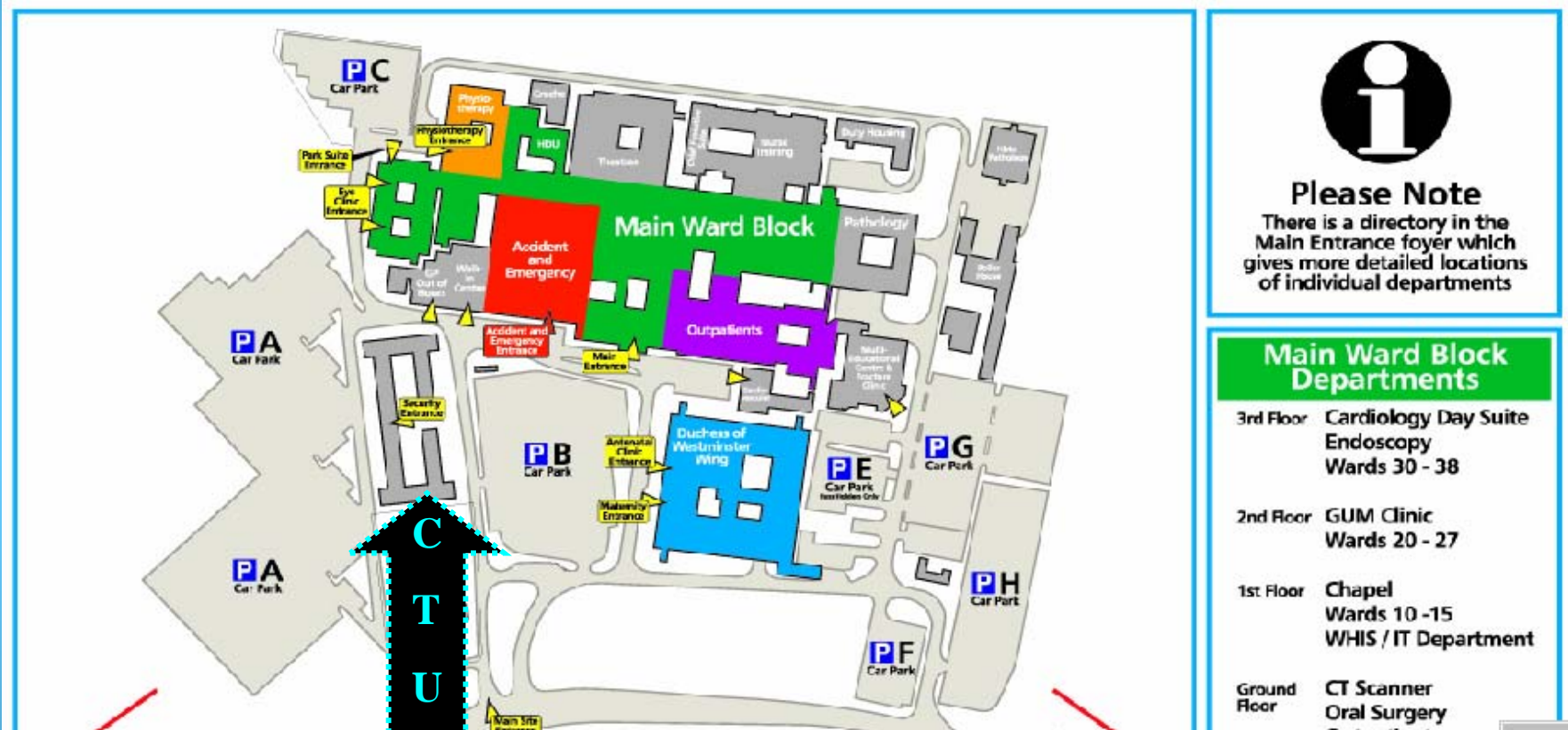


Wirral Clinical Trials Unit: From Concept to Christmas

Rod Owen; CTU Manager

Where is the CTU?

Arrowe Park Hospital Ward & Department Guide



C Block North, Arrowe Park Hospital



What **are** the Functions of the CTU?

- **Generate income from commercial trials**
- **Increase recruitment to clinical trials**
- **Facilitate trial set-up and approval (R&D)**
- **Promote research across the Trust**
- **Provide training in research practice**

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Who's Who in CTU?

