

## Written Submission Template

The consultation draft of the National Health Genomics Policy Framework (the Framework) is written as an outline and poses questions throughout as the basis for consultation. These questions are focussed on the key domains for priority action.

Feedback from the consultation will enable drafting of the National Health Genomics Policy Framework to be finalised and submitted for Australian Health Ministers' Advisory Council endorsement through the Hospitals Principal Committee.

### ***Confidentiality of submissions***

Unless otherwise indicated, all submissions may be published on the Department of Health website. If you wish any information to be treated as confidential, please explicitly and clearly identify that information and outline the reasons why you consider it confidential. General disclaimers in covering emails will not be interpreted as a specific request or taken as sufficient reason to submissions to be treated conditionally. Submissions including personal information identifying specific individuals will be de-identified prior to publication.

### ***How to submit your written submission***

Written submissions on the consultation draft of the National Genomics Policy Framework can be sent in Word format by email to [genomics@health.gov.au](mailto:genomics@health.gov.au) by close of business on **8 March 2017**.

1. **Full name:** Dr Merran Smith

2. **Email:** merran.smith@uwa.edu.au

3. **Are you providing your response on behalf of an organisation?**

Yes            If Yes, please specify: Population Health Research Network

4. **If applicable, please specify you and/or your organisation's area of expertise.**

The PHRN is Australia's national data linkage infrastructure.

5. **Do you consent to potentially being contacted to discuss the content of your submission further?**

Yes            Phone Number (Optional):.....

6. **Do you accept the terms specified above about the confidentiality of submissions?**

Yes            If no, refer to the instructions in the disclaimer above.

Section of Framework		Question	Response
<b>Glossary</b>	Pg. 2-5	7. Are there other key terms referenced in the Framework which should be added to the glossary? If so, please provide details.	
		8. Are the definitions easy to understand? Do any definitions require amendment? If yes, please provide details.	
<b>Preamble</b>	Pg. 7-8	9. Does the Preamble provide a sufficient overview of the Framework? If not, please provide further details.	YES
		10. Are there linkages with other key frameworks or strategies that should be explicitly referred to in the Preamble? If yes, please provide details.	
		11. Is a three year timeframe sufficient for the Framework? Please explain your answer.	

Section of Framework		Question	Response
<b>Strategic Context</b>	Pg. 10-12	12. Are the most critical international and national activities referenced? If no, please provide details of what may be included and why it is important.	<i>The implementation of the National Health Genomics Framework will require significant investment in genomics and data infrastructure. The significant contribution of the National Collaborative Research Infrastructure Strategy to genomics and data research infrastructure in Australia should be acknowledged and the soon to be released National Research Infrastructure Roadmap should also be mentioned.</i>
		13. Does the Strategic Context provide a clear case for improved national consistency in genomics policy? Please explain your answer.	
<b>An Australian Perspective</b>	Pg. 13-14	14. Are there additional barriers, issues or challenges to integrating genomics into the health system that should be included in this section? If yes, please provide details.	<i>Page 14, System capability and capacity issues, Para 1, Sentence 3</i>  <i>The importance of relating sequence data to phenotype data collected from medical records and diagnostic testing is recognised in the text. It is also important to relate sequence data to phenotype data sourced from administrative records (especially if population outcomes are</i>

Section of Framework		Question	Response
			<i>to be assessed, as mentioned on Page 13) and these should be mentioned.</i>
<b>A National Health Genomics Policy Framework for the next 3 years</b>	Pg. 15	15. Are the key guiding principles appropriate? Please explain your answer.	<i>Principles related to system focus and evidence-based policy are considered particularly important.</i>
<b>Enablers</b>	Pg. 16-17	16. Are there additional enablers that should be included? If yes, please provide details.	<i>With respect to enablers identified on Page 16, consider mentioning a national approach to linking genomics data to clinical, administrative and other data.</i>
<b>Strategic Intent</b>	Pg. 16-17	17. Is the Strategic Intent of the Framework appropriate? If no, what would you suggest?	
<b>Priorities Areas</b>	Pg. 17	18. Are the priority areas appropriate? Please explain why or why not.	
<b>Overarching priority – ethical, social and</b>	Pg. 18-24	19. Is the placement of ethical, social and legal (regulatory) issues as an overarching priority	<i>Yes, the ethical, social and legal issues should be an overarching priority.</i>

