an assent form of their own. Alternatively a joint parent/child consent form along the standard MREC format could be sued (see attached example). Assent is voluntary permission given by one with no legal status e.g. a child.

Since the law is untested with regard to the legal age of consent to take part in research, it is recommended that the legal age of consent in the country where the research is taking place is applied. In England, Wales and Northern Ireland, this is 18. In Scotland the age of consent is 16.

Some studies contain a number of randomisations over a long period of time, and it may be necessary to re-consent children several times during a study, i.e. when they reach the next age band.
It is important to give guidelines in your information about:

- How long each study visit will take (families are busy)
- How will the study affect the child at:
  - Home
  - School
  - Play

**Cultural differences**

You should be aware of cultural differences in sharing information with children, and the need to provide written information or an audiotape in second languages.

**Feedback**

It may be helpful to show your information sheets to a group of children for comment before you submit the formal version to the REC. This is important as it is not always easy to put oneself in their position. You might involve a local school, if the head thinks this is a good idea, or children under the care of a local paediatrician. This needs careful forward planning. Schools and hospital departments are very busy.

**NEONATES AND BABIES**

Obviously information is for parents for these studies.

The adult guidelines on information sheets should be followed. Trials on neonates and babies are undertaken when parents are particularly vulnerable and anxious.

**As stressed people do not absorb facts very well, it is helpful for your written information to be:**

- In short sentences
- Straightforward but not frightening
- Avoiding jargon

If at all possible, the idea that a newborn might need to be in a trial should be introduced during the pregnancy, or by information sheets in the maternity department or GP surgery.

Support from midwifery staff, health visitors and research nurses can be very helpful.

Some trials on pregnant women involve follow-up of the baby. If this is long-term, introducing the concept that their children were in a trial needs to be by the parent, until the age when the child can begin to be involved in the consent/assent process.

Newsletters and a telephone number for queries are helpful. Compensation arrangements for long-term complications (such as infertility or increased risk of malignancy) need to be considered.
UNDER EIGHT YEARS

This will need to be pictorial, with simple sentences which can be shown/read to the child. It should say at the top that it is intended to be shown/read to the child by their parent/guardian.

Careful thought in protocol planning is important here as specimens are not easy to obtain and medicine may be difficult to give to an awkward toddler.

Protocols could be supported by videos, or audio-tapes. (Those made by Johnny Ball for leukaemia and solid tumours which explain why thing have gone wrong, and what procedures are used e.g. Hickman Lines, come mind). Also the Captain Chemo site from the Mardsen (www.royalmarsden.org/captchemo) where the child can zap the bad cells, while learning a bit about drug action. Some good ideas are on www.goshkids.uk.

DO NOT SHOW NEEDLES IN PICTURES!
TEMPLATE INFORMATION SHEET

Research title
This should be in simple terms, although the full title of the protocol should be stated as well.

What is (e.g.) asthma?
It is helpful to have a short definition of their medical condition. This helps them understand why they have been asked to take part.

What is the research for?
Give an appropriate brief outline of the research.

Invitation to take part
Short sentences asking for participation (non coercive; no inducements!)

Why me?
Give reason why this child has been offered the chance to take part in the trial.

Do I have to take part?
This needs an explanation that taking part is up to both the child and parents. State that a child or parent can opt out at any time, and give reassurance that the doctor will discuss other treatment with child and parents. Include a sentence about what happens if child wants to take part but parents don’t and vice-versa (i.e. that both parties need to be in agreement for the child to take part). Children need reassurance that it is alright to change their mind and not take part and they mustn’t be made to feel guilty if they don’t want to take part.

What happens?
Any procedure needs explanation –

- This may be helped with leaflets from the participating hospital about (e.g.) CT/MRI/X-rays.
- Local anaesthetics must be used for blood tests. EMLA cream takes about an hour to work, but is not licensed for under 1 year. Ametop only takes 20 minutes to work but can cause skin reactions in children with eczema.
- General anaesthetics are usually used for biopsies – and a short explanation of what happens should be given (see Glossary).
- Whether the child will have to miss a meal, and if that meal will be provided afterwards.
- Reassurance should be given that the parent/carer will be encouraged to stay with, and support their child throughout all research procedures, and throughout the rest of their hospital stay.
- Travel expenses will be paid to parents. As there can be a lot of waiting around during research, some centres pay parents and child for snacks/modest meals as well.
- Storage of trial medicine – is it alright to keep it in the fridge next to all the other food? What measures are in place if the family pet chews up the medicine bottle?
- What measures are in place to stop another member of the family taking the tablets?
- How can the carers at home dispose of unused medicines, needles and syringes?

