



# Wales Cancer Bank

Annual Report  
April 2009 - March 2010

09/10

Funded By:





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## ABBREVIATIONS

|      |   |
|------|---|
| ASP  | Active Server Pages   |
| BMS  | Biomedical Scientist  |
| CGH  | Comparative Genome Hybridisation                                    |
| CRW  | Cancer Research Wales   |
| DNA  | Deoxyribonucleic acid   |
| ECMC | Experimental Cancer Medicine Centre                                 |
| ER   | Oestrogen Receptor  |
| GI   | Gastrointestinal  |
| H&E  | Haematoxylin and Eosin  |
| HTA  | Human Tissue Authority  |
| IT   | Information Technology  |
| LCM  | Laser Capture Microdissection                                       |
| LLEG | Lay Liaison and Ethics group  |
| MDT  | Multidisciplinary team  |
| NBF  | Neutral buffered formalin   |
| NHS  | National Health Service   |
| QA   | Quality Assurance   |
| RIN  | RNA Integrity Number  |
| RNA  | Ribonucleic acid  |
| SOP  | Standard Operating Procedure  |
| SLA  | Service Level Agreement   |
| TMA  | Tissue MicroArray   |
| UHW  | University Hospital of Wales  |
| WCB  | Wales Cancer Bank   |
| WCTN | Wales Cancer Trials Network   |
| WCTU | Wales Cancer Trials Unit  |
| WORD | Wales Office of Research and Development for Health and Social Care |

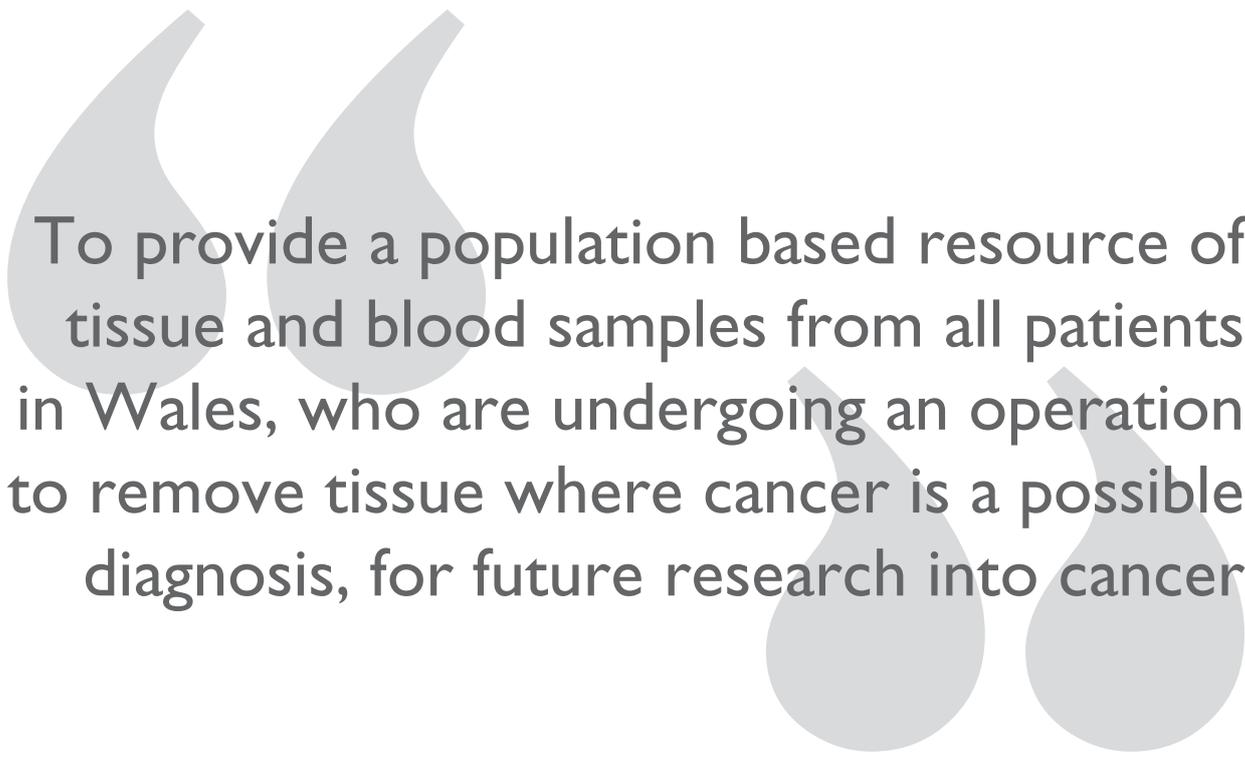


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To provide a population based resource of tissue and blood samples from all patients in Wales, who are undergoing an operation to remove tissue where cancer is a possible diagnosis, for future research into cancer

## DIRECTOR'S REPORT

As we go to press in this, the final year of our current period of funding by the Welsh Assembly Government, we are delighted to learn that our application for further funding has been approved, and that a new 5-year term begins from April 2010. We are proud that the Assembly has shown their confidence in this project in this manner, but are ever mindful of the responsibility that this imposes on us.

Our steady progress in sample collection is most encouraging, and in the next year we plan to exceed a target of four thousand patients donating to the WCB. This is a tremendous testament to the support and the generosity of the patients in Wales, and to them our heartfelt thanks. However, we also need to consider the next phase of our development, and to look beyond the collection of samples in itself. To that end, part of this report focuses on what is, after all, the prime purpose of the WCB, and that is the use of clinical samples for research. We are now seeing a steady flow of applications from scientists for access to our samples, and even the first scientific papers appearing in print, based on research using our samples. The flow of applications has receded slightly of late, due almost certainly to the effect of hard economic times that even researchers are not immune to. We also feel that we have a role and a responsibility to lead on research into new technologies and new scientific approaches to biobanking as a discipline, and some examples of this are also included in this report.

Can we go further? As the biological characteristics of many types of cancer are being elaborated in more detail, can we study our own samples, in order to characterise them as fully as we can given the current state of knowledge, so that our scientists can ask more sophisticated questions? We can do this, but in co-operation with other biobanks worldwide we might even herald a new era in the development of science using human samples, and we fully intend to maintain and further develop our national and international links.

Finally, I would like to thank all our staff, whose dedication and expertise have brought the Wales Cancer Bank to the stage that you see represented in this report.



A handwritten signature in black ink that reads "Malcolm Mason". The signature is written in a cursive, flowing style.

Professor Malcolm Mason  
*Director, Wales Cancer Bank*

The printed version of this year's Annual Report is an edited version to reduce printing and related costs. A link to the full version of the Annual Report can be found on the WCB website ([www.walescancerbank.com](http://www.walescancerbank.com)) homepage.

## TARGETS FOR 2009/10

| TARGETS for 2009/10                                      | Achieved      |
|--|---------------|
| Accrue 3500 patients in total                            | February 2010 |
| Supply six new projects with biosamples                  | October 2009  |
| Develop a web accessible version of database             | ongoing       |
| Collate clinical data for patients consented to end 2008 | 75% achieved  |
| Continue to raise awareness and promote WCB              | ongoing       |

## RECRUITMENT

862 patients were recruited between April 2009 and March 2010 across all collecting sites to take the total number of patients consented since the beginning of the project to 3650. The gender split of patients recruited since inception is 54% female and 46% male, showing a 3% shift towards male donors since last year. The majority of donors

(74%) are aged 60 or over and 90% of consents are obtained pre-operatively. Breast, colorectal and prostate remain the three largest collections in the bank and consent rates have increased from last year in four out of the five geographic locations.

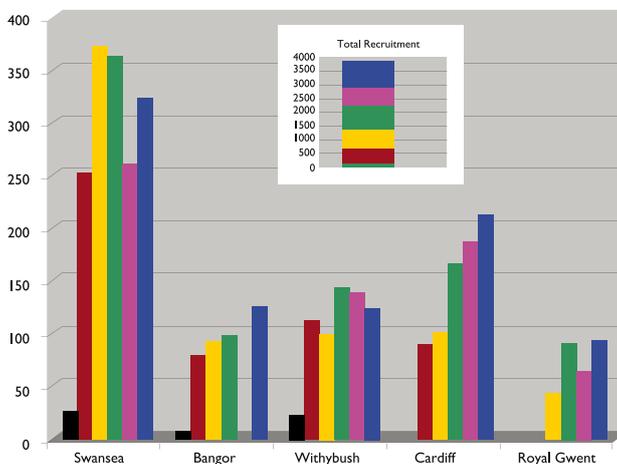


FIGURE ONE - Annual recruitment by centre

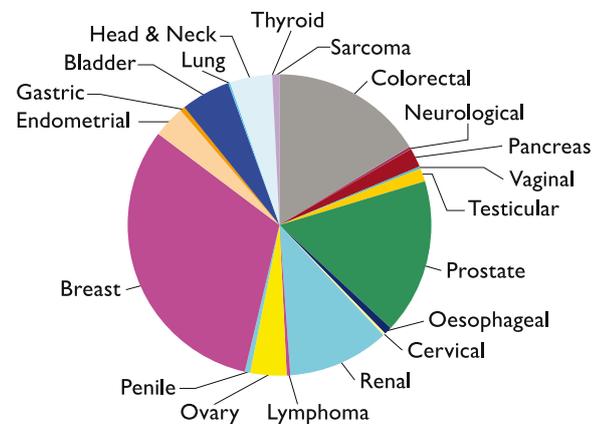


FIGURE TWO - Collection by tumour type

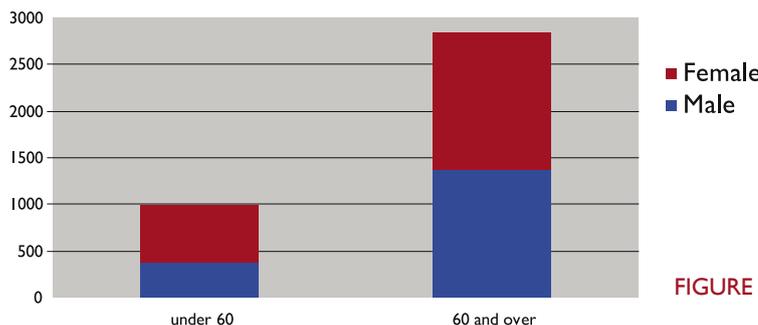


FIGURE THREE - Age/gender of donors

## LOCAL REPORTS

## Bangor Site

Since re-commencing Wales Cancer Bank recruitment in Bangor Hospital, 127 patients have been consented. Surgery is undertaken in local hospitals at Ysbyty Gwynedd and Llandudno Hospital and donations for colorectal, urology, gynaecology and breast are obtained for WCB.

