



**Research & Development  
Directorate**

**Annual Report**

**1999 - 2000**



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## **I. INTRODUCTION**

### **1. Background**

#### 1.1 Research in South Manchester

1.1.1 South Manchester University Hospitals NHS Trust (SMUHT) undertakes and reports high quality research which has national and international stature. Many of the Trust's research programmes reflect the synergy of research partnerships between clinical specialities in the Trust, the Universities of Greater Manchester and other academic and NHS organisations.

1.1.2 The establishment of a Clinical Research Division for SMUHT, within the research framework of the University of Manchester Faculty of Medicine Dentistry and Nursing, is being explored with the University. The University has demonstrated its commitment to increasing the Trust's involvement, along with the other teaching Trusts in Greater Manchester, in the development of joint University/NHS research and development (R&D) strategies and initiatives (Appendix 1).

1.1.3 This is in line with the Joint Medical Advisory Committee's recommendation in *Good Practice in NHS/Academic Links* (HEFCE, 1999) for "joint research strategies across universities, NHS trusts, health authorities and primary care and the development of research consortia".

1.1.4 Year 2 of the *R&D Agreement* has seen:

- consolidation of achievements in Year 1;
- completion of Year 2 objectives set out in the R&D Strategy;
- development of new R&D collaborations with academic and NHS organisations;
- review, restructuring and rationalisation of R&D themes;
- a range of initiatives to address local and national R&D priorities.

1.1.5 The R&D Directorate has made significant contributions to the business of the Trust through presentation of papers to standing committees and the Trust Board, development of management responses to NHSE policy, and, operational support to Trust researchers and organisational research partners.

## **II. PROGRESS AGAINST STRATEGIC ABILITY**

### **2. Strategic Framework**

#### 2.1 Trust Board Commitment

2.1.1 In 1998/99, the Trust Board endorsed R&D as a core activity of the Trust and gave its full support to the R&D Directorate's initial R&D strategy for the Trust.

2.1.2 The continuing commitment of the Chief Executive and Director of Finance is evidenced by bi-monthly progress meetings with the Director of R&D and R&D Manager. These meetings enable an exploration of R&D strategic issues, discussion of complex problems and agreement of action plans.

2.1.3 The Chairman receives copies of R&D Committee minutes and provides invaluable feedback on the business of the Committee. The Chairman has given particular support to the development of R&D capability building strategies; consumer involvement in R&D; management arrangements for Intellectual Property, and, investment of Trust endowment funding in innovative cancer research initiatives.

## 2.2 Challenges

2.2.1 Against this background, during 1999/00, new national R&D priorities and financial frameworks guided continuing efforts to focus Trust research programmes and to review the impact of research outputs on clinical services. The R&D Directorate continued to devise and implement management responses to address new strategic challenges and to build on the Trust's long-standing tradition of delivering high quality research.

2.2.2 Planning of the integrated Education and Research Centre drew researchers from the Withington and Wythenshawe sites together to develop a vision for a building which will serve as the future hub of the Trust's research activities. The needs of medical undergraduate and postgraduate education, Trust training, R&D, clinical audit, library and information services, and, IM&T have been accommodated through collaborative working by all parties with the SMUHT Estates Department.

## 2.3 R&D Strategy

2.3.1 The Trust's R&D strategy, which was formally adopted by the Trust Board in 1999, set out an action plan of year-on-year objectives and demonstrated medium- and long-term R&D goals to take account of local, regional and national R&D priorities.

2.3.2 In 1999/00, the R&D strategy was revised to reflect Trust achievements, the maturing of the organisation's R&D management capability and changes in R&D funding arrangements (Appendix 2). The creation of the Manchester Mental Health Partnership during 2000/01 and planned changes in R&D funding mechanisms will necessitate further revisions in the next financial year, when the detail of these changes is published.

2.3.3 The strategy now incorporates an R&D mission statement which augments the SMUHT mission statement and summarises key elements of the Trust's R&D philosophy.

2.3.4 The primary aim of the strategy is to ensure that high quality peer-reviewed research is conducted which addresses national R&D priorities, reflects the clinical expertise within the Trust, and, meets Health Authority and Trust objectives. The strategy also addresses the requirement to manage R&D, research governance and Intellectual Property generated by Trust staff.

2.3.5 The objectives for Years 1, 2 and 3 are set out in the R&D strategy under six headings. These are listed below, together with the sections of this report which detail Year 2 achievements:

- Management (Part III, Section 13, Section 22);

- Finance (Section 9, Part V, Section 19);
- Governance (Section 3, Section 20);
- Capability Building (Section 7, Section 8, Section 21, Section 23);
- Partnerships (Section 6, Section 7, Section 10);
- Intellectual Property (Part VII).

The strategic objectives for Years 1 and 2 have all been achieved. As well, substantial progress has been made on some of Year 3 objectives.

## 2.4 R&D Business Plan

2.4.1 A detailed R&D business agenda for the period of the *R&D Agreement* is set out in the R&D strategy. A summary of business achievements is provided in Appendix 3 and details are given in the relevant sections of this report.

## 2.5 Manchester Mental Health Partnership

2.5.1 The creation of the Manchester Mental Health Partnership (MMHP), from October 2000, provides a real opportunity to maximise mental health research in the North West, with the aim of improving the quality of services for patients and their carers.

2.5.2 SMUHT looks forward to collaborating with the new organisation in R&D activities. The potential for innovative collaborations is significant and is based on existing joint work being carried out within South Manchester. Adult Psychiatry, Old Age Psychiatry and Clinical Psychology all have well-established research collaborations with other SMUHT departments. Examples are:

- Old Age Psychiatry and the Vascular Studies Unit are conducting a pioneering investigation to determine whether dementia can be caused by paradoxical embolisation through a patent foramen ovale.
- Adult Psychiatry has collaborated with the Department of Medicine in studies of chronic fatigue syndrome in an attempt to find improved treatments.
- Clinical Psychology has worked with the Department of Medicine and the Burns and Reconstructive Surgery Unit to examine the prevalence of post traumatic stress disorder (PTSD) and psychological morbidity in stroke patients and burns patients.
- Clinical Psychology is collaborating with the Accident & Emergency Department to examine A&E staff attitudes towards patients who have attempted suicide and to develop predictors of PTSD in road traffic accident victims.

2.5.3 The development of the MMHP, by focusing high quality mental health research in one organisation, offers potential for additional research collaborations and joint projects with SMUHT clinical departments.

## 3. Quality

### 3.1 Governance

3.1.1 The R&D Manager is a member of the Trust's Clinical Governance and Quality

(CG&Q) Committee, which is a standing committee of the Trust Board. The aim of the Committee is to *ensure that the Trust develops systems to enable clinical governance and quality to be identified, assessed, monitored and continuously improved in every Directorate/Division.*

3.1.2 The R&D Committee has delegated responsibility for putting in place and administering a research governance framework.

3.1.3 In March 2000, a paper was presented to the CG&Q Committee outlining the R&D Committee's response to national guidance relating to *Good Clinical Practice (GCP)* and the research governance framework that the R&D Committee proposes to set in place during 2000/01 (Appendix 4).

### 3.2 Research Charter

3.2.1 In February 2000, the R&D Committee adopted a *Research Charter* (Appendix 5) which sets out a research governance framework for the Trust. The charter covers:

- *Good Clinical Practice* in research;
- research involving human tissue or genetic material obtained surgically;
- notification of serious adverse events;
- ethical and scientific standards;
- complaints;
- research misconduct;
- research monitoring.