What will happen to me?
- Sometimes a flow diagram or timetable may help a child feel part of the project – even coloured stickers to indicate completion of various stages.
- How many visits will there be? Will the child need to be off school? Miss sports?
- Children need to know that they won’t be forced to do anything they don’t want to.
**What is being tested?**
A short description of the drug or device is needed. The parents should be given a card if their child is in a trial (similar to a credit card) with relevant details. A copy may be needed for the school.

**Can this be done another way?**
If other treatments are available the family need to know.

**Will the medicine upset me?**
Any side effects need to be explained in simple, accessible language. You need to give clear instructions and a contact name and phone number if the child or parents are concerned. At each visit, side effects and other treatment will be asked about.

**What if something goes wrong?**
- Parents and children will want to know what arrangements may be made to compensate them in the unlikely event of something going wrong. This only applies to events which happened as a direct result of the child taking part in the research.
- Information about the disease needs to be honest, but not frightening. This is particularly so in oncology and HIV studies.

**Will joining in help me?**
Be honest – if the answer is ‘we don’t know’ say so. A phrase about the treatment not helping everyone, but we hope it will help you, and other in the future, for example, “You will learn something from taking part, perhaps more about how your body works and what happens when you are ill” may be suitable.

**What happens if a better medicine comes along?**
Whether the trial would stop if more effective treatment becomes available. Or just a statement that the doctor will keep the child up-to-date with new treatments if they are thought to be better for that person.

**What happens when the research finishes?**
Are medicines still going to be available – e.g. in the case of a new ointment for eczema or antibiotic for acne; new inhalers for asthma?

**Will anyone else know I’m doing this?**
Explanation of those in the team who will have access to the child’s data, brief explanation of methods to assure anonymity; explanation that GP will know trial is taking place; child and parents “consent” to GP being informed.

**What happens to what the researcher find out?**
It is in this section that researchers will have to explain briefly the data protection plans, including what will happen to blood and tissue samples. If genetic tests are being carried out, the child needs reassurance that they will not be cloned, or have DNA put INTO them. (There has been some unhelpful children’s fiction about this e.g. Spider Man/Dr Doom),

**Did anyone else check the study? (Is it safe?)**
A statement that doctors and nurses have looked at the programme to make sure it is sensible and well prepared may be included. Research ethics committees need not be mentioned. A phrase such as “The programme has been checked by several people, to make sure it is alright” could be used.
How can I find out more about this study?
“Your mummy, daddy or other grownup you trust may be able to answer your questions”, (or an informed member of the treatment team, preferably not taking part in the study, may be made available to answer questions if possible).

Length of information
The whole document should be three sides of A4, written in an appropriate style for children of this age group, in easily understood words, and a large font. The assent form can be the forth side of the document.

PREGNANCY TESTS, AND ADVICE FOR BOTH SEXES
This is a very sensitive area. It may be helpful, particularly if you are recruiting from a clinic where the children know one another, to have this information as an additional sheet.

Information for boys
Remember you may want to provide information for boys (as well as girls) e.g. “if you get a girl pregnant while you are taking this medicine, there is a chance that your baby might be harmed”.

For the parents of boys
“young men can be in situations when sexual activity occurs. It is important for them to be able to discuss these matters with someone, and either you, or the study doctor or make nurse may be able to make sure they understand this important matter”.

Information for girls
You may you use a phrase such as “Taking medicine may help people to get better, but if someone is pregnant, the medicine they take might harm their growing baby. Because of this, there are two things we have to ask all girls who have started their periods;

- To have regular pregnancy tests during the research project. This may be a blood test or a urine sample. If the test is positive, then the girl will be helped with advice from the doctor or research nurse. The girl will be asked for her permission for her parents to be involved.
- If a girl is going to have sex during the research project, she must make sure she takes care not to become pregnant. Advice is available from family planning clinics, or the girl can be advised to talk about this with her GP.

For the parents of girls
Who may also find this concept difficult, something along the lines of “We have to check that there is no chance your daughter may be pregnant. We need to do a pregnancy test, and sensitively ask whether pregnancy could be possible. We realise this is a difficult area, and you may find it intrusive, but the risks of the medicine on a growing baby, however helpful this medicine may be for a child of your daughter’s age, makes it important”.

Obviously if either child or parent has a problem with this, they should be able to withdraw from the trial.