Alexander Makanga, half time BMS and Jennifer Jones full time WCB Nurse, have negotiated for North Wales Lung Cancer patient tissue to be added to the collection

following Lung Cancer surgery in the Liverpool Heart and Lung Hospital, for which WCB is grateful for the enthusiasm and assistance of Dr J. Gosney Consultant Pathologist and his team in the pathology laboratory in Liverpool Royal Hospital.

The other area for development hoped for in the near future is upper GI tissue from surgery in Wrexham Maelor Hospital.

## Cardiff Site

201 patients were consented in Cardiff over the last year. The levelling in numbers was due to maternity leave, thereby reducing consenting in Llandough in the colorectal and gynae collections. This is now back to full strength following the return of Alison Davies from maternity leave in February 2010. The urology collection is well supported in UHW and continues to flourish especially in the supply of fresh tissue for culture to two local projects. Integration of WCB practice into routine histopathology in UHW has increased since the arrival of a second BMS, Fiona Martin. She has been able to build on the previous solid foundation of WCB activity and investigate additional avenues for amalgamation into routine workflows.

Neurosurgery has recently been centralised in Cardiff, unfortunately bidding farewell to Swansea. The WCB staff at Swansea had initiated the collection there and Cardiff staff have received a great platform from which they hope to continue and expand. Colorectal surgery is expected to move from Llandough to UHW during 2010 and contingency planning is underway to make adequate provision for the transition. The opportunity to acquire a fresh tissue collection may then become available and WCB staff will be ready to facilitate this. UHW also collates the numerous Clinical Trials hosted by WCB. Several new Trials opened with samples arriving daily over the last twelve months, including T-Frag, RT-Vin, Scalop and Succinct.

The senior BMS in Cardiff, Vicki Woods, has moved over to Velindre oncology hospital to set up a dedicated WCB laboratory within the Cancer Research Wales department to further her quality assurance role for the WCB using the MIRAX scanner. The Velindre lab was included onto the HTA licence in March 2010. She is also currently characterising WCB samples and using the TMA master to construct a bespoke TMA for the WCB, managing the further processing of the WCB hosting samples and applications and optimising new procedures for new equipment to the lab such as the MIRAX scan fluorescence module, TMA analysis module and the upcoming Laser Capture Micro dissection (LCM) system. The LCM will allow selective capture of specific cells from histological sections to provide research groups with samples which are not diluted by non specific material, consequently providing an extremely specific and high quality sample for research. A number of research groups are currently being provided with further processed samples from the Velindre site, for example micro dissected material for miRNA analysis to a research group at Imperial College, London, sections for polymerase chain reaction and immunohistochemistry to two local research groups and digital imaging for researchers locally and across the UK continues to be provided. Vicki has also started a part time PhD at Imperial College in London with Velindre NHS Trust as a partner institute, under the supervision of Professors Gerry Thomas and Malcolm Mason.

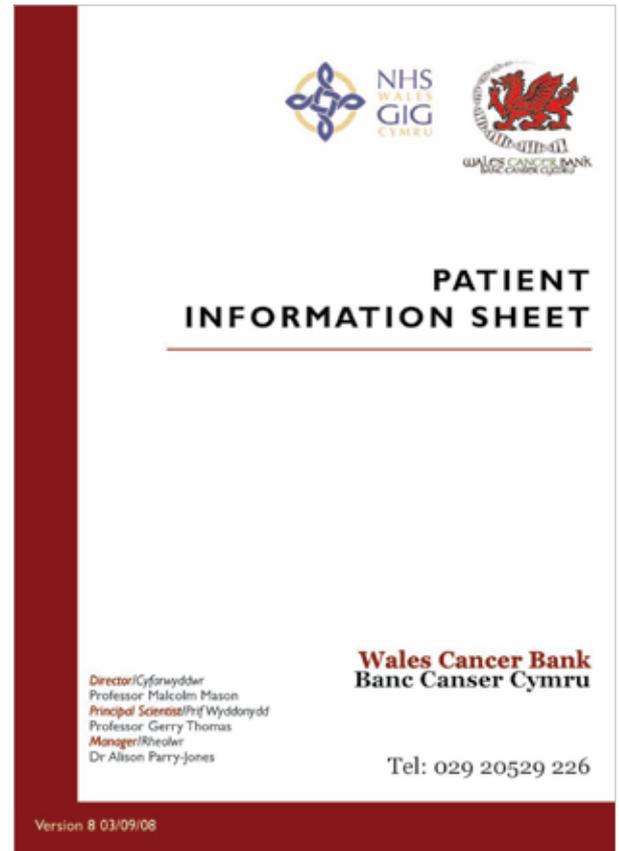
## Royal Gwent Site

The Royal Gwent Cancer Bank is coordinated by 2 part time nurses Lisa Gilby and Karen Wild who joined the team in June 2009. Both Nurses have attended various training/study days throughout the year to ensure their professional development is current and Mr Adam Carter, Consultant Urologist and WCB lead in Gwent, continues to give his full support to the team and regularly attends the local lead HTA meetings.

At present the collection spans across three tumour sites and 105 patients have been recruited during the reporting period. As planned the introduction of two new specialities; Colorectal and Head and Neck has been successful to date. Joining Mr D Ingrams Head and Neck team are Consultant Surgeons Mr C Passant and Mr R Parkin and two other Consultant Colorectal Surgeons; Mr K Swarnkar and Mr S Mckain are helping to increase WCB recruitment alongside Mr Gethin Williams.

In order to optimise recruitment, suitable patients are identified through MDT meetings as well as very close liaison with pre-assessment staff whose cooperation is essential in enabling as many samples as possible to be collected. A dedicated Senior BMS, Natalie Stacey, has now been identified in pathology, who works two days per week preparing the paraffin blocks and slides and

liaising with the nursing staff as required. During the next year discussions will take place to try and expand the collection to include fresh frozen tissue.



## Swansea Site

325 patients have been consented in Swansea during the reporting period and three new tumour sites; lung, sarcoma and neurological have been added to the collection. The nurses have become involved in fund-raising with Cancer Research Wales and raising awareness of both the charity and the WCB by doing interviews on Swansea Wave local radio station. Two of the nurses had the opportunity to travel abroad, one on the return leg of the nurse exchange with a tumour bank in Brazil and one

to give a presentation on the WCB to the 16th International Conference on Cancer Nursing in Atlanta, Georgia.

In June 2009 Suzanne Williams, lead WCB nurse, travelled to Brazil as part of the nurse exchange programme arranged between the tumour bank in the National Cancer Institute of Brazil (INCA BNT) and the WCB. Leila Couto from Brazil had visited the Wales Cancer Bank in Swansea in December 2008. Whilst in Brazil Suzanne



RIGHT: Suzanne Williams

shadowed the nursing staff and commented on the difficulty that the Brazilian nurses face gaining informed consent as the majority of the patients could not read or write. Suzanne was invited to give a presentation to the 2nd Forum of the Brazilian National Tumour and DNA Bank and also to join a debate discussing who is more appropriate to consent, nurses or doctors, where the consensus of opinion came down on the side of the nurses. Her presentation was entitled 'My role as a research nurse working for the Wales Cancer Bank and nurse work laws in bio-banking'. Suzanne also gave a presentation, via an interpreter, to the University of Brazil about her role as a research nurse for WCB. On her final day she visited the pathology department at the cancer institute and spent the morning in theatre and cut-up, observing a brain biopsy and lung resection. The trip gave Suzanne an invaluable insight into biobanking and research in South America and how some challenges are common to all cultures but others, such as poverty and illiteracy can provide additional hurdles for the researchers to overcome.

In March 2010, Catherine Lloyd-Bennett was delighted to be given the opportunity to attend the 16th International Conference on Cancer Nursing in Atlanta, Georgia, USA. Following the successful submission of an abstract for oral presentation titled "Making it Personal - Research Nurses, Tissue Banks and the Future of Cancer Treatment", Catherine travelled to Atlanta to represent the WCB and present the work of the project to her overseas colleagues. The conference was an excellent opportunity to learn from and share experiences with a variety of international cancer nurses, including tissue bank nurses from Brazil and Canada. Her presentation was well received and attracted much interest from all

who attended. Catherine was honoured to represent the WCB within such a prestigious collaboration of nurses and describes the experience as the highlight of her career.

Colleen Lloyd, BMS in Swansea, has been undertaking research for her MSc and the results were submitted and

accepted in poster format for two conferences, the 2010 Pathological Society Winter Meeting, held in Imperial College London in January and the Wales Cancer Conference, to be held in Cardiff City Hall in April 2010. The rationale for the project, of which the poster was entitled



LEFT: Leila Couto  
RIGHT: Catherine Lloyd-Bennett

*'Preservation on Morphology and Nucleic Acid Integrity in Paraffin Tissue - Can We Have Our Cake and Eat It?'* was to compare three different fixatives, two commercial - Finefix (Milestone Srl, Italy) and PAXgene (Qiagen Ltd); and one non-commercial - Z7 (Lykidis D, Van Noorden S, Armstrong A, et al., (2007) *Nucleic Acids Res.* 35: e85) with respect to their ability to preserve morphology when embedded into paraffin and to maintain the integrity of RNA and DNA. The details of the study can be seen in the scientific report on page 8.



