



South Glasgow University Hospitals Division

Research Ethics Committees

Southern General Hospital and Victoria Infirmary

Annual Report

April 2004 to March 2005

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Chairman's Report

This report covers the period from April 2004 to March 2005. During this time both Research Ethics Committees (RECs) within the South Glasgow University Hospitals Division experienced a number of changes in systems and personnel.

In advance of the European Directive 2001/20/EC, which came into force in the United Kingdom on 1st May 2004, the Central Office for Research Committees (COREC) introduced a national application form, database and standard operating procedures. REC members, administrators and researchers had to adopt the new procedures to comply with the Directive's regulations that:

- a single UK-wide opinion be provided for multi-centre studies;
- the time period of 60 days be set for the review of clinical trials of investigational medicinal products (CTIMPs).

Both Committees met on a regular basis and were kept busy reviewing a wide range of interesting research proposals. After many years of committed and enthusiastic services the following Members resigned:

Southern General Hospital

Reverend David Keddie (Chair)
Professor Ian Bone
Dr Elaine Morrison

Victoria Infirmary

Dr Douglas McLellan
Mr Ian Neeson
Ms Iona Reid

In March 2004 the Members of both RECs agreed to amalgamate and form a new Committee from April 2005, to be known as the South Glasgow REC. Unfortunately due to the change of meeting date and time the following Members were unable to remain on board:

Southern General Hospital

Mrs Margaret Brown

Victoria Infirmary

Dr Howard McAlpine
Mrs Violet Kimble

I would like to take this opportunity to thank all the REC Members, both past and present for their commitment and interest. In their name I send out this report.

Gerald F Belton OBE

Details of Committees

Name: Southern General Hospital Research Ethics Committee

Chair: Reverend David Keddie (until September 2004)

Administrator: Mrs Simone Smith

Name: Victoria Infirmary Research Ethics Committee

Chair: Mr Gerald Belton

Vice Chair: Mr Tim Hems

Administrator: Mrs Simone Smith

Address: Southern General Hospital
1345 Govan Road
Glasgow
G51 4TF

Telephone: 0141 201 1203

Email: simone.smith@sgh.scot.nhs.uk

Greater Glasgow NHS Board Model Constitution for 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.
- The purpose of LRECs in reviewing the proposed study is to protect the dignity, rights, safety and well being of all actual or potential research participants. It shares this role and responsibility with others, as described in the *Research Governance Framework for Health and Community Care*.
- 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.

An 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

A Chairman and Vice Chairman of an 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 Trust should continue to appoint the administrator/secretary, whose appointment to the post will be confirmed 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 Members as defined and at least one other Member who is independent of the institution or specific location where the research is to take place.
- A 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.

**Southern General Hospital REC
Committee Members**

Reverend David Keddie (Chairman)**	Church of Scotland Minister
Mr Naeem Akhtar	Consultant Urologist
Mr Brian Beacom MBE	Lay Member
Professor Ian Bone**	Consultant Neurologist
Mrs Margaret Brown	Senior Nurse Practice Development
Mr John Devitt	Lay Member
Professor Donald Hadley	Consultant Neuroradiologist
Mrs Christine Hogg	Lay Member
Dr Elaine Morrison**	Consultant Physician
Dr Stephen Noble	Consultant Anaesthetist
Dr Alison Thomson	GP Principal
Mrs Fiona Walker	Pharmacy Manager/Deputy Chief Pharmacist

** During the period covered by this report, the following Members resigned:

Reverend David Keddie
Professor Ian Bone
Dr Elaine Morrison

Southern General Hospital REC - Record Of Attendance - April 2004 to March 2005

Name	Apr	May	Jun	Jul	Aug	Sep	Oct	(Sc) Nov	Dec	Jan	(Sc) Feb	(Sc) Mar	Meetings Attended
Rev D Keddie (Chairman)	A	A	A	A	A	A	Resigned September 2004						6
Mr N Akhtar	R	A	A	R	A	R	A	A	A	A	A	A	9
Mr B Beacom MBE	A	A	A	A	A	A	A	A	R	A	A	R	10
Professor I Bone	R	R	A	R	R	Resigned September 2004						1	
Mrs M Brown	R	R	A	A	R	R	A	A	A	A	A	R	7
Mr J Devitt	A	A	X	A	A	A	A	A	A	A	A	A	11
Professor D Hadley	A	X	A	A	A	A	A	A	A	A	R	R	9
Mrs C Hogg	A	A	A	A	A	A	A	A	A	A	R	A	11
Dr E Morrison	R	R	R	A	A	R	R	Resigned November 2004					2
Dr S Noble	R	A	R	A	A	A	A	A	A	A	A	A	10
Dr A J Thomson	A	R	A	A	A	A	A	A	A	A	A	A	11
Mrs F Walker	A	R	A	A	R	A	A	A	R	A	R	A	8

A = Attended

R = Apologies Received

X = Absent

Sc = Sub-committee

**Southern General Hospital REC
Summary of Submissions**

2004	Research Proposals	Site Specific Assessments	Protocol Amendments	Other Business Items
27 April	2	0	0	4
25 May	0	1	3	7
29 June	1	5	3	13
27 July	3	3	2	4
31 August	21*	6	0	6
28 September	5	6	0	7
26 October	6	6	0	8
30 November	0	11	0	0
7 December	9	0	0	8
30 December	0	1	0	0