We realise this is difficult when life-saving treatment is involved, but the participants may then have to accept best available treatment, rather than the trial.
FURTHER INFORMATION

- Association of the British Pharmaceutical Industry, 12 Whitehall, London, SW1A 2DY
  - www.abpi.org.uk

- British Medical Association, BMA house, Tavistock Square, London, WC1H 9JR
  - www.bma.org.uk

- Central Office for Research Ethics Committees, Room 7B, B Block, 40 Eastbourne Terrace, London, W2 3QR
  - www.corec.org.uk

- Children’s Commissioner
  - www.childcom.org.uk

- Children's Task Force
  - www.doh.gov.uk/childrenstaskforce

- Consent – a guide for children and young people; a guide for parents; seeking consent; working with children (Department of Health November 2001)
  - www.doh.gov.uk/consent/childconsent.htm
  - www.doh.gov.uk/consnet/parentsconsent.htm

- General Medical Council, 178 Great Portland Street, London, W1N 6JE
  - www.gmc-uk.org

- Good Clinical Practice Journal
  - www.gcpj.com

- Human Genetics Commission
  - www.hgc.gov.uk

- Information about chemotherapy
  - www.royalmarsden.org/captchemo

- Medical Research Council, 20 Park Crescent, London, W1B 1AL
  - www.mrc.uk

- National Children’s Bureau
  - www.ncb.org.uk

- National Institute for Clinical Excellence, Strand, London, WC2N 5HR
  - www.nice.org.uk

- Nuffield Council on Bioethics, 28 Bedford Square, London, WC1B 3EG
  - www.nuffield.org.uk/bioethics

- Royal College of General Practitioners, 14 Princes Gate, London, SW7 1PU
  - www.rcgp.org.uk

- Royal College of Paediatrics and Child Health, 50 Hallam Street, London, W1N 6DE
  - www.rcpch.ac.uk
INFORMATION SHEET AND CONSENT/ASSENT FORM FOR CHILDREN AGED 13-17 IN ENGLAND, WALES AND NORTHERN IRELAND,

12-16 YEARS IN SCOTLAND

The guidance which follows applies primarily to multi-centre pharmaceutical studies, and academic studies and encompasses the ICH Good Clinical Practice guidelines. However, the principles and much of the content will be of use to researcher writing information sheets in their particular fields, for parents and children. We suggest you also read the Department of Health Guidance on seeking consent and working with children (see further information).

It is essential for young adults to discuss the research with their parents or guardian, wherever possible, and, as it is research, to ask them if they agree. Legally, young adults can give their own consent to treatment aged sixteen in Scotland, and eighteen in England, Wales and Northern Ireland. Since the laws regarding the legal age of consent to research is untested, it is recommended that the legal age of consent in the county where the research is to take place is applied.

You should provide sufficient information to allow potential subject to decide whether or not they want to take part. Information should be written in simple, non-technical terms, and be easily understood, by lay people. Use short words, sentences and paragraphs. ‘The readability’ of any text can be roughly estimated by the application of standard formulae. Checks on readability are provided in most work processing packages. It may also be helpful to run the information past a focus group of young people, either by getting a school involved, or a local paediatric department.

Use headed paper of the hospital/institution where the research is being carried out. Patient Information Sheets submitted to an MREC should be headed simply ‘Hospital/Institution/GP Practice head paper’. If you are a local researcher for an MREC approved study, the Patient Information Sheet should be printed on local hospital/surgery paper with local contact names and telephone numbers before it is submitted to the LREC. Unheaded paper is not acceptable.

1. Study title
   Is the title self explanatory to a young person? If not, a short title which is easily understood.

2. Invitation paragraph
   This should explain briefly what research is and that the young person is being asked to take part in a research study. The following is a suitable example:

   ‘You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with your family and anything that is not clear, or if you would like more information. You can take time to decide whether or not you wish to take part.

   Thank you for reading this.

3. What is the purpose of the study?
   The background and aim of the study should be given here. Also mention how long the study lasts.
4. **Why have I been chosen?**
You should explain how the young person was chosen and how many other children will be studied. If the research is on a specific disease e.g. asthma this should be explained in simple terms to help them understand why they have been chosen.

5. **Do I have to take part?**
You should explain that taking part in the research is entirely voluntary. You could use the following paragraph –

'It is up to you to decide whether or not you take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign an assent form. If you decide to take part you are still free to stop taking part at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the care you receive.'

6. **What will happen to me if I take part?**
You should say how long the young person will be involved in the research, how long the research will last (if this is different), how often they will need to visit a clinic (if this is appropriate) and how long these visits will be. You should explain if they will need to visit the GP (or clinic) more often than for his/her usual treatment and if travel expenses are available. Explain exactly what will happen e.g. blood tests, x-rays, (over and above those involved in standard diagnosis and treatment), interview etc. Whenever possible you should draw a simple flowchart or plan indicating what will happen at each visit. What are the parent’s and child’s responsibilities? Set down clearly what you expect of them.

You should set out simply the research methods you intend to use – some simple definitions in the glossary may help you.

7. **What do I have to do?**
Are there any lifestyle restrictions? You should say if there are any dietary restrictions. Can they play games? Swim? Learn to drive? Go to clubs? Discos? Can they take their usual medicines? What happens if the patient thinks she is pregnant? (more advice on this is given in section 11 and in the information for younger children). Explain (if appropriate) that medicine must be taken regularly.

