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AUSTRALIAN BUREAU OF STATISTICS

National Health Measures Study

Privacy Impact Assessment

7 September 2021

Contents

Part A EXECUTIVE SUMMARY

1. Introduction

1.1 Maddocks is pleased to provide this privacy impact assessment (**PIA**) report to the Australian Bureau of Statistics (**ABS**) in respect of the 2022-2023 National Health Measures Study (**NHMS**).

1.2 The Department of Health (**Health**) has engaged the ABS to undertake the Intergenerational Health and Mental Health Study (**IHMHS**) in 2020-2023. The ABS will deliver a suite of health surveys that collectively form the IHMHS, including the NHMS, which is the biomedical component of the IHMHS.

1.3 The purpose of the IHMHS is to capture statistics related to mental health and wellbeing, health status, risk factors, nutrition, physical activity, biomedical status and dietary intake, and it will be the most complete picture ever compiled of Australia's physical and mental health.

1.4 The purpose of the NHMS is to collect additional information from study participants on selected biomedical markers of chronic disease, nutrition and environmental measures. It is intended that this information will have a direct influence on improving health policy and delivery of services across Australia. The NHMS will look at approximately 20 specific health indicators and forms the biomedical component of the IHMHS as it involves the collection of blood and/or urine samples.

1.5 We note that unlike many other studies undertaken by the ABS, participation in the NHMS is completely voluntary and consent based (i.e. it will not be an offence under section 14 of the *Census and Statistics Act 1905* (Cth) to not participate in the NHMS). Further, consent to participate in the NHMS can be withdrawn by a Participant at any time.

1.6 The implementation of the NHMS has also offered the opportunity for the Australian Government to consider the establishment of a biobank. There are a number of biobanks that are currently operating in Australia, but none at the Commonwealth level. This biobank would be a national research asset, with access to the samples in the biobank granted for approved research projects only (**Biobank**). Health is in the process of engaging a Commonwealth government entity to perform the important function of being the entity responsible for establishing and operating the Biobank (the **Biobank Custodian**).

1.7 In addition to seeking consent to participate in the NHMS, the ABS will also seek the informed consent of participants in the General Population component of the NHMS to store their collected biomedical sample(s) in the Biobank for the purposes of future health research, including potentially genomic testing. This is a separate (though related) process to that of the implementation of the NHMS. In this report we refer to '**Process 1**' as relating to the NHMS and '**Process 2**' in relation to the Biobank.

1.8 Ensuring public trust in the ABS' implementation of the NHMS will be crucial to the future undertaking of any similar studies. The ABS has commissioned this PIA to help foster that trust and to assist in ensuring that privacy risks are appropriately considered and addressed throughout the development and implementation of the NHMS.

1.9 While the arrangements for the establishment of the Biobank are at an early stage of development, the ABS has also commissioned this PIA report to consider, at a high level, privacy issues with the establishment of the Biobank, particularly given ABS's crucial role in collecting the necessary consents for long term storage and use of biomedical samples covered under Process 2 (Biobank). It is acknowledged that the consideration of privacy impacts for Process 2 will need to be further considered as the arrangements for the Biobank are considered. This PIA report is intended to inform this further work.

2. This PIA process

2.1 This PIA:

2.1.1 considers compliance with the *Privacy Act 1988* (Cth) (**Privacy Act**), including the Australian Privacy Principles (**APPs**);

2.1.2 sets out the information flows (including visual information flows at **Attachment 1** for Process 1 and Process 2), which helps to highlight privacy risks and areas for improvement in terms of risk mitigation;

2.1.3 is intended to help the ABS manage identified privacy risks and impacts in respect of the NHMS

2.1.4 considers the safeguards that have been, or should be, put in place to secure personal information from misuse, interference or loss, or from unauthorised access, modification or disclosure;

2.1.5 provides high level guidance to inform the development work on the Biobank; and

2.1.6 may be used as a reference tool for stakeholders when discussing privacy elements and risks associated with the conduct of the NHMS and the establishment and management of the Biobank.

3. Summary of findings

3.1 We consider that ABS has taken a proactive approach to considering and addressing privacy risks associated with the implementation of the NHMS, demonstrating its commitment to incorporating 'privacy by design' into its processes. We also note that the processes for the Biobank are currently evolving but see that undertaking a PIA at this early stage as a positive step, by providing the opportunity to ensure that associated privacy risks are identified early, so that safeguards for protecting privacy can be built into the design for the operation of the Biobank.

3.2 We have identified that further work needs to be undertaken to address potential privacy risks in relation to the following:

3.2.1 that the proposal to bundle consent of Participants to participate in the NHMS, with consent for data linkage with other ABS datasets (such as, as the Multi-Agency Data Integration Project (**MADIP**)), may not meet community expectations;

3.2.2 the need to consider whether the proposed consent processes for the handling of Participant personal information for the Biobank meet privacy best practice;

3.2.3 the desirability of there being further communication to the public with clarity about the intended processes for operation of the Biobank, prior to the NHMS commencing;

3.2.4 that Participants may not have adequate time to consider all relevant information before consenting to have biomedical samples stored in the Biobank; and

3.2.5 the need for all reasonable steps to be taken by the entities involved in the implementation of the NHMS and the Biobank to secure personal information from misuse, interference or loss, or from unauthorised access, modification or disclosure, including ensuring contractual arrangements include necessary privacy and security protections.

3.3 Set out in **Table 1** below is a summary of the compliance of Process 1 (NHMS) and Process 2 (Biobank) against the APPs. A finding of 'Compliant' indicates that the APP is either not relevant in the circumstances or that we have concluded that no further mitigation steps are required. A finding of 'Compliance can be further enhanced' indicates that we have identified issues that are not significant, but which we consider should be addressed in order to further enhance the privacy protections for Participants. A finding of 'Further work required' indicates that more extensive work is required before the ABS and the Biobank Custodian will be able to be fully satisfied about compliance with the relevant APP and best privacy practice. In this respect, we note that the latter findings are all in relation to Process 2 (Biobank), which is still at an early stage of development.