2005

25 January	8	8	0	3
22 February	0	6	0	6
29 March	0	6	2	1

55

59

10

67

* includes 15 submissions from Glasgow Caledonian University

Southern General Hospital REC - Project Index - April 2004 to March 2005

Study Ref No.	Title of Study	Principal Investigator	Date Received	Date Approved
04/S0702/3	Examining The Effect Of A Swimming Participation On Psychological Morbidity And Body Image Following Amputation	Dr B O'Neill Clinical Psychologist Southern General Hospital	07/04/04	10/05/04
04/S0702/5	Gene Expression Profiles In Alzheimer's Disease Examined Using cDNA Microarray Technology	Dr W Stewart Registrar in Neuropathology Southern General Hospital	13/04/04	27/04/04
04/S0702/8	A Prospective Randomised Double Blind Placebo Controlled Dose Ranging Multicentre Study Of The Safety And Efficacy Of Three Days Continuous Intravenous Infusion Of GR270773 In The Treatment Of Suspected Or Confirmed Gram-Negative Severe Sepsis In Adults	Dr M Garrioch Consultant Anaesthetist Southern General Hospital	17/05/04	25/05/04
04/S0702/9	Betaferon Vs. Rebif Investigating Higher Tolerability Observational Study To Assess Injection Site Pain In Multiple Sclerosis Patients Treated With Betaferon Vs. Rebif – BRIGHT	Dr C O'Leary Consultant Neurologist Southern General Hospital	28/05/04	29/06/04
04/S0702/10	An Open Label Extension Study With Requip (Ropinirole) CR For Subjects From Studies 101468/165 101468/168 And 101468/169	Dr D Grosset Consultant Neurologist Southern General Hospital	14/06/04	29/06/04
04/S0702/11	M-Health Support Networks And Rehabilitation Of Patients	Professor R Richardson Deputy Service Manager Dietetics Southern General Hospital	18/06/04	27/07/04
04/S0702/12	Exploring Employers' Experience / Perceptions Of Supporting Employees Affected By Cancer	Mr I Stewart Consultancy World Edinburgh	25/05/04	29/06/04

Study Ref No.	Title of Study	Principal Investigator	Date Received	Date Approved
04/S0702/13	Cerebral Intravascular Microthrombosis And Delayed Ischaemic Deficit In Fatal Subarachnoid Haemorrhage	Professor D Graham Professor of Neuropathology Southern General Hospital	15/06/04	29/06/04
04/S0702/14	Bell's Palsy Early Acyclovir And/Or Prednisolone In Scotland A Multicentre Factorial Trial Of The Early Administration Of Steroids And/Or Antivirals For Bell's Palsy	Mr B Bingham Consultant ENT Surgeon Southern General Hospital	11/05/04	29/06/04
04/S0702/15	A Phase III Randomised Evaluation Of Convection-Enhanced Delivery Of IL13-PE38QQR Compared To Gliadel® Wafer With Survival Endpoint In Glioblastoma Multiforme Patients At First Recurrence	Mr V Papanastassiou Consultant Neurologist Southern General Hospital	15/06/04	29/06/04
04/S0702/16	European Registry Of Patients With Refractory Angina Pectoris (Intended To Be) Treated With Spinal Cord Stimulation - EARL	Dr G McCallum Pain Anaesthetist Southern General Hospital	12/07/04	27/07/04
04/S0702/17	A Multicentre Double Blind Randomised Placebo Controlled Parallel Group Trial Investigating Methylprednisolone In Combination With Interferon-Beta-1a For The Treatment Of Relapsing – Remitting Multiple Sclerosis	Dr C O'Leary Consultant Neurologist Southern General Hospital	30/07/04	31/08/04
04/S0702/18	Imaging Of Non Patient Volunteers On 3T MRI Scanner At The Institute Of Neurological Sciences	Professor D Hadley Consultant Neuroradiologist Southern General Hospital	08/07/04	27/07/04
04/S0702/20	Does Patient Education Influence Readiness To Adopt A "Self-Help" Approach To Chronic Pain Management?	Dr D Craig Clinical Psychologist Southern General Hospital	12/07/04	27/07/04
04/S0702/21	Analysis Of Cell Proliferation And Neuronal Migration Patterns After Traumatic Brain Injury	Professor D Graham Professor of Neuropathology Southern General Hospital	13/07/04	27/07/04

Study Ref No.	Title of Study	Principal Investigator	Date Received	Date Approved
04/S0702/22	Use Of Residual Tissue For Research	Mr D Meek Consultant Orthopaedic Surgeon Southern General Hospital	24/07/04	31/08/04
04/S0702/23	A Prospective Study To Evaluate The Safety Tolerability And Efficacy Of Intravesical Injection Of Botulinum Toxin Type A Into Detrusor Muscle In Patients With Symptoms Of Interstitial Cystitis	Mr I G Conn Consultant Urologist Southern General Hospital	15/07/04	31/08/04
04/S0702/24	Do People With Psychophysiologic Insomnia Display Pre-Sleep Cognitive And Physiological Arousal On Both Subjective And Objective Sleep Measures?	Miss J Taylor Trainee Clinical Psychologist Gartnavel Royal Hospital	23/07/04	27/07/04
04/S0702/25	A Double Blind Comparative Study To Determine The Efficacy Of A 25% Urea Cream A 10% Urea Cream And A White Soft Paraffin Cream With Lanolin In Treating Anhidrosis	Mr S Baird Head of Division of Podiatry Glasgow Caledonian University	26/07/04	31/08/04
04/S0702/26	Painful Diabetic Neuropathy An Investigation Into Diabetes Control And Levels Of Neuropathic Pain	Mrs C Skinner Lecturer in Podiatry Glasgow Caledonian University	26/07/04	31/08/04
04/S0702/27	Do Asians Who Suffer From Diabetes Understand The Effects Diabetes May Have On The Lower Limb And Foot More Clearly When Explained In Punjabi Rather Than English	Mrs C Skinner Lecturer in Podiatry Glasgow Caledonian University	26/07/04	31/08/04
04/S0702/28	A Comparative Study Of Patient Satisfaction Following Nail Surgery That Was Carried Out At The Southern General Hospital Or Stobhill Hospital	Ms G Tavener Lecturer in Podiatry Glasgow Caledonian University	26/07/04	31/08/04
04/S0702/29	Patient Reactions To Footwear Advice	Ms G Tavener Lecturer in Podiatry Glasgow Caledonian University	26/07/04	31/08/04
04/S0702/30	Patient Use Expected Outcomes And Attitudes To Internet Based Rheumatology Information	Ms G Tavener Lecturer in Podiatry Glasgow Caledonian University	26/07/04	31/08/04