8. **What is the drug or procedure that is being tested?**
You should include a short description of the drug or device and give the stage of its development, and what this means. You should include any arrangements that will be in place for the continued availability of the drug and the trial if the subject finds it helpful, e.g. compassionate release programme.

You should also state the dosage of the drug and method of administration. For drug trials, the parents and child should each be given a card (similar to a credit card) with brief details of the trial they are in, and emergency contact numbers. They should be asked to carry it at all times.

9. **What are the alternatives for diagnosis or treatment?**
For therapeutic research the young person should be told what other treatments are available.

10. **What are the side effects of any treatment received when taking part?**
For any new drug or procedure you should explain the possible side effects. If they suffer these or any other symptoms they should note them and report them next time you meet. You should also give them a contact name and number to phone if they or their parents become concerned about something. The name and number of the person to contact in the
event of an emergency (if that is different) should also be given. Contact names should be continually updated if they change.

The known side effects should be listed in terms that are understandable (e.g. ‘damage to the heart’ rather an ‘cardiotoxicity’, ‘changes in tests showing how the liver works’ rather than ‘raised liver enzymes’). For any new drug it should be explained that there may be unknown side effects.

11. What are the possible disadvantages and risks of taking part?
The issue of fertility in adolescents requires sensitive handling and discussion of appropriate procedures, particularly in oncology trials. Consideration needs to be given to the possibility or wish to have eggs or sperm banked, and the impact this may have on the time of the trial entry. As fertility treatment subsequently may not be funded by the NHS this may need to be pointed out. Specially trained counsellors may be needed for help and advice.

For studies where there could be harm to an unborn child if the patient were pregnant or became pregnant during the study, the following (or similar) should be said:

'It is possible that if the treatment is given to someone who is pregnant it will harm the unborn child. If you think you may be pregnant you must tell you research nurse or doctor as soon as possible. We have to check a pregnancy test, whether or not you feel it is necessary, at certain stages of the trial, because the treatment, which may help you, could harm a growing baby'.

'It is possible that young men who take new treatment could have their sperm damaged for the period they are taking the drug and a short while after they have stopped taking the drug. Young men who are having sex are advised to use adequate contraception to avoid this possibility. If there is a slip-up, and a partner becomes pregnant, the young man should ask her whether he can let the researchers know when she had decided what she wants to do. The young man should be able to tell his partner that confidential advice is available (see below)'.

Use these statements carefully. You should have a plan of action for coping with the disclosure of a pregnancy (taking into account whether the parents or responsible adults know), with confidential counselling available for the young person, and options for referral to a midwife or gynaecology specialist nurse of the GP or other doctor as appropriate to the subjects wish.

A statement should be included about whether the treatments could affect growth (e.g. cause growth retardation).

If the family have private medical insurance, they may need to check if this is altered if one of the family members takes part in a trial.

You should state what happens if you find a condition of which the young person was unaware. Is it treatable? What are you going to do with this information? What might be uncovered?

12. What are the possible benefits of taking part?
Where there is no intended clinical benefit to the person from taking part in the trial this should be stated clearly. The EU directive, to be implemented in May 2004, makes it illegal to perform studies on children where they child may not benefit clinically.

It is important not to exaggerate the possible benefits to the particular subject during the course of the study, e.g. by saying they will be given extra attention. This could be seen as coercive. It would be reasonable to say something similar to:
‘We hope that both (all) the treatments will help you. However, this cannot be guaranteed. The information we get from this study may help us to treat future patients including yourself, with (name of condition) better’.

13. **What if new information becomes available?**
If additional information becomes available during the course of the research you will need to tell the patient about this. You could use the following:

‘Sometimes during the course of a research project, new information becomes available about the treatment/drug that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your research doctor will make arrangements for your care to continue. If you decide to continue in the study you will/may be asked to sign an updated consent form’.

Also on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue.

14. **What happens when the research study stops?**
If the treatment will not be available after the research finishes this should be explained carefully. You should also explain what treatment will be available instead. Occasionally the company sponsoring the research may stop it. If this is the case the reasons should be explained.

15. **What if something goes wrong?**
You should inform the family how complaints will be handled and what redress may be available. Is there a procedure in place? You will need to distinguish between complaints from children or their family as to their treatment by members of staff (doctors, nurses etc) and something serious happening during or following their participation in the trial, i.e. a reportable serious adverse event.

Where there are no Association of the British Pharmaceutical Industry (ABPI) or other no-fault compensation arrangements, and the study carried risk of physical or significant psychological harm, the following (or similar) should be said:

‘If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone else’s fault, then you may have ground for legal action. If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will be available to you’.