Section of Framework		Question	Response
legal (regulatory) issues		appropriate?	<p><i>On Page 19 the paper recognises ‘the need to balance maintaining confidentiality and permitting wide access to data’. Access to population-based data also is mentioned on Page 23.</i></p> <p><i>Access to genomics (and related) data for approved population-based research is considered very important. The framework may wish to make further mention of access to genomics data, including for linkage to population-based administrative data, in this section (perhaps on Page 20 under use of data) and/or in Priority Area 6.</i></p>
		20. Should these issues be considered prior to the six priority areas, or after?	
		21. Are there any other broad ethical, legal or social issues that should be addressed under this priority? If yes, please provide details.	<p><i>Given the Framework covers both the clinical application of genomics and genomics research the principles outlined in the National Statement on Ethical Conduct in Human Research should also be referenced.</i></p>

Section of Framework		Question	Response
<b>Priority Area 1 – Strong leadership and governance</b>	Pg. 25-26	<p>22. With regard to <i>Priority Area 1 – Strong leadership and governance</i>, is anything missing or what should change, for:</p> <p>(a) the current situation;</p> <p>(b) why is this important;</p> <p>(c) opportunities for improvement; and/or</p> <p>(d) what the future looks like?</p>	
<b>Priority Area 2 – A skilled and literate genomics workforce</b>	Pg. 27-29	<p>23. With regard to <i>Priority Area 2 – A skilled and literate genomics workforce</i>, is anything missing or what should change, for:</p> <p>(a) the current situation;</p> <p>(b) why is this important;</p> <p>(c) opportunities for improvement; and/or</p> <p>(d) what the future looks like?</p>	

Section of Framework		Question	Response
<p><b>Priority Area 3 – Application of genomic knowledge is evidence based, high quality and safe</b></p>	<p>Pg. 30-31</p>	<p>24. With regard to <i>Priority Area 3 – Application of genomic knowledge is evidence based, high quality and safe</i>, is anything missing or what should change, for:</p> <p>(a) the current situation;</p> <p>(b) why is this important;</p> <p>(c) opportunities for improvement; and/or</p> <p>(d) what the future looks like?</p>	
<p><b>Priority Area 4 – Integration of genomic knowledge into person-centred health care, supported by equity of access to services</b></p>	<p>Pg. 32-33</p>	<p>25. With regard to <i>Priority Area 4 – Integration of genomic knowledge into person-centred health care, supported by equity of access to services</i>, is anything missing or what should change, for:</p> <p>(a) the current situation;</p> <p>(b) why is this important;</p> <p>(c) opportunities for improvement; and/or</p> <p>(d) what the future looks like?</p>	

Section of Framework		Question	Response
<p><b>Priority Area 5 – Sustainable investment in health genomics</b></p>	<p>Pg. 34-35</p>	<p>26. With regard to <i>Priority Area 5 – Sustainable investment in health genomics</i>, is anything missing or what should change, for:</p> <p>(a) the current situation;</p> <p>(b) why is this important;</p> <p>(c) opportunities for improvement; and/or</p> <p>(d) what the future looks like?</p>	
<p><b>Priority Area 6 – Effective and appropriate collection, management and utilisation of genomic data</b></p>	<p>Pg. 36-38</p>	<p>27. With regard to <i>Priority Area 6 – Effective and appropriate collection, management and utilisation of genomic data</i>, is anything missing or what should change, for:</p> <p>(a) the current situation;</p> <p>(b) why is this important;</p> <p>(c) opportunities for improvement; and/or</p> <p>(d) what the future looks like?</p>	<p><i>The use of the term and concept of “data ownership” is this section and throughout the document perpetuates a misperception that Australian law gives individuals ownership rights to data about them. It is recommended that this term is not used in the framework. The recent Productivity Commission Draft Report on Data Availability and Use (Chapter 1.3) includes more information about this issue.</i></p> <p><i>Opportunities for improvement also include the systematic linkage of genomic data to</i></p>



Section of Framework		Question	Response
			<i>phenotype data through Australia's existing data linkage infrastructure (the Population Health Research Network).</i>
<b>Implementing the Framework</b>	Pg. 39	28. Is the suggested approach to implementing the Framework reasonable and appropriate? Please explain your answer.	
<b>Overarching questions (Relates to the entire Framework)</b>	Pg. 39	29. Is the structure of the Framework appropriate and easy to follow? Please explain your answer.	
		30. How could the review and evaluation of the Framework be strengthened?	
		31. Do you have any other feedback on the Framework?	
		32. Are there any issues you would like covered at the stakeholder consultation forums in February	

Section of Framework		Question	Response
		2017?	
<b>Genomics Framework One Page Outline and the Companion Document</b>		33. Do you have any feedback on the Genomics Framework One Page Outline (noting that it provides a summary of the Framework) or the Companion Document?	