

Clinical research and the role of the Research Nurse

Anele Waters
Senior Research Charge Nurse
Grahame Hayton Unit
Barts Health Trust-The Royal London



- Research definitions
- History of guidelines and regulations
- Role of the Research Team
- Role of the Research Nurse
- Organisation and Funding of UK Research

What is Clinical Research?

Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects.

National Institute for Health, USA (NIH)
http://keck.usc.edu/Research/Clinical_Research/Definition



What Are Clinical Trials?

Clinical trials are research studies that explore whether a medical strategy, treatment, or device is safe and effective for humans.

National Institute for Health, USA (NIH)
<http://www.nih.gov/studies/clinicaltrials>



Terminology

Controlled trial: comparing groups to a standard

Blinding: concealment of the group assignment

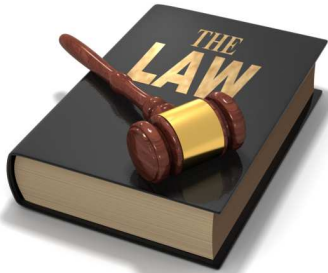
Randomisation: participants are assigned to arms of a clinical trial by chance

Randomised Control Trial (RTC): Gold standard for clinical trials

Phases of Clinical Trials

- Phase I: 1st in man, safety, pharmacokinetics
 - Healthy volunteers, 10's - days
- Phase II: safety, efficacy
 - HIV +ve, 100's - months
- Phase III: safety, efficacy, side effects
 - HIV +ve 100's-1000's - years
- Phase IV: post-marketing surveillance studies

Development of Clinical Trials Regulations



Nazi Experiments



Nuremberg trials

Nuremburg Code

1. Voluntary consent
2. Beneficial to society, results not found by other means
3. Knowledge base prior to study
4. Cause no physical or mental suffering
5. Cause no death or disability
6. Benefit should outweigh risk
7. Proper preparation & facilities
8. Qualified scientific persons
9. Subject can withdraw at any time
10. Study can be terminated at any time to prevent death or injury

Thalidomide



Guidance and Law

- 1964: Declaration of Helsinki
- 1965: European Community Pharmaceutical Directive (65/65/EEC)
- 1996: International Conference on Harmonization-ICH-6:Good Clinical Practice (GCP)
- Clinical Trials Directive (2001/20/EC)
- GCP Directive (2005/28/EC)
- The Medicines for Human Use (Clinical Trials) Regulations of 2004 (SI 2004/1031)