Where there are ABPI or other no-fault compensation arrangements the following (or similar) should be included:

‘Compensation for any injury caused by taking part in this study will be in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI). Broadly speaking, the ABPI guidelines recommend that ‘the sponsor’, should compensate you without you having to prove that the sponsor did something wrong. This applies in cases where it is likely that the injury happened because you have been given a new drug or from any other procedure carried out according to the protocol for the study. ‘The sponsor’ will not compensate you if the injury results from any procedure carried out which was not following the protocol for the study. However, in this case, you can still claim compensation through a court of law. Copies of these guidelines are available on request’.
16. **Will my taking part in this study be kept confidential?**
Researchers will need to obtain permission to allow restricted access to the young person’s medical records and to the information collected about them in the course of the study. You should explain that all information collected will be kept strictly confidential. A suggested form of words is:

'If you assent to take part in the research, any of your medical records may be inspected by the company sponsoring (and/or the company organising) the research for purposes of analysing the results. They may also be looked at by people from the company and from regulatory authorities to check that the study is being carried out correctly. Your, name, however, will not be disclosed outside the hospital/GP surgery.

Or for other research:

'All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital/surgery, will have your name and address removed so that you cannot be recognised from it'.

'All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital/surgery, will have your name and address removed so that you cannot be recognised from it'.

You should remember that you, as the researcher, are responsible for ensuring that when collecting or using data, you do not contravene any legal or regulatory requirement in any part of the UK. **This is not the responsibility of the REC.**

You should explain that for studies not being conducted by a GP, the young person’s own GP will be notified of their participation in the trial. This should include other medical practitioners, not involved in the research, who may be treating them. You should seek agreement from the child and parents that their GP can be informed is a precondition of entering the trial.

The length of time data, photographs, questionnaires, videos etc will be kept needs to be stated.

17. **What will happen to the results of the research study?**
You should be able to tell the young person what will happen to the results of the research. When are the results likely to be published? Where can they obtain a copy of the published results? Will they be told which arm of the study they were in? You must add that they will not be identified in any report/publication. Permission needs to be sought for quotes from the subject’s views, and for video or audio recordings. Written consent/assent is also necessary for photographs, which must not identify the individual.

18. **Who is organising and funding the research?**
The answer should include the organisation or company sponsoring or funding the research (e.g. Medical Research Council, Pharmaceutical Company, charity, academic institution).

The family should be told whether the doctor conducting the research is being paid for including and looking after the patient in the study. **This means payment other than that to cover necessary expenses** such as laboratory tests arranged locally by the researcher, or the costs of a research nurse. You could say:
'The sponsors of this study will pay (name of hospital department or research fund) for including you in this study' or

'Your research doctor will be paid for including you in this study'.

19. **Who has reviewed the study?**
You may wish to give the name of the Research Ethics Committee(s) which reviewed the study (you do not however have to list the members of the Committee).

20. **Contact for further information**
You should give the young person and parents or responsible adult a contact point for further information. This can be your name or that of another doctor/nurse involved in the study. It is important that contact numbers are kept up to date.

Remember to thank people for considering taking part in this study!

The patient information sheet should be dated and given a version number.

The Patient Information Sheet should state that the patient will be given a copy of the information sheet and a signed consent/assent form to keep. A similar form should be designed for parents or responsible adults for their child's participation.
Glossary of terms which may be helpful for researchers

- **‘Randomised Trial’**

A randomised trial is one where there are two or more types of treatment, only one of which is given to each person taking part, to see if one treatment is better than the others. The person who gives you the treatment does not know which type you are getting to make it fair. If your doctor needs to know which treatment you are having, they can find out. But, if they have to do this, (break the code), then you would be taken out of the trial and put on another treatment which your doctor would tell you about.

- **‘Blind Trial’**

In a blind trial you will not know which treatment group you are in. If the trial is a double blind trial, neither you nor your doctor will know in which treatment group you are (although, if your doctor needs to find out, he/she can do so).

- **‘Cross-over Trial’**

In a cross-over trial the groups each have different treatments in turn. There may be a break between treatments so that the first drugs are cleared from your body before you start the new treatment.

- **‘Placebo’**

A placebo is a pretend treatment such as a pill which looks like the real thing but is not. It contains no active medicine.

**BIOPSIES**

- **‘What is a biopsy’**

A biopsy means taking a very small sample (usually smaller than a pea) from your body, usually while you are under anaesthetic, to look at it in more detail. Your body is made up of a huge number of tiny individual building blocks called cells. Each cell is invisible to the human eye and can only be seen under a microscope. When a doctor takes a biopsy, they take a very small bit of skin, or bone, or kidney, or gut, or from a lump or any part of your body that could be related to your illness. This is then looked at under a microscope by a pathologist who can see hundreds of cells and is able to say what they look like and whether they are behaving normally.