1: WUTH Staff

Rod Owen: CTU and R&D Manager

Carol Eames: R&D Co-ordinator

Ruth Plant: R&D Administrator

Mike Pritchard: CTU Research Nurse

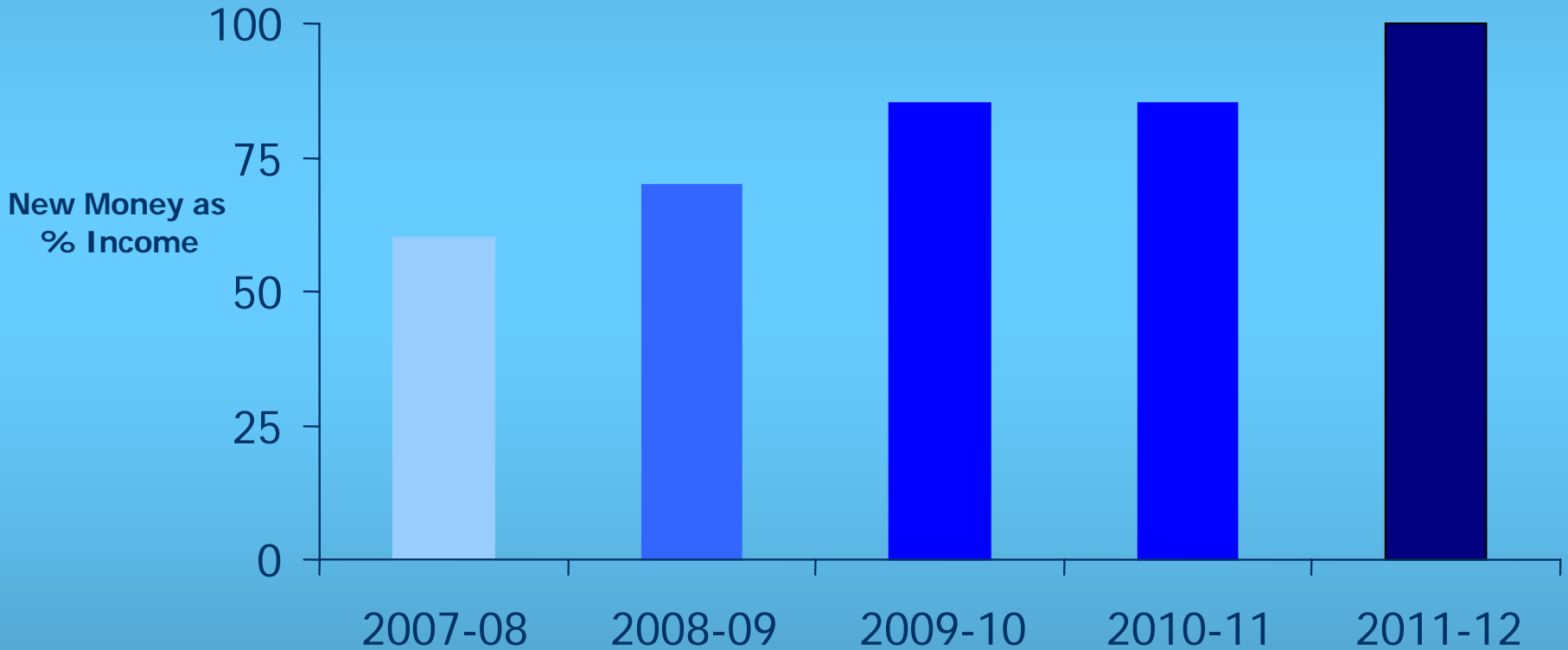
Lyn Trabernnor: CTU Research Nurse

Commercial Trials at Wirral University Teaching Hospital Foundation NHS Trust

Clinical Trial Agreements signed since 1st April

Renal Medicine	1
Diabetes	1
Rheumatology	3
Surgery (Infection)	1
Ophthalmology	1
Orthopaedics	1

Potential Income from CTAs **signed** since 1st April 2007



New Commercial Trials at Wirral University Teaching Hospital Foundation NHS Trust

Currently in set up or approval (MREC/SSA/R&D)

Orthopaedics	3
Diabetes & IV Feeding	1
Rheumatology	2
Pathology	1 (With CCO; 'Portfolio' study)
Cardiology	1

Site evaluations

Cardiology	1 (Date to be confirmed)
Gynaecology Oncology	1 (Undertaken; result awaited)
LMW Heparin	1 (Preliminary stages)

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Who's Who in CTU?