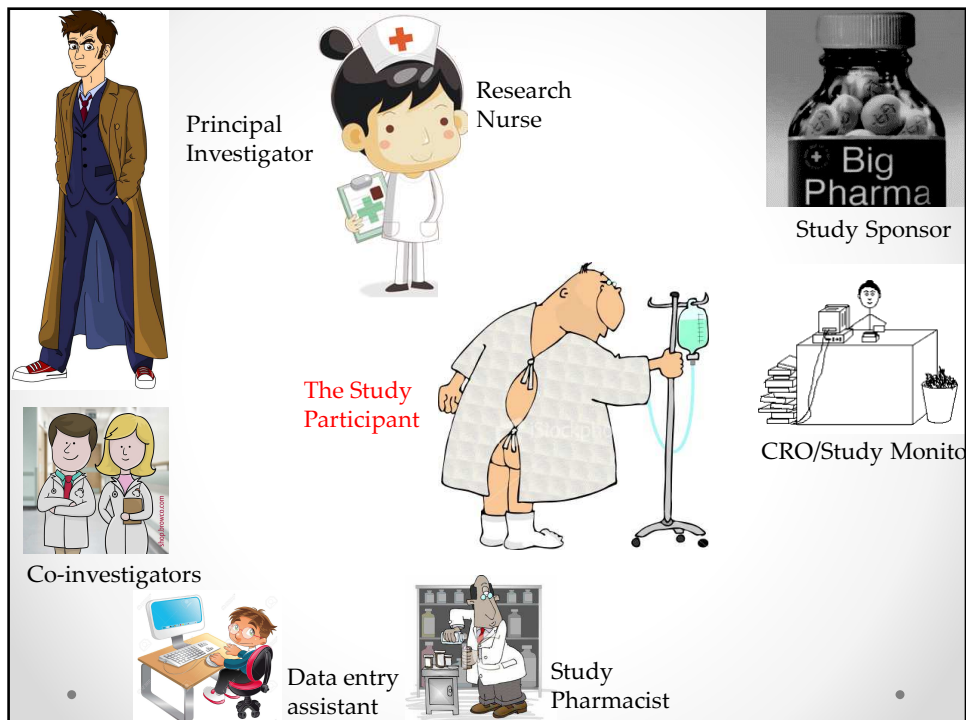
13 March 2006



- Phase 1 trial/TGN1412 monoclonal antibody
- 6 Volunteers hospitalised



The Research Team



The Clinical Research Nurse



What is a Clinical Research Nurse

- A nurse who is 'employed principally to undertake research within the clinical environment'.
- Bands 5-8
- Variety of funding streams (NHS, Pharma, CLRN)

Gibbs CL, Lowton K (2012) The role of the clinical research nurse.
Nursing Standard. 26, 27, 37-40. Date of acceptance: December 19 2011.

Knowledge and Responsibilities

- Clinical
- Managerial
- Educational



<http://irnn.ie/resources/role-of-research-nurse>

Clinical

- Primary advocate for the patient
- Communication with study patient
- Knowledge about disease under study
- Monitoring participants-vital signs, lab tests
- Tissue and sample collection and processing
- Informed consent
- Drug administration
- Adverse event management

<http://irnn.ie/resources/role-of-research-nurse>

Managerial

- Management and co-ordination of research studies
- Submission and maintenance of ethics and regulatory documents
- Screening and Recruitment of patients into studies
- Maintenance of study files resolving data queries
- Data Collection, documentation and reporting
- Preparation of samples for storage and shipment
- Financial account management

<http://irnn.ie/resources/role-of-research-nurse>



Educational

- Ensuring study team member is familiar with protocol, amendments and their role within the team
- Training and supervising nursing, medical and new research team members.

<http://irnn.ie/resources/role-of-research-nurse>



Your role

WE WANT YOU! (To know)

- Be aware of research ongoing in your area
- Understand the importance of documentation
- Report adverse events or serious adverse events to the research team

Funding and Organisation of Research in the UK

National Institute for Health Research (NIHR)

- Created in April 2006
- Provides structure and funding
- Clinical Research Networks established 2006
- UK Clinical Research Network Portfolio
- Created Research Passport scheme in 2007
- Coordinated System for Gaining NHS permissions in 2008

NHS commitment to Research

NHS pledge (Section 3a NHS Constitution 2013)

- “The NHS commits to inform you of research studies in which you may be eligible to participate.”
- This pledge aims to give people better access to the potential benefits of participating in research studies including clinical trials

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170656/NHS_Constitution.pdf
f role of research in the NHS

Government Commitment to Health Research 2010 - 2015

These papers confirm research as a core role of the NHS

- The Coalition Programme 2010
- The NHS White Paper, 2010
- The NIHR Annual Report, 2010
- The Public Health White Paper, 2010
- The Spending Review, 2010
- The Arm's-Length Bodies Review, 2010
- The Command Paper, 2010
- The PM speech on life sciences and opening up the NHS, 2011
- The UK Life Science Strategy, 2011
- The Plan for Growth, 2011
- The NHS Outcomes Framework, 2011/12; 2012/13; 2013/14
- The NHS Operating Framework, 2011/12; 2012/13
- The Health and Social Care Act, 2012
- The NHS Constitution, March 2013

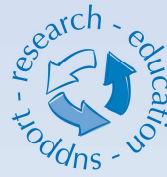
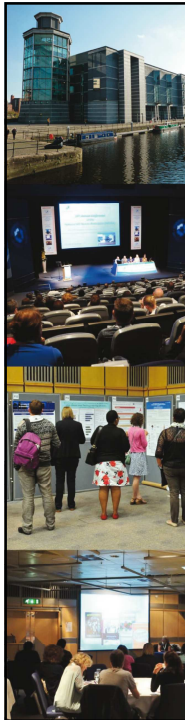
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170656/NHS_Constitution.pdf
f role of research in the NHS

Summary

- Extensive guidelines and regulations have developed as a result of experience
- Research nurses work to a high standard of regulation
- Guidelines and regulations are in place primarily for the safety of the research participants
- Research nurses play a pivotal role in the clinical environment
- All nurses have a role to play within research



**KEEP
CALM
I'M A
RESEARCH
NURSE**



National HIV Nurses Association

***17th Annual Conference
of the
National HIV Nurses Association
(NHVNA)***

17–19 June 2015

Royal Armouries International