SECOND FROM LEFT: Catherine Lloyd-Bennett

## Withybush Site

Rachel Hughes joined the Withybush team in August 2009 and with her wide and varied nursing career has become a valuable addition to the Withybush family. Approximately 140 people have consented to donate tissue and blood since the last annual report. Pathologists Laura Pineyro and Iwona Kaminska continue to support WCB along with all other hospital staff including the surgeons, nurses, doctors, secretaries, x-ray staff, laboratory staff and theatre staff. The Poetic trial is expected to commence in May 2010 and the WCB role in this trial will help encourage closer partnership working with the WCTN team.

In 2009 the local radio station, Radio Pembrokeshire, invited the local WCB team to be part of the Murco Unsung Hero advertising network, promoting worthwhile causes, people and local events. This involved a radio interview to answer five questions: What is WCB? How long has it been going? How well known were we? Is it painful to make a donation? The answers, along with any messages for the Pembrokeshire people, were broadcast separately five times a



Lindy Kirk on Radio Pembrokeshire

day for a week and a certificate was awarded stating that the Wales Cancer Bank are 'unsung heroes' in an award ceremony held locally. The Withybush WCB team were subsequently invited back onto Radio Pembrokeshire and given the opportunity to record a short piece to promote WCB that was also broadcast regularly during that week. Feedback has been very positive from people who heard the broadcast and hopefully this has raised local public awareness.

## FUNDING

The WCB received notification in December 2009 that a further five years funding would be made available from the Welsh Assembly Government and the level of funding was confirmed in March 2010. This ensures the continuation of the project in the current collection sites and, in conjunction with the funding received from Cancer Research Wales, will allow a small expansion in collection sites over the coming few years. A collection profile and sample review will take place during 2010 to inform a considered collection strategy, both in terms of geographic coverage and tumour coverage, for the next funding period.



## SCIENTIFIC REPORT

The Wales Cancer Bank prides itself on being a high quality resource for researchers. As soon as tissue is removed from the body it starts to decay. One important objective is to limit this decay by stabilising the tissue as soon as possible. There are several ways in which this can be done, one of which is to freeze the tissue immediately therefore stopping further enzymatic action. The other is to 'fix' using chemicals that prevent proteolytic digestion and therefore the destruction of the tissue architecture. The next step is to make the fixed tissue rigid enough to enable thin slices to be cut and stained so that the pathologist can examine the morphology. The combination of the preservation of intact nucleic acids, which are the tools used in research, with preservation of morphology, the most important tool used for diagnosis, in paraffin embedded tissue has proved to be extremely difficult. The solution to this problem could improve the development of molecular testing in the routine histopathology laboratory and have significant impacts on tissue banking for research. We therefore need to balance the preservation of morphological integrity for diagnosis and the integrity of nucleic acid for research, in other words can we have our cake and eat it?

One of the Wales Cancer Bank Biomedical Scientists, Colleen Lloyd, working with Professor Thomas' research group in Imperial College London, compared the effect of fixation with three different fixatives (two commercial, Fine Fix and Paxgene - Qiagen Ltd, and one non-commercial - Z7 - Lykidis D, Van Noorden S, Armstrong A, et al., (2007) *Nucleic Acids Res.* 35: e85) followed by embedding in paraffin, with respect to their ability to preserve morphology and to maintain the integrity of RNA and DNA. Snap frozen samples were taken as the gold standard for maintenance of nucleic acid integrity and samples fixed in neutral buffered formalin and processed to paraffin as the gold standard for morphology.

## MATERIALS AND METHODS

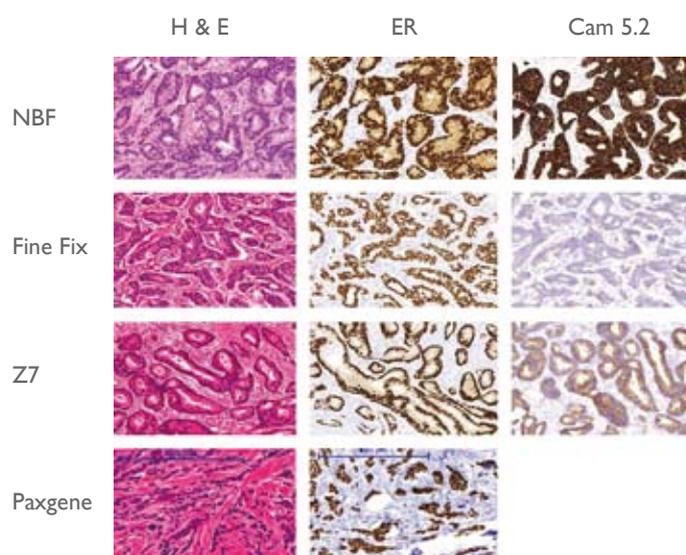
Material was provided by the Wales Cancer Bank and the Hammersmith Biological Resource Centre. Samples from the same operative specimen were snap frozen and stored at  $-80^{\circ}\text{C}$ , fixed in Z7 fixative, FineFix, or neutral buffered formalin. In a second series, samples from the

same operative specimen were snap frozen and stored at  $-80^{\circ}\text{C}$ , fixed using the Paxgene system, according to the manufacturer's specification, or fixed in neutral buffered formalin. Fixed samples were processed to paraffin on a dedicated processor to ensure that samples fixed in Z7, Paxgene or FineFix were not contaminated with formalin during processing.  $2 \times 4$  mm sections were cut from paraffin blocks and RNA and DNA was extracted using the appropriate Qiagen kit. The quality of extracted nucleic acid was assessed by nanodrop spectrophotometer and then by Agilent Bioanalyser (RNA) or electrophoresis and multiplex PCR (DNA). Morphological assessment of the tissue was carried out to assess shrinkage, nuclear and cytoplasmic integrity.

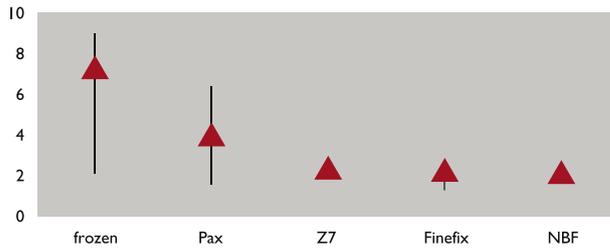
## RESULTS

*Morphology:*

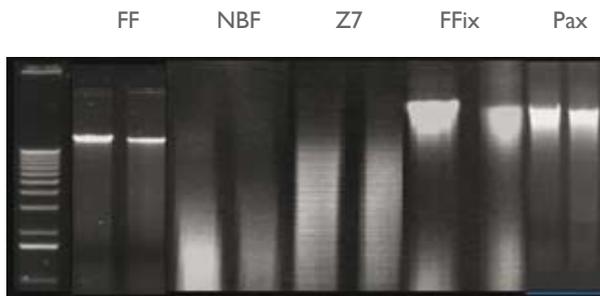
Morphological assessment showed that FineFix and Z7 produced some shrinkage and loss of preservation at both the nuclear and cytoplasmic level Paxgene sections where similar in quality to NBF, but were more eosinophilic (Figure 4).



**FIGURE FOUR** - The figure shows serial sections from invasive breast cancers, fixed in each of the different fixatives stained with Haematoxylin and Eosin (H&E), Oestrogen Receptor (ER), which is located in the cell nucleus, and Cam5.2, an antibody to cytokeratins which are located in the cytoplasm. Tissue fixed in formalin (NBF) is taken as the gold standard for preservation of morphology. Tissue fixed in FineFix, Z7 and Paxgene were much more eosinophilic on H&E, but nuclear morphology was well preserved in Paxgene samples and NBF fixed samples, as evidenced by the results on ER immunohistochemistry. There was considerable loss of cytokeatin staining in both FineFix and Z7 fixed material as evidenced by the weaker result on cam5.2 immunochemistry. Taken together, these results suggest that protein preservation is probably best achieved by fixation in formalin and Paxgene fixation. Further studies are planned to investigate this further.



**FIGURE FIVE - RNA quality.** The median RINs were 7.3 (range 2.2-9) for frozen tissue, 2.45 (range 1.8-2.6) for Z7, 2.3 (range 1.4-2.6) for FineFix and 2.2 (range 1.9-2.7) for NBF. Paxgene samples showed considerably higher RINs (4.75, range 1.6-6.4).



**FIGURE SIX - DNA quality.** High molecular weight DNA was extracted from Fine Fix, frozen and Paxgene samples. DNA was severely degraded in NBF and Z7 samples, although the majority of samples, regardless of fixative used, produced amplicons of > 400 bp on multiplex PCR.

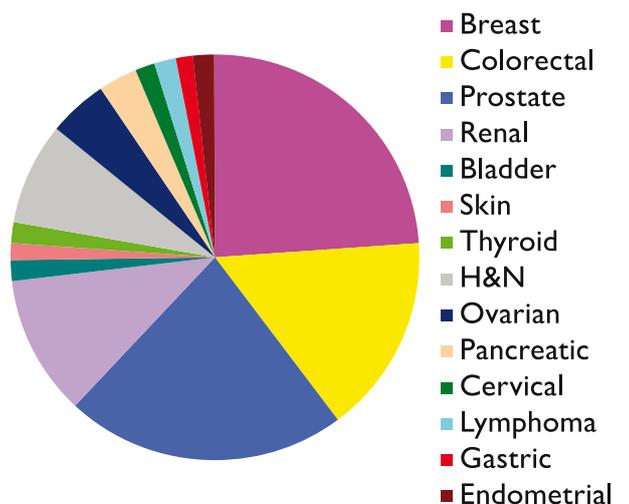
**CONCLUSION**

The necessity to preserve morphology for diagnosis compromises the integrity of nucleic acid and therefore diminishes the utility of diagnostic material for research use and use in clinical molecular diagnostics. Our study suggests that the Paxgene preservation system is a significant advance in providing better specimens for both diagnosis and research and has advantages over the other two novel fixatives assessed in this study. Given the fact that the nucleic acid quality is better than fixation in NBF, but not as good as frozen tissue, it is unlikely, however, that it will replace the necessity for frozen tissue for some applications (e.g. Affymetrix expression arrays). We are currently investigating whether the DNA quality is suitable for use in DNA methylation arrays and improves assessment of copy number alteration when using array CGH.

