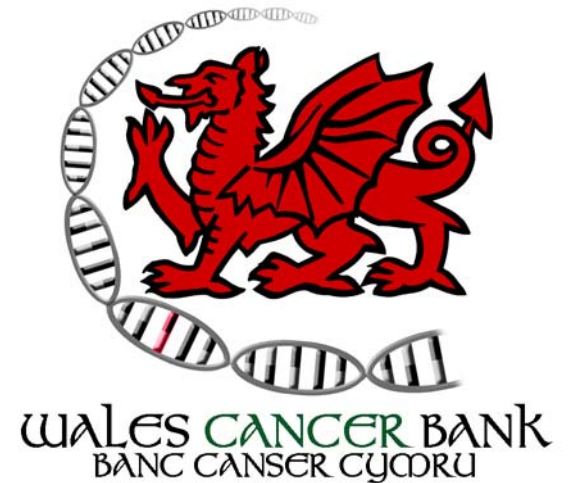


'THE HTA AND ME'



Dr Alison Parry-Jones

Manager, Wales Cancer Bank



Human Tissue Act 2004

- The Human Tissue Act (2004) gained Royal Assent in November 2004 and arose from concern raised by events at Bristol Royal Infirmary and the Royal Liverpool Children's Hospital (Alder Hey) 1999 - 2000.
- A new regulatory body, The Human Tissue Authority (HTA), was set up to regulate the removal, storage, use and disposal of human bodies, organs and tissue for a number of Scheduled Purposes – such as research, transplantation, and education and training – as set out in the Human Tissue Act.

Human Tissue Authority licensing



- Storage of human tissue for research is a licensable activity under the Human Tissue Act under section 16 (2) (e) (ii) ‘the storage of relevant material which has come from a human body for use for a scheduled purpose’
- Unless the intended research is covered by specific current ethics approval from a UK REC and samples are anonymised



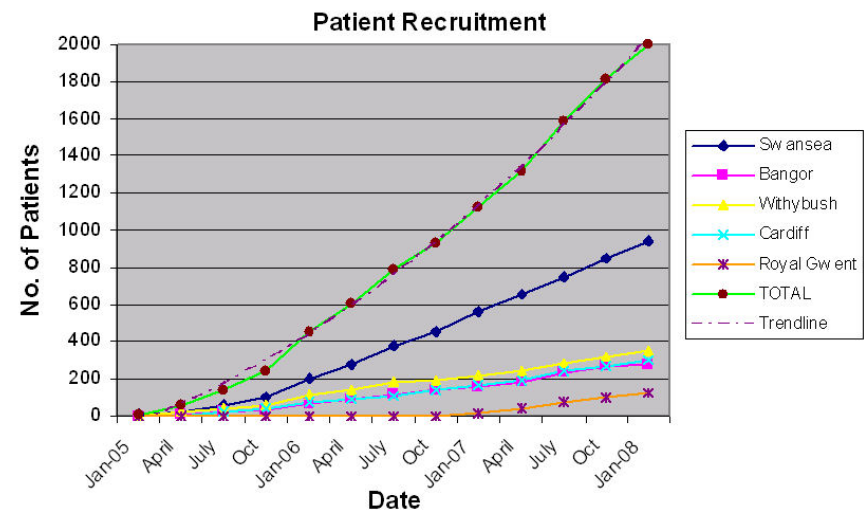
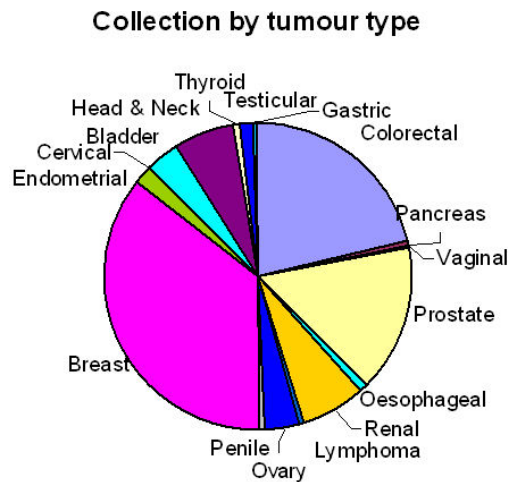
Wales Cancer Bank