3.2.2 Development of the *Research Charter* involved a major consultation with 43 key SMUHT consultants and researchers to obtain a consensus of views about the current guidance from the Nuffield Council on Bioethics on consent requirements for research on human tissue and/or genetic material derived from it. This initiative is dove-tailing with the development of Trust guidelines for retention of tissues at post mortem examination.

3.2.3 The R&D Committee also adopted an *Investigator Agreement for the Conduct of Research* (Appendix 5). Researchers will be required to sign this agreement confirming their compliance with the SMUHT *Research Charter*.

### 3.3 *Good Clinical Practice (GCP)* in Research

3.3.1 The achievement of *GCP* in the designing, conducting, recording and reporting of research in the Trust was endorsed as a strategic aim in February 2000 by the R&D Committee. To this end, the Committee has adopted the ICH *GCP* (1997) guidelines as the future standard for researchers in the Trust.

3.3.2 The R&D Committee has approved an outline plan for a rolling *GCP* audit of research to be conducted in the Trust (Appendix 6). The audit will be conducted by the former head of the Medicines Control Agency Inspection and Enforcement Division, with the aim of developing exemplar *GCP* audit procedures for the NHS. An audit plan will be agreed annually by the R&D Committee to ensure compliance with *GCP* and to improve standards year-on-year.

3.3.3 The R&D Committee has also approved the format of a rolling *GCP* education programme for Trust researchers (Appendix 6) which is being organised by the Medicines Evaluation Unit at SMUHT.

### 3.4 New Project Approval Procedures

3.4.1 From 1 November 1999, new procedures for research notifications, approvals, indemnifications and contracts were implemented (Appendix 7).

3.4.2 The procedures cover:

- all research projects whether internally or externally funded;
- research grants, commercial sponsorship and donations for R&D from all external sources;
- industrial and commercial R&D contracts;
- government and charity R&D contracts.

### 3.5 Risk Management

3.5.1 A restructuring of the Trust's risk management arrangements is in progress. A Corporate Risk Group is being established and will include the R&D Manager in its membership. Its remit will be to ensure organisation-wide coordination and prioritisation of risk management issues.

### 3.6 Quality Assurance

3.6.1 Research funded within the mutual obligation arrangements in *HSG (97)32* is not submitted to local peer review.

3.6.2 Currently, other projects (ie sponsored by charitable or commercial organisations and own account) are assessed by the Director of R&D and Theme Leads on the basis of *NRR* records. This is primarily an assessment of their fit within the R&D themes and does not include a specialist view.

3.6.3 During the year, the R&D Committee explored the issue of peer review of own account research. A consultation document, *Framework for Peer Review of Own Account Research* (Appendix 8), setting out procedures for peer review of individual projects, was considered. Peer review of programmes of research remains the R&D Committee's preferred option.

3.6.4 Attempts during 1998/99 to devise a tripartite arrangement with Central Manchester Healthcare and Salford Royal Hospitals NHS Trusts for local peer review did not prove to be feasible. SMUHT is now collaborating in a region-wide initiative to try and create a *North Western Regional Register of Reviewers for Own Account and Local Charity Funded Research*.

## 4. Ethics

### 4.1 Measures to Support Ethics Agenda

4.1.1 There is a direct input into the South Manchester Local Research Ethics Committee (LREC) through the membership of the Deputy Director of R&D and

the R&D Support Nurse.

- 4.1.2 The R&D Information Officer provides advice and guidance to researchers about requirements for ethical approval and administers effective information flows between the R&D Directorate and LREC.
- 4.1.3 LREC has agreed, in principle, that SMUHT research projects will not be considered for ethical approval unless approved by the R&D Directorate (see 3.4.1 and 3.4.2). In practice, LREC applications are sent simultaneously to the Directorate and to LREC and projects are passed by LREC on the understanding that the Directorate has given approval.
- 4.1.4 During the first quarter of the year, the R&D Manager worked with R&D and clinical audit managers from the adult and paediatric teaching hospitals in Greater Manchester and Liverpool, in consultation with LRECs, to develop an outline for a multi-centre patient consent audit project. This project was not implemented because of staff resource requirements but served as a catalyst to the SMUHT R&D Committee to begin addressing the *GCP* agenda.

## **5. Relevance, Impact and Importance**

### 5.1 National

- 5.1.1 The Trust's R&D themes map directly to three of the national R&D and three of *Our Healthier Nation* priority areas: cancer and palliative care; coronary heart disease (CHD) and stroke; mental health. These three priorities represent 60% of the Trust's current research projects. There is also major research activity related to other national priorities - ageing (old age psychiatry; cardiovascular and cardiothoracic surgery and cardiology; respiratory disease) and primary care. The latter is a major focus, with 19% of the Trust's research projects linking to primary care.
- 5.1.2 The development of *National Service Frameworks (NSFs)* for CHD, mental health and older people will have a major influence on shaping the Trust's research in these activity areas. Relevant and rigorous research and the wide dissemination of research findings are the keys to ensuring that *NSF* standards and recommendations are evidence-based.

### 5.2 Regional

- 5.2.1 The Trust's R&D strategy includes objectives which contribute to the achievement of the four R&D objectives set out in the NHS Executive North West 1999/2002 Business Plan.

### 5.3 Local

- 5.3.1 Relevance of the Trust's research programmes to Manchester Health Authority's priorities for action in its 1999/00 *Health Improvement Programme (HimP)* can also be demonstrated. The priorities for action in the *HimP* for 1999/00 are given below, with examples of SMUHT research areas which relate to these priorities.

<b>Priorities</b>	<b>Research Areas</b>
Children/Young People	asthma and allergy; community epidemiology; suicide and self-harm.
Mental Health/Mental Health Promotion	severe mental illness; models of community care; suicide and self-harm; psychological factors associated with medical disorders.
Older People	Alzheimer's disease; needs of relatives and carers; interventions in nursing homes; chronic wounds, ulceration and pressure sores.
Coronary Heart Disease/Stroke	angina; coronary syndromes; stroke; vascular surgery; cardiac transplantation.
Health Inequalities/Social Exclusion	community epidemiology; membership in Primary Care Research in South Manchester (PRiSM); medicines information needs of people with mental illness.

5.3.2 Manchester Health Authority is also working to achieve better integration of clinical effectiveness, clinical audit, R&D, education and training. The joint working of these teams in SMUHT mirrors these Health Authority initiatives.

## **6. Primary Care**

### **6.1 Research Activity Involving Primary Care**

6.1.1 A significant number of the research projects within the Trust have one or more of the following links with primary care:

- at least one research investigator is a primary care professional;
- patient recruitment and data collection take place within primary care;
- the research topic relates specifically to the activities of primary care professionals.

6.1.2 19% of the Trust's research work in 1999/00 linked across the clinical interface with primary care (compared with 16% in 1998/99). This activity formed a proportion of R&D theme activities as follows: *Cancer* (5%); *Cardiovascular Disease* (9%); *Developing Fields* (21%); *Mental Health* (38%); *Physiological Studies* (12%); *Respiratory Disease* (35%).

Examples of primary care-linked research projects were:

- study of indoor pollutants in local Manchester communities;

- asthma advice on the high street;
- development of nurse-led palliative care services in acute settings and primary care;
- effect of postgraduate training of pharmacists on provision of pharmaceutical care to the terminally ill;
- an evidence-based approach to treatment of depression in pregnant and postnatal women in primary care;
- effect of specialist medical assessment of older people prior to admission to long term care;
- the impact of respiratory symptoms on primary care workload and prescribing costs;
- environmental manipulation: practical measures in the home to benefit asthma patients;
- preventative measures in residential care/nursing homes to reduce osteoporosis and consequent fractures;
- incidence of foot ulceration in diabetic patients following education programmes in the home;
- general practitioners' opinions of patients' own drugs (PODs) and self-medication scheme in SMUHT;
- validation of simple scoring system for asthma.