2: Network Research Nurses

Anna Lenfesty:	Stroke Network
Clair Williams:	Medicines for Children Network
Linda Moss, Linda Schofield, Leanne Westmoreland:	Dendron Network

3: Network Support Staff

Clare Jones:	Dendron Network Administrator
Tracey Wellman:	Cancer Network Data Co-ordinator

UKCRN 'Portfolio' Studies at WUTH: 1

a) In Progress (by Network)

Cancer	5
Diabetes	1
DenDron	3
Medicines for Children	1
Stroke	4
'Orphan' studies	3
	(17)

UKCRN 'Portfolio' Studies at WUTH: 2

b) In set up or approval (by Network & Status)

Medicines for Children	2 (final approvals awaited)
Stroke	2 (final approvals awaited)
Cancer	1 (in 'set up' by Network)

c) Portfolio status being sought from UKCRN

Medicines for Children	1
Diabetes	1
'Orphan'	3

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St. Mark's Hospital
and Academic Institute

The North West London Hospitals
NHS Trust



General Information

Patient Information

Clinical Services

Academic Information

Online Shop

Walk-in Bowel Investigation Service

“One-Stop Bowel Investigation Shop”

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Clinical Trials Unit

Established in April 2007, the Clinical Trials Unit (CTU) is housed in C Block on the Arrowe Park Hospital site. The manager of the CTU, Dr Rod Owen, also serves as the R&D Manager for the Trust. The CTU currently provides office space for administrators, data co-ordinators and research nurses from the Cancer, Diabetes, DenDron, Medicines for Children and Stroke Research Networks. It was anticipated from the outset that the most effective way to increase patient accrual to trials would be to have a single Unit, with Network staff sharing facilities with the CTU Team. This 'model' has proved very successful and is being considered for adoption by Networks in other regions.

The Unit is tasked with generating income from commercially funded research and is also required to maximise patient recruitment to clinical trials organised by Research Networks. Additionally, the CTU actively promotes research across the Trust and provides Research Governance & ICH-GCP Training (jointly with Clatterbridge Centre for Oncology).

The CTU Team are responsible for all aspects of project set-up – from contract negotiation, assisting with NRES applications (MREC or SSA) to obtaining Trust R&D approval via the Head of the Clinical Practice Research Unit. The Trust does not act as a sponsor for any trials involving medicinal products or devices, but will sponsor (or co-sponsor) non-interventional studies. The Trust endorses and has adopted the ABPI-NHS 'generic' CTA (and the newly released CRO version) for UK Sponsors, but has a flexible approach to non-UK Sponsors who wish to use

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Research Handbook

 [Research Handbook: 1st Edition August 2007](#) (Adobe PDF Format)

Standard Operating Procedures

-  [001 - Preparation, Review, Approval and Issue of Standard Operating Procedures](#) (Adobe PDF Format)
-  [002 - Study Team - Definition of Responsibilities](#) (Adobe PDF Format)
-  [003 - Organisation and Planning](#) (Adobe PDF Format)
-  [004 - Submission to Research Ethics Committee](#) (Adobe PDF Format)
-  [005 - Data Protection](#) (Adobe PDF Format)
-  [006 - Study Files and Filing](#) (Adobe PDF Format)
-  [007 - Informed Consent](#) (Adobe PDF Format)
-  [008 - Recruitment and Screening Records](#) (Adobe PDF Format)
-  [009 - Case Report Form \(CRF\) Completion](#) (Adobe PDF Format)
-  [010 - Adverse Event and Serious Adverse Event Reporting](#) (Adobe PDF Format)
-  [011 - Review of Protocol Amendments](#) (Adobe PDF Format)
-  [012 - Monitoring Visits](#) (Adobe PDF Format)
-  [013 - Archiving](#) (Adobe PDF Format)
-  [014 - Pre-Study Site File Check](#) (Adobe PDF Format)

THE RESEARCH HANDBOOK

1st Edition; August 2007

(Developed from 'Researcher Pack'; 2002-05)

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Appendix 1 Consent Form for Research Participants

3.6 Medicines for Human Use (Clinical Trials) Regulations

The Medicines for Human Use (Clinical Trials) Regulations 2004 (The Regulations) came into English Law in response to the EU 'Clinical Trials' (2001/20/C) and 'Good Clinical Practice' (EU/2005/28EC) Directives. The Regulations have been amended twice since, the most recent version being the No2 Amendment Regulations 2006. As with the Data Protection Act 1998 (*page 8 above*) breaches of the Regulations constitute a criminal offence, and successful prosecution may lead to imprisonment, fines or both; the Chief Executive of the Trust also faces similar penalties for breaches by Trust staff.