Study Ref No.	Title of Study	Principal Investigator	Date Received	Date Approved
04/S0702/31	A Comparative Study Investigating Blood Pressure Measurement Before During And After Nail Surgery In An NHS Podiatry Clinic	Mr G Burrow Senior Lecturer in Podiatry Glasgow Caledonian University	26/07/04	31/08/04
04/S0702/32	A Question Of Posture – A Comparative Study Using The Bambach Saddle Seat™ And A Conventional Clinical Seat	Mr G Burrow Senior Lecturer in Podiatry Glasgow Caledonian University	26/07/04	31/08/04
04/S0702/33	An Evaluation Of The Foot Care/Foot Health Knowledge Of Patients With Diabetes Mellitus	Mrs M O'Donnell Senior Lecturer in Podiatry Glasgow Caledonian University	26/07/04	31/08/04
04/S0702/34	Diagnosis Of Skin Fungal Infections Of The Foot Based On Clinical Signs And Symptoms And Wood's Light	Mrs M O'Donnell Senior Lecturer in Podiatry Glasgow Caledonian University	26/07/04	31/08/04
04/S0702/35	The Investigation And Comparison Of The Clinical Diagnosis Of Fungal Infections Of The Skin And Diagnosis Using A Wood's Light	Mrs M O'Donnell Senior Lecturer in Podiatry Glasgow Caledonian University	26/07/04	31/08/04
04/S0702/36	Fungal Concentrations Within Footwear And Hosiery Of Patients With Untreated Tinea Pedis	Dr N McLarnon Lecturer in Podiatry Glasgow Caledonian University	26/07/04	31/08/04
04/S0702/37	Does Podospray™ Influence The Amount Of Viable Microbes In The Podiatric Environment?	Dr N McLarnon Lecturer in Podiatry Glasgow Caledonian University	26/07/04	31/08/04
04/S0702/38	A Comparison Of Blood Pressure Measurements Before During And After Nail Surgery	Mr P Madigan Lecturer in Podiatry Glasgow Caledonian University	26/07/04	31/08/04
04/S0702/39	A Study Examining The Effects Of Music On Anxiety Of Patients Undergoing Nail Surgery	Mr P Madigan Lecturer in Podiatry Glasgow Caledonian University	26/07/04	31/08/04
04/S0702/40	Recurrence Rate And Disability Following Excision Of Dorsal Wrist Ganglions – A Retrospective Analysis	Mr L Campton Specialist Registrar in Orthopaedics Victoria Infirmary	11/08/04	28/09/04

Study Ref No.	Title of Study	Principal Investigator	Date Received	Date Approved
04/S0702/41	A Multicentre Multinational Phase 3 Open Label Extension Trial To Assess The Safety Of Long Term Treatment Of Rotigotine Patch In Subjects With Advanced Stage Idiopathic Parkinson's Disease Who Are Not Well Controlled On Levodopa	Dr D Grosset Consultant Neurologist Southern General Hospital	26/07/04	31/08/04
04/S0702/43	Changes In Brain Function Across Treatment For Post Traumatic Stress Disorder	Professor T M McMillan Chair in Clinical Neuropsychology Gartnavel Royal Hospital	26/07/04	31/08/04
04/S0702/44	Effect Of Surgical Approach On Vastus Lateralis Function After Operative Fixation Of Fractured Neck Of Femur	Mr D Meek Consultant Orthopaedic Surgeon Southern General Hospital	17/08/04	31/08/04
04/S0702/45	A Long Term Double Blind Randomised Parallel Group Carbidopa/Levodopa Controlled Multicentre Study To Evaluate The Effect Of Stalevo In Patients With Parkinson's Disease Requiring Initiation Of Levodopa Therapy	Dr D Grosset Consultant Neurologist Southern General Hospital	10/08/04	31/08/04
04/S0702/46	A Multicentre Single Arm Open Label Phase IV Study To Evaluate The Immunogenicity And Safety Of Subcutaneously Administered r-hIFN beta-1a (Rebif) Using Clone 484-39 In The Treatment Of Subjects With Relapsing Remitting Multiple Sclerosis	Dr C O'Leary Consultant Neurologist Southern General Hospital	04/08/04	31/08/04
04/S0702/47	The Feasibility Of Using Bone Morphogenic Protein (rhBMP-7) For The Reconstruction Of Alveolar Cleft A Pilot Study	Professor A Ayoub Honorary Consultant in Oral & Maxillofacial Surgery Southern General Hospital	17/08/04	26/10/04
04/S0702/48	Nausea Vomiting And Retching In Pregnancy	Ms H Nicol Midwife Southern General Hospital	17/08/04	31/08/04
04/S0702/49	Study Of The Bone Density Adaptation Around The Knee After ACL Reconstruction	Mr D Meek Consultant Orthopaedic Surgeon Southern General Hospital	16/08/04	31/08/05

Study Ref No.	Title of Study	Principal Investigator	Date Received	Date Approved
04/S0702/50	Regional And Temporal Distribution Of Activated Microglia Over Expressing 1-1 And Related Factors In Genesis Of Alzheimer Type Changes In Down's Syndrome	Professor D Graham Professor of Neuropathology Southern General Hospital	12/07/04	28/09/04
04/S0702/51	Development Of A Novel Single Photon Emission Computed Tomography Brain Imaging Ligand For The Noradrenaline Transporter	Dr D Dewar Senior Lecturer in Neuroscience University of Glasgow	24/09/04	26/10/04
04/S0702/52	Do Metacognitive Beliefs And Plans For Processing Distinguish Between People With Insomnia Sleep Apnea And Good Sleepers?	Miss J Waine Trainee Clinical Psychologist University of Glasgow	06/09/04	28/09/04
04/S0702/53	Incidence Of Solitary Fibrous Tumour Of The Meninges Within The Surgical Tissue Archive Of The Department Of Neuropathology	Professor D Graham Professor of Neuropathology Southern General Hospital	26/08/04	28/09/04
04/S0702/54	The Relationship Between The Systemic Inflammatory Response Lean Body Mass And Outcome In Patients With Metastatic Prostate Cancer	Mr P McArdle SHO III in Urology Southern General Hospital	05/10/04	26/10/04
04/S0702/55	Betaferon Vs. Rebif Investigating Higher Tolerability Observational Study To Assess Injection Site Pain In Multiple Sclerosis Patients Treated With Betaferon Vs. Rebif – BRIGHT	Dr C O'Leary Consultant Neurologist Southern General Hospital	23/07/04	28/09/04
04/S0702/57	Prospective Data Collection On 100 Consecutive Patients With Tremor Presenting To The Movement Disorders Group	Dr D Grosset Consultant Neurologist Southern General Hospital	02/09/04	28/09/04
04/S0702/58	Spectroscopic Evaluation Of Lesion Evolution In Stroke Trial Of Insulin For Acute Lacticacidosis – SELESTIAL	Dr K Muir Senior Lecturer In Neurology Southern General Hospital	01/09/04	28/09/04
04/S0702/59	To Determine The Efficacy Of The Dentron Biogun In The Management And Eradication Of 3 Common Foot Disorders/Conditions Affecting The Foot	Mr G Burrow Senior Lecturer Glasgow Caledonian University	13/09/04	28/09/04
04/S0702/60	Relationship Between Chromium VI Levels And Aseptic Loosening Of Metal Implants	Mr D Meek Consultant Orthopaedic Surgeon Southern General Hospital	08/09/04	28/09/04