**APPLICATIONS FOR BIOMATERIALS**

During the period 1st April 2009 - 31st March 2010, twelve applications for biosamples were received by WCB, taking the total number of applications received since 2006, to 57.

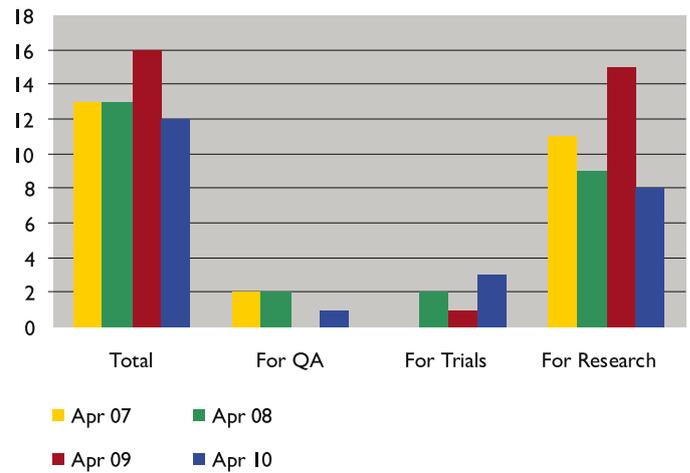
Of the 57 applications received by WCB, 37 research projects have been approved for supply of tissue. The time taken from receipt of full application in the central office to circulation to the review panel was an average of 6.5 days and the average length of review, when the review panel requested no further information to reach a decision, was 42 days. The pie chart below shows the composition of the requests received since 2006, with the largest number of requests being for breast, prostate, colorectal and renal samples.



**FIGURE SEVEN - Samples requested 2006 - 2010**

Of the twelve applications from this reporting year, one was for QA, three were for clinical trials, one was withdrawn and one was rejected after a resubmission and six were approved for research. All six applications were received from within the UK.

FIGURE EIGHT - Applications Received



## SUPPLY OF BIOMATERIALS

439 samples were supplied to 15 different projects and 1 clinical trial (SUPREMO) during this year.

of these samples were a continued supply to projects reported in last year's annual report.

61% of those were sent to applications received in previous years and 39% to applications received during this reporting year. The breakdown of sample type and tumour type is shown in Figure 9 below, and some

Lay summaries for the new projects supplied can be found in Appendix A.

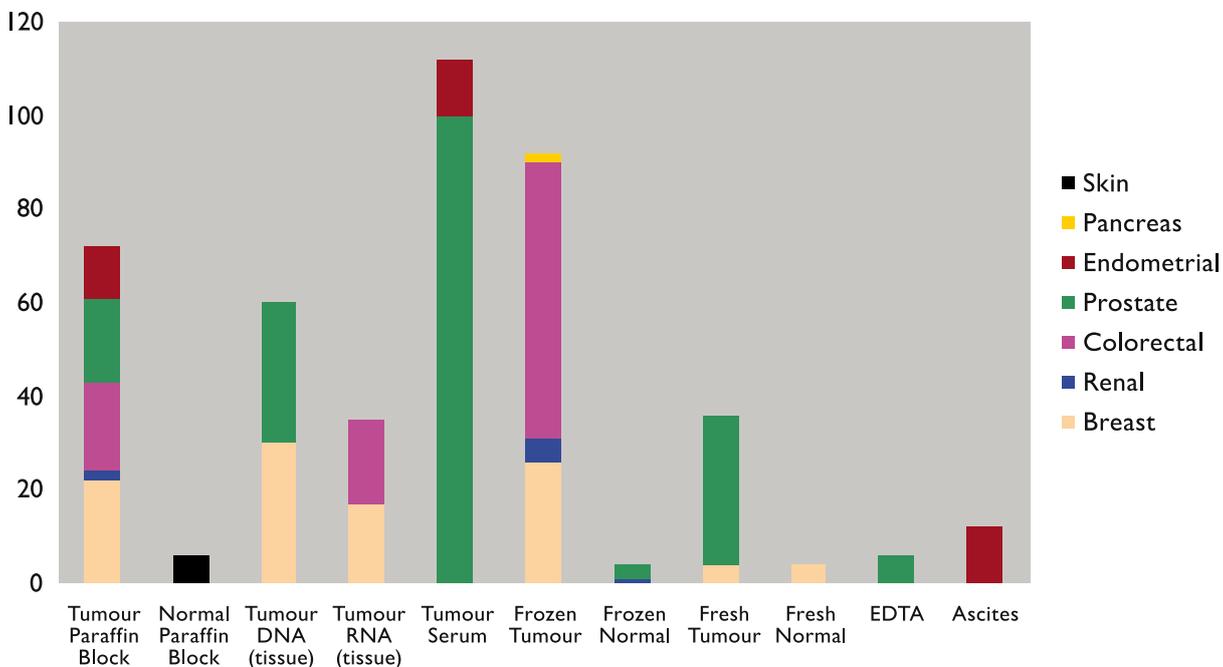


FIGURE NINE - Samples Supplied by Tumour Type and Format

## GOVERNANCE

## Advisory Board

In the autumn of 2009 Mr Calum Campbell stepped down as Chair of the Advisory Board when he left NHS Wales to take up a new post with the NHS in Scotland. Vice-chair, Mr Nick Ross, agreed to take up the position of Chair and at the March 2010 meeting Professor Robert

Leonard was voted in as the new Vice-Chair. A number of other resignations and new members have taken place over the last period and an updated list of Advisory Board members is detailed below.

|   |                                    |                             |
|---|------------------------------------|-----------------------------|
| <b>WCB Funders</b>                      |                                    |                             |
| Dr Sue Denman                           | Welsh Assembly Government          | Deputy Director WORD        |
| Dr John Pritchard                       | Cancer Research Wales              | Deputy Chairman             |
| Andrea Hague                            | Velindre NHS Trust                 | Cancer Services lead        |
| <b>Cardiff University</b>               |                                    |                             |
| Professor Steve Tomlinson               | Cardiff University                 | Provost                     |
| <b>NHS in Wales</b>                     |                                    |                             |
| VACANT                                  |                                    |                             |
| <b>Cancer Services in Wales</b>         |                                    |                             |
| Dr Jane Hanson                          | Cancer Services Coordinating Group | Director of Cancer Services |
| <b>IT specialist/Health informatics</b> |                                    |                             |
| Dr Dave Morrey                          | Velindre Hospital                  | Cancer Informatics Unit     |
| Dr Stuart Bell                          | NCRI Informatics Initiative        |                             |
| <b>Tissue Banking</b>                   |                                    |                             |
| Dr Brian Clark                          | onCore UK                          | CEO                         |
| <b>Nursing</b>                          |                                    |                             |
| Professor Tony Hazell                   | UK Nursing and Midwifery Council   | Chairman                    |
| <b>Bioethicist</b>                      |                                    |                             |
| Professor Hazel Biggs                   | Southampton University             |                             |
| <b>Oncologist</b>                       |                                    |                             |
| Professor Robert Leonard                | Imperial College                   | Lead Cancer Clinician       |
| <b>Pathologist</b>                      |                                    |                             |
| Professor Gordon Stamp                  | Royal Marsden hospital             |                             |

|                                |                                   |          |
|--------------------------------|-----------------------------------|----------|
| <b>Surgeon</b>                 |                                   |          |
| Mr Graeme Poston               | University Hospital Aintree       |          |
| <b>Translational scientist</b> |                                   |          |
| Professor Mitch Dowsett        | The Institute of Cancer Research  |          |
| <b>Industry</b>                |                                   |          |
| Dr Rick Greville               | ABPI Cymru                        | Director |
| Professor Barry Furr           | Llangarth Limited and AstraZeneca |          |
| <b>Lay member</b>              |                                   |          |
| Mr Nick Ross                   |                                   |          |

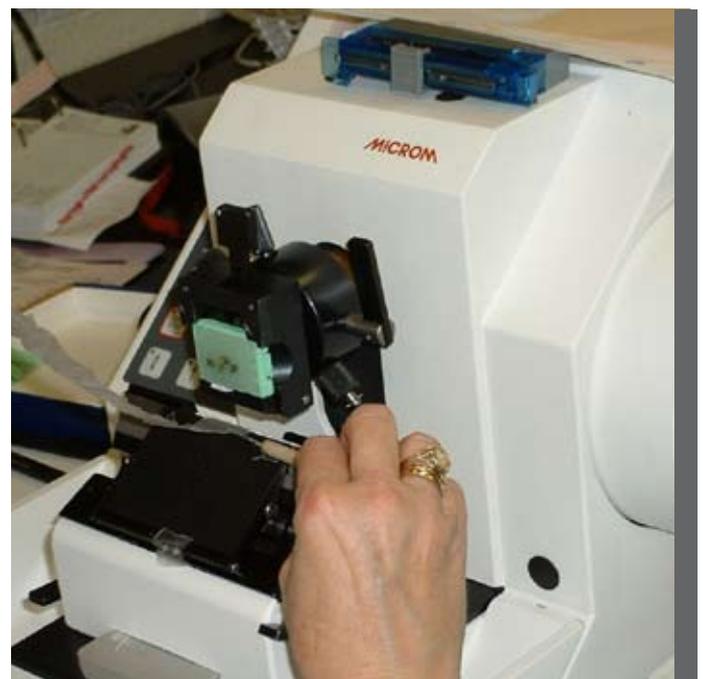
## Lay Liaison and Ethics group (LLEG)

The LLEG continues to monitor the WCB communications strategy, which is currently the main thrust of their involvement for the Wales Cancer Bank. An action plan was devised from the communication strategy and programmed events and projects continue to be devised by the different members of the group.

