Genomics and Your Hospital

A toolkit to support high-quality genomic care

Model screening tool for review of new genomic care

*This document is part of the **Genomics and Your Hospital toolkit**, a resource developed to support a 'whole of hospital' approach to genomic care. The complete toolkit is available at **GenomicsToolkit.org.au.***

The genomics toolkit was co-designed with many of Victoria's leading health services. This screening tool has been developed to support decision-making about new genomic care in your hospital. It has been designed to be adapted locally as needed.

It's recommended that the form is completed by a clinician or department lead prior to starting use of a genomic test in their model of care. This can then be reviewed by your genomics leadership group to support a structured, transparent decision about next steps to be made.

Applicant details			
Name:	Position:		
Department/Unit:	Email:		
Head of Unit details			
Name:	Signature	Date	
Conflict of Interests	*Hospitals may wish to include a COI statement here in line with local requirements*		
Model of care			
Has a genomics model of care been drafted? ▪ If so, please attach it to this document ▪ If not, please provide a brief summary of what the new genomic care model involves			
Please describe what test(s) will be used			
Please describe the proposed patient cohort			
What is the clinical need for the test? ▪ Please include in your response the purpose of doing the test? (e.g., initiate treatment that would not otherwise be started, assess recurrence risk, removal of diagnostic odyssey)			
Please describe the evidence base for use of **this** test in **this** patient cohort. ▪ If there are guidelines in use elsewhere that include this model of care, please attach.			

Please describe whether this test is broadly considered: standard of care, emerging practice or research.	
Is this new genomic model being used in other hospitals in Australia or Internationally? ▪ If Yes, please provide details.	
Please describe the number of tests expected to be undertaken annually. How will these be funded?	
Workforce considerations	
Has a genomic workforce review been undertaken? ▪ If so, please attach here ▪ If not, please answer the questions below.	
Who will be the clinical lead for the new model? (e.g. for questions, concerns, feedback, expertise) ▪ What are the qualifications and credentialing the clinical lead relevant to their clinical leadership of this program of work? ▪ How will their leadership role be communicated to stakeholders?	
Please describe which clinicians may undertake autonomous decision making in this model of care ▪ Are there any training or credentialling requirements for autonomous practice? If so, please describe (e.g. further training, proctoring, further qualifications)	
Please describe which clinicians may undertake supervised decision making in this model of care ▪ Are there any training requirements for supervised practice? If so, please describe (e.g. further training, proctoring, further qualifications)	
Please describe what supports the workforce can access if they have questions or need to escalate concerns	
Which, departments apart from yours, may be involved in the care? ▪ Where have their relevant workforce, risk and operational considerations have been discussed and documented ▪ Have all other involved departments been consulted and approved their proposed involvement and the model of care?	
Risk considerations	
Has a risk assessment been undertaken? ▪ If so, please attach here ▪ If not, please answer the questions below	
Please describe any risks with this new model compared with previous model of care	
Please describe how any risks will be mitigated	
Testing considerations	
Will testing be done in house or externally?	
Is the laboratory NATA accredited for this type of testing?	
Is there an agreed mechanism for communication between the laboratory and person ordering tests if there are questions or concerns about appropriateness of test(s)	

Is there an agreed escalation person for the laboratory if there are further questions or concerns about appropriateness of test(s)	
How will uncertain results be managed and approaches agreed and documented?	
Resource considerations	
What new activity will this model entail? How will staff be resourced to undertake new work?	
How will the test be funded? ▪ Additional approval may be needed from hospital operations	
Are there any other resource changes (e.g., use of outpatients capacity, new investigations etc)	
Are there any potential savings associated with this care? (e.g., anticipated reduction in other investigations)	
Quality considerations	
Describe where completed test results will be available?	
How will the ordering clinician/team know that results have been finalised?	
Is there a multidisciplinary team meeting that will discuss cases? ▪ If yes, please describe ▪ If no, describe how complex cases and VUS will be reviewed and optimal management agreed	
What processes are in place to ensure completed tests are returned to the patient/family in a timely way?	
Has clinical reanalysis of patient data from this or prior tests been considered?	
What metrics will be collected to demonstrate that the new care is safe, effective and value-based? ▪ Who is accountable for overseeing quality data collection? ▪ How will this data be collected? ▪ Where will the data be reported and monitored?	
Consumer considerations	
Who will consent the patient for the test and ramifications including e.g. family ramifications?	
Is written consent required for this test? ▪ If yes, please attach a copy of the consent form for review. Where will this be stored? ▪ If no, outline where and how evidence of consent will be documented?	

Please confirm staff undertaking consent have requisite skills to include the full range of discussion points including, but not limited to: findings of unknown significance, incidental findings, risk of nonpaternity, sharing of result for counselling of other family members, potential reanalysis. Please confirm your systems and processes are established to ensure effective, holistic consent including the above elements.	
Has a patient and family information sheet been developed? (this may provide information on the test and/or the process and model of care) ▪ If so, please attach here ▪ If not, please describe: – what information will be provided to patients, families and carers – Who will provide this information – Where this will be documented	
How will patients be supported to communicate genetic risk to family members? How will confidentiality be managed when considering sharing of result for counselling of other family members?	
What supports are available for the patient and their family in the model of care? ▪ How will the patient and the family know who to contact, and how, if questions / concerns arise?	