6.1.3 The 1999/00 investment of R&D support funding in primary care research in each of the six research activity areas is detailed in Table 2 (Appendix 9).

## 6.2 Primary Care Research in South Manchester (PRiSM) Network

6.2.1 SMUHT is a collaborative partner in the *Budget 2*-funded PRiSM network. Trust researchers are available for advice and assistance in developing links with hospital and university researchers and the R&D Directorate staff provide operational support to the primary care members of the network.

6.2.2 The R&D Manager and the Director of R&D have mentored the PRiSM member from the Mancunian Community Health NHS Trust (now from South Manchester Primary Care NHS Trust) in developing a PhD proposal for a research project to examine loneliness and social isolation in the elderly living in their own homes. The R&D Manager also set up discussions with the University of Salford Faculty of Health Care and Social Work Studies leading to agreement to collaborate on this research.

6.2.3 Collaborative research in respiratory disease at the North West Lung Centre (NWLC) was already well-established with one of the PRiSM member general practices, Bowland Road Medical Centre. The North West Lung Foundation continues to fund elements of this research.

6.2.4 The lack of access to library and information services (LIS) is a major handicap for PRiSM members. The R&D Manager arranged for the Regional Director of Library Services to attend a PRiSM meeting to explore this matter. The outcome of this meeting was agreement to set out the access issues in a paper which was considered by the South Manchester PCG (PCT) Clinical Governance, Research and Development and Education (CRED) Group in February 2000. The R&D Manager prepared the paper, *Primary Care Access to the Knowledge Base* (Appendix

10), on behalf of PRiSM, and obtained agreement by the SMUHT Chief Executive to fund the pilot project proposed in the paper.

6.2.5 Members of PRiSM were invited to the Trust's annual R&D conference for the non medical professions (nursing, midwifery and professions allied to medicine). This provided the opportunity for PRiSM members to network with Trust researchers from the non medical professions as well as clinical support services and academic laboratories.

### 6.3 Withington Community Hospital Development

6.3.1 SMUHT researchers with strong community-based research programmes within South Manchester support the concept of the community hospital serving as a base for primary care and community-based research. The potential to accommodate peripatetic researchers from University or NHS partner organisations – whose research would be most appropriately conducted from a community base as opposed to an acute hospital base - has been included in the business case for the community hospital development.

## 7. Partnership

### 7.1 Regional, National and International Partnerships

7.1.1 Trust researchers are involved in a wide range of pan Manchester, regional, national and international research partnerships: for example, *the Manchester Burns Research Group; York Medical Economics Consortium; MRC GP Framework; UK Pulmonary Hypertension Consortium; Greater Manchester Lung Fibrosis Consortium; Early Breast Cancer Trialists' Collaborative Group; North West Diabetic Foot Project; International Stroke Trials Collaboration; European Group for Serum Tumour Markers in Breast Cancer; Scandinavian Breast Group; Royal College of Radiologists Clinical Oncology Information Network; Manchester Asthma and Allergy Study; UK Small Aneurysm Trial Participants.*

7.1.2 Researchers are also involved in partnerships which have contributed to the development of national and international clinical guidelines: for example, *British Thoracic Society Standards of Care Committee: Diagnosis, Assessment and Treatment of Diffuse Parenchymal Disease in Adults; ACC/AHA Guidelines for the Management of Patients with Acute Myocardial Infarction; Royal College of Radiologists Guidance on Screening and Symptomatic Breast Imaging; UK Guidelines for the Management of Functional Bowel Disorders; Royal College of Radiologists Guidelines on the Non-surgical Management of Lung Cancer; WHO Scheme for the Measuring and Expression of Prothrombin Time Results; National Burn Care Review; International Consensus Conference on the Management of Chronic Leg Ulcers.*

7.1.3 The SMUHT Chief Executive, Director of R&D and R&D Manager were named collaborators in a multi-centre (Sweden, UK, Bulgaria and Germany) bid to the European Commission *Fifth Framework Programme* for funding to support a comparative study of resource utilisation and functioning of European healthcare systems. The other UK partner is UMIST.

### 7.2 Universities of Greater Manchester

- 7.2.1 During the year, the University of Manchester and SMUHT agreed the principles for setting up a Cardiovascular Institute. Two Chairs will be associated with this development: one to support laboratory-based research and one to be centred around clinical practice. Interaction with the Vascular Studies Unit at SMUHT will be an integral component of this research partnership.
- 7.2.2 The R&D Manager and the Head of the University of Manchester Research & Graduate Support Unit (RGSU) meet bi-monthly to ensure that NHSE/HEFCE policies and issues are addressed by their organisations' R&D management arrangements. In 1999/00, a major exercise was conducted with RGSU staff to validate University research details held by both organisations and to assist the RGSU with the gathering of data for the Research Assessment Exercise.
- 7.2.3 The R&D Manager also meets bi-monthly with the Faculty Research Administrator (Medical School) to discuss matters of mutual interest and to strengthen SMUHT's research profile within the Faculty. The Director of R&D contributed a summary of the *Strategic Review of the R&D Levy* to the December 1999 issue of the Faculty's *Research Newsletter* and provided regular updates on NHSE R&D policy issues to the Faculty of Medicine's Research Board.
- 7.2.4 The R&D Manager has encouraged the RGSU Proposals Adviser and the Faculty Research Administrator to be regular participants in the North West R&D Managers' Forum.
- 7.2.5 During the latter part of the year, SMUHT began to explore with the Universities of Manchester and Salford mechanisms for providing research support to Trust researchers in the non medical professions who are beyond novice level. A range 4 of options, via jointly-funded posts, are being considered.
- 7.2.6 The R&D Manager initiated contacts with a number of nurse researchers at the University of Manchester to formalise their links into the Trust to access research subjects. This led to a presentation to the Primary Care Research Group in the School of Nursing, Midwifery and Health Visiting about NHSE R&D policies, funding and management arrangements and ways to develop research collaborations with Trust staff.
- 7.3 Trusts within the North West Region
- 7.3.1 The R&D Directorate enjoys close working relationships with the R&D Directorates at Central Manchester Healthcare, Christie Hospital and Salford Royal Hospitals NHS Trusts. During the current year, similar working partnerships have been established with Royal Liverpool and Broadgreen University Hospitals, Manchester Children's Hospitals, The Royal Liverpool Children's Hospital and Aintree University Hospitals NHS Trusts. These links enable collective problem-solving, joint development of management solutions to national R&D policies and directives, and, the sharing of best practice.
- 7.3.2 The R&D Manager has worked closely with the Christie Hospital NHS Trust R&D Manager to identify inter-Trust research working and to make pro rata allocations of external R&D funding to reflect each Trust's contributions to joint research projects.

