BIOBANKING WORKSHOP - MINUTES

Date: 29 10 2018
Time: 2:00-5:00pm
Venue: Harry Perkins Medical Research Institute

TIME	SUBJECT	SPEAKER	MEETING NOTES AND ACTIONS
14:00	**OPENING**		
14:00-14:10	Welcome and introduction	Dr Aron Chakera – SCGOPHCG Director of Research	Dr Aron Chakera opened the meeting. *Purpose*: • First steps in collegial approach to developing a central Biobank Hub that is a mechanism for unity of governance and infrastructure to support a sustainable and scalable Biobank for WA *The aims/outcomes of the workshop:* 1. To identify common biobank resources required for diagnostics and research work in WA 2. To invite users to express their views in developing a centralise bio banking facility in WA and to address the needs and potential problems associated with a national biobank resource 3. To provide an overview of the opportunities for biobank users in WA 4. to develop a working group with expertise in (i) Governance, (ii) Ethics, (iii) Quality standards, (iv) IT and (v) Expert advice to government and funders
14:10	**QUALITY CONTROL AND ETHICS IN BIOBANKING**		
14:10-14:20	Presentation	Prof David Broadhurst – Director of Centre for Integrative Metabolomics & Computational Biology, ECU	*For consideration:* • Centralised resource – harmonisation of collection protocols • Sample tracking and management system • Central sourcing/storage and distribution of barcoded vials • Automated/robot system to improve efficiency and reduce human error • Centralised training *Attendee Question*: Q - Error rate for automated/robot system?

14:20-14:30	Presentation	Felicity Flack – Human Research Ethics Committee Chair, SCGOPHCG	*For consideration:* • Biobanks are research infrastructure, not research projects – do not follow standard templates for research protocol, write your own consent safeguards • Governance (communications policy) • Community involvement/participant relationships • Data linkage *Attendee Question*: Q - Is there an issue with using your own template for submissions when they are required to be submitted at different HREC's? *Presenter Answer:* A - SCGOPHCG HREC can approve ethics on projects nationally so there is no issue with this.
14:30	**NEEDS AND REQUIREMENTS FROM POPULATION COHORTS**		
14:30-14:40	Presentation	Peter Eastwood – Scientific Director, RAINE Study	*For consideration:* • Secure curation of invaluable resource • Funding access to biosamples – researchers/government • Governance and ethics – overarching & study specific • National versus state biobank resource *Attendee Question*: Q - What percentage of samples that have had research conducted on them? *Presenter Answer:* A - 80% remain untouched. *Attendee Follow on Question*: Q - Do you see this as an issue? *Presenter Follow on Answer:* A - The main reason for this is that applications to use the samples have not come in. We see benefit in engaging researchers to add value.
14:40-14:50	Presentation	Jennie Hui – Director, Busselton Health Study Laboratory	*For consideration:* • Sustainability • Security/integrity of data and samples storage • Data sharing and access • Economies of scale through collaborations *Attendee Question*: Q - For long term cohort studies, do you do check the samples to see if they are degrading? *Presenter Answer:*

			A - When there is a request that comes in to use a particular specimen, it is checked. Especially older samples. *Attendee Statement*: S - More studies are identifying that samples deteriorate at -80 degrees Celsius.

14:50-15:00	Presentation	Jackie Davis – Program Manager, ORIGINS Study	*For consideration:*
			• Facilities and logistics
			  o Need for lab and freezer space with adequate capacity
			  o Impact on time critical samples
			  o Lack of dedicated facilities e.g. cryosite facilities
			• Data management of sample information – Laboratory Information Management System (LIMS) to implement
			• Consistency across sites and processes
			• Governance of implementing protocols for collecting and storing samples/managing complexity of ORIGINS
			• Staff
			  o Experiences staff
			  o Training staff
			• Engaging stakeholder to comply
			• Protecting longitudinal samples
			• Ethics consideration
			• Future – proofing and new technologies
			Attendee Question:
			Q - Can you comment on how this biobank was funded?
			Presenter Answer:
			A - This biobank operates on a cost recovery basis
			Attendee Question:
			Q - Was there a time limit put on the sample collection?
			Presenter Answer:
			A - The sample collection was based around consent.