The Regulations bring Good Clinical Practice Guidelines up to full legal status and enforce compliance with specific regulatory requirements in order to ensure that clinical trials with investigational medicinal products (CTIMPs) conducted in the UK will be conducted to the same standard as elsewhere in Europe. Currently, the UK is widely regarded as having one of the best Ethics Committee systems anywhere in the world. Under the Harmonised Guidelines drawn up during an International Conference in 1996, the Competent Authority in the US (FDA^A), Japan (PFSB^B) and EU (EMEA^C) recognise clinical trials carried out in the UK for licensing applications.

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Many of the links below can also be accessed via the research Handbook

Caldicott Committee Report on the review of identifiable patient information 1997
<http://static.oxfordradcliffe.net/confidential/gems/caldrep.pdf>

The Data Protection Act

<http://www.opsi.gov.uk/ACTS/acts1998/19980029.htm>

The Human Tissue Act

<http://www.hta.gov.uk>

The Mental Capacity Bill

<http://www.dca.gov.uk/menincap/bill-summary.htm>

Ethical Approval

National Research Ethics Service

NRES website

<http://www.nres.npsa.nhs.uk/applicants/index.htm>

The REC that considers SSIs and single-site research projects for Wirral University Teaching Hospital NHS Foundation Trust is **Cheshire Research Ethics Committee:**

Chair: Mr Jonathan Deans & Dr Noel Murphy
Co-ordinator: Mr Rob Emmett

Research Ethics Office
Victoria House, Bishop Goss Complex
Rose Place, Liverpool L3 3AN
Telephone; 0151 330 2075, or 0151 330 2051 (Amy Sclater – Administrator)
Email: rob.emmett@wcheshirepct.nhs.uk.

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The UK Clinical Research Network

[The UK Clinical Research Network](#) was established to support research and to facilitate the conduct of clinical trials and other well-designed studies across the UK. As part of the UK Clinical Research Collaboration, it works towards the development of a world class infrastructure to support clinical research in the UK.

Wirral University Hospital NHS Foundation Trust has links with the following Research networks - Cancer, Dementias and Neurodegenerative Diseases, Diabetes, Medicines for Children, Primary Care, Stroke.

Employees of the above Research Networks regularly 'hot-desk' in the The Clinical Trials Unit (CTU).

The UK Clinical Research Network aims to develop and strengthen NHS infrastructure to support the delivery of clinical research in the UK. This is being achieved through the work of Clinical Research Networks.

Click on the links below for further information.

[Cancer Research Network](#)

[Dementias and Neurodegenerative Diseases Research Network \(DeNDRoN\)](#)

[Diabetes Research Network \(DRN\)](#)

[Medicines for Children Research Network \(MCRN\)](#)

[Mental Health Research Network \(MHRN\)](#)

[Stroke Research Network \(SRN\)](#)

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**Wirral University Teaching Hospital Foundation Trust
&
Clatterbridge Centre for Oncology Foundation Trust**

Mandatory Research Training

CERTIFICATE OF ATTENDANCE

This is to confirm that:

Candidate Name

Attended a Morning Training Session on:

ICH–GCP & Research Governance

At
Education Centre
Arrowe Park Hospital, Wirral

28th September 2007



2 Non-clinical CPD Credits

.....
Dr Rod Owen
R&D Manager, WHT

.....
Gill Sims
R&D Manager, CCO

Course Dates:

11th June 2007

28th September 2007

10th January 2008

April/May 2008

October 2008

Institute of Clinical Research: Official Response to Science Council 'Careers in Science, 2007'

"There needs to be a blurring of the distinction between 'academic' and commercial research; in reality, there is a continuum between an invention and the licensed intervention"

Submitted by Rod Owen FICR: 25/04/2007

THANK YOU

**TO EVERYONE WHO HAS HELPED AND
SUPPORTED THE CTU OVER THESE
FIRST FEW MONTHS**

and

**TO ALL WHO HAVE CONTRIBUTED TO
OUR 'RESEARCH DAY'**

HAPPY CHRISTMAS & NEW YEAR