Study Ref No.	Title of Study	Principal Investigator	Date Received	Date Approved
04/S0702/61	A Study To Determine The Effectiveness Of The Antimicrobial Dressing Contreet As A Post Operative Wound Dressing Following Total Nail Avulsion With Phenolisation Of The Nail Matrix And Bed	Mr S Baird Head of Division of Podiatric Medicine and Surgery Glasgow Caledonian University	07/09/04	28/09/04
04/S0702/62	An Open Pharmacodynamic Phase I Study Of A Single Dose Of 200mg/m2 AQ4N Administered To Cancer Patients Scheduled For Elective Surgery	Professor R Rampling Professor of Neuro-Oncology Western Infirmary	20/07/04	28/09/04
04/S0702/63	Comparison Of Balloon Vs. Non Balloon Rectal Catheters In The Prevention Of Incontinence During Routine Barium Enema Examinations	Dr A Downie Consultant Radiologist Victoria Infirmary	13/08/04	28/09/04
04/S0702/64	An Intergroup Trial Of Rituximab Vs. A Watch And Wait Strategy In Patients With Advanced Stage Asymptomatic Non-Bulky Follicular Lymphoma	Dr A Morrison Consultant Haematologist Southern General Hospital	28/09/04	26/10/04
04/S0702/65	High Definition 3T MR Imaging Of The Hippocampal Complex In Temporal Lobe Epilepsy And Its Correlation With Semiology EEG And SPECT	Dr S Elnaas SpR in Neuroradiology Southern General Hospital	11/10/04	26/10/04
04/S0702/66	Solifenacin In The Treatment Of Urgency Symptoms Of Overactive Bladder In A Rising Dose Randomised Double Blind Trial - SUNRISE	Mr I G Conn Consultant Urologist Southern General Hospital	05/10/04	26/10/04
04/S0702/67	Randomised Study Of ICE +Rituximab (R-ICE) Vs. DHAP +Rituximab (R-DHAP) In Previously Treated Patients With CD20 Positive Diffuse Large B-Cell Non-Hodgkin's Lymphoma Eligible For High Dose Chemotherapy And Transplantation Followed By Randomised Maintenance Treatment With Rituximab	Dr A Morrison Consultant Haematologist Southern General Hospital	05/10/04	26/10/04
04/S0702/68	Development And Testing Of A Method For Characterising Prescribing Activity And Associated Pharmaceutical Care	Miss M White Principal Pharmacist Southern General Hospital	11/10/04	26/10/04
04/S0702/69	Microphthalmia Transcription Factor - A Possible Successor To Existing Melanoma Markers?	Miss L Duffy BMS 1 Southern General Hospital	13/10/04	26/10/04

Study Ref No.	Title of Study	Principal Investigator	Date Received	Date Approved
04/S0702/70	A Long Term Double Blind Randomized Parallel Group Carbidopa/Levodopa Controlled Multicentre Study To Evaluate The Effect Of Stalevo In Patients With Parkinson's Disease Requiring Initiation Of Levodopa Therapy	Dr D Grosset Consultant Neurologist Southern General Hospital	12/10/04	26/10/04
04/S0702/71	A Comparison Of Cyclo-Oxygenase-2 (COX-2) Expression In Core Biopsies And Excision Biopsies Correlation With Other Biological Parameters	Mrs L Kane BMS Southern General Hospital	13/10/04	26/10/04
04/S0702/72	Scottish Neurological Symptoms Study Treatment Development Project	Dr J Cavanagh Senior Lecturer in Psychiatry Gartnavel Royal Hospital	13/10/04	26/10/04
04/S0702/73	Electrically Powered Indoor/Outdoor Wheelchair (EPIOC) And Quality Of Life Examining The Effect Of EPIOC Provision And Predicting Use	Dr B O'Neill Clinical Psychologist Southern General Hospital	12/10/04	15/12/04
04/S0702/74	A Phase III Study Comparing A Gel Containing Calcipotriol 50mcg/g Plus Betamethasone 0.5mg/g (As Dipropionate) With Betamethasone 0.5mg/g (As Dipropionate) In The Gel Vehicle And Calcipotriol 50mcg/g In The Gel Vehicle All Applied Once Daily In The Treatment Of Scalp Psoriasis	Dr A Drummond Consultant Dermatologist Southern General Hospital	08/11/04	30/11/04
04/S0702/75	Using Discrete Choice Conjoint (Economic) Analysis To Estimate Women's Preferences For Alternative Methods Of Treatment For Prolapse	Ms L Sinclair Acting Programme Leader Glasgow Caledonian University	08/11/04	30/11/04
04/S0702/76	Acute Care Nurses' Perspective of 12-Hour Shifts	Dr A O'Neill Lecturer Glasgow University	11/11/04	07/12/04
04/S0702/77	A Preliminary Investigation Of The Influence Of Urinary Urge Symptoms On The Gait Of Older Women With Parkinson's Disease	Dr J Booth Senior Research Fellow Glasgow Caledonian University	11/11/04	22/02/05
04/S0702/78	A Prospective Multicentre Double Blinded Placebo Controlled Trial To Evaluate The Effectiveness Of Patent Foramen Ovale Closure With The STARFlex Septal Repair Implant To Resolve Refractory Migraine Headache	Dr K Muir Senior Lecturer in Neurology Southern General Hospital	04/11/04	30/11/04