15:10	**CURRENT EXPERIENCE FROM WA DNA BANK**		
15:10-15:20	Presentation	Eric Moses – Director, GoHAD	*For consideration:* • The Ark tool – funded by Nectar • Long-term guaranteed funding concern
15:20	**PROSPECTIVE FROM DIAGNOSTICS/CLINICAL SETTINGS**		

15:20-15:30	Presentation	John Beilby – Head, Diagnostic Genomics, PathWest	*For consideration:* • Reliability of fridges and freezers • Good tracking system • Avoiding of sample mix-ups • Biobank would need to be NATA accredited • DNA samples >10 years could be BioBanked • Collect samples and patient data on all hospital admissions in the future - unable to cope and greater measures required • See a great advantage and benefit in the future *Attendee Question*: Q - When you discussed the requirements for storage, were these minimum requirement and any further up storage then up to your discretion? *Presenter Answer:* A – Yes. *Attendee Question*: Q - Is there disposal guidelines? *Presenter Answer:* A – No. *Attendee Question*: Q - What does the patient sign when their samples are taken for diagnostics? *Presenter Answer:* A - In genetics, there is a form that is given to the patient stating "the sample has been collected and testing for XXXX condition" there is an option to tick also for research, but they do not have to.
15:30-15:40	Presentation	Siobhain Mulrennan – Head, Cystic Fibros	*For consideration:* • Biobanks would be useful for both current and future project collaborations • Bacterial biobank particularly useful • Funding and sharing resources • Established programs versus up and coming • Ethics processes and patient buy in • Who owns the samples – custodianship • Access to data • Ideal situation would be to have sputum, stool and blood from every patient in a biobank • Longitudinal studies important in CF particularly in the age of

			CFTR modulation • Collaborative approach and sharing of resources • Collaborations between paediatric/adult etc. • Applicable to other respiratory conditions
15:40	**FACILITATED DISCUSSION**		
15:40 -16:50	Introduction from facilitator and person reflection.	Karina Moore – Senior Development Officer, Health Network	Facilitator Karina More introduced this next session of round table discussion activities. *Facilitator question to round tables:* <u>Q - What does the gold standard state-wide Biobank Hub look like? Is there an example of this anywhere in the world?</u> *Activity:* • Document personal reflection on blank A4 paper on table • Nominate table scribe and presenter *Feedback:* o Example of a biobank version of the cloud
15:50-16:15	Issues identification	Karina Moore – Senior Development Officer, Health Network	*Facilitator question to round tables:* <u>Q - In the context of sustainability and scalability - What would it take to set up a collegial Biobank with agreed processes and mechanisms? How do we collectively achieve gold standard?</u> *Activity:* • Table top discussion to identify and list the issues • Scribe documents one issue per medium post it note *Feedback:* o Reliable ongoing funding o Specialised space (e.g. liquid nitrogen) o Equipment o Automated o IT & Metadata (e.g. private cloud, not commercial) o Ethics and Governance o Staff – suitably trained and qualified
16:15-16:35	Plenary feedback and clustering of the table top issues.	Karina Moore – Senior Development Officer, Health Network	*Facilitator question to round tables:* <u>Q - Can issues by table be clustered into common issue streams?</u> *Activity:* • Table speaker provides feedback for table • Plenary discussion and clustering/streaming of issues on to a large A3 post it note as each table presents *Feedback:*