- 7.3.3 The Trust's R&D strategy calls for the R&D Directorate to assist with the building of R&D capability on a pan-regional bases. The R&D Manager, in conjunction with the R&D Manager from Central Manchester Healthcare NHS Trust, runs the North West R&D Managers' Forum which meets bi-monthly to build understanding of the national agenda for R&D. The R&D Directorate undertakes the administration of the bi-monthly meetings of the regional forum. The R&D Manager is, therefore, an early point of contact for R&D Managers/Coordinators in the region for advice and support.
- 7.3.4 The R&D Directorate has made available exemplar policies, procedures and pro formas to R&D Directorates across the North West Region to assist them in putting in place management arrangements for the notification and approval of research, peer review of research, indemnification of research, and, management of Intellectual Property.
- 7.3.5 During the latter part of the year, the Director of R&D met with counterparts from Trusts across Greater Manchester to discuss ways to enhance R&D collaborations. The product of this meeting was a paper, *Research and Development across Greater Manchester: a Strategic Way Forward*, which was a response to the *Clarke Review* and proposed changes to R&D funding.
- 7.4 NHS Purchaser
- 7.4.1 The R&D Manager has worked closely with the R&D Facilitator, Manchester Health Authority, to establish the effective working of PRiSM and to ensure feedback to the Health Authority on issues arising from the North West R&D Managers' Forum and from the Wellcome CRF consortium.
- 7.4.2 The Director of R&D and R&D Manager meet annually with the Medical Director, Manchester Health Authority, to review the Trust's performance within the NHS strategic framework for use of the *R&D Levy*, as detailed in the SMUHT R&D Annual Report.
- 7.5 Community Health Council
- 7.5.1 The collaborative work with Manchester Community Health Council is described in Section 24.
- 7.6 Manchester Intellectual Property (manIP) Consortium
- 7.6.1 During the year, the R&D Manager became Secretary of the manIP Management Group, as part of SMUHT's in-kind contribution required by the consortium's contract with the Department of Trade and Industry (DTI). This has increased the Trust's liaison role with the seven other partners – University of Manchester, University of Salford, UMIST, Manchester Metropolitan University, Central Manchester Healthcare NHS Trust, Salford Royal Hospitals NHS Trust and Lyndon Davies Associates.
- 7.6.2 Expansion of university research links has been prompted by the manIP technology audits which have identified common areas of research work.
- 7.6.3 In 1999/00, manIP identified five synergies/focus areas of research activity

generating significant Intellectual Property in the partner organisations:

- rehabilitation and medical devices;
- microbiology and plants;
- therapeutics;
- genetics and diagnostics;
- software, training and education.

7.6.4 These have served as catalysts to initiate inter-institution meetings of researchers to collaborate in the further development of research innovations and to explore ways to group Intellectual Property for assessment of commercial potential. Work by SMUHT with Manchester Metropolitan University during 1998/99, to develop areas of mutual clinical and research interest, has been useful groundwork to this current inter-institution initiative.

## 7.7 Wellcome Clinical Research Facility

7.7.1 In 1999, the SMUHT Chief Executive, together with University of Manchester, Central Manchester Healthcare NHS Trust and Salford Royal Hospitals NHS Trust partners, signed an agreement with the Wellcome Trust for provision of a clinical research facility (CRF). A partnership agreement, including an outline business plan, was negotiated by the three Trust R&D Managers with the University of Manchester and signed by the four partner organisations. Promotio

7.7.2 During the year, the R&D Manager contributed to the planning of the CRF facility and operational arrangements through the CRF Operational Committee. The R&D Manager and the CRF Administrator met with lead SMUHT researchers to identify proposed research that would be appropriate for siting within the CRF and to promote the generation of new research for location in the CRF.

## 8. Appropriate Disciplinary Mix

### 8.1 R&D Support to the Non Medical Professions

8.1.1 The Trust is committed to multidisciplinary research and, to this end, created the post of R&D Support Nurse in 1997 to provide a lead to both established and novice researchers in the non medical professions.

8.1.2 The role of the post was:

- to develop an R&D strategy for the non medical professions;
- to develop research awareness;
- to identify training needs;
- to promote research skills training;
- to develop access to library and information services (LIS).

Success in meeting these objectives is documented in the 1998/99 R&D Annual Report.

### 8.2 R&D Mentoring

8.2.1 As the R&D Support Nurse was on maternity leave from June 1999, the R&D

Manager (who is an experienced researcher with extensive experience at national level in teaching research skills) assumed responsibility for providing advice and support to novice researchers in the non medical professions.

8.2.2 The R&D Manager dealt, on average, with 3-6 requests per month for assistance with:

- development of research questions;
- writing research proposals;
- preparation of applications for training bursaries;
- preparation of grant applications;
- preparation of abstracts;
- poster presentations.

8.2.3 The profile of researchers requesting assistance changed in the course of the year to include staff seeking to move from own account research to externally funded work. The type of support needed by these staff changed accordingly, requiring the R&D Manager to identify researchers from SMUHT/University of Manchester/University of Salford with the appropriate methodological expertise to serve as mentors.

### 8.3 Review of R&D Support Requirements

8.3.1 A review of support requirements was undertaken in the last quarter of 1999/00 by the R&D Manager and the Senior Nurse (Professional and Clinical Development). This confirmed that the support requirements to continue the task of building research capability had changed and that an experienced researcher was needed to deliver the revised capability building agenda.

8.3.2 SMUHT is currently exploring with the Universities of Manchester and Salford mechanisms for providing research support to non medical researchers who are ready to undertake research as principal investigators. A range of options, via jointly-funded posts, are being considered.

### 8.4 Access to the Knowledge Base: Library and IT Facilities

8.4.1 A review of the Trust's 1998/99 initiative to broaden access to library databases and information retrieval services by the non medical professions (through provision of four clinical resource rooms equipped with networked workstations) was undertaken during the year. As an outcome of this review, the R&D Directorate will be funding the relocation of one of the clinical research rooms and the installation of an additional workstation in the most heavily used clinical research room.

8.4.2 In recognition that further improvements in access to the knowledge base require inter-departmental cooperation, the R&D Manager and the Head of IM&T have established a forum of IT, education, LIS and R&D support staff. The forum's remit is to develop a joint Trust/University IM&T strategy and a single approach to IM&T infrastructure across the Trust.

### 8.5 Educational Programmes to Support R&D Capability Building

8.5.1 During the year, the in-house programme of R&D capability building for the non medical professions continued, including two workshops on *Writing for Publication* and input to Trust CPD programmes on 'putting research into practice'.

## 8.6 Dissemination of R&D Information

8.6.1 The R&D Information Officer undertook R&D awareness-building for the non medical professions through:

- maintaining a database of all specialist, research and education staff in the non medical professions who have a research remit within their role;
- circulating calls for grant applications;
- searching web sites for funding sources relevant to researchers' research fields;
- circulating R&D-related information.

8.6.2 In April 1999, the *2<sup>nd</sup> Annual R&D Conference for Nurses, Midwives and PAMS* was held. The programme, which included 12 papers and 30 posters, demonstrated a 'coming of age' in two ways: by the number of staff who, unprompted, submitted abstracts, and, by the improved rigour of the projects that were reported. As in 1998, the event was well attended by staff from neighbouring acute and community trusts.

## 9. Cost

### 9.1 Changes in Research Activity

9.1.1 R&D support expenditure in 1999/00 and indicative expenditure for 2000/01 (see Part V) reflect on-going changes in research activity. Research activity has been re-focused from five to six areas of research activity (Section 13.1).

9.1.2 From 1 April 1999, research projects in specialties formerly badged to *Specialist Interests* were re-listed by topic in one of the four original R&D themes (*Cancer, Cardiovascular Disease, Mental Health, Respiratory Disease*), where appropriate, and the remainder were re-allocated to one of the new themes - *Developing Fields* and *Physiological Studies* - according to specialty (see Sections 13.1.3 and 13.1.4).

9.1.3 From 1 April 1999, the sub-projects of large externally funded projects were no longer listed separately (see Section 13.1.5).