Study Ref No.	Title of Study	Principal Investigator	Date Received	Date Approved
04/S0702/79	A Phenomenological Study To Investigate The Experiences Of Nurses With Regard To Brain Stem Death Testing With Particular Emphasis On Relations With The Next Of Kin	Miss C Ronayne Senior Staff Nurse Southern General Hospital	12/11/04	07/12/04
04/S0702/81	A Randomised Placebo Controlled Trial Of Tarceva (OSI-774 Erlotinib) In Patients With Advanced Non-Small Cell Lung Cancer (NSCLC) Unsuitable For Chemotherapy	Dr N O'Rourke Consultant Oncologist Western Infirmary	09/11/04	30/11/04
04/S0702/82	A Randomised Controlled Trial Of Active Symptom Control With Or Without Chemotherapy In The Treatment Of Patients With Pleural Mesothelioma	Dr N O'Rourke Consultant Oncologist Western Infirmary	09/11/04	30/11/04
04/S0702/83	A Comparison Of Complications Following Insertion Of A Percutaneous Endoscopic Gastrostomy Or A Radiological Gastrostomy In Patients With Head And Neck Cancer	Mrs G McHattie Nutrition Nurse Specialist Southern General Hospital	15/11/04	17/01/05
04/S0702/84	Ovarian Protection Trial In Oestrogen Non-Responsive Pre-Menopausal Breast Cancer Patients Receiving Adjuvant Or Neo-Adjuvant Chemotherapy	Dr A Al-hasso Consultant Oncologist Western Infirmary	08/11/04	30/11/04
04/S0702/85	Prospective Study Of Outcome Of Sporadic Vs. Hereditary Breast Cancer	Dr A Al-hasso Consultant Oncologist Western Infirmary	08/11/04	30/11/04
04/S0702/86	A Partially Blind Phase III Randomised Trial Of Fulvestrant (Faslodex) With Or Without Concomitant Anastrozole (Arimidex) Compared With Exemestane In Post Menopausal Women With ER+ve Locally Advanced/Metastatic Breast Cancer Following Progression On A NSA1	Dr A Al-hasso Consultant Oncologist Western Infirmary	08/11/04	30/11/04
04/S0702/87	A Comparison Of The Accuracy And Clinical Utility Of Portable Ultrasound Bladder Scanners As Compared With An MRI Gold Standard	Dr D Small Principal Physicist Southern General Hospital	16/11/04	07/12/04
04/S0702/88	The Effect Of Alendronate On Periprosthetic Bone Loss Following Total Knee Replacement	Dr R Abu-Rajab SpR in Orthopaedics Southern General Hospital	17/11/04	07/12/04

Study Ref No.	Title of Study	Principal Investigator	Date Received	Date Approved
04/S0702/89	The Scottish Pregnancy Intervention Study The Effect Of Low Molecular Weight Heparin And Aspirin Therapy On Recurrent Pregnancy Loss	Dr M Gaudoin Consultant Obstetrician Southern General Hospital	17/11/04	30/11/04
04/S0702/90	Nasendoscopy And Management Implications in Otodontogenic Abscesses	Dr V Lochhead Consultant Neuroanaesthetist Southern General Hospital	17/11/04	07/12/04 Rejected
04/S0702/91	A Multicentre Randomised Double Blind Placebo Controlled Parallel Group Phase II Study To Evaluate The Safety And Efficacy Of Oral Dosing With GW679769 (50 Mg Or 150 Mg) For Three Consecutive Days When Administered With A Single Intravenous Dose Of Ondansetron Hydrochloride For The Prevention Of Post-Operative Nausea And Vomiting And Post-Discharge Nausea And Vomiting In Female Subjects With Known Risk Factors For Post-Operative Nausea And Vomiting Who Are Undergoing Laparoscopic/Lapartomic Surgical Procedures Associated With An Increased Emetogenic Risk	Dr D Russell Consultant Anaesthetist Southern General Hospital	16/11/04	30/11/04
04/S0702/92	Pharmaceutical Palliative Care Of Patients With Heart Failure	Miss A Balfour Senior Pharmacist Southern General Hospital	17/11/04	07/12/04
04/S0702/93	Development And Testing Of A Medication Compliance Risk Assessment Tool	Professor S Hudson Professor of Pharmaceutical Care Strathclyde University	17/11/04	07/12/04
04/S0702/94	Development And Testing Of A Medication Compliance Risk Assessment Tool	Miss A Muir Lead Pharmacist Education Southern General Hospital	17/11/04	30/11/04
04/S0702/95	An Open Label Multicentre Study To Assess The Efficacy Of Switching To A Combination Tablet Ezetimibe / Simvastatin 10 mg/40 mg Compared To Doubling The Dose Of Statin In Patients Hospitalised With A Coronary Event	Dr D Murdoch Consultant Cardiologist Southern General Hospital	29/12/04	25/01/05

Study Ref No.	Title of Study	Principal Investigator	Date Received	Date Approved
04/S0702/96	PD GEN Parkinson's Disease Bank	Dr G Macphee Consultant Geriatrician Southern General Hospital	13/01/05	25/01/05 Objection
04/S0702/97	A Double Blind Placebo Controlled Multicentre Phase III Study To Evaluate The Safety And Efficacy Of Sarotizan HCl 1mg b.i.d. In Patients With Parkinson's Disease Suffering From Treatment Associated Dyskinesia - PADDY1	Dr D Grosset Consultant Neurologist Southern General Hospital	14/12/04	30/12/04
05/S0702/2	Determination Of Novel Methods Of Exercise Testing During Treadmill Gait In Incomplete Spinal Cord Injury	Professor K Hunt Mechanical Engineering University Of Glasgow	29/12/04	22/02/05
05/S0702/3	Electrophysiological Assessment Of Central Nervous System (CNS) Organisation Following Spinal Cord Injury (SCI)	Dr B Conway Reader in Bioengineering University of Strathclyde	06/01/05	25/01/05
05/S0702/4	A Novel Activation Paradigm For Functional MRI An Examination Of Healthy Volunteers	Dr J Cavanagh Senior Lecturer in Psychiatry Gartnavel Royal Hospital	29/12/04	25/01/05
05/S0702/5	Aspirin Esomeprazole Chemoprevention Trial A Phase 111b Randomised Study Of Aspirin And Esomeprazole Chemoprevention in Barrett's Metaplasia - ASPECT	Dr R Park Consultant Gastroenterologist Southern General Hospital	06/01/05	25/01/05
05/S0702/6	A Prospective Randomised Trial Comparing TVT-O & TOT In Surgical Management Of USI (Urodynamic Stress Incontinence)	Dr I Ramsay Consultant Obstetrician Southern General Hospital	11/01/05	25/01/05
05/S0702/7	Determination Of Novel Methods Of Exercise Testing During Treadmill Gait In Incomplete Spinal Cord Injury	Mr D Allan Clinical Director, Spinal Injury Unit Southern General Hospital	07/01/05	25/01/05
05/S0702/8	The Development Of A Pharmaceutical Care Service To Meet The Needs Of Patients With Rheumatoid Arthritis	Miss A Muir Lead Pharmacist Education Southern General Hospital	30/12/04	25/01/05
05/S0702/9	A Double Blind Placebo Controlled Multicentre Phase III Study To Evaluate The Safety And Efficacy Of Sarotizan HCl 1mg b.i.d. In Patients With Parkinson's Disease Suffering From Treatment Associated Dyskinesia - PADDY1	Dr D Grosset Consultant Neurologist Southern General Hospital	11/01/05	25/01/05