Table 1: Summary of compliance against the APPs

APP	Content of APP	Findings: Process 1 (NHMS)	Findings: Process 2 (Biobank)
APP 1	open and transparent management of personal information	Compliance can be further enhanced	Further work required
APP 2	anonymity and pseudonymity	Compliant	Compliant
APP 3	collection of solicited personal information	Compliance can be further enhanced	Further work required
APP 4	dealing with unsolicited personal information	Compliant	Compliant
APP 5	notification of the collection of personal information	Compliance can be further enhanced	Further work required to be fully compliant
APP 6	use or disclosure of personal information	Compliance can be further enhanced	Further work required
APP 7	direct marketing	Compliant	Compliant
APP 8	cross-border disclosure of personal information	Compliant	Compliance can be further enhanced
APP 9	adoption, use or disclosure of government related identifiers	Compliant	Compliant
APP 10	quality of personal information	Compliant	Further work required
APP 11	security of personal information	Compliant	Further work required
APP 12	access to personal information	Compliant	Compliant
APP 13	correction of personal information	Compliant	Compliant

3.4 The above risks (including the level of compliance with the APPs), have been considered throughout this PIA report. The recommendations set out in paragraphs 4 and 5 of this **Part A** are designed to address the identified risks and further enhance privacy protections, and/or further strengthen compliance with the APPs.

4. Recommendations in relation to Process 1 (NHMS)

4.1 This PIA makes the following recommendations in relation to Process 1 (NHMS):

Recommendation 1 **ABS implement further openness and transparency measures**	**Relevant APPs**
Recommendation 1.1: We **recommend** the ABS consider publishing this PIA report, or a summary form outlining its findings and recommendations, on its website.	**APP 1**
Recommendation 1.2: We **recommend** the ABS consider developing scripts for its contact centre staff to use when responding to questions from Participants about the NHMS and the Biobank (noting that once the Biobank is operational the Biobank Custodian will be primarily responsible for responding to queries about the Biobank), including in particular the role of the ABS in relation to the two processes.	
Recommendation 1.3: We **recommend** the ABS consider working with the Biobank Custodian on the scripts or other materials it will use in connection with Biobank and the NHMS, to ensure consistency in messaging.	

Recommendation 2 **Revising nature of consent for the NHMS**	**Relevant APPs**
We **recommend** that the ABS review the proposed Tier 1 consent which bundles participation in the NHMS with data linkage of results from the NHMS to the MADIP, to determine whether it is practicable to unbundle these consents, so that Participants are provided with choice about how information about them is used. If for operational reasons the ABS considers it undesirable or not feasible to unbundle the consents in Tier 1, the ABS should explain its reasoning as to why they are bundled in any publicly available information (such as in the Participant Information Sheets, 'frequently asked questions' document and/or in any collection notice), so that Participants can make informed choices about participating in the NHMS. The position ABS ultimately reaches on data linkage will need to be reflected in the collection notice (see **Recommendation 3**).	**APP 3** **APP 6**

Recommendation 3 **Preparing simple collection notice for NHMS**	**Relevant APPs**
The relevant collection notice for the NHMS for APP 5 can form part of the Participation Information Sheets. We **recommend** that a layered approach is taken for the collection notice which will support collections, uses, disclosures for the NHMS. That is, a short notice is included in the relevant Participation Information Sheet with: • links or references to a publicly available website containing a more detailed collection notice, and more information (such as the ABS Privacy Policy for Statistical Information); and • a telephone number for people to call so they can listen to the full collection notice and relevant Privacy Policy or speak to someone if they have questions. The collection notice (and Privacy Policy) should be available in a range of languages (or there should be assistance for translation), and otherwise also in an accessible format. The AMSs and the Pathology Provider are APP entities, and as such will also be required to comply with APP 5 in connection with their collections of personal information as part of the NHMS. We recommend that the more detailed collection notice that is developed by the ABS also reference the collections by those entities, so that a specific collection notice is not required to be given by the entities in relation to their role in the NHMS.	**APP 3** **APP 5**

Recommendation 4 Protecting and strengthening privacy in arrangements with third parties	Relevant APPs
Recommendation 4.1: We **recommend** that the ABS ensure that its contractual arrangements with the Pathology Provider include obligations designed to facilitate the ABS' ability to be open and transparent about the handling of personal information (such as, if applicable, a requirement to provide any information about the NHMS and the handling of Participant Information to Participants, either as required or as directed by the ABS).	**APP 2** **APP 3** **APP 4** **APP 5** **APP 6** **APP 8** **APP 9** **APP 10** **APP 11** **APP 12** **APP 13**
Recommendation 4.2: We **recommend** that the ABS ensure that its contractual arrangements with the Pathology Provider include the ability to provide a protocol or direction that Pathology Provider personnel are required to adhere to (for example, relating to the checking of consent forms and information inputted into the Pathology Provider ICT systems) to ensure that ABS receives quality personal information and to mitigate risk of mis-handling.	
Recommendation 4.3: We **recommend** that the ABS ensure that its contractual arrangements with the Pathology Provider include provisions that expressly prohibit the storage, and disclosure, of Participant Information to any overseas entity for any reason without ABS' consent (particularly including in relation to any storage of data, or data processing, analysis or interpretation services).	
Recommendation 4.4: We **recommend** that the ABS ensure that its contractual arrangements with the Pathology Provider include provisions to expressly provide that the Pathology Provider cannot use any personal information for direct marketing purposes.	
Recommendation 4.5: We **recommend** that the ABS ensure that its contractual arrangements with the Pathology Provider include provisions that require the Pathology Provider to implement appropriate measures to ensure any subcontractor's handling of Participant Information is appropriate (i.e. information disclosed by, and collected from the Central Pathology Laboratory).	
Recommendation 4.6: We **recommend** that the ABS ensure that its contractual arrangements with the Pathology Provider include provisions requiring the return of all documents with personal information or destruction of personal information collected in connection with the services provided as required by the ABS, including in particular provisions that require the Pathology Provider to delete the unique identifier after a certain period of time so that it does not retain this number.	