This year has seen a new, revised WCB newsletter due to a new member of the group, David Buswell, whose previous work was in marketing. His skills enabled a fresh and modern design to the newsletter and it is intended in the new financial year to also revamp and update the WCB website. It is intended to widen the circulation of the newsletter but still keep a balance of articles to appeal to both the researcher/scientist and the general public which includes Cancer Groups and charities, patients and allied professional groups to maintain a regular awareness of the work of the WCB.

Raising awareness is the key to gaining more support from potential patients. The Bank has now reached over 3,500 patients and obtained consent for samples but this is an on going process. Individual members have taken up the challenge of raising interest in the Bank. Vice Chair Neil Formstone, based in North Wales is a Macmillan Trainer and has produced materials and devised several training days for patient and professional groups, to highlight the issues of research and the work of the

Bank. Suzanne Williams Lead Nurse based in Swansea has been involved in several events from Race for Life Fun Run, to Radio interviews and, teaching in-house WCB staff when new specific cancer sites are identified. She has now been commissioned to teach pre and post registered student nurses about the issues of research and the work of the Bank as part of their training course.



## INFORMATION TECHNOLOGY (IT)

The informatics that supports the WCB remains a very important part of the project. One of the important factors of the data collected has been the additional clinical notation on treatment and outcome of the patients who have so generously donated to the bank. This clinical data is critically important to scientists who seek to find new methods of treating cancer patients successfully. Due to recent advances many patients are living with, rather than dying from their cancer. Therefore, the research focus is now on identifying which patients are more likely to have a poor outcome and identifying the biological processes that can provide targets

for future drugs. New modules that capture data on radiation, chemo and hormone therapy, the length of time between response to therapy and relapse and the ultimate fate of our patients is now available on 30% of WCB patients.

The project initiation document detailing further development of modules for the WCB database in ASP and .net was agreed by the IT Board and development is ongoing and on schedule. This focuses on delivering functionality that permits access over the web to Clinical Trial co-coordinators and researchers.



FIGURE TEN - The new ASP re-write configuration module

## CLINICAL TRIAL HOSTING

### HOSTING

The Wales Cancer Bank is continuing to host sample collections attached to clinical trials. Samples continue to be collected for COIN, XERXES, SCOPE and ZICE and new trial collections that commenced during 2009 are T-FRAG, RT-VIN, SCALOP and SUCCINCT.

### T-FRAG

T-FRAG is the 'Collection and Storage of Tumour and Blood Samples from Participants with Lung Cancer in the FRAGMATIC trial'. FRAGMATIC is a Randomised Phase III clinical trial investigating the effect of FRAGMin Added to standard Therapy In patients with lung Cancer. FRAGMATIC has 2 arms, a control arm and a research arm, patients with lung cancer can either be randomised to anticancer cancer treatment according to local practice (without dalteparin), and in the research arm, patients receive anticancer treatment according to local practice plus dalteparin for 24 weeks. After the 24 weeks patients are entered into the followed up arm. T-FRAG collects blood samples pre- and post-treatment and a biopsy tissue sample during treatment from both arms. The aim of T-FRAG is to establish a resource of samples for future research.

### RT-VIN

RT3 VIN is a randomised phase II multi-centre clinical trial of topical treatment in women with vulval intraepithelial neoplasia (VIN). Women with biopsy proven VIN 3 will be randomised to receive either imiquimod or cidofovir. The purpose of this research is to determine whether there is evidence that either of these topical treatments is active, safe and feasible to use and would therefore warrant further investigation in a larger phase III trial against an agreed control.

The aim is to recruit 204 patients to this trial over the next two years. Topical treatment with either imiquimod or cidofovir will be applied by the patient for a maximum of 24 weeks. Participants with a complete response by 30 weeks will be followed up to observe any recurrence for two years after their post treatment assessment visit. Any participant for whom there is no improvement (disease progression at any time or stable disease after

a minimum of 12 weeks treatment) will have the option to be treated with the alternative topical treatment, if appropriate, for a maximum of 24 weeks and followed up in the same way for a maximum of 30 weeks. Blood and biopsy samples will be collected and stored for translational research.

RT3 VIN is a Cancer Research UK funded, Cardiff University sponsored study, with free cidofovir supplied to research centres. It is also in the NCRI portfolio of studies. This multi-centre trial is being run by the Wales Cancer Trials Unit. It recruited its first patient on 7th October 2009 and now has 43 patients. The Chief Investigator, Professor Alison Fiander, is a consultant Gynaecologist based at Cardiff University and Llandough Hospital in Wales. Currently, 20 centres across the UK are open and a further 12 will be opened in the coming months. For further information please contact: Jeanette Isaac, WCTU, Tel: **02920 687 477** or email: [Isaacj3@cardiff.ac.uk](mailto:Isaacj3@cardiff.ac.uk)

### SCALOP

SCALOP is a multi-centre randomised phase II study of induction chemotherapy followed by gemcitabine or capecitabine based chemoradiotherapy for locally advanced non-metastatic pancreatic cancer (LANPC). Current standard treatment is chemotherapy but there is evidence that suggests that the addition of radiotherapy may improve survival. Participants in SCALOP will have 12 weeks of GEMCAP chemotherapy followed by a CT scan. Those patients who have responded or have stable disease will then be randomised to receive either gemcitabine or capecitabine based chemoradiotherapy for five and a half weeks (following a further cycle of GEMCAP while radiotherapy is being planned).

SCALOP is currently open at fifteen centres across the UK, and in set-up at another 22. A total of 102 patients will be registered into the trial, with approximately 76 going on to be randomised at the 12 week stage. SCALOP will be recruiting for a further year and is keen to extend the trial to other centres, so if you would like to find out more, please contact Sarah Bridges at the WCTU on [BridgesSE@cardiff.ac.uk](mailto:BridgesSE@cardiff.ac.uk) or **029 2068 7463**.

## SUCCINCT

SUCCINCT is a non-commercial, Phase II clinical trial to evaluate the addition of sunitinib to the standard two-drug cisplatin/gemcitabine chemotherapy for first line treatment of patients with advanced bladder cancer. The trial is non-randomised and open label, therefore all 63 participants will be enrolled to a single trial arm and receive the same three-drug cisplatin/gemcitabine/sunitinib treatment regime. The trial is sponsored by Cardiff University and funded through a Cancer Research UK CTAAC FSC grant award.

All patients will be asked to participate in an optional translational sub-study involving the

provision of additional blood samples before, and 26 weeks after, receiving the trial treatment. Patients will also be asked for permission to analyse previous tumour tissue specimens (paraffin blocks prepared from prior TURBT and/or cystectomy/nephro-ureterectomy). All of these translational samples will be stored long term at the Wales Cancer Bank (WCB).

SUCCINCT opened to recruitment on 27 July 2009 and has recruited six centres and five participants to date. A further eight centres are in the late stages of set up. Three partially complete participant sample sets have been submitted to the WCB to date for this trial.

## CONFERENCES AND MARKETING

The Wales Cancer Bank continues to be involved with a variety of conferences and workshops during the year either as invited speakers, organisers or exhibitors. A full list can be found in Appendix C.



June 2009 marked five years since the public launch of the WCB in the Coal Exchange in Cardiff. To celebrate the anniversary a series of 'open house' road-show events were organised in three hospitals in South Wales in partnership with Carl Zeiss Ltd. The road-shows allowed members of the public to hear about the generosity of cancer patients in Wales, talk to staff involved

in the project and find out more about how the samples are used. The Zeiss promotional lorry was packed full of cutting edge technology currently available for the modern pathology department and pathologists and scientists were invited to view demonstrations of the equipment.

WCB organised and ran a biobanking day entitled, 'Tissue Banking in the NHS - the advantages for Pathology Departments' immediately prior to the winter PathSoc meeting in London in January 2010. Despite the snowy weather and related travel disruption, eighty delegates heard from a selection of speakers addressing topics from the perceptions and realities of a pathology department's involvement in organised biobanking to the requirements of pharmaceutical and biotechnology companies.

The Confederation of Cancer Biobanks, in association with WCB, ran a highly successful meeting in March 2010 entitled, 'Biobanking in Support of Clinical Trials'. Two hundred and twenty five delegates attended the day at the Kings Fund in London and heard some interesting

presentations leading to lively discussions and good networking opportunities. Excellent feedback was received from the delegates who were from a range of backgrounds.

### 'PATHOLOGY GOES BACK TO SCHOOL'

As part of National Pathology week 2009, the Wales Cancer Bank took a pathology roadshow to the year



*'Identifying the liver diseases was fun' Year 11 student*

11 pupils of Howell's School, Llandaff in Cardiff to demystify the discipline of pathology and encourage the students to consider science, medicine and especially pathology, as future career options. The students had the opportunity to meet, listen and talk to a

pathologist, Dr Meleri Morgan from Llandough hospital, hear about the role of the Biomedical scientist and discover, from Professor Geraldine Thomas from Imperial College, a little of what molecular pathology research was doing to help inform treatment pathways in breast cancer. The girls had a chance to play detective and, using microscopes and the information given by Dr Morgan, matched three different liver slides to the correct medical history and diagnosis. Most fun (and noise) came from the laboratory where the students were extracting DNA from kiwi fruit. All students seemed to enjoy mashing the fruit and all were successful in extracting and hooking out some DNA.

*'I enjoyed the breast cancer talk and hearing about different methods of treatment being developed' Year 11 student*

*'I really enjoyed the Disease Detectives section and learnt a lot about medicine in general. It was really interesting!' Year 11 student*

At the end of the school day a debate on organ donation was also arranged for the College (year 12 and 13) students. Twenty two students participated and gave some very insightful and interesting arguments when tackling the two scenarios given for discussion. The topics of; whether a teenager has the right to refuse a life prolonging transplant, and which of two candidates for an organ transplant should receive it, provided a thought provoking debate that challenged the students to think more deeply about the issues and decisions taken during transplantation.