### 9.2 Review of R&D Support Costs

9.2.1 In 1998/99, the R&D Management Accountant and the R&D Manager developed a model for re-visiting the indicative funding set out in the Trust's *R&D Agreement*. The aim of this exercise was to agree with Divisional Directors the support costs of research activity in each clinical division and to map these costs to declared research activity.

9.2.2 During 1999/00, the Mental Health Division was selected to pilot a review of R&D support costs, to produce an R&D expenditure plan (Appendix 11), and, to link this into the division's business planning cycle.

9.2.3 The four R&D Leads within Mental Health agreed a pro rata distribution of R&D support funding across the four research programmes and were able to map this funding to current or planned R&D projects.

9.2.4 Rolling out this pilot work to other clinical divisions has proved problematical; in part, because the other five themes extend across two or three clinical divisions, and, in part, because both the volume of research activity within given specialities and the specialties which are research-active have altered considerably since the *Culyer* declaration.

### 9.3 Recovery of Full Costs of Commercial Research

9.3.1 Processes for agreeing the costs of commercial research and for re-investing commercial income in R&D activity were implemented during the third quarter of 1999/00 (Sections 3.4.1 and 3.4.2).

### 9.4 Costing of Research Contracts

9.4.1 As outlined in Sections 3.4.1 and 3.4.2, new procedures for the approval of commercial and non commercial contracts ensure the involvement of the R&D Directorate in the costing of projects and, where applicable, in the negotiation of contract prices with commercial sponsors of research.

## 10. Integration with Other NHS Activities

### 10.1 Local Patient Care Services

10.1.1 The R&D themes reflect the Trust's areas of clinical excellence and promote research programmes which are consistent with the Trust's service profile. Research programmes also reflect established service links with primary and community care (eg *Developing Fields*, *Mental Health* and *Respiratory Disease*) and with other NHS Trusts (eg *Cancer*).

10.1.2 The R&D Directorate's March 2000 publication, *Using Research to Improve Patient Care*, demonstrates ways that research findings have informed changes in clinical practice.

### 10.2 National R&D Priorities

10.2.1 Three of the R&D themes reflect national priorities for *R&D Levy* funding - cancer; CDH and stroke; mental health (Section 5) - and demonstrate significant success in bids for regional and national *Budget 2* funding (Part V). Links with primary care are detailed in Section 6.

### 10.3 Community Health Council

10.3.1 The collaborative work with Manchester Community Health Council is described in Section 24.

### 10.4 Education and Training

10.4.1 The R&D Manager is a member of the Trust's Education and Research Centre Capital Project Group, the Medical Education Steering Committee and the Multidisciplinary Education Forum. The R&D Directorate contributed to the 1999/00 Education & Training Annual Report produced by the Clinical and Professional Development Directorate.

#### 10.5 Clinical Audit

10.5.1 The Clinical Audit Manager is an observer at R&D Committee meetings and the R&D Manager is a member of the Clinical Audit Committee, providing the opportunity for the regular exchange of information and ideas.

10.5.2 Nursing and midwifery Audit Leads are designated within clinical divisions to promote the development of nursing and midwifery audit and to identify research issues from audit results.

10.5.3 The R&D Manager has contributed to the planning of a multi-centre audit of the process of obtaining patient consent to participate in research studies (Section 4.1.4).

### **III R&D MANAGEMENT**

#### **11. Infrastructure**

##### 11.1 R&D Directorate

11.1.1 The R&D Directorate has been strengthened by the creation of an additional administrative post. The new post of R&D Administrator will have overall responsibility for financial, administrative and IM&T systems, and is supported by the R&D Information Officer who has responsibility for administering research notifications, approvals, indemnifications and contracts.

11.1.2 The R&D Directorate establishment is given in Appendix 12. Figure 1 illustrates reporting relationships for R&D within the Trust.

11.1.3 The remit of the R&D Directorate is:

*Development of strategy, infrastructure and operational arrangements to manage research and development in accordance with the Trust's R&D Agreement with the Secretary of State through the NHSE North West.*

11.1.4 Mid-year, the functions of the R&D Directorate were reviewed and revised to reflect the completion of strategic objectives and to address new NHSE statements of policy and principles. Appendix 12 sets out the expanded functions which the Directorate now fulfils.

##### 11.2 R&D Committee

11.2.1 The R&D Committee membership (see Appendix 12), which includes the Chief Executive and Director of Finance, ensures that the Committee's discussions are informed by input from senior Trust officers and that decisions and actions link appropriately to other Trust fora. The terms of reference of the R&D Committee

are given in Appendix 12.

11.2.2 A formal record of the monthly meetings of the R&D Committee is prepared by the R&D Manager. (See Appendix 13 for minutes of meetings held in 1999/00.)

11.2.3 The R&D Committee has matured, in both its strategic and operational roles, providing a lead to the Trust in defining the principles which underpin the Trust's R&D activities. The R&D mission statement, adopted in February 2000, encapsulates these principles (Appendix 2).

### 11.3 R&D Theme Leads

11.3.1 During the year, R&D Theme Leads have taken an increasing role in developing R&D strategy, focusing the Trust's research programmes and promulgating the mission of the R&D Directorate. (See Appendix 12 for R&D Theme Leads' terms of reference.) New appointments for *Cancer*, *Developing Fields* and *Physiological Studies* were made and a Co-Lead for *Cardiovascular Disease* was also appointed.

### 11.4 Statistical Support

11.4.1 In April 1999, the R&D Committee considered a business case for an additional statistician to enable:

- provision of a statistical advisory service to all Trust researchers undertaking R&D Directorate-approved projects;
- establishment of an Open Access Statistics Clinic to enable rapid access to statistical support;
- inclusion of researchers in the non medical professions in the customer base for the statistical support service;
- provision of a rolling statistics education programme open to all researchers;
- increase in collaborations in major non commercial externally funded projects.

11.4.2 Funding was approved and an additional 1.0 WTE statistician was appointed in August 1999, bringing the establishment of the Department of Medical Statistics to 2.0 WTEs.

11.4.3 During the year, researchers were surveyed to identify requirements for statistical training. Monthly training half-days were delivered by the SMUHT statisticians covering:

- study design (protocol, sample size, randomisation);
- simple statistical analyses (descriptive statistics, comparative tests, confidence intervals);
- practical guide to the use of *SPSS*;
- presentation of results for publication;
- critical appraisal of research papers.

11.4.4 Open Access Statistics Clinics were established at Wythenshawe Hospital (Monday afternoons) and Withington Hospital (Friday mornings). These are heavily used by both experienced and novice researchers.

## 12. Information and Communication

### 12.1 Information Management

12.1.1 During 1999/00, the Trust has demonstrated its continuing commitment to improving information systems. The R&D Information Officer processes all notifications of new research projects and, upon receipt of the *NRR* minimum data set, LREC/MREC application form(s) and letter(s) of ethical approval, registers projects on the *R&D Database*. The mechanisms for management approval of research are outlined in Sections 3.4.1 and 3.4.2. Peer review processes are outlined in Sections 3.6.1 and 3.6.2.

12.1.2 The R&D Manager checks commercial indemnity agreements prior to signature by the Chief Executive and commercial and non commercial contracts prior to signature by the Director of Finance.

12.1.3 The R&D Information Officer works closely with the University and Trust IT support staff and with the librarians on both sites to ensure that Trust *Intranet* and *Internet* links are fully utilised to support the work of the R&D Directorate. The R&D Manager is a member of the Trust's IM&T Steering Group.

12.1.4 During the final quarter of the year, the R&D Directorate was connected to the SMUHT University network, enabling the *R&D Database* to be lodged on the University file server. This will permit multi-user access to the database by R&D Directorate staff and, in due course, read-only access by Trust researchers.