Recommendation 4.7: We **recommend** that the ABS ensure that its contractual arrangements with the Pathology Provider include provisions in relation to data quality and assurance steps that are required to be taken to minimise data corruption.	
Recommendation 4.8: We **recommend** that the ABS ensure that its contractual arrangements with the Pathology Provider include provisions in relation to data security obligations, including how the Pathology Provider must hold and transfer personal information to other entities as part of the contracted services.	
Recommendation 4.9: We **recommend** that the ABS ensure that its contractual arrangements with the Pathology Provider include provisions regarding a Notifiable Data Breach, with the requirement to consult with the ABS in handling any breach.	
Recommendation 4.10: If AMSs will be engaged directly by the ABS, we **recommend** that the ABS ensure it includes similar requirements to those in **Recommendation 4** (in relation to the Pathology Provider) in its arrangements with the AMSs.	

5. Recommendations in relation to Process 2 (Biobank)

This PIA makes the following recommendations in relation to the Biobank:

Recommendation 5 Openness and transparency measures for the ABS in relation to the Biobank	Relevant APPs
Recommendation 5.1 We **recommend** that, before commencement of the NHMS, the ABS consider confirming with the Biobank Custodian and Health the respective entities' role in the governance structure for the Biobank, and in particular any ABS role in relation to handling of any research results obtained from the use of biomedical samples in the Biobank by researchers. Any clarification could be supported by the development of a shared governance document which could provide clarity, for example, about ABS exercising its contractual rights against the Pathology Provider where the services of the Pathology Provider impact on the operations of the Biobank.	**APP 1**
Recommendation 5.2: We **recommend** that the ABS consider, once the ABS's role has been confirmed in relation to the Biobank, placing these governance arrangements on a publicly available website so that Participants interested in participating in the Biobank can refer to this information when deciding whether or not to give their consent (this ideally should be one website covering all Biobank related matters, with relevant links from ABS websites).	

Recommendation 6	Biobank Custodian to implement a full suite of openness and transparency measures	Relevant APPs
To ensure that personal information is managed in an open and transparent way in relation to the Biobank, we **recommend** that the Biobank Custodian, as part of developing its policies and processes, consider: • developing a consent framework or policy document setting out the reasoning for the consent processes that will be adopted for the Biobank (for example, tiered consent, or whether it will use dynamic consent tools) and how these will operate in practice (what the consent covers, how it can be withdrawn, implications of withdrawal where research has already been undertaken, how it intends to deal with deceased persons, and data retention policies), and placing this on the Biobank website so that persons have a thorough understanding of the consent process including how it was developed; • after further development of its proposed policies and processes and consideration of the recommendations in this PIA report, undertaking a further new or supplementary PIA process to fully assess the Biobank information flows, particularly in relation to matters that have not been decided at this early stage, such as any risks arising from the identity of, or arrangements with, the Biobank Storage Facility operator; the use of any third party ICT provider in developing and managing systems; and any systems or tools to handle dynamic consent processes which have the potential to capture further personal information about individuals in connection with the Biobank; • publishing any PIA report it undertakes, or a summary form of its findings and recommendations, on a dedicated website for the Biobank (**Biobank website**); • developing a standalone Privacy Policy for the Biobank which it provides on the Biobank website; and • being as open and transparent as possible about the operation of the Biobank by placing any governance arrangements (particularly those relating to the roles of different government agencies in the operation of the Biobank) and any protocols developed (subject to the need to maintain any confidentiality in commercial in confidence material) on the Biobank website, ideally before the NHMS commences collecting personal information.		**APP 1**

Recommendation 7 Structure and content of consent documentation	Relevant APPs
We **recommend** that ABS and Biobank Custodian consider implementing the following structure for consent documentation provided to the Participants: • one Participation Information Sheet for the NHMS; • one Participation Information Sheet for the Biobank; • one Consent Form covering participation in the NHMS; • one Consent Form covering the Biobank with each Tier of consent (Tier 2 and Tier 3) clearly separated on the Form; • for Tier 2 and Tier 3 consents (and any other Tiers that may be determined in relation to the Biobank) Participants should clearly have the option at the beginning of the relevant section of the Form to indicate that they are not interested in that Tier; and • for Tier 2 and Tier 3 consents (and any other Tiers that may be determined in relation to the Biobank) Participants consent to be further contacted by the Biobank Custodian (which will allow further refinement of consent models in the future (e.g., the introduction of dynamic consent); The section in the Form relating to a Tier for the Biobank should include a series of statements that Participants are asked to agree with, such as, *"I understand and agree to the following: I have read and understood the Participant Information Sheet, My sample and personal information will be used in research studies, My sample and records will not include my name and contact details when sent to researchers");* We **recommend** that in developing the content of the Biobank Consent Form, the Biobank Custodian: • apply, as far *as* feasible, the strategies embodied by the *NSW Health Consent Toolkit* which provides a plain English approach to seeking informed consent in the context of biobanking; and • consider and apply research findings in relation to consent language in the biobanking context which includes using reassuring language, as set out in the work of Beskow et al, 'Developing model biobanking consent language: what matters to prospective participants?' BMC Medical Research Methodology, 119 (2020).	**APP 3** **APP 6**

Recommendation 8	Strengthening consent mechanisms for the Biobank	Relevant APPs
We **recommend** that the Biobank Custodian consider the feasibility of implementing a dynamic consent platform to provide an interface to support ongoing Participant-led management of their involvement in research studies conducted using samples in the Biobank**.** Any position reached on the implementation of dynamic consent (why it has been implemented or not implemented) should be published on the Biobank website. We **recommend** that the Biobank Custodian consider as part of establishing its process for the operation of the Biobank whether it is possible to have greater nuanced consent for the Biobank, that is, more tiers. For example, separate consents allowing Participants to choose to provide: • consent for particular categories of research (including genomic research); or • consent for specific projects only. All the above are premised on the assumption any future research must have the relevant ethics clearance.		**APP 3** **APP 6**

Recommendation 9	Biobank Custodian to prepare a simple collection notice	Relevant APPs
The relevant collection notice for Biobank required for APP 5 can form part of the Participation Information Sheets. We **recommend** that a layered approach is taken for the collection notice which will support collections, uses, disclosures for the Biobank. That is, a short notice is included in the relevant Participation Information Sheet with: • links or references to a publicly available website containing a more detailed collection notice, and more information (such as the Biobank Privacy Policy, more details about how information is used, and the consent framework in relation to the Biobank); and • a telephone number for people to call so they can listen to the full collection notice and relevant Privacy Policy or speak to someone if they have questions. The collection notice (and Privacy Policy) should be available in a range of languages and otherwise also be in accessible format.		**APP 3** **APP 5**