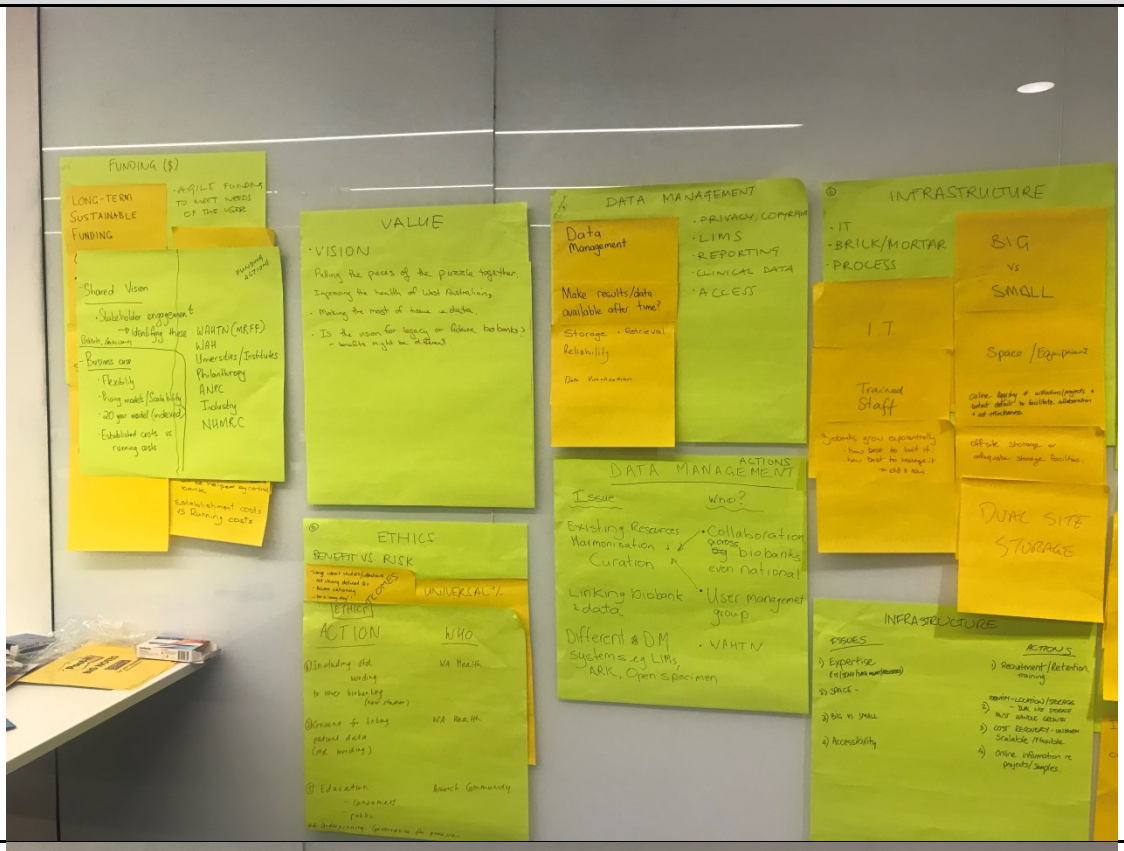
			1. Funding 2. Quality assurance 3. Data management 4. Governance 5. Ethics 6. Infrastructure 7. Values ***See Attachment-1***
16:35-16:45	Action planning	Karina Moore – Senior Development Officer, Health Network	*Facilitator question to round tables:* <u>Q - Are there any 'natural' leaders/owners of the issues? Are they engaged? How do they get engaged? Who needs to assist them?</u> *Activity:* • Table top discussion – Scribe lists on A3 posit note divided into 2 columns – column 1 the issue, column 2 suggested action by whom
16:45-16:55	Action feedback	Karina Moore – Senior Development Officer, Health Network	*Feedback:* ***See Attachment-2***
16:55	**CLOSE**		
16:55-17:00	Next steps and thank you	Dr Aron Chakera – SCGOPHCG Director of Research	Dr Aron Chakera thanked presenters and attendees of the Biobanking workshop. Discussion on plenary next steps and future outcomes. *Next steps:* • Engagement of the key stakeholders • Agreement on the coordinated approach and action required to achieve coordination in the areas of: ethics and governance, collection and storage of samples, recording of clinical data, scalability • Mechanisms that link Bio samples to clinical support. Such as; agreed templates for ethics application etc.. on a shared access hub • Agreed process for developing a catalogue of genotypes/phenotypes to me made available to researchers who need comparative data The workshop was closed at 17:05.