- **‘Why do I need it done?’**

Generally, children need biopsies doing for several reasons, to that the doctor who looks after you can know as much as possible about what might be wrong with you to plan the proper treatment for you. He/she can also see if the treatment you were given has worked. The information the doctor finds out from examining a biopsy cannot be got in any other way and is usually very helpful in planning the proper treatment.

- **‘How is it done?’**

You may have a general anaesthetic, which means that you will be completely asleep and won’t feel or remember anything, or you may be given sedation, which will make you very sleepy so you will also not feel or remember anything. Sometimes you may have a local anaesthetic when an injection, or a special anaesthetic cream, makes a small part of your body feel numb for a while. For the biopsy to be taken, you may have a needle put into you
or a small cut in your skin, which then has stitches in it. This usually heals very quickly. Sometimes the stitches are removed later but often they dissolve by themselves and all that is left is a tiny scar on the skin.

- ‘Does it need to be done again?’

Often a biopsy needs to be done only once. Sometimes you may need another one if doctors still cannot understand why you are feeling unwell, or to see if everything is better.

- ‘What happens to the biopsy?’

Usually a biopsy sample is preserved in a special liquid and sent to the pathology laboratory. It is then made into little wax blocks (which look like Lego blocks) from which very thin slices are prepared for the pathologist to look at the cells under the microscope. Thee “Lego blocks” are kept in the hospital for a long time so whenever in the future there is a need to look again at your sample, this can be done without you having another biopsy.

Sometimes doctors want to take the samples of cells to look at your genes, which makes you the person you are, and this is called “genetic analysis”. This type of test helps doctors to understand more about your condition and whether there may be any increased risk of your particular disease in your family.

It is not possible to clone another person like you from these cells kept for such a genetic examination, as cloning of people is illegal (against the law) in the United Kingdom.

**BONE MARROW TESTS**

- ‘What is a bone marrow test?’

A bone marrow test is a type of special test, rather like a blood test, only the needle is put onto your bone to take the sample. This test is done when the doctor needs to know whether the bone marrow, which makes your blood, is working properly. This is usually done under a general anaesthetic for children, so they are ‘asleep’, but older children may be offered the chance for it to be done with a local anaesthetic. Mostly, the test is done from the hip bone. When you wake up, or when the anaesthetic wears off, it may be a bit sore, and if it bothers you, the nurse can give you something for the pain.

The sample, which is usually about a teaspoon of marrow, is sent to the laboratory, where is it spread on small glass slides, stained and looked at under the microscope, by a pathologist. Some of the marrow or slides may be sent to other hospitals for special stains or tests. Sometimes a marrow test is repeated during treatment to see how health it is, and you are.

- ‘Bone marrow donation and transplant’

Bone marrow donation happens when one person has bone marrow taken to give to someone else, because their bone marrow is not working properly, or has a disease in it.

If someone gives bone marrow for a transplant, this is done by taking several samples of marrow from different places in the pelvic or hip bones, and the marrow is put into a bag, like a blood bag, for transfusion. Taking the bone marrow may feel quite sore for a day or so, as if they had played a hard game of football.

The person who gets the bone marrow has it given just like a blood transfusion, and the new marrow settles in the right place and starts growing. This person may need a bone marrow test to see how the new marrow is growing after a month or so.
Guidelines for information sheets for parents of children who cannot give their own consent

The guidance which follows applies primarily to multi-centre pharmaceutical studies, and academic studies and encompasses the ICH Good Clinical Practice guidelines. However, the principles and much of the content will be of use to researcher writing information sheets in their particular fields, for parents and children. We suggest you also read the Department of Health Guidance on seeking consent and working with children (see further information).

Legally, young adults can give their own consent to treatment aged sixteen in Scotland, and eighteen in England, Wales and Northern Ireland. Since the laws regarding the legal age of consent to research is untested, it is recommended that the legal age of consent in the county where the research is to take place is applied.

You should provide sufficient information to allow potential subject to decide whether or not they want to take part. Information should be written in simple, non-technical terms, and be easily understood, by lay people. Use short words, sentences and paragraphs. ‘The readability’ of any text can be roughly estimated by the application of standard formulae. Checks on readability are provided in most work processing packages. It may also be helpful to run the information past a focus group of young people, either by getting a school involved, or a local paediatric department.

Use headed paper of the hospital/institution where the research is being carried out. Patient Information Sheets submitted to an MREC should be headed simply ‘Hospital/Institution/GP Practice head paper’. If you are a local researcher for an MREC approved study, the Patient Information Sheet should be printed on local hospital/surgery paper with local contact names and telephone numbers before it is submitted to the LREC. Un headed paper is not acceptable.