### 12.2 Communication with Trust Researchers

12.2.1 The R&D Directorate has an R&D web page on the SMUHT web site ([www.smuht.man.ac.uk/rd](http://www.smuht.man.ac.uk/rd)). The web page includes electronic versions of R&D Directorate policies and forms; LREC guidance and applications; R&D Directorate notices; selected funding applications.

12.2.2 The R&D Information Officer has been trained in web page management to enable in-house updating of the R&D web pages and expansion of web-based services including signposting to other relevant web sites.

12.2.3 The Trust's quarterly publication for staff, *Trust Talk*, has regular features on R&D compiled by the R&D Directorate staff. The monthly *Staff News* is also used to give R&D updates to staff. Occasional *R&D Briefing Notes* enable the Directorate to circulate a digest of information and requests for researchers' action. R&D Directorate boxes for reference copies of documents relating to the work of the Directorate as well as R&D notice boards are provided in both libraries.

12.2.4 The Chief Executive holds an annual *Researchers' Meeting with the Chief Executive* to provide a forum for discussion and debate between researchers and the Chief Executive (supported by the Director of Finance, the Director of R&D, Deputy Director of R&D and the R&D Manager). The purpose of these meetings is to address complex issues and undertake consultations with researchers.

## 12.3 Other Initiatives

12.3.1 Other information management responses are described elsewhere in this report:

- Research Outputs (Section 20, Section 28.2.1);
- Sharing Information with Partners (Section 7.2, Section 7.3);
- Documenting/Protecting Intellectual Property (Section 26).

## IV PROGRESS AGAINST ACTIVITY AREAS

### 13. R&D Themes

#### 13.1 Review of R&D Themes

13.1.1 The Trust's *portfolio funding* bid included 16 activity areas which were subsequently reduced to five R&D themes in 1998/99: *Cancer*, *Cardiovascular Disease*, *Mental Health*, *Respiratory Disease* (reflecting national priority areas for health gain and for R&D) and *Specialist Interests* (representing clinical specialities – many of them Regional services – which act as catalysts for significant research activity).

13.1.2 During the first quarter of the year, representatives of the specialities within the *Specialist Interests* theme had a 'Time Out' afternoon to review the theme. This theme, unlike the other four, was based on clinical specialities rather than research topics. The consensus was to re-badge research into more cohesive groups – *Physiological Studies* and *Developing Fields*. The latter theme was regarded as essential to oversee and support emerging areas of research in the Trust, a high proportion of which (58%) is multidisciplinary. The research areas within each theme are listed in Appendix 14.

13.1.3 In recognition that some *Specialist Interests* project topics belonged in other themes (particularly, *Cancer*, *Cardiovascular Disease* or *Respiratory Disease*), these projects were re-allocated to the other four original themes, as appropriate, and the remainder were listed under the new themes as follows:

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#### Physiological Studies

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Allergy	Intensive Care
Anaesthesia	Pharmacy
Biochemistry	Radiology
Endocrinology	Renal Medicine
Gastroenterology	Urology

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#### Developing Fields

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Accident & Emergency	Obstetrics & Gynaecology
Burns & Plastics Surgery	Paediatrics
Clinical Engineering	Rehabilitation



14.4.1 In 1999/00, the Trust generated a total of £ £7.1m in external non commercial income, compared with £4.4m in 1998/99. This represents 61% growth.

## **15. Service Support Costs**

### 15.1 Expenditure by Funding Categories/Management/Training

15.1.1 Table 1 (Appendix 9) details 1999/00 expenditure of R&D support funding in each category of externally funded research and for own account work, training and management costs.

15.1.2 The R&D support costs of externally funded research within the mutual obligation arrangements was 48% of total allocation, compared with 29% in 1998/99 (see Section 13).

15.1.3 The R&D support costs of non commercial externally funded research outside the mutual obligation arrangements was 32% of total allocation, compared with 12.6% in 1998/99 (see Section 13).

15.1.4 The R&D support costs of own account research was 12%.

### 15.2 Expenditure by Activity Areas

15.2.1 Table 2 (Appendix 9) details 1999/00 indicative and actual expenditure of R&D support funding in each research activity area, including primary care. Indicative R&D support expenditure for 2000/01 is also shown.

## **16. Changes in Research Activity**

### 16.1 Indicators of Change

16.1.1 342 research projects were in progress during 1999/00. Their distribution, by theme, was as follows: *Cancer* (59); *Cardiovascular Disease* (70); *Developing Fields* (33); *Mental Health* (79); *Physiological Studies* (67); *Respiratory Disease* (34). In cost terms, Table 2 (Appendix 9) shows the proportion of activity in Year 2, the degree to which it has altered, and, the nature of the replacement activity.

## **17. Funding from Trust Endowments**

### 17.1 Cancer Research

17.1.1 In June 1999, Trust researchers in oncology were invited to bid for funding against a sum of £295,000 identified by the SMUHT Endowment Committee to be dedicated to cancer research (*The Gardner Bequest*). The purpose of this initiative was to pump prime new cancer research initiatives.

17.1.2 Eleven applications for funding to support cancer research within SMUHT were received and sent for external peer review to four referees including applicants' nominees and experts selected by the committee. Referees were asked to provide a view on four criteria: scientific merit; value to the NHS and to patients; feasibility, and, value for money.

17.1.3 The selection committee was chaired by Sir Kenneth Calman and included both a surgical and medical oncology specialist from outside the North West Region – Professor S Kay (Glasgow) and Professor R E Mansel (Cardiff).

17.1.4 The selection committee met in December 1999 and awarded £215,005, in total, to four projects. The project details and funding awards are given in Appendix 15.

## 17.2 Intellectual Property

17.2.1 In 1999/00, the SMUHT Endowment Committee also awarded £20,000 to provide a budget for the costs of evaluating and protecting Intellectual Property (see Section 25.5).

## VI PERFORMANCE INDICATORS

### 18. Strategic Ability

The performance indicator, *Strategic Ability*, is covered in Part II.

### 19. External Funding

#### 19.1 Sources of Funding

19.1.1 External funding and external income, within the mutual obligation arrangements, were as follows:

Source	Funding (%)	Income (%)
Research Councils	£803,580 (10%)	826,374 (15%)
Universities	£440,720 (6%)	440,720 (8%)
Charities	£1,478,189 (19%)	1,263,184 (23%)
DH/NHSE	£3,446,333 (43%)	2,591,809 (47%)
Other Government/EU	£1,748,878 (22%)	376,878 (7%)
TOTAL	£7,917,700	£5,498,965

19.1.2 Total external non commercial income, outside the mutual obligation arrangements, was £1,561,910. (See Section 14 for additional details.)

19.1.3 In 1999/00, SMUHT was the joint recipient of £60k in funding from the DTI for the manIP consortium and benefited from £40k in extra in-kind contributions from Vuman, on behalf of the University of Manchester, to the project. SMUHT also shared with the three other Wellcome CRF partners an award of £4.2m from Wellcome Trust for the capital costs of the CRF.

### 20. Publication Output

#### 20.1 Peer-reviewed Publications

20.1.1 Details of papers/abstracts in peer-reviewed journals and books/chapter

contributions, published by Trust researchers in the 1999 calendar year, are listed in Appendix 16.