Study Ref No.	Title of Study	Principal Investigator	Date Received	Date Approved
05/S0702/10	Rehabilitation Of Reading By Training In Eccentric Viewing In Subjects With Age Related Macular Degeneration A Functional Magnetic Resonance Imaging Study	Ms J Chisholm Senior Clinical Scientist Southern General Hospital	10/01/05	09/02/05
05/S0702/11	A Case Controlled Trial Comparing Tension Free Vaginal Tape (TVT) Vs. Transobturator Tension Free Vaginal Tape	Dr I Ramsay Consultant Obstetrician Southern General Hospital	11/01/05	29/03/05
05/S0702/12	Electrophysiological Assessment Of Central Nervous System (CNS) Organisation Following Spinal Cord Injury (SCI)	Mr D Allan Clinical Director, Spinal Injury Unit Southern General Hospital	10/01/05	25/01/05
05/S0702/13	A Novel Activation Paradigm For Functional MRI An Examination Of Healthy Volunteers	Professor D Hadley Professor of Neuroradiology Southern General Hospital	11/01/05	25/01/05
05/S0702/14	Nasendoscopy And Management Implications In Otodontogenic Abscesses	Dr V Lochhead Consultant Neuroanaesthetist Southern General Hospital	12/01/05	25/01/05 Rejected
05/S0702/16	An 18 Week Multicentre Randomised Double Blind Placebo Controlled Parallel Group Study Of The Efficacy Safety And Tolerability Of Donepezil HCl (E2020) In Patients With CADASIL Who Have Cognitive Impairment	Dr K Muir Senior Lecturer In Neurology Southern General Hospital	18/01/05	25/01/05
05/S0702/17	A Double Blind Randomised Placebo Controlled Parallel Group Study Of Sativex In Subjects With Symptoms Of Spasticity Due To Multiple Sclerosis	Dr C O'Leary Consultant Neurologist Southern General Hospital	01/02/05	22/02/05
05/S0702/18	International Study Of Unruptured Intracranial Aneurysms Phase III	Dr K Lindsay Consultant Neurologist Southern General Hospital	07/02/05	22/02/05
05/S0702/19	A Randomised Controlled Trial Of Excisional Surgery Vs. Imiquimod 5% Cream For Nodular And Superficial Basal Cell Carcinoma	Dr R Herd Consultant Dermatologist Beatson Oncology Centre	04/02/05	22/02/05

Study Ref No.	Title of Study	Principal Investigator	Date Received	Date Approved
05/S0702/25	Evaluation Of Gastrointestinal Tolerance Of A New Thickening Powder In Patients With Dysphagia - EVATT	Professor R Richardson Head of Nutrition & Dietetics Victoria Infirmary	07/02/05	22/02/05
05/S0702/27	Conservative Treatment For Urinary Incontinence In Men After Prostate Surgery (MAPS) Multicentre Randomised Controlled Trial Of Pelvic Floor Muscle Training Biofeedback And Bladder Training	Mr N Akhtar Consultant Urologist Southern General Hospital	04/02/05	22/02/05
05/S0702/29	Comparative Study Of Different Orthotic Treatments To Provide Knee Control In Persons With Knee Extensor Insufficiency	Dr B Meadows Head of Neurobiomechanics Southern General Hospital	10/02/05	22/02/05
05/S0702/31	Illness Perceptions Neuropsychological Impairment And Quality Of Life In Chronic Fatigue Syndrome Auto Immune Thyroid Failure And Healthy Controls	Ms A Dickson Post-Doctoral Research Fellow University of Stirling	11/03/05	29/03/05
05/S0702/32	Verteporfin Photodynamic Therapy In Subfoveal Choroidal Neovascularisation - UK Cohort Study	Dr W Wykes Consultant Ophthalmologist Southern General Hospital	11/03/05	29/03/05
05/S0702/35	3T MR Imaging Of Caratoid Plaque Morphology In Symptomatic Patients Correlation With Transcranial Doppler Ex-vivo 77 MRI And Histopathology	Dr K Forbes Consultant Neuroradiologist Southern General Hospital	16/03/05	29/03/05
05/S0702/40	Micro Nutrient Status Of Elderly Hospitalised Patients Pilot Study	Ms T Fujiwara State Registered Dietitian Southern General Hospital	15/03/05	29/03/05
05/S0702/41	A British Thoracic Oncology Group Phase III Trial Of Gemcitabine Plus Cisplatin At 80mg/m2 Vs. Gemcitabine Plus Cisplatin At 50mg/m2 Vs. Gemcitabine Plus Carboplatin AUC6 In Stage IIIB/IV Non Small Cell Lung Cancer - BTOG2	Dr J Sarvesvaran Consultant Physician Victoria Infirmary	15/03/05	29/03/05
05/S0702/42	A Phase III Randomised Double Blind Placebo Controlled Trial Of Carboplatin/Etoposide With Or Without Thalidomide In Small Cell Lung Cancer - Study 12	Dr J Sarvesvaran Consultant Physician Victoria Infirmary	15/03/05	29/03/05

**Victoria Infirmary REC
Committee Members**

Mr Gerald Belton OBE	Lay Member
Mr Graham Boyle	Lay Member
Mr Robert Burleigh	Lay Member
Dr James Curran	GP
Mr Con Gillespie	Acting Senior Nurse Manager
Mr Tim Hems	Consultant Orthopaedic Surgeon
Mrs Violet Kimble	Senior Clinical Pharmacist
Dr Howard McAlpine	Consultant Cardiologist
Dr Douglas McLellan**	Consultant Pathologist
Mr Ian Neeson**	Lay Member
Ms Iona Reid**	Consultant Surgeon
Dr Deepa Singh	Consultant Anaesthetist