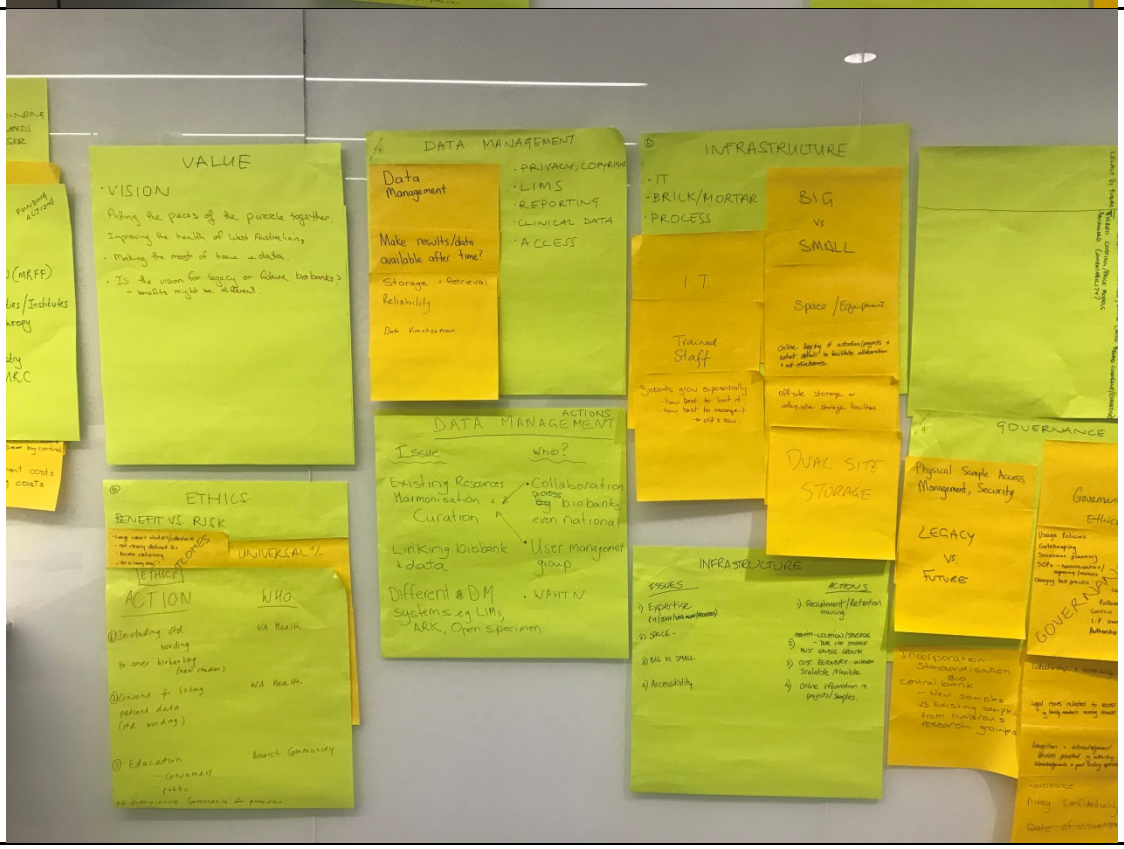
BIOBANKING WORKSHOP ATTACHMENT-1

Plenary feedback and clustering of the table top issues:	
• Long-term sustainable funding • Sample quality and testing over time (storage and assurance testing). QA issue on those samples • Long term vs short term users – access to samples • Infrastructure funding vs cost recovering funding • Funding models consistent • Agility in funding to allow different types of uses to access the biobank to meet the needs of the user • Data management • Making the data publically available after a certain number of years. Open access issue, IP issue and privacy issue. • Physical sample access • Management of samples • Security of samples (who can access and how it is looked after) • Accreditation • Consent • Legacy versus future • Big versus small (e.g. agile funding and mechanisms/key expertise and staff that can enable small groups) • Scalable flexible infrastructure • Harmony • Values and beliefs • Laboratory Information Management System (LIMS) • Reliable ongoing funding • Specialised space (e.g. liquid nitrogen) • Equipment • Automated • IT (e.g. private cloud, not commercial) • Metadata • Ethics • Governance • Staff- suitably trained and qualified • Infrastructure (e.g. processes and responsibilities) • Usage policies • Sustainable cost structure • Should it have an upper limit? What would that look like? Biobanks grow exponentially • Off-site storage and adequate storage facilities	• Gatekeeping • Succession planning • Rollover – move of PIs • Changing landscape that is best practice • Sample curation • Cold chain management and sample flow • Challenge of getting