1. Study title
   Is the title self explanatory? If not, a short title which is easily understood.

2. Invitation paragraph
   This should explain briefly what research is. The following is a suitable example:

   ‘Your child is being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with other members of your family. Please let us know if of anything that is not clear, or if you would like more information. You can take time to decide whether or not you wish your child to take part.

    Thank you for reading this.

3. What is the purpose of the study?
   The background and aim of the study should be given here. Also mention how long the study lasts.

4. Why has my child been chosen?
   You should explain how the child was chosen and how many other children will be studied. If the research is on a specific disease e.g. asthma this should be explained in simple terms to help them understand why they have been chosen.
5. **Does your child have to take part?**
   You should explain that taking part in the research is entirely voluntary. You could use the following paragraph –

   *No it is up to you to decide whether or not you wish your child to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to stop taking part at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the care your child receives.*

6. **What will happen if my child takes part?**
   You should say how long the child will be involved in the research, how long the research will last (if this is different), how often they will need to visit a clinic (if this is appropriate) and how long these visits will be. You should explain if they will need to visit the GP (or clinic) more often than for his/her usual treatment and if travel expenses are available. Explain exactly what will happen e.g. blood tests, x-rays, (over and above those involved in standard diagnosis and treatment), interview etc. Whenever possible you should draw a simple flowchart or plan indicating what will happen at each visit. What are the parent’s responsibilities? Set down clearly what you expect of them.

   You should set out simply the research methods you intend to use – some simple definitions in the glossary may help you.

7. **What do I have to do?**
   Are there any lifestyle restrictions? You should say if there are any dietary restrictions. Can the children play games? Swim? Can they take their usual medicines? What happens if the patient thinks she is pregnant? (more advice on this is given in section 11 and in the information for younger children). Explain (if appropriate) that medicine must be taken regularly.

8. **What is the drug or procedure that is being tested?**
   You should include a short description of the drug or device and give the stage of its development, and what this means. You should include any arrangements that will be in place for the continued availability of the drug and the trial if the subject finds it helpful, e.g. compassionate release programme.

   You should also state the dosage of the drug and method of administration. For drug trials, the parents and child should each be given a card (similar to a credit card) with brief details of the trial they are in, and emergency contact numbers. They should be asked to carry it at all times.

9. **What are the alternatives for diagnosis or treatment?**
   For therapeutic research the young person should be told what other treatments are available.

10. **What are the side effects of any treatment received when taking part?**
    For any new drug or procedure you should explain the possible side effects. If they suffer these or any other symptoms they should note them and report them next time you meet. You should also give them a contract name and number to phone if they or their parents become concerned about something. The name and number of the person to contact in the event of an emergency (if that is different) should also be given. Contact names should be continually updated if they change.

   The known side effects should be listed in terms that are understandable (e.g. ‘damage to the heart’ rather than ‘cardiotoxicity’, ‘changes in tests showing how the liver works’ rather than
raised liver enzymes’). For any new drug it should be explained that there may be unknown side effects.

11. **What are the possible disadvantages and risk of taking part?**
The issue of fertility in adolescents requires sensitive handling and discussion of appropriate procedures, particularly in oncology trials. Consideration needs to be given to the possibility or wish to have eggs or sperm banked, and the impact this may have on the time of the trial entry. As fertility treatment subsequently may not be funded by the NHS this may need to be pointed out. Specially trained counsellors may be needed for help and advice.

For studies where there could be harm to an unborn child if the patient were pregnant or became pregnant during the study, the following (or similar) should be said:

'It is possible that if the treatment is given to someone who is pregnant it will harm the unborn child. If you think you may be pregnant you must tell your research nurse or doctor as soon as possible. We have to check a pregnancy test, whether or not you feel it is necessary, at certain stages of the trial, because the treatment, which may help you, could harm a growing baby'.

'It is possible that young men who take new treatment could have their sperm damaged for the period they are taking the drug and a short while after they have stopped taking the drug. Young men who are having sex are advised to use adequate contraception to avoid this possibility. If there is a slip-up, and a partner becomes pregnant, the young man should ask her whether he can let the researchers know when she had decided what she wants to do. The young man should be able to tell his partner that confidential advice is available (see below)'.

Use these statements carefully. You should have a plan of action for coping with the disclosure of a pregnancy (taking into account whether the parents or responsible adults know), with confidential counselling available for the young person, and options for referral to a midwife or gynaecology specialist nurse of the GP or other doctor as appropriate to the subjects wish.

A statement should be included about whether the treatments could affect growth (e.g. cause growth retardation).

If the family have private medical insurance, they may need to check if this is altered if one of the family members takes part in a trial.

You should state what happens if you find a condition of which the young person was unaware. Is it treatable? What are you going to do with this information? What might be uncovered?