** During the period covered by this report, the following Members resigned:

Dr Douglas McLellan
Mr Ian Neeson
Ms Iona Reid

Victoria Infirmary REC - Record Of Attendance – April 2004 to March 2005

Name	Apr	Jun	(Sc) Jul	(Sc) Aug	Sept	Oct	Nov	(Sc) Dec	(Sc) Jan	Feb	Mar	Meetings Attended
Mr G Belton OBE (Chairman)	A	R	R	A	A	A	A	A	A	A	A	9
Mr W G Boyle	A	A	A	A	A	A	R	R	R	R	A	7
Mr R Burleigh	A	R	A	A	A	A	A	A	A	A	A	10
Dr J Curran	R	R	R	R	A	A	A	R	A	A	A	6
Mr C Gillespie	R	A	R	R	A	R	A	A	A	A	A	7
Mr T Hems (Vice Chairman)	A	A	A	A	A	A	A	A	A	X	A	10
Mrs V Kimble	A	R	A	A	A	A	A	R	A	A	A	9
Dr H McAlpine	A	A	A	R	A	A	X	A	X	A	R	7
Dr D McLellan	A	A	R	R	A	R	X	Resigned November 2004			3	
Mr I Neeson	A	A	R	R	R	X	R	X	Resigned January 2005		2	
Miss I Reid	X	Resigned May 2004									0	
Dr D Singh	R	A	A	A	A	R	A	R	R	A	R	6

A = Attended

R = Apologies Received

X = Absent (Sc) = Sub-committee

**Victoria Infirmery REC
Summary of Submissions**

2004	Research Proposals	Site Specific Assessments	Protocol Amendments	Other Business Items
6 April	0	1	2	9
1 June	0	2	0	5
14 July	0	4	0	3
20 August	0	1	0	3
8 September	2	2	0	7
5 October	1	3	0	1
10 November	2	3	0	4
7 December	1	4	0	2

2005

12 January	0	1	0	4
1 February	0	3	0	3
9 March	6	1	0	1

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25

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Victoria Infirmary REC - Project Index - April 2004 to March 2005

Study Ref No.	Title of Study	Principal Investigator	Date Received	Date Approved
MREC/ 02/0/47	Scottish Register Of Children With Cerebral Palsy	Ms M Smart Administrative Secretary Cerebral Palsy Register for Scotland	18/03/04	06/04/04
04/S0707/1	Bell's Palsy Early Acyclovir And/Or Prednisolone In Scotland A Multicentre Factorial Trial Of The Early Administration Of Steroids And/Or Antivirals For Bell's Palsy	Mr B Bingham Otolaryngology Consultant Victoria Infirmary	11/05/04	01/06/04
04/S0707/2	A Prospective Randomised Double Blind Placebo Controlled Dose Ranging Multicentre Study Of The Safety And Efficacy Of Three Days Continuous Intravenous Infusion Of GR270773 In The Treatment Of Suspected Or Confirmed Gram Negative Severe Sepsis In Adults	Dr A Davidson Consultant Anaesthetist Victoria Infirmary	17/05/04	01/06/04
04/S0707/3	A Phase IIIb Study To Determine Efficacy And Safety Of Extended Drotrecogin Alfa (Activated) Therapy In Patients With Persistent Requirement For Vasopressor Support After 96 Hour Infusion With Commercial Drotrecogin Alfa (Activated)	Dr A Davidson Consultant Anaesthetist Victoria Infirmary	13/05/04	08/09/04
04/S0707/4	Randomised Prospective Trial Of Scorpio Vs. LCS Knee Replacement	Mr A Shaw Consultant Orthopaedic Surgeon Victoria Infirmary	30/07/04	15/11/04
04/S0707/5	M-Health Support Networks And Rehabilitation Of Patients	Ms L McKechnie Senior Dietitian Victoria Infirmary	18/06/04	14/07/04 Objection
04/S0707/6	Does Vitamin D Supplementation Reduce Falls In Older Patients?	Dr E Burleigh Specialist Registrar Mansionhouse Unit	16/06/04	14/07/04
04/S0707/7	Does Patient Education Influence Readiness To Adopt A "Self-Help" Approach To Chronic Pain Management?	Dr D Craig Clinical Psychologist Victoria Infirmary	16/06/04	14/07/04 Objection

Study Ref No.	Title of Study	Principal Investigator	Date Received	Date Approved
04/S0707/8	Measures To Improve Tissue Oxygenation	Mr A Krishna Research Fellow/Registrar Victoria Infirmary	07/07/04	01/11/04 Withdrawn
04/S0707/9	Myeloma IX Myeloma Randomised Controlled Trial Multicentre Phase III Thalidomide Bisphosphonate	Dr P Tansey Consultant Haematologist Victoria Infirmary	29/06/04	20/08/04
04/S0707/11	Cartilage Repair By Autologous Chondrocyte Transplantation Vs. Existing Conventional Treatments	Mr A Shaw Consultant Orthopaedic Surgeon Victoria Infirmary	23/08/04	05/10/04
04/S0707/12	Recurrence Rate And Disability Following Excision Of Dorsal Wrist Ganglions A Retrospective Analysis	Mr L Campton SpR in Orthopaedics & Trauma Victoria Infirmary	11/08/04	10/11/04
04/S0707/13	Application To Investigate Patients With Pathology On Both 1.5T And 3T Magnetic Resonance Systems At The Institute Of Neurological Sciences And To Compare The Acquired Data	Professor D Hadley Consultant Neuroradiologist Southern General Hospital	26/08/04	05/10/04
04/S0707/14	Comparison Of Balloon Vs. Non Balloon Rectal Catheters In The Prevention Of Incontinence During Routine Barium Enema Examinations	Dr A Downie Consultant Radiologist Victoria Infirmary	13/08/04	07/12/04
04/S0707/15	A Phase 3 Multicentre Randomised Placebo Controlled Double Blind Three Arm Study To Evaluate The Safety And Efficacy Of Tifacogin (Recombinant Tissue Factor Pathway Inhibitor) Administration In Subjects With Severe Community Acquired Pneumonia	Dr A Davidson Consultant Anaesthetist Victoria Infirmary	15/09/04	05/10/04
04/S0707/16	An Inter Group Trial Of Rituximab Vs. A Watch and Wait Strategy In Patients With Advanced Stage Asymptomatic Non-Bulky Follicular Lymphoma	Dr P Tansey Consultant Haematologist Victoria Infirmary	10/09/04	05/10/04