fresh tissue • Possibility of opt out • Waiver of consent if a patient is deceased and have previously opted in • One form for all hospitals • Cost will go up with the costs of new technology • Unclear outcomes • Access rationing • Benefit versus risk • Security • Sustainability • Expertise in the materials and data management (e.g. collection and scribing • Custodianship and accessibility) • Legal issues related to the access of the samples (e.g. cancer patient deceased with family seeking access) • Online registry of custodians and projects serviced by such facilities to enhance usage – facilitates collaboration and cost effectiveness. (e.g. clinical trials.gov.au) • Recognition and acknowledgement of services provided • Storage and retrieval • Data visualisation – how it is produced • Marketing • Funding – starting off from scratch (e.g. universal Denmark model). What about all the existing samples, incorporating physically or from an infrastructure point of view • Export data in a meaningful way (biobanking tool that gives back the data back in a user friendly way) • How are you going to obtain the Clinical information? Efficient and in good quality. • Researchers to obtain customised data. • Dual site storage • Improving the provision of the healthcare • Key stakeholders • vision

Q - Can issues by table be clustered into common issue streams?	
• **Funding** • **Quality assurance** • **Data management** • **Governance**	• **Ethics** • **Infrastructure** • **Values**

Activity: Table speaker provides feedback for table. Plenary discussion and clustering/streaming of issues on to a large A3 post it note as each table presents.