Recommendation 10 Protecting and strengthening privacy in arrangements with third parties	Relevant APPs
We **recommend** that the Biobank Custodian consider the privacy protections set out in **Recommendation 4** when entering into its arrangements (including with third parties) that involve handling of personal information in connection with the Biobank (so that Health can ensure the appropriate protections are built into its arrangements with the Biobank Custodian).	**APP 2** **APP 3** **APP 4** **APP 5** **APP 6** **APP 8** **APP 9** **APP 10** **APP 11** **APP 12** **APP 13**

Part B METHODOLOGY AND ASSUMPTIONS

6. Our methodology

6.1 PIA has been conducted in accordance with the *Privacy Impact Assessment Guide* (**PIA Guide**) issued by the Office of the Australian Information Commissioner (**OAIC**), using the following methodology.

Stage	Description of steps
1.	**Plan for the PIA:** We have reviewed relevant background material provided by the ABS (as set out in **Attachment 2**) and were briefed by officers from the ABS. We discussed the intention behind the collection of personal and sensitive information through the NHMS and clarified our understanding of the technical and other arrangements for the NHMS. We discussed and agreed the scope and timeframes for carrying out this PIA. We provided the ABS with a report that outlined a project plan (including a timetable for meeting PIA milestones), and the scope of the PIA.
2.	**Stakeholder consultation:** Given the significance of the NHMS and the establishment of a Biobank at the Commonwealth level, the ABS recognised that community consultation was desirable to inform the PIA report. We attended a series of workshops with a range of stakeholders conducted by the ABS. A summary of the feedback from this consultation is described in **Part E,** and a copy of the Consultation Report is at **Attachment 4**. When undertaking our analysis and forming our views about risks, we have considered: • issues raised by stakeholders in the consultation sessions that we attended, together with further feedback provided by stakeholders after receiving the Consultation Report; • published material, including NHMRC guidelines; and • our research about reasonable community expectations of privacy. For example, the *Australian Community Attitudes to Privacy Survey 2020* (**OAIC Survey**) commissioned by the OAIC contains useful information regarding current community expectations, including about the level of trust in government agencies' handling of personal information.
3.	**Privacy impact analysis and compliance check:** In this step we focussed on compliance against each APP and privacy best practice. The analysis set out in this PIA is consistent with the *Australian Privacy Principles Guidelines* (**APP Guidelines**) issued by the OAIC, which outline the mandatory requirements of the APPs, how the OAIC will interpret the APPs, and matters that may be taken into account when assessing the ABS's (and the Biobank Custodian's) compliance with the Privacy Act.
4.	**Privacy management and addressing risks:** We considered potential mitigation strategies that could reduce or remove the privacy impacts and risks identified during the previous step.
5.	**Recommendations:** From the steps referred to above, we developed our recommendations, designed to remove or reduce privacy risks.
6.	**Draft report:** We prepared a draft version of this PIA report.
7.	**Further stakeholder engagement:** The ABS provided a draft of this PIA report to key stakeholders for further comment. We received and considered comments about the draft PIA report to refine the potential mitigation strategies and recommendations.
8.	**Report:** We finalised this PIA report.

6.2 We understand that the ABS will review this PIA report, in consultation with other stakeholders as required, and separately respond to our recommendations.

6.3 A glossary of defined terms and acronyms is at **Part H** of this PIA report.

7. Assumptions and Qualifications

7.1 We have conducted our analysis on the basis that the factual information provided by the ABS (as set out in **Part C** of this PIA report) is up-to-date, correct and complete (as at the date of the analysis).

7.2 This PIA has been undertaken from the perspective of the ABS, covering matters under its control under Process 1 (NHMS), including the collection of consents necessary for the disclosure of personal information to, and the further use and disclosure by, the Biobank Custodian. However, this PIA also covers matters in Process 2 (Biobank) on a principles basis, to inform and guide the work of the Biobank Custodian.

7.3 This PIA has not been conducted from the perspective of any other entity, such as the Pathology Provider (except to the extent where we have identified matters that would further ensure the protection of privacy for study participants in the NHMS and Biobank).

7.4 We note that the ABS has processes in place for considering privacy impacts associated with the integration of data into the Multi-Agency Data Integration Project (**MADIP**) and has conducted a number of privacy impact assessments in relation to MADIP. This PIA does not seek to re-examine those processes.

Part C PROJECT DESCRIPTION AND INFORMATION FLOWS

8. Overview of the National Health Measure Study

8.1 As part of the IHMHS, the ABS will conduct the:

8.1.1 National Study of Mental Health and Wellbeing;

8.1.2 National Health Study (**NHS**) - including the National Health Survey and the National Aboriginal and Torres Strait Islander Health Survey;

8.1.3 National Nutrition and Physical Activity Study (**NNPAS**) - including the National Nutrition and Physical Activity Survey and the National Aboriginal and Torres Strait Islander Nutrition and Physical Activity Survey; and

8.1.4 the 2022-2023 National Health Measures Study (**NHMS**) including the National Health Measures Survey and the National Aboriginal and Torres Strait Islander Health Measures Survey.

8.2 The NHMS is the biomedical component of the IHMHS and will involve the collection of blood and/or urine samples. Individuals already participating in the NHS and NNPAS components of the IHMHS will be invited to participate in the NHMS (**Participants**[1]). Participation in the NHMS is completely voluntary and consent based. Consent to participate in the NHMS can be withdrawn by a Participant.

8.3 The purpose of the NHMS is to collect additional information from Participants on selected biomedical markers of chronic disease, nutrition and environmental measures. It is intended that this information will have a direct influence on improving health policy and delivery of services across Australia. The NHMS will look at approximately 20 specific health indicators.