- Prospectively collect tissue (tumour and normal) and blood (EDTA and serum) from patients in Wales having surgery to remove tissue where cancer is a possible diagnosis and also blood from a non-blood related control
- Samples stored for future, as yet unknown, research, accessible by researchers worldwide regardless of sector
- Licensable by HTA



WCB samples

- 1920 patients consented at end December 07
- Frozen and paraffin embedded tissue stored
- 17 different tumour types



HTA Mock Inspection 2006



- What we did
 - Exact run of what became a full HTA licensing application
 - Application form (compliance report) and site visit
- The application
 - Identify Licence holder, Designated Individual and a Person Designated at each of the 7 satellite sites
 - Review SOPs to ensure sufficient compliance evidence
 - Put in place missing management processes

Compliance Report



- The compliance report for research addresses four areas:

- Consent
- Governance and Quality Systems
- Premises, facilities and equipment
- Disposal

HTA Standards

Consent

- C1 Consent is obtained in accordance with the requirements of the HT Act 2004 and as set out in the Code of Practice.

Self-assessment rating			
1	2	3	4

Please provide examples

HTA rating			
1	2	3	4

Examples of evidence of compliance

- Consent forms comply with the HTA Code of Practice
- Consent forms are in records and are made accessible to those using or releasing body parts, tissue or cells for a Scheduled Purpose
- If third parties act as procurers, Service Level Agreements require third parties to ensure that consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Code of Practice
- If the establishment acts as a procurer an effective and reliable process is in place for acquiring consent with the requirements of the HT Act 2004 and the HTA's Code of Practice
- Consent procedures have been ethically approved

Consent



- Consent can be generic and enduring
- The Act is not retrospective with regard to consent
 - Lawful to keep archived tissue (collected before 1 September 2006) without consent in place but a licence is required if stored for a scheduled purpose (research)
- Lawful to use 'surplus to diagnostic requirement' material from the living without consent as long as the samples are anonymised and have ethics approval



Site Visit

- Conducted interviews with the potential DI, Licence holder, quality manager, IT manager, nurse and biomedical scientists

- Paperwork

- Approvals
 - MREC
 - R&D
 - Sponsor
- SOPs

SOP number	SOP name
Management SOPs	
WCB M01	Central Management – Operational, Finance and Reporting
WCB M02	Change control
WCB M03	Creation, Amendment, Retention and Destruction of WCB Documentation
WCB M04	Audit
WCB M05	Application and Approval of projects requesting Biomaterials
WCB M06	Staff recruitment, evaluation, grievance, resignation and dismissal
WCB M07	Staff induction and training
WCB M08	Equipment use, maintenance and failure contingency
WCB M09	Information Management and Technology Policy
WCB M10	Disposal of Human Tissue
WCB M11	Sample Management
WCB M12	Receiving non WCB samples
Donor related SOPs	
WCB D01	Donor documentation
WCB D02	Consenting procedure
WCB D03	Withdrawal of consent
WCB D04	Information distribution
WCB D05	Donor feedback and complaints
Sample procurement SOPs	
WCB S01	Blood collection
WCB S02	Tissue collection
WCB S03	Isopentane freezing
WCB S04	Liquid nitrogen freezing
WCB S05	Laboratory cleaning

Sample Storage SOPs	
WCB SS01	Sample storage and security
WCB SS02	Storage labelling system
Sample Tracking SOPs	
WCB ST01	Removal from storage
WCB ST02	Removal for transportation within WCB
WCB ST03	Removal for logging in/out
WCB ST04	Removal for issue
WCB ST05	Removal for destruction
WCB ST06	Transportation of samples
Further Processing SOPs	
WCB FP01	Pathology QA – taking a frozen section
WCB FP02	Extraction of DNA and RNA from tissue
WCB FP03	Use of the Nanodrop Spectrophotometer (Labtech 3102)
WCB FP04	Gel electrophoresis for QA of DNA extracted from tissue
WCB FP05	Quality Assurance of RNA using the Agilent Bioanalyser DE34903875
WCB FP06	Aliquoting of RNA and DNA extracted from tissue
WCB FP07	DNA extraction from frozen blood sample
WCB FP08	Receipt of blood samples
WCB FP09	Operation of Autopure DNA extractor for extraction from frozen blood
WCB FP10	Quality Assurance for DNA extracted from blood samples
WCB FP11	Subdivision of Extracted DNA samples from blood
WCB FP12	Preparation of tissue microarrays from paraffin blocks
Information Technology SOPs	
WCB IT01	Data confidentiality policy
WCB IT02	IT Security policy
WCB IT03	Application usage scenarios and requirements
WCB IT04	IT Training policy
WCB IT05	User passwords
WCB IT06	Data entry