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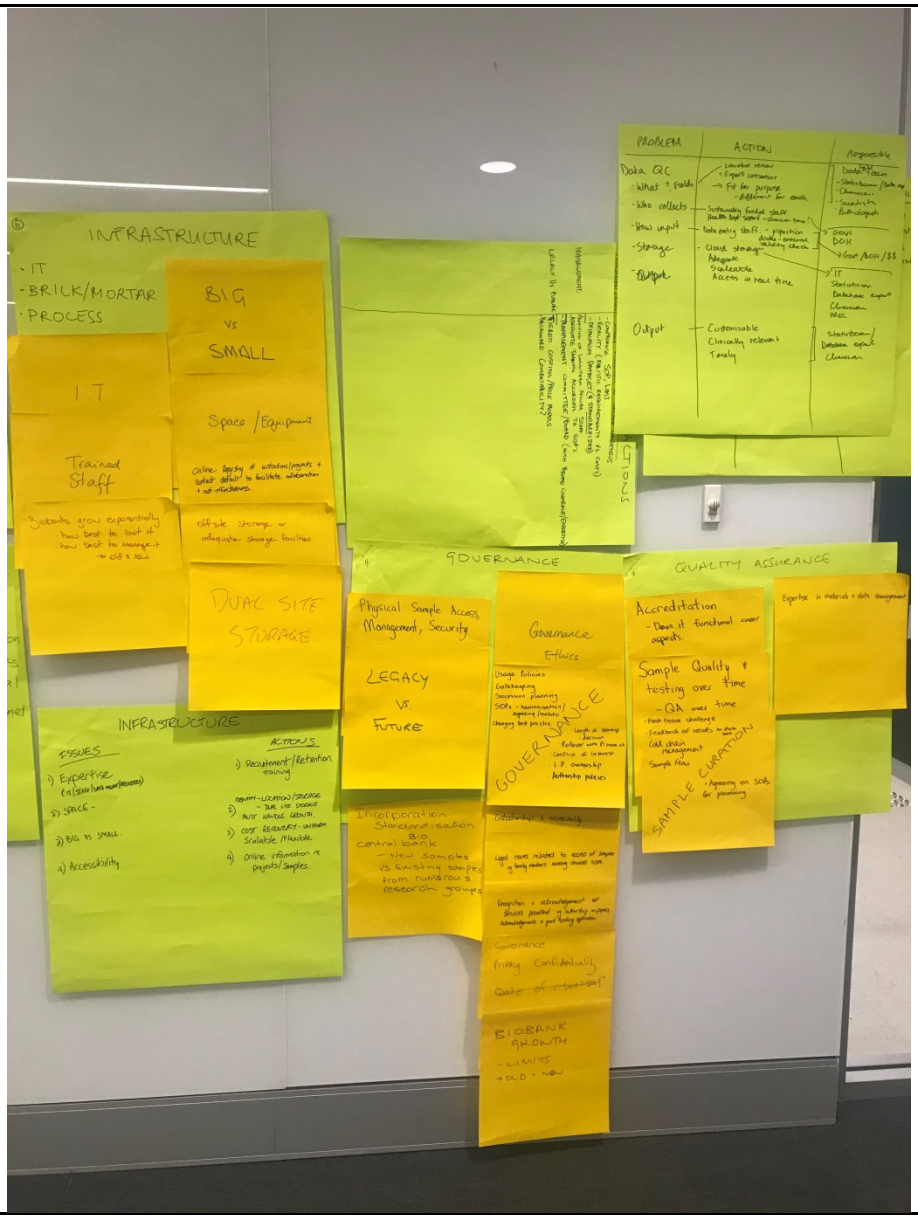