8.4 The biomedical information collected from the NHMS will be de-identified and combined with other IHMHS survey data to measure for markers of chronic disease and health risk factors, including measuring for:

8.4.1 the prevalence of diagnosed and undiagnosed chronic disease (e.g. cardiovascular disease, chronic kidney disease and Type 2 diabetes);

8.4.2 levels of nutrients associated with biomedical risk factors (e.g. sodium and potassium);

8.4.3 levels of nutrients where food is not the only source of nutrition (e.g. vitamin D absorbed through the skin);

8.4.4 levels of nutrients subject to food fortification programs (e.g. folate and iodine);

8.4.5 prevalence of nutrient deficiencies (e.g. iron and vitamin B12); and

8.4.6 an Australian baseline/reference standard of per- and poly-fluoroalkyl substances (**PFAS**) levels of exposure.

[1] In this PIA, a reference to a 'Participant' covers a person who has been invited to participate in the NHMS and a person who has consented to participate (as discussed at section 8.20, **Step 5** below), unless specifically distinguished.

8.5 The NHMS will be comprised of Participants from the following cohorts:

8.5.1 children who are between the ages of 5 - 11 years (however if a child in this age group does participate, they will only provide a urine sample and not a blood sample with the consent of their Parent, Legal Guardian or Legally Authorised Representative (**Guardian**));

8.5.2 children between the ages of 12 -17 years (who may provide a urine and/or blood sample with the consent of their Guardian); and

8.5.3 adults aged 18 years and over.

8.6 ABS is looking to receive samples from children and adults split across two collections – one for Aboriginal and Torres Strait Islander peoples (**Indigenous Population**) and one for the rest of the population (**General Population**).

8.7 Participants will be provided a gift card[2] from the ABS when they provide a biomedical sample for the NHMS, in recognition that Participants may have incurred costs to provide the sample (such as, childcare or travel expenses). This PIA report refers to this as the **Reimbursement Arrangement**.

8.8 The ABS has engaged Sonic Pathology Australia Pty Ltd (**Pathology Provider**) to provide the pathology services for the NHMS. The biomedical samples will be collected from Participants at a collection centre of the Pathology Provider (**Pathology Collection Centre**), or other facilities, such as Aboriginal Medical Services (**AMS**)[3] for Participants who identify as Aboriginal and Torres Strait Islander people. The Pathology Provider will transport the biomedical samples from the place of collection to a central laboratory where the testing of the Participant's biomedical sample will occur (**Central Pathology Laboratory**). The Central Pathology Laboratory is run by Douglass Hanly Moir Pathology Pty Ltd. Both Sonic Pathology Australia and Douglass Hanly Moir Pathology are members of the Sonic Healthcare group.

8.9 The NHMS data collected will also be compared with health measures surveys through a time series comparison of population results from the previous national health measures study undertaken in 2011-2013.

8.10 For completeness, we understand that the ABS undertook a pilot study in April-May 2021, which was designed to test the effectiveness of the processes to be used by the NHMS as described in this **Part C - Project Description** (but which did not involve any data integration or long-term storage of samples). The conduct of this pilot study is not within the scope of this PIA, but we understand that the ABS will use its evaluation of the pilot study, in combination with this PIA report, to inform the final design of the NHMS.

[2] Under the Reimbursement Arrangement, each Participant (rather than each household) will receive a gift card.
[3] The arrangements for utilising AMSs are still being considered, but it is likely that they will involve direct contractual arrangements with the ABS.

Storage of biomedical samples in the Biobank

8.11 The ABS will also seek as part of the NHMS the informed consent of adult Participants from the General Population study only to store the Participant's collected biomedical sample(s) in the **Biobank** indefinitely for the purposes of future health research, including potentially genomic testing. Biomedical samples for Biobank storage will not be collected from minors. The Biobank is a national research asset with access to the samples in the Biobank granted to approved researchers for approved research projects only[4]. Access will be strictly assessed in terms of whether the proposed research will contribute to improving the health and wellbeing of the Australian population. Proposed research projects which seek to use the collected biomedical samples will also require separate ethics approval.

8.12 Health is in the process of engaging a Commonwealth government entity to establish and manage the Biobank (referred to as the '**Biobank Custodian**'), including to manage access to the biomedical samples in the Biobank.

8.13 The biomedical samples will be stored in a custom facility (**Biobank storage facility**) arranged by the Biobank Custodian.

NHMS and Biobank Processes

8.14 The processes for the handling of personal information for the NHMS and the Biobank are two distinct processes. For convenience, we refer to these overarching processes in this PIA report as:

8.14.1 **Process 1** - which includes the 'ABS controlled' process for the conduct of the NHMS (as discussed in detail at section 9 below) and involves:

(a) selection of Participants, initial interview of Participants and follow-up (**Steps 1, 2** and **3**);

(b) Pathology Provider collection of consents and collection of biomedical samples (including seeking consent for the Biobank) (**Steps 4** and **5**);

(c) Pathology Provider testing of biomedical samples (**Steps 6** and **7**);

(d) Pathology Provider disclosure of Participant Information and Participant Results to the ABS, and collection of information by the ABS (**Step 8**);

(e) use and analysis of the data that is derived from the biomedical testing by ABS, including integration of the data into the MADIP (**Step 9**); and

(f) Pathology Provider disclosure of Participant Information and Participant Results to others (**Step 10**); and

8.14.2 **Process 2** – which includes the 'Biobank Custodian controlled' processes relating to the establishment and operation of the Biobank (discussed in detail at section 10 below) and involves:

(a) storage of the biomedical sample in the Biobank storage facility and destruction of samples (**Step 11**);

(b) disclosure of information by the Pathology Provider to the Biobank Custodian (**Step 12**);

(c) collection, storage and use of the personal information associated with each biomedical sample by the Biobank Custodian (**Steps 12** and **13**); and

[4] We understand that approved research projects will include both commercial (i.e. pharmaceutical) and non-commercial research. Commercial research projects that will be excluded from access to biobank samples are likely include food, tobacco and insurance research.

(d) governance arrangements controlling access to and use of the biomedical sample for purposes of research or genomic testing (**Step 14**).

9. Process 1: How the NHMS will be undertaken

9.1 Set out below is the process for the NHMS. We note that many of the Steps undertaken below may not happen in a sequential order. Some Steps may occur concurrently.

Step 1: ABS selects individuals to participate in the NHMS

9.2 The ABS will **use** information collected and held about NHS and NNPAS participants to select persons to participate in the NHMS. The ABS maintains the ABS Address Register, an up-to-date, comprehensive list of all known physical addresses within Australia (this ABS Address Register does not include any personal information). From the ABS Register, the ABS uses a 'list-based frame' to select units in the survey population to identify a list of potential participants.