Inspection Team and Feedback

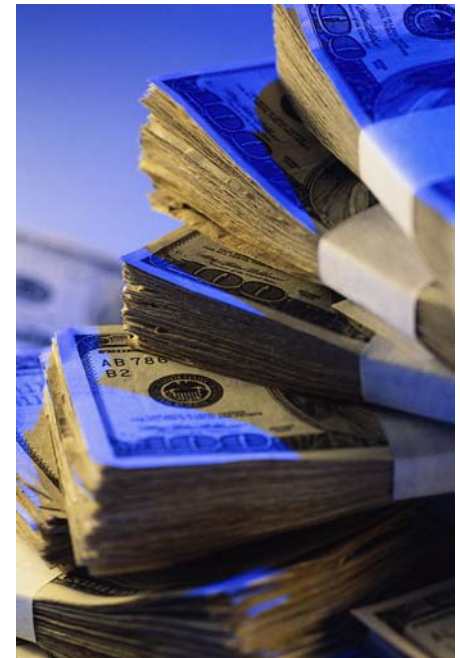


- Inspection team consisted of:
 - Inspections Manager
 - Regulatory Officer
 - Independent expert
- HTA is contracting out some inspection work
- Verbal feedback from inspection team on the day
- Previewed inspection report template

What effect will licensing have?



- Gives accreditation
- Encourages centralisation of samples
- Encourages good practice
- Attract more clinical trials to house their sample collection with WCB
- Unannounced inspection visits
- Cost us money, £10,800 per year!



What does it all mean for individuals?

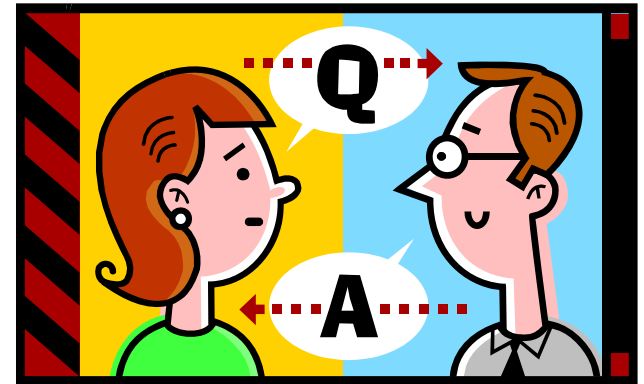


- As long as procedures are followed – probably very little:
 - Print out and **READ** the SOPs
 - Document anything that is a variation to an SOP
 - Make sure site file is up to date
 - Data entry as soon as possible
 - Log samples in and out EVERY time



Summary – what you need

- SOPs for EVERYTHING!
- Robust systems for
 - Audit
 - Sample tracking
 - QA
 - Consent
- £6,000 per year plus £800 per satellite site



**PATIENCE, A SENSE OF HUMOUR AND THE
HTA'S PHONE NUMBER!!!**

Information



- Human Tissue Act

<http://www.opsi.gov.uk/acts/acts2004/20040030.htm>

- Human Tissue Authority website

www.hta.gov.uk



Contact details

- Director, Wales Cancer Bank – Professor Malcolm Mason
- Principal Scientist, WCB – Professor Gerry Thomas
- Manager, WCB – Dr Alison Parry-Jones

Telephone: 029 2068 2108

Email: walescancerbank@cf.ac.uk

Website: www.walescancerbank.com