20.1.2 There were 458 publications, distributed across the R&D themes as follows:

<b>Theme</b>	<b>Number of Publications (%)</b>
Cancer	64 (14%)
Cardiovascular Disease	87 (19%)
Developing Fields	47 (10%)
Mental Health	54 (12%)
Physiological Studies	120 (26%)
Respiratory Disease	86 (19%)

20.1.3 An analysis of journal impact factors is included in Appendix 16. 83% of publications appeared in journals with an *ISI* impact factor (compared with 65% in 1998/99). Of these, 67% were published in journals with an impact factor of >2 (compared with 44% in 1998/99) and 42% were published in journals with an impact factor of >3.

## **21. Multidisciplinary R&D**

### **21.1 Multidisciplinary Working**

21.1.1 Whilst the majority of research undertaken in the Trust in 1999/00 was conducted by multidisciplinary teams, the proportion of projects within each theme, where a non medical practitioner took a primary role, was as follows: *Cancer* (10%); *Cardiovascular Disease* (10%); *Developing Fields* (58%); *Mental Health* (35%); *Physiological Studies* (13%); *Respiratory Disease* (6%).

21.1.2 Examples of multidisciplinary projects, with a principal investigator from the non medical professions, were:

- eutrophic stimulation to optimise the management of tendon repairs and recovery from major nerve injuries;
- prescription of oxygen;
- effect of radiotherapy on voice;
- beliefs and attitudes of palliative care nurses;
- effect of providing hearing aids to people with dementia with undiagnosed hearing loss;
- development of a theory of clinical credibility in nursing;
- impact of a cardiac liaison nurse following myocardial infarction;
- investigation of A&E patients who leave prior to medical review;
- use of thespoons in the swallowing and speech rehabilitation of oral cancer patients;
- investigation of the psychological support needed by parents bereaved by suicide.

21.1.3 £32,525 was spent on R&D training in 1999/00 to support multidisciplinary working (Table 1 in Appendix 9). This represents a £14k increase on 1998/99

training expenditure. Details of the training are given in Section 23, including a breakdown of expenditure.

21.1.3 An account of the support provided within the Trust to multidisciplinary research is given in Section 23.

## **22. National Research Register**

### **22.1 NRR Returns**

22.1.1 The success of the SMUHT *NRR* returns in 1999/00 reflects the close working by the R&D Information Officer with researchers and South Manchester LREC to obtain the minimum dataset on all registered projects. It also reflects work by the R&D Manager with staff from the University of Manchester RGSU to improve information flows from the RGSU to the Trust.

### **22.2 Database Management**

22.2.1 During 1999/00, the R&D Information Officer has developed the database into an extremely effective management tool. User-designed reports enable:

- monitoring of current research activity and funding;
- retrospective and prospective analyses to align R&D activities with agreed priorities;
- selective targeting of researchers with relevant R&D funding information;
- identification of potential research partnerships both within the organisation and with other partner organisations.

## **23. Training**

### **23.1 R&D Training Programme**

23.1.1 Research training for the non medical professions, comprising University-based research skills modules, was coordinated through the Directorate for Clinical and Professional Development. Expenditure on this training was £13,230.

### **23.2 Clinical Fellowships**

23.2.1 For a second year, the Trust ran a bursary scheme for the non medical professions. Two bursaries were awarded on a competitive basis to staff to undertake MPhil programmes of research at the University of Manchester in the 1999/00 academic year. Details of the two research topics are as follows:

<b>Research Theme</b>	<b>Topic</b>	<b>Department</b>
Developing Fields	Development of a Theory of Clinical Credibility in Nursing	Training
Cardiovascular Disease Respiratory Disease	Is Clinical Supervision sustainable in Clinical Practice?	Coronary Care Unit

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23.2.2 Expenditure on MPhil bursaries in 1999/00 was £7,450 (4 second year bursaries; 2 first year bursaries).

23.2.3 Twelve specialist nurses also received a contribution from the Trust towards the payment of registration fees for Masters-level studies in support of the research remit of their specialist nurse role. Expenditure in 1999/00 totalled £10,045.

### 23.3 In-house Training Programme

23.3.1 Two courses, *Writing for Publication*, were provided for non-medical researchers, with priority given to staff who presented papers or posters at the *2<sup>nd</sup> Annual R&D Conference for Nurses, Midwives and PAMs* (see Section 8.6.2). Expenditure was £1,800.

23.3.2 A rolling programme of monthly half-day courses on basic and advanced statistics was provided during the year to Trust researchers (medical and non medical professions and scientists from clinical support services and academic laboratories) by staff of the Department of Medical Statistics (see Section 11.4.3). The salary costs of statistical staff are included in R&D overhead costs.

## 24. Consumer Involvement

### 24.1 Research Associate

24.1.1 During the first quarter of year, the Research Associate (Public Participation in R&D) submitted a paper, *Proposal to discuss the feasibility of incorporating consumer involvement into the SMUHT R&D programme*, to the Director of R&D (Appendix 17). The paper set out:

- a summary of current NHSE policy;
- a review of relevant literature;
- a critical appraisal of existing/emerging models of public participation;
- recommendations for engaging public participation in the Trust's R&D activities.

### 24.2 Partnership with Community Health Council

24.2.1 The Manchester Community Health Council (CHC) Lead on Consumer Involvement and the R&D Manager attended the January 2000 launch of the Consumers in NHS Research Support Unit's briefing notes, *Involving Consumers in Research & Development in the NHS*. A workshop with other North West delegates provided the opportunity to begin building alliances. The R&D Manager and CHC Lead are members of the NHSE North West User Advisory Group which was established as a result of this workshop.

24.2.2 In February 2000, the CHC Lead gave a presentation on consumer involvement in health research to the R&D Committee and the R&D Manager presented the Research Associate's paper for discussion.

### 24.3 Local Community Meeting about SMUHT Research

24.3.1 The R&D Committee endorsed the proposal to hold an evening meeting about the Trust's research for members of the local community. The meeting is scheduled for September 2000 and the programme, agreed with the CHC, will include short presentations about research projects of particular interest to local residents and posters of research and clinical audit projects.

#### 24.4 Involvement of Consumers in the Research Process

24.4.1 Involvement of consumers in the research process is at an early stage, but there are many examples of good practice in the Trust :

- Arterial Surgery: consultation with patients at risk of stroke and graft thrombosis about the design of clinical studies on these topics;
- Stroke: consultation with consumers (both physicians treating stroke and patients suffering stroke) about the design of clinical trials relating to prevention and early treatment of stroke;
- Rheumatology: liaison with small groups of patients and local community residents to ascertain their priorities;
- Old Age Psychiatry: involvement of carers of patients with dementia in identifying research questions;
- Gastroenterology: involvement of patients with irritable bowel syndrome and their GPs in prioritising the symptoms of these disorders for investigation;
- Rehabilitation: involvement of wheelchair users in developing design modifications to address their mobility needs.

## **VII INTELLECTUAL PROPERTY (IP)**

### **25. Management of IP**

#### 25.9 IP Awareness

25.9.1 The following mechanisms have been employed to raise awareness about IP:

- meetings with each clinical division;
- designation of IP lead for each division;
- IP information pack for divisions and libraries;
- regular IP column in *Trust Talk*;
- IP news items in monthly *Staff News*;
- meetings with key staff (eg Risk Manager; Staff Trainers) who may encounter staff-developed innovations in the course of their duties.

#### 25.10 Trust Policy

25.10.1 During 1999/00, a Trust policy for the management of IP, including revenue-sharing arrangements, was developed and formally adopted (Appendix 18). The parties involved in this major initiative and the timetable are detailed below:

- R&D Manager developed policy, in consultation with NHSE National IP Adviser and manIP Project Manager, during first quarter;
- SMUHT Director of Human Resources agreed policy terms in July 1999;
- R&D Committee endorsed policy in August 1999;
- SMUHT Finance and Strategy Committee agreed revenue-sharing arrangements in October 1999;
- R&D Manager and Director of Human Resources undertook staff

consultations with the Joint Consultative Committee and the Consultants' Committee in December 1999 and amendments to the policy were made in response to consultations;

- SMUHT Chairman confirmed final version of policy in January 2000;
- Trust Board approved policy in February 2000.