9.3 The ABS has a list-based frame for dwellings participating in the NHS and NNPAS. From the randomly selected dwellings the pool of participants will be further refined to randomly selected adults and children (if any) residing in the household. The personal information of NHS and NNPAS participants is collected and held by ABS. From this existing pool of the survey population, ABS will be inviting these selected adults and children to participate in the NHMS.[5]

9.4 The ABS provides a brief letter to selected dwellings notifying householders that their dwelling has been selected to participate in the NHS, NNPAS and NHMS. For Aboriginal and Torres Strait Islander people being selected in the National Aboriginal and Torres Strait Islander Health Survey and the National Aboriginal and Torres Strait Islander Nutrition and Physical Activity Survey, an ABS Interviewer approaches the household directly and provides participant materials.

Step 2: ABS collects personal information from Participants

9.5 ABS interviewers, after conducting a face to face interview for the NHS or NNPAS, will ask:

9.5.1 the individual if they are willing to participate in the NHMS; and

9.5.2 if applicable, the Parent, Legal Guardian or Legally Authorised Representative of the selected child (**Guardian**) if they are willing to consider consenting to the child's participation in the NHMS.

9.6 If the individual expresses a willingness to participate in the NHMS (including for their child, if relevant), the ABS Interviewer will **collect** contact information from the Participant to facilitate the Reimbursement Arrangement and for any follow-up contact. The information collected will include the Participant's:

9.6.1 name (and where the Participant is a child, the name of their Parent/Legal Guardian/Legally Authorised Representative);

9.6.2 contact email address;

9.6.3 contact phone number; and

9.6.4 postal address (if the Participant does not provide a contact email address or phone number).

[5] Those who consent to participate in the NHMS are defined as Participants for the purposes of this PIA.

9.7 The ABS Interviewer will ask for the Participant's consent to be contacted as a reminder or 'follow-up' if they do not attend a Collections Centre for the collection of their biomedical sample despite indicating that they are willing to participate in the NHMS. This will be a new **collection** of personal information by the ABS.

Information provided to Participants

9.8 The ABS Interviewer will then provide to the Participant:

9.8.1 **Participant Information Sheets** (which may also be known as a 'brochure') providing information covering Process 1 (NHMS) and Process 2 (Biobank), regarding:

(a) what biomedical samples will be collected;

(b) why biomedical samples will be collected;

(c) potential side effects from having a biomedical sample collected;

(d) what biomedical samples will be tested for;

(e) how personal and health information will be treated, this includes that blood and/or urine sample will be analysed as part of the NHMS, test results will be provided to the ABS, and the ABS will link the individual's test results with their other IHMHS results, and other data sets such as the MADIP (that is, by consenting to participate in the NHMS, the Participant will be consenting to these uses of their test results by the ABS) (referred to as '**Tier 1**' consent in this PIA report);

(f) providing additional samples for use in future research (including genomic testing) for Process 2 (Biobank);

(g) the Reimbursement Arrangement for the NHMS; and

(h) contact details for any queries or complaints that Participants may have, including an 1800 phone number to call if the Participant has any questions regarding the NHMS and/or the Biobank[6]

9.8.2 a **Referral and Consent Form for NHMS** that the Participant is to provide to the Pathology Collection Centre or AMS as relevant (and which will later be provided to the ABS electronically) that includes:

(a) the **referral** section of the Referral and Consent Form for NHMS facilitates the collection and analysis of biomedical samples. It is anticipated that the referral section will include the following information:

(i) ABS Reference Number – which will be affixed by the ABS Interviewer;

(ii) age and gender of the Participant – to be completed by the ABS Interviewer;

(iii) Patient Details (name, date of birth, residential address, phone number) – to be completed by the Participant;[7]

(iv) email address - to be completed by the Participant if they wish to receive a copy of their test results by email instead of by mail;

[6] Participants can also contact the ABS or Biobank Custodian to withdraw their consent from participating in the NHMS and/or from the Biobank any point after the collection of their biomedical samples.
[7] For clarity, no information about a Participant or their results will be sent to the Participant's My Health Record as part of the NHMS.

(v) details of their medical practitioner - to be completed by the Participant if they would like a copy of their test results to be provided to their nominated medical practitioner (this will likely be their general practitioner (**GP**));

(vi) information about the pathology collection centre staff – to be completed by the relevant collection centre for the Pathology Provider;

(vii) health information (which is sensitive information) from the Participant about:

A. whether the Participant takes prescription medication (including for high cholesterol, diabetes, reduced kidney function, and reduced liver function);

B. whether the Participant is pregnant; and

C. whether the Participant regularly takes or uses supplements (including multivitamins, folate, B12, vitamin D, iodine, and iron);

(viii) a note to Pathology Provider collection staff outlining:

A. the blood sample and/or urine samples to collect for the NHMS; and

B. a mechanism to facilitate the collection of additional biological samples for the Biobank where a Participant consents to participate in the Biobank[8]; and

(b) the **consent** section for adult Participants, which is intended to capture the Participant's consent to participate in the NHMS and is proposed to include the following wording:

I have read and understood the information in the brochure. I give permission for my blood and/or urine samples to be analysed as part of the National Health Measures Survey and for the test results to be provided to the Australian Bureau of Statistics; and

(c) for Guardians to Participants that are minors, that they consent to the collection of the relevant biomedical samples of the minor[9] and their analysis as part of the NHMS; and

9.8.3 a **Biobank Consent Form**:

(a) which is intended to capture the Participant's consent to:

(i) the collection and long-term storage and use of biomedical samples in the Biobank for health-related research purposes (Participants must have consented to participate in the NHMS as described in order to consent to this) (referred to as '**Tier 2**' consent in this PIA report); and

(ii) genomic testing on stored biomedical samples in the Biobank (Participants must have consented to participate in the NHMS and the matters in paragraph (ii) in order to consent to this) (referred to as '**Tier 3**' consent in this PIA report); and

[8] This aspect of the form is still under development, and details of this mechanism are not yet known.
[9] See 8.5 for the samples collected from minor cohorts.