Study Ref No.	Title of Study	Principal Investigator	Date Received	Date Approved
04/S0707/17	Randomised Study Of ICE + Rituximab (R-ICE) Vs. DHAP + Rituximab (R-DHAP) In Previously Treated Patients With CD20 Positive Diffuse Large B-Cell Non Hodgkins Lymphoma Eligible For High Dose Chemotherapy And Transplantation Followed By Randomised Maintenance Treatment With Rituximab	Dr P Tansey Consultant Haematologist Victoria Infirmary	10/09/04	05/10/04
04/S0707/18	Retrospective Audit Of Patients' Pain Following Discharge From Intensive Care Unit	Dr G Gordon Consultant in Anaesthesia and Pain Management Victoria Infirmary	27/10/04	10/11/04
04/S0707/20	Multicentre Randomised Trial Comparing The Cost Effectiveness Of Contrast-Enhanced High Field MR Imaging In Women Scheduled For Wide Local Excision - COMICE	Dr S Stallard Consultant Surgeon Victoria Infirmary		10/11/04
04/S0707/21	Using Discrete Choice Conjoint (Economic) Analysis To Estimate Women's Preferences For Alternative Methods Of Treatment For Prolapse	Lesley Sinclair Acting Programme Leader NMAHP Research Unit Glasgow Caledonian University	27/10/04	10/11/04
04/S0707/22	Assessment Of Post-Operative Pain Control In Orthopaedic Patients	Miss J McIntosh Pre-Registration Pharmacist Victoria Infirmary	26/10/04	22/11/04
04/S0707/23	Multicentre Randomised Double Blind Parallel Group Confirmatory Phase III Study To Compare The Efficacy And Safety Of Cizolirtine Citrate 300 mg bid (600 mg/d) Cizolirtine Citrate 400 mg bid (800 mg/d) Placebo And Tolterodine 2 mg bid (4 mg/d) In The Treatment Of Urge Urinary Incontinence	Mr N Akhtar Consultant Urologist Southern General Hospital	15/11/04	07/12/04
04/S0707/24	Experience of Nurses With Regard To Brain Stem Death Testing	Ms C Ronayne Senior Staff Nurse Victoria Infirmary	12/11/04	07/12/04

Study Ref No.	Title of Study	Principal Investigator	Date Received	Date Approved
04/S0707/25	A Randomised Controlled Trial Of Active Symptom Control With Or Without Chemotherapy In The Treatment Of Patients With Malignant Pleural Mesothelioma	Dr N O'Rourke Consultant Oncologist Western Infirmary	03/11/04	10/11/04
04/S0707/26	A Randomised Placebo Controlled Trial Of Tarceva (OSI-774 Erlotinib) In Patients With Advanced Non-Small Cell Lung Cancer (NSCLC) Unsuitable For Chemotherapy	Dr N O'Rourke Consultant Oncologist Western Infirmary	12/11/04	07/12/04 Objection
04/S0707/27	A Multicentre Randomised Double Blind Placebo Controlled Parallel Group Phase II Study To Evaluate The Safety And Efficacy Of Oral Dosing With GW679769 (50 mg Or 150 mg) For Three Consecutive Days When Administered With A Single Intravenous Dose Of Ondansetron Hydrochloride For The Prevention Of Post-Operative Nausea And Vomiting And Post-Discharge Nausea And Vomiting In Female Subjects With Known Risk Factors For Post-Operative Nausea And Vomiting Who Are Undergoing Laparoscopic/Laparotomic Surgical Procedures Associated With An Increased Emetogenic Risk	Dr Davidson Consultant Anaesthetist Victoria Infirmary	06/12/04	21/12/04
05/S0707/1	Aspirin Esomeprazole Chemoprevention Trial A Phase 111b Randomised Study Of Aspirin And Esomeprazole Chemoprevention in Barrett's Metaplasia - ASPECT	Dr G Gray Consultant Surgeon Victoria Infirmary	23/12/04	12/01/05
05/S0707/2	A Prospective Randomised Trial Comparing TVT-O & TOT In Surgical Management Of USI (Urodynamic Stress Incontinence)	Dr S Bjornsson Consultant Gynaecologist Victoria Infirmary	18/01/05	01/02/05
05/S0707/3	A Case Controlled Trial Comparing Tension Free Vaginal Tape (TVT) vs. Transobturator Tension Free Vaginal Tape	Dr S Bjornsson Consultant Gynaecologist Victoria Infirmary	18/01/05	01/02/05

Study Ref No.	Title of Study	Principal Investigator	Date Received	Date Approved
05/S0707/4	A Phase 2 Multicentre Randomised Double Blind Dose Escalating/De Escalating Study To Evaluate The Safety Efficacy And Pharmacokinetics Of A Single Dose Of Sustained Release Encapsulated Bupivacaine (SKY0402) In The Management Of Post Operative Pain In Subjects Undergoing Inguinal Hernia Repair	Dr Davidson Consultant Anaesthetist Victoria Infirmary	21/01/05	01/02/05
05/S0707/5	Patient Internet Usage Within An Urban Orthopaedic Outpatient Practice	Ms J McCaul SHO III Orthopaedic Surgery Victoria Infirmary	24/02/05	09/03/05 Provisional
05/S0707/6	Evaluation Of Gastrointestinal Tolerance Of A New Thickening Powder In Patients With Dysphagia – EVATT	Professor R Richardson Head of Nutrition & Dietetics Victoria Infirmary	16/02/05	07/03/05 Withdrawn
05/S0707/7	Study Of The Adherence Of Stalevo Entacapone and Levodopa	Dr D Grosset Consultant Neurologist Southern General Hospital	08/02/05	04/04/05
05/S0707/8	Prevalence Of Patent Foramen Ovale In CADASIL	Dr K Muir Senior Lecturer In Neurology Southern General Hospital	09/02/05	29/04/05
05/S0707/9	Comparative Study Of Different Orthotic Treatments To Provide Knee Control In Persons With Knee Extensor Insufficiency	Dr B McHugh Senior Lecturer NCTEPO University of Strathclyde	10/02/05	05/05/05
05/S0707/10	Updated Consent Form For Use Of Patient Case History Or Patient Case History And Video Recording (Or Patient Photograph And Or Other Images) For Publication Or Presentation	Dr D Grosset Consultant Neurologist Southern General Hospital	03/02/05	09/03/05
05/S0707/11	A Pilot Study To Determine The Best Method To Optimise Tissue Oxygen Tension In Healthy Volunteers	Mr A Krishna Research Fellow Victoria Infirmary	25/02/05	09/03/05 Provisional