25.10.2 The policy was notified to staff in the March 2000 issue of *Staff News* (included with salary statements). Copies of the policy were circulated to Heads of all Wards and Departments in April 2000 and copies placed in the R&D Directorate boxes in both libraries.

25.10.3 In March 2000, the policy was circulated, as an exemplar policy, to the R&D Directorates of Trusts which are members of the North West Innovation Management Project (NWIMP). A number of these Trusts, to date, have adopted the SMUHT policy.

## 25.11 Memorandum of Understanding

25.11.1 In March 2000, a *Memorandum of Understanding* between SMUHT and Manchester Innovation Limited (MIL), on behalf of the University of Manchester, was signed by the Chief Executives of SMUHT and MIL. The memorandum sets out the management and revenue-sharing arrangements for IP jointly developed by the University of Manchester and SMUHT.

25.11.2 SMUHT is the first Trust to enter into a written IP agreement with the University of Manchester.

## 25.12 Technology Audits

25.12.1 Technology audits are carried out by the manIP Technology Coordinator who draws on the expertise of the other manIP and NWIMP Coordinators and the manIP Project Manager, as required. The Coordinator prepares an initial audit report on identified technologies and meets fortnightly with the R&D Manager to review these and agree action plans. The Coordinator documents all actions, via file notes, for the R&D Directorate.

25.12.2 The Coordinator also:

- arranges evaluations of IP by assessments of prior art and patent searches;
- determines whether the criteria for protection are met;
- ascertains whether a clear product/process/diagnostic etc can be identified and achieved;
- obtains expert opinions about market options;
- arranges market research to assess the business potential of IP (ie define the market; identify the major players and their products);
- calls for expressions of interest from commercial companies in licence agreements.

25.12.3 Innovations identified through manIP audits in the seven university and NHS partners have been grouped into five synergies/focus areas. During the financial year, 22 SMUHT innovations with market potential were identified. Appendix 19 gives details of these innovations grouped by focus areas. They demonstrate

the Trust's strength in developing new devices and therapeutics to improve patient care.

25.12.4 Nine *Invention Records* were completed during the year, enabling assessment of the scope for protection of these innovations.

25.12.5 One UK patent is held by SMUHT and four patent applications are in preparation.

25.12.6 One licence agreement is under negotiation; the business potential of five innovations has been assessed through market research, and, four calls for expressions of interest in selected technologies by commercial companies are in preparation.

25.12.7 To date, no income has been received to the Trust from the commercial exploitation of technologies.

### 25.13 Evaluation of IP

25.13.1 In January 2000, the Director of R&D presented a paper to the SMUHT Endowment Committee requesting a £20,000 budget, in the first instance, to cover the costs of evaluating and protecting IP. This funding was awarded to cover the costs of:

- prior art/patent searches;
- obtaining an independent expert assessment of the commercial potential of IP;
- drawing up a patent specification;
- filing a UK patent.

25.13.2 These budgetary arrangements will be reviewed after one year.

### 25.14 Patenting of IP

25.14.1 The decision to protect IP by patenting rests with the Trust Board but is delegated to the R&D Manager for UK patent applications and to the Director of R&D/Chief Executive for all other patent applications, with advice from the R&D Manager.

### 25.15 Re-assignment of Ownership of IP

25.15.1 The decision to assign ownership of IP to an employee of the Trust rests with the Trust Board but is delegated to the Chief Executive. The Chief Executive bases decisions on a file summary prepared by the R&D Manager.

### 25.16 Exploitation of IP

25.16.1 The decision to pursue the exploitation of IP is dependent on the IP meeting three criteria:

- IP must be within one of the manIP focus areas (see Section 7.6.3);
- a substantial market potential has been identified;
- IP is patentable or licensable.

25.16.2 A number of potential exploitation partners in the North West business community have been identified, and ways to link Trust IP with business entrepreneurs are being explored.

## **26. Administration of IP**

### 26.1 Systems

26.1.1 The R&D Directorate has developed and implemented IP administration systems which include:

- logging date of notification of IP;
- assigning SMUHT number to IP;
- setting up document file for IP;
- obtaining completed *Invention Record*;
- obtaining dated sealed envelope containing design details;
- providing annotated *Confidential Disclosure Agreement/Statement of Confidentiality*.

### 26.2 IP Protection Documents

26.2.1 A range of documents have been developed to assist in the protection of IP (Appendix 20):

- *Confidentiality Disclosure Agreement* (for potential commercial partners);
- *Statement of Confidentiality* (for funding sponsors);
- *Invention Record* (for R&D Directorate and patent agent);
- *Ideas for Improvement in Equipment, Software and Procedures* (for R&D Directorate);
- guidance on protection of design rights and software copyright (for Trust staff).

## **27. Leadership in IP Management**

### 27.1 National Forum

27.1.1 The R&D Manager has been invited to join the NHSE National IP Adviser's panel that will be visiting all the regions in England to outline the NHSE IP agenda and policy requirements to NHS Trusts and to advise on action plans. SMUHT has been selected as a model Trust for the successful development and implementation of IP management arrangements.

### 27.2 Regional Forum

27.2.1 The R&D Manager has been invited, by the North West Development Agency, to be one of two NHS representatives at the North West venue of the *2000 Annual Innovation Lecture*, an interactive multi-centre national debate involving the UK business community and its partners in technological innovation.

## **VIII OUTCOMES OF RESEARCH ACTIVITY**

### **28. Application of Research Results**

#### 28.1 Addressing R&D Priorities

28.1.1 Details about the local and national priorities addressed by the Trust's research programmes are given in Sections 5, 6, 7 and 10.

#### 28.2 Impact on Clinical Practice

28.2.1 An overview of recent research achievements in SMUHT, *Using Research to Improve Patient Care*, was published in March 2000. (A copy of this document has been provided, separately, to the Director of R&D, NHSE North West.) The document demonstrates the volume and variety of research that underpins the Trust's clinical and teaching activities; the type of collaborative research partnerships that researchers have established; successes in attracting major research grants, and, the pragmatic impact of the research on clinical service provision.

#### 28.3 Publications

28.3.1 Details are given in Appendix 16 and discussed in Section 20.

#### 28.4 Partnerships

28.4.1 Details of collaborative partnerships are given in Sections 6, 7 and 10.

## **IX CONCLUSION**

### **29. Change and Challenges**

#### 29.1 Reflection on Achievements

29.1.1 This year has seen major achievements which confirm the Trust as an effective provider and manager of R&D activity and disseminator of research findings.

29.1.2 The organisation's current planning of major changes in the location and mix of clinical services is paralleled by an ongoing review, re-focusing and rationalisation of research programmes and R&D management arrangements.

#### 29.2 Future Challenges

29.2.1 The Chief Executive has already agreed with the Director of R&D, R&D Manager and R&D Theme Leads an outline action plan for 2000/01 to address the challenges in the new R&D funding arrangements.

29.2.2 The hallmarks of these initiatives will be the promotion of externally-funded research within the national R&D priority areas; development of new research collaborations; greater integration of Trust research with research programmes of the Universities of Greater Manchester, and, continuing efforts to utilise research

outcomes to promote clinical excellence and evidence-based practice.