(b) which will be[10]:

(i) provided to the Pathology Collection Centre by the Participant (with the hardcopy later provided to the Biobank Custodian); or

(ii) provided to the Pathology Collection Centre by the Participant (with the hardcopy later provided to the ABS to provide to the Biobank Custodian); or

(iii) collected by the ABS interviewer from the Participant at the time of the household interview for NHS and NNPAS, with the hardcopy later provided by ABS to the Biobank Custodian.

Step 3: If required, the ABS uses the Participant's personal information to follow up

9.9 As stated above (at 9.7), if the Participant has indicated that they are willing to be contacted, staff within the National Data Acquisition Division (**NDAD**) of the ABS may **use** the Participant's contact information collected (outlined at 9.7) to either:

9.9.1 remind the Participant to attend a Pathology Collection Centre; or

9.9.2 ask if the Participant if they have changed their mind about participating in the NHMS.

9.10 This will be a new **use** of Participant's personal information by the ABS.

9.11 Only ABS staff within NDAD, with a 'need to know', will have access to the contact information collected by the ABS Interviewer. Further, only NDAD staff who have been identified as needing access will have access to the contact information. At the end of the survey period the contact information will be deleted in accordance with the ABS data retention policy.

9.12 In addition, the ABS Household Survey Centre Staff will also have access to a Participant's contact information and will **use** this personal information for the purpose of organising the Reimbursement Arrangement. Only select staff within the Centre who have a 'need to know' the Participant's contact information will have access to that information. Again, this will be a new **use** of the Participant's personal information by the ABS.

Step 4: Pathology Provider collects personal information when Participant attends Pathology Collection Centre

9.13 A Participant will attend a Pathology Collection Centre for the collection of their biomedical sample. At this point, the Participant will **disclose** their personal information to the Pathology Provider (or another entity that manages a Pathology Collection Centre). There will be a corresponding **collection** of a Participant's personal information by the Pathology Provider.

9.14 This results in a:

9.14.1 **disclosure** of Participant's personal information to the Pathology Provider by the Participant; and

9.14.2 corresponding **collection** of Participant's personal information by the Pathology Provider.

[10] The way that a completed Biobank Consent Form for a Participant will be handled is still being considered.

Step 5 Collection of biomedical samples

9.15 When the Participant attends a Pathology Collection Centre, staff at the Pathology Collection Centre will check that a Participant's Referral and Consent Form for the NHMS (and potentially the Biobank Consent Form, as discussed below) have been completed appropriately prior to taking any biomedical samples.

9.16 The information in the completed Referral and Consent Form for the NHMS will contain personal information and sensitive information about a Participant (as set out at paragraphs 9.8.2 and 9.8.2(a)) (**Participant Information**).

9.17 The Pathology Collection Centre will then collect the biomedical sample(s) (if the Participant has consented to their biomedical sample(s) being stored in the Biobank, an additional amount of specimen will be collected for this purpose (**Secondary Sample**)). It is only at this time that a Participant is considered to have consented to participate in the NHMS.

9.18 This **Step 5** results in:

9.18.1 a **disclosure** of Participant Information by a Participant to a Pathology Collection Centre; and

9.18.2 a corresponding **collection**[11] and **use** of Participant Information by the Pathology Provider when it checks a Participant's Referral and Consent Form for the NHMS for completeness (including whether a particular test can be undertaken);

9.19 **Step 5** also involves **collection** of a Participant's biomedical samples by the Pathology Collection Centre for the NHMS and if relevant, for the Biobank.

Step 6: The Pathology Provider transfers biomedical samples for testing[12]

9.20 When a Pathology Collection Centre receives the completed and properly executed Referral and Consent Form for the NHMS, staff at the Pathology Collection Centre will scan the Referral and Consent Form for the NHMS and save electronic copies of the form onto the Pathology Provider's ICT system.

9.21 An electronic copy of the Referral and Consent Form for the NHMS will be sent by the Pathology Provider to the ABS via a Secure File Transfer Protocol (**SFTP**). The hardcopy form will be destroyed by the Pathology Provider. (However, this process is yet to be confirmed).

9.22 As indicated above at paragraph 9.8.3(b), consideration is still being given as to whether the Pathology Provider will handle the hardcopy Biobank Consent Forms.

9.23 In circumstances where a Collection Centre, other than one run by the Pathology Provider (for example an AMS) collects the biomedical sample(s) and the Participant's Referral and Consent Form for the NHMS, the biomedical sample(s) will be labelled and transported to the Central Pathology Laboratory where the information from the Form will be entered on the Pathology Provider's ICT system. The AMS will not be using Participant Information other than to label vials or specimen jars.

9.24 This **Step 6** results in:

9.24.1 **use** of Participant Information by the Collection Centre, or the Central Pathology Laboratory, to update the Pathology Provider's ICT systems;

[11] The collection of personal information by the Pathology Provider is subject to the Pathology Provider's usual business-as-usual processes, including the provision of any relevant privacy statements

[12] **Step 9** deals with transfer of the biomedical samples to the Biobank

9.24.2 **use** of Participant Information by the Pathology Provider, or the AMS, to organise the transfer of the biomedical samples to the **Central Pathology Laboratory** for testing;

9.24.3 **disclosure** of Participant Information (via a separate attendance file) to the ABS to notify the ABS that the Participant has attended a Pathology Collection Centre. This will result in a corresponding **collection** of new personal information by the ABS.

Step 7: Central Pathology Laboratory undertakes testing on biomedical samples

9.25 The Central Pathology Laboratory will undertake testing on the biomedical samples. Participants' test results, which will be health information about Participants (**Participant Results**), will be uploaded to the Pathology Provider's ICT systems. This will be a **disclosure** of Participant Information and Participant Results from the Central Pathology Laboratory to the Pathology Provider, and corresponding **collection** by the Pathology Provider.

9.26 It is anticipated that biomedical samples for the NHMS will be destroyed after seven days of arriving at the laboratory, in accordance with standard clinical waste destruction procedures. However, a longer period of retention may be required depending on the sequencing of PFAS testing. All biomedical samples for the NHMS will be destroyed after the finalisation of PFAS testing (i.e. June 2024). Participant Results will be retained by the Pathology Provider in accordance with established standard practice.