*'I loved extracting the DNA from the kiwi' Year 11 student*



Mrs Churchman, Head of Science, commented, 'Thank you very much for a brilliant day; the students have said how much they enjoyed it and also how useful the debate was for university interviews - so it was worth all the hard work'. The following day Miss Jenkins, Head of Biology added, 'The students I've seen so far this morning have been inspired!!! They thought the sessions were fun and it was nice to have some 'real'

scientists in just at a time when they're choosing their A level options'. The Wales Cancer Bank would like to thank the Royal College of Pathologists for the support and promotional items it supplied for the students, the microscopy division of Carl Zeiss Ltd for supplying microscopes, Howell's school science department and staff and all the students who participated and helped make the day a success.

## LOOKING AHEAD

The trend line on the graph below forecasts the patient recruitment to the end of April 2011, using the accumulated recruitment totals since inception. It predicts that a total of 4,300 patients will be consented by the end of the next reporting period, assuming current staffing levels and patient access are maintained across all current recruiting sites.

to the requests received by researchers. The existing collection will be profiled and compared to the biosample and tumour types requested in applications to WCB. The Advisory Board will review the policy on supplying samples and consider the implications of amending the policy in the current economic climate.

The news that the Welsh Assembly Government has made a commitment to continue the core funding of the Wales Cancer Bank means that a strategy plan can be drafted to ensure the collection becomes focussed and appropriate

New hospital sites will be explored along with additional tumour types in existing collection centres and the availability and amount of clinical data will be explored to ensure complete sample annotation is achievable.

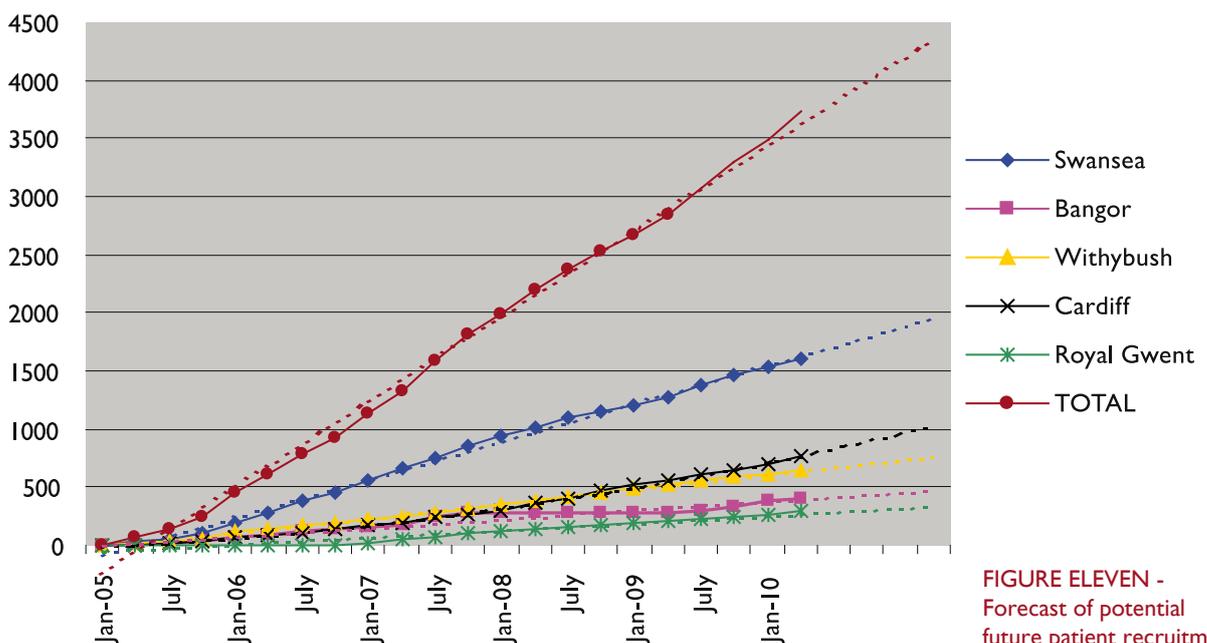


FIGURE ELEVEN - Forecast of potential future patient recruitment

# 18

## TARGETS FOR 2010/11

- Accrue 4,300 patients in total
- Profile sample collection and requests
- Begin characterising sample sets
- Continue development of the web accessible version of database
- Supply five new projects with biosamples



## FINANCIAL STATEMENT

|                              | Assembly Funding | CRW             | Velindre       | CRUK*          | General Account |                  |
|------------------------------|------------------|-----------------|----------------|----------------|-----------------|------------------|
|                              | Expenditure      | Expenditure     | Expenditure    | Expenditure    | Expenditure     | Income           |
| <b>STAFF COSTS</b>           |                  |                 |                |                |                 |                  |
| Central Staff                | £150,040         | £62,390         | £23,989        |                |                 |                  |
| Swansea Site                 | £152,304         | £31,869         |                |                |                 |                  |
| Cardiff Site                 | £41,561          |                 |                | £36,423        |                 |                  |
| Haverfordwest Site           | £60,366          |                 |                |                |                 |                  |
| Bangor Site                  | £45,088          |                 |                |                |                 |                  |
| Newport Site                 | £16,098          | £28,805         |                |                |                 |                  |
| <b>SUB TOTAL</b>             | <b>£465,457</b>  | <b>£121,064</b> | <b>£23,989</b> | <b>£36,423</b> |                 |                  |
| <b>NON STAFF COSTS</b>       |                  |                 |                |                |                 |                  |
| Equipment/Consumables        | £36,713          | £64,822         |                |                |                 |                  |
| Travel/Conference/Training   | £36,839          |                 |                |                |                 |                  |
| HTA Licence                  | £13,200          |                 |                |                |                 |                  |
| Office Expenses              | £13,588          |                 |                |                |                 |                  |
| IT                           | £1,584           | £24,612         |                |                |                 |                  |
| <b>SUB TOTAL</b>             | <b>£101,924</b>  | <b>£89,434</b>  |                |                |                 |                  |
| Cost Recovery                |                  |                 |                |                | £6,601          | -£23,323         |
| Trial related                |                  |                 |                |                | £3,716          | -£13,977         |
| <b>Brought Forward 08/09</b> |                  |                 |                |                |                 | <b>-£72,238</b>  |
| <b>TOTAL</b>                 | <b>£567,381</b>  | <b>£210,498</b> | <b>£23,989</b> | <b>£36,423</b> | <b>£10,362</b>  | <b>-£109,538</b> |

\* Cancer Research UK (CRUK) funding is via the Experimental Cancer Medicine Centre in Cardiff University

# Appendix A

## PROJECTS SUPPLIED WITH BIOMATERIALS

**08/015**

**PROFESSOR CHRIS WOMACK,  
ASTRAZENECA**

This application is for access to matched fresh-frozen and formalin-fixed-paraffin-embedded human colorectal cancer tissue samples to investigate a range of markers of disease that can be detected in patient tissue samples in the laboratory using a variety of established technologies that measure different aspects of molecular interaction in colorectal cancer cells. The application is an extension to the previous application “Human Biomaterials to support Oncology Drug Discovery” that did not cover access to frozen tissue samples. Most cancer diagnosis is based on formalin-fixed-paraffin-embedded material but frozen tissue is better for identifying some of the molecules and genetic changes we propose to investigate e.g. using technologies that allow quantification of soluble factors, transcript quantification, microRNA profiling, phosphoprotein analysis. Results from frozen tissue samples can be compared to the formalin-fixed-paraffin-embedded material.

**09/003**

**LISA SPARY, CARDIFF UNIVERSITY**

We are interested in the effects of androgen deprivation therapy (ADT) on the immune system of patients diagnosed with prostate cancer (PCa). In order to analyse the effects of ADT we require PCa cells for use in the laboratory to establish PCa cell lines for further research. It is extremely difficult to grow prostate cancer cells in the laboratory and most PCa cell lines available are derived from PCa that has spread throughout the body. We therefore wish to grow PCa cells, from the original PCa in the aim to develop PCa cell lines that can be used in our experiments. Once numerous cell lines are established we will perform multiple experiments to characterise the

cells and also see the effect of hormones on these cells. We are currently establishing a method which enables us to grow sufficient numbers of primary PCa cells from small biopsies for experiments in the future.

**09/005**

**DRS DIMITY PSHEZHETSKIY, JUSTIN STEBBING AND LEANDRO CASTELLANO,  
IMPERIAL COLLEGE, LONDON**

We propose to investigate a novel mechanism used by prostate cancer to spread to other parts of the body like the bone. This process is called metastasis and is the major cause of death from prostate cancer. Metastasis is currently an incurable aspect of the disease. In our recent work we have discovered a new molecular event in prostate cancer cells that could allow them to spread by the process of metastasis. These are particularly exciting results because drugs that can block this molecular event are available so could easily be tested in patients in clinical trials to see if they can stop their metastasis.

**09/006**

**DR CLAIRE AUKIM-HASTIE, PORTSMOUTH UNIVERSITY**

Prostate cancer (PCa) has an extremely variable outcome with apparent indolent (slow growing) and aggressive forms of the disease and survival periods ranging from 2 to >15 years. Therefore there is a pressing need to enhance the early detection and appropriate management of prostate tumours. At present however, prognostic information for PCa is extremely limited and the markers in use are unreliable. Using protein analysis methods to study PCa patient serum samples, we have carried out a pilot study to identify proteins associated with the clinical stage of disease. This pilot study

identified 26 putative markers of progression with 3 of those markers capable of predicting aggression of the disease based on Gleason score. Additionally, 16 potential biomarkers have also been found that correlate with recurrent disease with 1 of those capable of predicting recurrence based on prostate specific antigen (PSA) level and metastasis.

We aim to validate these findings by studying a geographically distinct population of PCa patients using the same technique. In addition, we aim to further validate these potential biomarkers using both sample sets but utilizing different protein analysis methods.

