



**Operating Models to support
cancer biobanking throughout
Wales**



WALES CANCER BIOBANK
BIOFANC CANCER CYMRU



Operating Models to support cancer biobanking throughout Wales

The Wales Cancer biobank (WCB) has been operational since 2005 and consents patients in Wales with known or suspected cancer to donate biosamples and data to the biobank for use in future cancer related research. The WCB is licensed by the Human Tissue Authority to store human tissue for research and is approved as a Research Tissue Bank by Wales Research Ethics Committee 3. WCB is currently (financially) limited to routinely consenting patients in Cardiff and Newport although it previously consented in 14 hospitals around Wales. The model used to consent patients and process and store samples relies mainly on WCB dedicated staff.

It is recognised that there are many other centres in Wales where cancer patients are having tissue removed and blood (and other fluid samples) taken as part of their diagnosis and treatment and local researchers may be collecting samples and data for use in projects under project specific ethics or wish to initiate collections, either project specific or more generic collections.

WCB would like to help enable cancer biosample collection and research throughout Wales and investigate whether support can be given to help streamline processes, reduce time to set up projects and/or facilitate patients to participate in research by donating biosamples. WCB is happy to use its reputation and experience to support researchers in their projects which will require human biospecimens. This may include quotations, strategic delivery, support letters as Collaborator or as Co-Investigators.

Scenarios

1. Projects with specific, existing ethics

If a project wishes to utilise the Wales wide potential of WCB consenting to expand a project with specific ethics, then WCB approvals could be utilised to open up new collection sites. Projects would need to complete a WCB application form to cover the ethics for the use of the samples consented by WCB. WCB would not necessarily be able to undertake consent or sample collection, depending on location and staffing resources. There would be no charge to the researcher unless processing was required in WCB labs. If a greater volume/quantity is collected than is required by the project, then the remainder will be absorbed into the regular biobank collection and made available to researchers worldwide to access.

2. Local teams/Researchers wishing to collect under WCB ethics for a new, defined project

A sub-collection can be set up where the researchers use the WCB approvals and documentation to consent, collect and store samples for a project. The project needs to be approved by the WCB External review panel in order for deemed ethics to be conferred for use. The researchers have responsibility for all aspects of the sample pathway, storage and processing and register the samples on a project module on the WCB database. Any sample remaining at the end of the project would be adopted into the general WCB collection and made available for wider use. WCB



will train researchers and audit storage prior to set up. There would be no charge to the researcher.

3. Local teams wishing to collect under WCB ethics with no defined projects but interest in utilising collected samples

If local teams can support the consenting, sample acquisition and temporary storage of samples then the WCB approvals and documentation can be used to set up a satellite site. Teams will be trained, and facilities audited to ensure compliance with WCB HTA licence.

If there is no defined project at the time of collection and there is sufficient sample volume/amount to split the donation, half will be absorbed into the regular biobank collection and made available to researchers worldwide to access. The other half will be ring-fenced for 2 years for use by the local team. If no project is received from the local researchers within the 2 years, the ring-fenced samples will be absorbed into the regular biobank collection and made available to researchers worldwide to access. If there is no defined project and insufficient sample to split, samples will be absorbed into the regular biobank collection and made available to researchers worldwide to access.

When a defined project has been identified, the local team should complete a WCB application form and once that is approved, the samples collected and remaining in the biobank will be ring-fenced for that project. Projects should include sample acquisition related costs in grant applications to help support the continued activity. Costings will be provided by WCB on a project by project basis.

4. Local teams wishing to collect under WCB ethics for general biobanking

If local teams can support the consenting, sample acquisition and temporary storage of samples for general biobanking then the WCB approvals and documentation can be used to set up a satellite site. Teams will be trained, and facilities audited to ensure compliance with WCB HTA licence. Samples will be transferred to WCB sites in Cardiff at regular intervals and made available for open access.

5. Biobank with own approvals and documentation wishing to share resources

Separate operations

Can act as a signposting service – if researchers apply to WCB for samples and WCB doesn't have sufficient or any, signpost to other biobank as a potential source, and vice versa. Applications for use would be to each biobank.

- Would be useful to have a common access procedure to reduce time and effort of researcher



Integration (to greater or lesser extent)

- a) Other biobank uses WCB approvals and documentation to consent patients in their area and store samples locally
 - a. Samples would be ring fenced for local research if a project is submitted and approved by WCB, OR
 - b. Samples could be split and 50% (eg. 1 block and 1 blood) stay locally for local use and 50% (second block and blood) to virtual WCB storage and available for wider use, OR
 - c. Samples could be transferred on a regular basis to WCB storage in Cardiff
- b) Other biobank continues to use own approvals and documentation to consent and store samples but samples could be adopted under WCB ethics at the end of a defined time period.

Considerations

If sample collection is required in Health Boards where WCB does not currently have a collaboration agreement, an agreement will need to be reviewed and signed by legal departments before any consenting/collection can take place. WCB has template agreements.

If researchers accessing samples collected under WCB ethics are based within Cardiff University an internal sample transfer agreement will be required and if external to CU, a Material Transfer Agreement will be required. WCB has standard documentation for signature.

Unless costs to cover items below are included in a grant application¹:

- Consent would need to be carried out by local teams, WCB cannot fund a consent post.
- Access to tissue via histology departments may incur a cost – local teams to negotiate. WCB cannot provide a per sample payment to histology departments for prospective samples. IF samples are for a specific project, any costs could be passed onto the researcher.
- To come under the WCB HTA licence, storage facilities would require audit by WCB. WCB cannot fund technicians or storage, eg. -80 freezers

Advantages of collecting samples under WCB

- Overarching ethics already in place under WCB approvals, projects do not need individual NHS REC approval
- Established Consent model and training
- Coordination of sample retrieval by experienced personnel
- Processing available
- Storage available

¹ WCB is happy to provide costings and supportive letter as collaborator or Co-I upon request