12. **What are the possible benefits of taking part?**
Where there is no intended clinical benefit to the person from taking part in the trial this should be stated clearly. The EU directive, to be implemented in May 2004, makes it illegal to perform studies on children where the child may not benefit clinically.

It is important not to exaggerate the possible benefits to the particular subject during the course of the study, e.g. by saying they will be given extra attention. This could be seen as coercive. It would be reasonable to say something similar to:

'We hope that both (all) the treatments will help you. However, this cannot be guaranteed. The information we get from this study may help us to treat future patients including yourself, with (name of condition) better'.

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13. What if new information becomes available?
If additional information becomes available during the course of the research you will need to tell the patient about this. You could use the following:

'Sometimes during the course of a research project, new information becomes available about the treatment/drug that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your research doctor will make arrangements for your care to continue. If you decide to continue in the study you will/may be asked to sign an updated consent form'.

Also on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue.

14. What happens when the research study stops?
If the treatment will not be available after the research finishes this should be explained carefully. You should also explain what treatment will be available instead. Occasionally the company sponsoring the research may stop it. If this is the case the reasons should be explained.

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You should inform the family how complaints will be handled and what redress may be available. Is there a procedure in place? You will need to distinguish between complaints from children or their family as to their treatment by members of staff (doctors, nurses etc) and something serious happening during or following their participation in the trial, i.e. a reportable serious adverse event.

Where there are no Association of the British Pharmaceutical Industry (ABPI) or other no-fault compensation arrangements, and the study carried risk of physical or significant psychological harm, the following (or similar) should be said:

'If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone else’s fault, then you may have ground for legal action. If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will be available to you'.

Where there are ABPI or other no-fault compensation arrangements the following (or similar) should be included:

'Compensation for any injury caused by taking part in this study will be in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI). Broadly speaking, the ABPI guidelines recommend that ‘the sponsor’, should compensate you without you having to prove that the sponsor did something wrong. This applies in cases where it is likely that the injury happened because you have been given a new drug or from any other procedure carried out according to the protocol for the study. ‘The sponsor’ will not compensate you if the injury results from any procedure carried out which was not following the protocol for the study. However, in this case, you can still claim compensation through a court of law. Copies of these guidelines are available on request'.
16. **Will my taking part in this study be kept confidential?**

Researchers will need to obtain permission to allow restricted access to the young person’s medical records and to the information collected about them in the course of the study. You should explain that all information collected will be kept strictly confidential. A suggested form of words is:

‘If you assent to take part in the research, any of your medical records may be inspected by the company sponsoring (and/or the company organising) the research for purposes of analysing the results. They may also be looked at by people from the company and from regulatory authorities to check that the study is being carried out correctly. Your name, however, will not be disclosed outside the hospital/GP surgery.

Or for other research:

‘All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital/surgery, will have your name and address removed so that you cannot be recognised from it’.

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You should remember that you, as the researcher, are responsible for ensuring that when collecting or using data, you do not contravene any legal or regulatory requirement in any part of the UK. **This is not the responsibility of the REC.**

You should explain that for studies not being conducted by a GP, the young person’s own GP will be notified of their participation in the trial. This should include other medical practitioners, not involved in the research, who may be treating them. You should seek agreement from the child and parents that their GP can be informed is a precondition of entering the trial.

The length of time data, photographs, questionnaires, videos etc will be kept needs to be stated.

17. **What will happen to the results of the research study?**

You should be able to tell what will happen to the results of the research. When are the results likely to be published? Where can they obtain a copy of the published results? Will they be told which arm of the study they were in? You must add that they will not be identified in any report/publication. Permission needs to be sought for quotes from the subject’s views, and for video or audio recordings. Written consent/assent is also necessary for photographs, which must not identify the individual.

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The answer should include the organisation or company sponsoring or funding the research (e.g. Medical Research Council, Pharmaceutical Company, charity, academic institution).

The family should be told whether the doctor conducting the research is being paid for including and looking after the patient in the study. **This means payment other than that to cover necessary expenses** such as laboratory tests arranged locally by the researcher, or the costs of a research nurse. You could say:

‘The sponsors of this study will pay (name of hospital department or research fund) for including you in this study’ or ‘Your research doctor will be paid for including you in this study’. 
19. **Who has reviewed the study?**
You may wish to give the name of the Research Ethics Committee(s) which reviewed the study (you do not however have to list the members of the Committee).

20. **Contact for further information**
You should give the young person and parents or responsible adult a contact point for further information. This can be your name or that of another doctor/nurse involved in the study. It is important that contact numbers are kept up to date.

Remember to thank people for considering taking part in this study!

The parent information sheet should be dated and given a version number.

The Parent Information Sheet should state that they will be given a copy of the information sheet and a signed consent/assent form to keep.