**09/007**

**DR JANE WAKEMAN, UNIVERSITY OF WALES,  
BANGOR**

Colorectal cancer is a major cause of death throughout the western world. A particular feature some tumours is the ability of a sub-group of cells, tumour initiating cells, to leave the primary tumour site and establish a new tumour at a more distant site within the body, a process known as metastasis. Such movement of cells from the primary site and re-establishment at a secondary site occurs in the more aggressive tumours and involves the dynamic regulation of factors that are not normally expressed in the tumour. Using a laboratory model for this dynamic process, we have identified a factor, which may be important in maintaining such tumour initiating cells in colorectal tumours. We would now like to extend our data from the laboratory model to determine the expression patterns of this factor in patient derived, colorectal tumour samples. This will allow us to assign significance to our lab based data, in terms of the importance of this factor in generating new tumours.



# Appendix B

## WALES CANCER BANK AUDIT 2009

The annual audit schedule in 2009 took place between 9th November and 4th December 2009. The Cardiff and Bangor sites were visited by the WCB Director of Scientific Services and Manager. Withybush was visited by the WCB Director and Manager and Swansea and Royal Gwent sites were visited by the WCB Manager and BMS from Cardiff. A random selection of donations, spanning all years of collection, was inspected at each site with a sample trail completed for all audited donations. A list of incomplete data was generated to show donations with no samples, no diagnosis, questionable ischaemic times or no pathology report after one month.

Four sites have been collecting for nearly five years and the 2009 audit was the fifth such internal inspection during this time. Royal Gwent has been collecting samples for three years and this was the third internal audit at the site. The workflows and role responsibilities of staff at

each site have local variation in order to fit in with routine clinical practice. Role responsibilities at each site are documented and included in the Service Level Agreements signed by each participating NHS Trust. Due to the change of structure of the Health Service in Wales over the last 12 months, the SLAs have been adopted by the new Health Boards as part of previous Trust incorporation. All SLAs expire at the end of March 2010 and will be re-drafted in January 2010 to cover the new funding period.

Each site is covered by a HTA licence to store tissue for research purposes. No major issues were highlighted that could potentially jeopardise the licence at any site. All sites are working within local and WCB guidelines on Health and Safety and adhere to WCB Standard Operating Procedures, although staff are reminded to ensure that they are fully conversant with all SOPs.

### AUDIT SCHEDULE

| Site                            | Date of Audit      |
|---------------------------------|--------------------|
| Cardiff (UHW, Medical Genetics) | 9th November 2009  |
| Swansea (Singleton, Morrision)  | 10th November 2009 |
| Withybush                       | 23rd November 2009 |
| Royal Gwent                     | 25th November 2009 |
| Bangor                          | 4th December 2009  |

A number of data queries were run to check integrity of data at each site:

1. Donations with missing diagnosis.
2. No pathology reports for donations over 30 days old.
3. Samples without a donation.
4. Query ischaemic time.

Similar data queries will be generated every 3 or 4 months and sent to each site as interim data quality/completeness checks.

## GENERAL

Some specialities are not on the database so pathology reports not able to be completed. Information is held on paper copies but transfer to database not possible. Therefore a number of the missing pathology reports highlighted on the audit paperwork are as a direct consequence of datasets not being available on database. Diagnosis should be entered onto the database to ensure information present for potential applications.

## ACTIONS

To be implemented centrally:

- Issue 3 monthly local sample tracking and missing data audit exercise.
- Ensure SOP log is current and circulated when SOPs are updated
- Insert data fields on treatment and outcome database page to allow recording of when notes were last accessed
- Discussion around collecting follow up data to be incorporated into next training meeting

To be implemented at sites:

- Diagnosis needs to be entered regardless from paper pathology report
- QA needs to be kept up to date to ensure prompt fulfilment of sample transfer to projects or extraction for projects
- Incomplete records to be checked regularly to enter new data when available
- Follow up treatment and outcome data to be collected
- Scanning of H&E slides to be kept current
- Ensure training and SOP knowledge is up to date and SOPs are followed

## CONCLUSIONS

All sites are generally operating well and the audit gave a good opportunity for the exchange of views and discussions about local practice and the project in general. The action points identified involve both central and local activity. It is hoped that all points can be actioned by the end of March 2010.

Regular reviews of data to be encouraged via the quarterly mini audit scheme and the importance of collecting clinical data reinforced with all staff.

Sample tracking and shipment procedures are now well established in all sites and need to be continued to ensure the exact location of every sample is known and quarterly internal audits will continue in 2010.

The management teams wishes to express its thanks to all staff, not only for their hospitality during the audit visits, but for their continued enthusiastic support for the project.

## NOTES BY CENTRES

### CARDIFF

The data queries were run against the live WCB database on 17th November 2009 and the results are outlined below.

1. Donations with missing diagnosis - 45 instances were found at Cardiff
2. No pathology reports for donations over 30 days old - 16 instances were found at Cardiff.
3. Samples without a donation - 0
4. The ischaemic time query returns results for those donations that have either a negative ischaemic time or the ischaemic time is greater than 3 hours - 11 instances to be checked

A list of the missing data was sent to the WCB technician to address following the audit due to IT difficulties. In addition, 8 WCB numbers from UHW and 5 from Medical Genetics were randomly chosen to check the data and sample tracking. Samples in Llandough will be audited on the return of the Cardiff nurse from maternity leave. All paperwork for the UHW samples is also in Llandough so will be checked at a later date.

Site file was present and up to date with SOPs etc

**UHW****Donation 079**

- All samples in correct place

**Donation 082**

- All samples in correct place
- Duplicate H&E slides present that need entering on database

**Donation 271**

- Serum samples have been reversed in freezer compared to database co-ordinates. Now corrected to reflect database information.

**Donation 335**

- All samples in correct place

**Donation 369**

- All samples in correct place

**Donation 381**

- All samples in correct place

**Donation 608**

- All samples in correct place

**Donation 736**

- All samples in correct place

**Medical Genetics**

5 records showing either EDTA or extracted DNA being present in Medical Genetics were randomly chosen for checking. Donations originated from 4 different collecting sites.

Donations:     **405 from Withybush**  
                   **245, 397 from Swansea**  
                   **191 from Cardiff**  
                   **227 from Bangor**

All samples were present in correct place and all internal shipment requests are filed in the site file. Extraction worksheets and lists are filed.

NB. No dry ice available to put samples onto whilst auditing.

**ROYAL GWENT**

The data queries were run against the live WCB database on 17th November 2009 and the results are outlined below.

1. Donations with missing diagnosis - none
2. No pathology reports for donations over 30 days old - 3 instances found
3. Samples without a donation - none
4. The Ischaemic time query returns results for those donations that has either a negative ischaemic time or the ischaemic time is greater than 3 hours - none

A list of the missing data was left with the nurse to address. 10 WCB numbers were randomly chosen to check the data and sample tracking. Numbers generated were 41, 91, 92, 140, 148, 155, 167, 194, 243 and 253.

Site file was present and up to date with SOPs etc

**Donation 041**

- No paraffin form
- All samples in correct place

**Donation 091**

- Difference in date on consent form
- No paraffin form
- All samples in correct place

**Donation 092**

- No paraffin form
- All samples in correct place

**Donation 140**

- No pathology report available
- All samples in correct place

**Donation 148**

- All paperwork present
- One serum sample barcoded as 148 but cap on tube showing handwritten 138

**Donation 155**

- All paperwork present
- All samples in correct place

**Donation 167**

- All paperwork present
- All samples in correct place
- Paraffin block showing on database as being stored in H&E cabinet

**Donation 194**

- All paperwork present
- All samples in correct place

**Donation 243**

- All paperwork present
- Patient not dated the consent form
- All samples in correct place

**Donation 253**

- All paperwork present
- All samples in correct place
- Blocks and pathology report to following as very recent surgery

Serum boxes need to be relabelled and barcode positioning altered to ensure successful scanning

**BANGOR**

The data queries were run against the live WCB database on 17th November 2009 and the results are outlined below. Only samples consented since June 2009 were audited.

1. Donations with missing diagnosis - 7 instances found.
2. No pathology reports for donations over 30 days old - none.
3. Samples without a donation - none
4. The Ischaemic time query returns results for those donations that has either a negative ischaemic time or the ischaemic time is greater than 3 hours. -7 results were found with negative times and 1 greater than 3 hours.

A list of the missing data was left with the WCB staff to address. In addition, 7 WCB numbers were randomly chosen to check the data and sample tracking. Numbers generated were 288, 289, 296, 307, 308, 324 and 358.

**Donation 288**

- All paperwork present
- All samples in correct place

**Donation 289**

- All paperwork present
- All samples in correct place

**Donation 296**

- All paperwork present
- All samples in correct place

**Donation 307**

- All paperwork present
- Paraffin form not signed and dated
- H&E slides appear on database but no information completed on paperwork
- Donor EDTA tubes have been reversed compared to database co-ordinates. Rectified to reflect database information

**Donation 308**

- All paperwork present
- Slides removed from storage for re-cutting due to slide damage. Suggested a note be inserted in slide cabinet for easy reference.

**Donation 324**

- All paperwork present
- All samples in correct place

**Donation 358**

- Consent form present
- Very recent surgery so no paraffin paperwork
- All samples in correct place

Barcode printer not working and replacement printer from Llandough appears to have similar issues. The Llandough printer was functional in Cardiff so assumption is that either permissions, firewall or drivers need attention. Bangor IT to be contacted.

**SWANSEA**

The data queries were run against the live WCB database on 4th November 2008 and the results are outlined below.

1. Donations with missing diagnosis - 179 instances were found
2. No pathology reports for donations over 30 days old - 135 instances found
3. Samples without a donation - none
4. The Ischaemic time query returns results for those donations that has either a negative ischaemic time or the ischaemic time is greater than 3 hours - 10 instances found

A list of the missing data was left with the WCB staff to address. In addition, 6 WCB numbers from Singleton and 7 WCB numbers from Morriston were randomly chosen to check the data and sample tracking. Numbers generated for Singleton were 412, 471, 662, 711, 1179, and 1198. Numbers generated for Morriston were 444, 473, 611, 742, 1064, 1205 and 1275.