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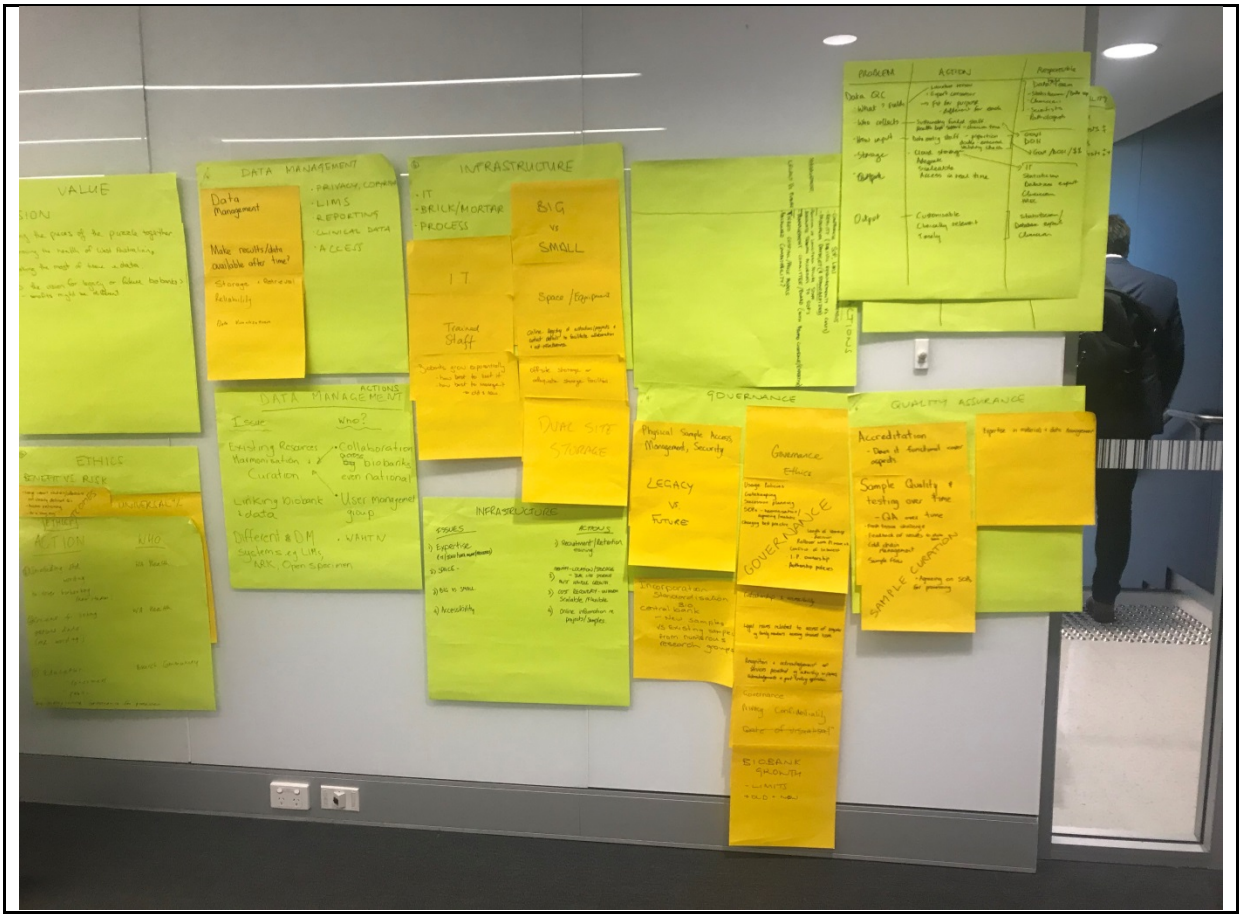

BIOBANKING WORKSHOP ATTACHMENT-2

Activity: Table speaker provides feedback for table	
1. Funding • Patients • Shared visions • Stakeholder engagement • Funders e.g. WAHTN, universities, NHMRC (potential donors and financial partners) • Business case – provision to be flexible • Funding needs to be sustainable (e.g. 20 year period) • Established cost versus running costs **2. Quality assurance** • Biological and data QA to ensure sample quality • ensure sample integrity while stored long term • Sample expire – how we test and dispose and the feedback to custodians-solved by SOPs • Ongoing plan for testing structure (formed by a lit review) which is specimen specific • Ensure fit for purpose • Entry staff for how this is input and validity testing • Cloud storage • Multidisciplinary data team responsible • Buy in from government – as to what will happen to data entry and clinician time **3. Data management** • Existing resources • Harmonisation and curation – collaboration across biobanks. If it was national we would suggest a user management group with WA interest • Linking of biobank data • Different data management laboratory systems • WAHTN in charge	**4. Governance** • Harmony and ego • Gather a consensus gather as many people as you can from the start • Make compromises • Be realistic of requirements e.g. relative to costs • Management – long term security of staff for continuity • Adequate training to standard operating procedures • Management/board with broad expertise • Legacy vs future – tiered costing model to operate on • Backwards compatibility **5. Ethics** • Short term working with WA health for standard wording to cover Biobanking • Consent for linking of patient data. • Long term access of data • Education – consumers and the public, engaging the research the community, support **6. Infrastructure** • Expertise across all areas • Staff, data management, processes and IT • Space – dual sit storage • Specialised training of all staff • Uniform cost recovery, scalable and flexible • Accessibility – online information of what projects and samples are available to enhance collaboration between groups and an effective use of tissue **7. Values** • Improving health outcomes and wellbeing of community • Putting the pieces if the puzzle together • Improving the health of West Australians • Is the vision for legacy or future biobanks? • Biobank Service (e.g. an IT cloud) • 3 different models, benefits IT cloud, legacy, bit of both