**Singleton****Donation 412**

- All paperwork present
- Patient and consenting nurse signed and dated in different pens. GCP good practice is for the same pen to be used
- All samples in correct place

**Donation 471**

- All paperwork present
- No tissue taken
- EDTA tubes packed ready for transportation to Gene Park so not in co-ordinates stated on database

**Donation 662**

- All paperwork present
- H&E slides not in storage as logged out for scanning
- All samples in correct place

**Donation 711**

- All paperwork present
- All samples in correct place

**Donation 1179**

- All paperwork present
- No obvious mass so no tissue taken
- All samples in correct place

**Donation 1198**

- All paperwork present
- All samples in correct place

One DNA aliquot from a Cardiff donation (RWMBV00082) not in storage as removed for Nanodrop. Need to log aliquot out to Nanodrop storage.

Internal transfer forms all present

**Morriston****Donation 444**

- All paperwork present
- All samples in correct place

**Donation 473**

- All paperwork present
- All samples in correct place

**Donation 611**

- All paperwork present
- All samples in correct place

**Donation 742**

- All paperwork present
- No tissue taken
- All samples in correct place

**Donation 1064**

- All paperwork present
- All samples in correct place

**Donation 1205**

- All paperwork present
- All samples in correct place

**Donation 1275**

- Paperwork present
- All samples in correct place

**Withybush**

The data queries were run against the live WCB database on 17th November 2009 and the results are outlined below.

1. Donations with missing diagnosis - 3 instances was found
2. No pathology reports for donations over 30 days old - 16 instances found
3. Samples without a donation - none
4. The Ischaemic time query returns results for those donations that has either a negative ischaemic time or the ischaemic time is greater than 3 hours - 10 instances found

A list of the missing data was left with the WCB staff to address. In addition, 9 WCB numbers from Withybush were randomly chosen to check the data and sample tracking. Numbers generated were 303, 324, 407, 456, 487, 509, 539, 587 and 592.

**Donation 303**

- All paperwork present
- All samples in correct place

**Donation 324**

- All paperwork present
- All samples in correct place

**Donation 407**

- All paperwork present
- All samples in correct place

**Donation 456**

- All paperwork present
- All samples in correct place

**Donation 487**

- All paperwork present
- All samples in correct place

**Donation 509**

- All paperwork present
- All samples in correct place

**Donation 539**

- All paperwork present
- All samples in correct place

**Donation 587**

- No pathology report
- All samples in correct place

**Donation 592**

- All paperwork present
- H&E slides present on database and in cabinet but processing and co-ordinate information not on paperwork
- All samples in correct place

# Appendix C

## CONFERENCES, WORKSHOPS AND COURSES ATTENDED

|                      |  |                        |
|----------------------|--|------------------------|
| <b>MAY 2009</b>      |  |                        |
| 11th - 15th          | ISBER Annual meeting<br>Professor Thomas gave talk   | Portland, USA          |
| 13th                 | NHS R&D Forum Annual Conference<br>Dr Parry-Jones gave talk on 'Research and Human Tissue Regulations'                     | London                 |
| 26th                 | IQPC Biobanking and Sample Management conference<br>Dr Parry-Jones was invited to give a talk on 'Patient Involvement'     | Frankfurt, Germany     |
| <b>JUNE 2009</b>     |  |                        |
| 13th                 | Royal College of Radiologists Oncology Travel club<br>Dr Parry-Jones gave talk on 'Helping oncology research move forward' | Cardiff                |
| 24th                 | Translational Cancer Research Event  | Cardiff                |
| 27th June - 6th July | Brazil nurse exchange<br>Suzanne Williams  | Rio de Janeiro, Brazil |
| <b>JULY 2009</b>     |  |                        |
| 20th                 | WCB Open Day   | Swansea                |
| <b>SEPT 2009</b>     |  |                        |
| 15th                 | IQPC<br>Professor Thomas and Dr Parry-Jones ran a morning workshop on 'Starting in Biobanking'                             | London                 |
| 16th                 | BBMRI stakeholders group<br>Mr Neil Formstone gave a talk about 'Patient Involvement'.                                     | Brussels, Belgium      |
| <b>OCT 2009</b>      |  |                        |
| 4th - 7th            | NCRI Annual Conference   | Birmingham             |
| 7th - 8th            | Qiagen Biobanking workshop<br>Professor Thomas gave a talk on 'Role of Tissue Banks in the age of 'omics' research'        | Hilden, Germany        |
| 15th                 | Marble Arch working group meeting  | Cardiff                |
| 16th                 | EORTC 'Molecular markers in Cancer'<br>Professor Thomas gave a talk  | Brussels, Belgium      |
| 20th                 | Human Tissue conference  | London                 |

|                 |   |                                   |
|-----------------|---|-----------------------------------|
| <b>NOV 2009</b> |   |                                   |
| 2nd             | ProCare Cardiff patient group meeting<br>Dr Parry-Jones gave a talk about WCB   | Cardiff                           |
| 4th             | National Pathology week event   | Cardiff                           |
| 16th - 19th     | Biobanking and Biorepositories<br>Professor Thomas organised a workshop about 'Developing a Biobank'                  | Basel, Switzerland                |
| 20th            | WCTN Annual symposium   | Chester                           |
| <b>DEC 2009</b> |   |                                   |
| 1st - 4th       | Histological Dissection course  | Walsall                           |
| <b>JAN 2010</b> |   |                                   |
| 6th             | Tissue Bank meeting   | London                            |
| <b>FEB 2010</b> |   |                                   |
| 2nd             | SARTRE workshop<br>Dr Parry-Jones gave talk on 'Ethics and Governance for Research Tissue Banks'                      | Bristol                           |
| 5th             | Visiongain<br>Dr Parry-Jones gave talk on 'Access and Sample issue from Research biobanks'                            | London                            |
| 25th - 26th     | Human Tissue Network Summit<br>Professor Thomas gave the dinner keynote address                                       | Cambridge                         |
| 26th            | Dangerous Goods Handling course   | Cardiff                           |
| <b>MAR 2010</b> |   |                                   |
| 7th - 11th      | ICCN International conference<br>Catherine Lloyd-Bennett gave talk  | Atlanta, USA                      |
| 9th             | MSc. Biomedical Science students, University of the West of England<br>Vicki Woods gave lecture on WCB and biobanking | University of the West of England |
| 12th            | CCB conference, 'Biobanking for Clinical Trials'<br>Dr Parry-Jones gave talk  | London                            |
| 17th - 19th     | ISCO conference<br>Vicki Woods presented a poster, entitled 'Wales Cancer Bank, biobanking on a national scale'       | Dresden, Germany                  |

Suzanne Williams regularly lectures to pre and post-registration nursing students at Swansea University about communication, WCB and clinical Trials.

All staff have attended courses to update GCP, communication and skill sets relevant to their post.

# Appendix D

## WALES CANCER BANK PERSONNEL LIST AS AT 31ST MARCH 2010

### Staff

| NAME                    | SITE            | TITLE                           |
|-------------------------|-----------------|---------------------------------|
| Professor Malcolm Mason | Central         | Director                        |
| Professor Gerry Thomas  | Central         | Director of Scientific Services |
| Dr Alison Parry-Jones   | Central         | Manager                         |
| Mr Daniel Naeh          | Central         | IT Manager                      |
| Miss Sarah Phillips     | Central         | Project Officer                 |
| Dr Yasmin Friedmann     | Central         | Web Developer                   |
| Mrs Debbie Way          | Central         | Clerical officer                |
| Miss Claire Alford      | Central/Swansea | Information Assistant           |
| Suzanne Williams        | Swansea         | Lead nurse                      |
| Janette Gwillim         | Swansea         | Nurse                           |
| Catherine Lloyd-Bennett | Swansea         | Nurse                           |
| Pam Hayward             | Swansea         | Nurse                           |
| Colleen Lloyd           | Swansea         | Biomedical Scientist            |
| Emma Miles              | Swansea         | Biomedical Scientist            |
| Alison Davies           | Cardiff         | Nurse                           |
| Kevin Pearse            | Cardiff         | Nurse                           |
| Vicki Woods             | Cardiff         | Biomedical Scientist            |
| Fiona Martin            | Cardiff         | Biomedical Scientist            |
| Jennifer Jones          | Bangor          | Nurse                           |
| Alex Makanga            | Bangor          | Biomedical Scientist            |
| Linda Kirk              | Withybush       | Nurse                           |
| Rachel Hughes           | Withybush       | Nurse                           |
| Helen Smith             | Withybush       | Medical Laboratory Assistant    |
| Lisa Gilby              | Newport         | Nurse                           |
| Karen Wild              | Newport         | Nurse                           |

## HTA/Local Management committee

| NAME                     | SITE                | TITLE                              |
|--------------------------|---------------------|------------------------------------|
| Professor Malcolm Mason  | Central             | Director                           |
| Professor Gerry Thomas   | Central             | Director of Scientific Services    |
| Dr Alison Parry-Jones    | Central             | HTA Designated Individual          |
| Professor Nick Stuart    | Bangor              | HTA Person Designated / Local lead |
| Professor Julian Sampson | Cardiff             | Local lead                         |
| Professor Bharat Jasani  | Cardiff             | HTA Person Designated              |
| Dr Paul Griffiths        | Swansea - Morriston | HTA Person Designated              |
| Mrs Christine Davies     | Swansea             | HTA Person Designated / Local lead |
| Dr Martin Sevenoaks      | Withybush           | HTA Person Designated / Local lead |
| Mr Adam Carter           | Royal Gwent         | HTA Person Designated              |
| Dr Meleri Morgan         | Llandough           | HTA Person Designated              |

**For general information please contact:**

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