9.27 Where the Participant has provided additional biomedical samples for storage in the Biobank, these samples will be retained by the Central Pathology Laboratory until **Step 11** can occur.

Step 8: The Pathology Provider discloses Participant Information to the ABS

9.28 The Pathology Provider will **disclose** Participant Results (**collected** under **Step 7**) to the ABS via a SFTP. The test results will be accompanied with Participant Information, including the Participant's:

9.28.1 ABS Reference Number;

9.28.2 age;

9.28.3 sex;

9.28.4 sensitive information (including health information).

9.29 There will then be a corresponding **collection** of new personal information (Participant Results) about Participants by the ABS.

Step 9: ABS undertakes analysis

9.30 The ABS will use the test results of Participants in accordance with the NHMS protocols. This will involve de-identifying and aggregating the data, to draw health insights from the data and comparison of the aggregate results from the previous NHMS 2011-2013. To facilitate this, the test results will be merged (linked) with survey responses from the NHS or NNPAS progressively throughout the survey cycle through the unique identifier allocated to the Participant at the time of interview.

9.31 After all NHMS data is collected (in early 2024), the ABS will use the standard process developed by the ABS for secure data linkage under the MADIP initiative to prepare the NHMS data for inclusion in, and storage and the use as part of, the MADIP dataset. This is a use of the NHMS data by ABS.[13]

Step 10: Pathology Provider discloses Participant's test result to others

9.32 The Pathology Provider will **disclose** a Participant's test results to:

9.32.1 a Participant, through a phone call where a 'critical limit threshold' has been reached that indicates that the Participant should seek urgent medical attention;

9.32.2 a Participant, by mail, if the Participant has chosen to receive a copy of their test results in this manner via the Referral Form;

9.32.3 a Participant, by email (instead of through mail), if the Participant has chosen to receive a copy of their test results in this manner via the Referral Form;

9.32.4 a Participant's regular GP, if:

(a) the Participant has nominated for this to occur in their Referral Form; and/or

(b) the Participant has provided their regular GP's contact information, and the Participant's test result reaches a 'critical limit threshold'.

9.33 If further disclosures by the Pathology Provider, as described at paragraph 9.32 occur, there will be a corresponding **collection** of Participant Information by the permitted party.

10. Process 2: Biobank Processes

10.1 Set out below is the process related to the Biobank, which do not form part of the NHMS.

Step 11: Pathology Provider prepares samples to be transferred to the Biobank storage facility

10.2 Once the Central Pathology Laboratory has undertaken the necessary testing for the NHMS and provided results to the ABS and others, the Pathology Provider will transfer the Secondary Sample(s) (and potentially samples collected for the Study tests) to the Biobank storage facility[14] where the Participant has consented to this.[15]

10.3 It is anticipated that the Pathology Provider will:

10.3.1 **collect** an ABS unique identifier that will be associated with a particular biomedical sample for a Participant (this is likely to be included on the Referral Form); and

10.3.2 **use** the unique identifier attributed to samples for a Participant to prepare an 'inventory list', which will contain no identifying information.

10.4 The biomedical sample will be transferred for long term storage and will be accompanied by the inventory list.

[13] Throughout this process, personal identifiers and analytical information are never stored, accessed or used together. The ABS treats all MADIP data in the ABS environment, including administrative data, with standards appropriate for personal information regardless of whether the data contains personal information or not.
[14] The Biobank storage facility may be operated by a third party engaged by the Biobank Custodian.
[15] At this stage, it is envisaged that at the time of transferring Secondary Sample(s), left over urine samples from the NHMS tests and any pristine blood samples collected for the NHMS may also be transferred to the Biobank.

Step 12: Pathology Provider discloses Participant Information to the Biobank Custodian

10.5 It is anticipated at this stage, that the Pathology Provider will then **disclose** to the Biobank Custodian in relation to a Participant:

10.5.1 the physical copy of the executed Consent Form (which includes personal information, as outlined at 9.8.3) (though consideration is being given to whether the ABS will be responsible for this instead of the Pathology Provider);

10.5.2 Participant Information, being the Participant's:

(a) name;

(b) contact information; and

(c) the unique identifier allocated to the biomedical samples for a Participant.[16]

10.6 There will be a corresponding **collection** of personal information (described above) by the Biobank Custodian.

Step 13: the Biobank Custodian uses Participant Information

10.7 The Biobank Custodian will then **use** the Participant Information to:

10.7.1 process any withdrawal of the Participant's consent to store a Participant's biomedical samples (including to arrange for the destruction of the biomedical sample at the Biobank storage facility);

10.7.2 communicate with Participants on matters relating to the Biobank, including maintaining contact lists and distributing newsletters; and

10.7.3 identify potential research candidates on application from Researchers.

Step 14: Researchers may use biomedical samples in the Biobank

10.8 The Biobank Custodian will be responsible for managing requests by a Researcher for access to the stored biomedical samples for a research project. This will be in accordance with governance processes approved by Health.

10.9 Consideration is being given to the processes for this, but it is anticipated that the approved governance processes will include, at a minimum, the following requirements that:

10.9.1 Researchers will need ethics approval in order to use biomedical samples stored in the Biobank for a research project;

10.9.2 if a Researcher is provided with access to a sample to conduct an approved research project, the Researcher would not be provided with any identifying information about the Participant to whom the sample belongs; and

10.9.3 under the *National Statement on Ethical Conduct in Human Research* (**National Statement**), where information could be of significance to the health of a participant in a research project, or their relatives or other family members, Researchers should prepare and follow an ethically defensible plan to disclose or withhold the findings or results of the research (**Results Plan**).[17] A Results Plan would need to be approved as part of the ethics approval for any proposed research project.

[16] Consideration is being given to additional demographic information (such as age and gender) being provided to the Biobank Custodian by the ABS, or whether any additional personal information should be collected as part of the Biobank Consent Form.
[17] National Statement, Chapter 3.3: Genomic Research

10.10 It is intended that the governance processes for access to biomedical samples held in the Biobank will document who, under any Results Plan, will be responsible for conveying any significant findings to Participants in future research projects. If a Results Plan provides that the Researcher or a partnered genetic counsellor will convey any significant health findings to the Participant, then (noting that the Biobank Custodian will maintain details of Participants) the Biobank will enable contact to be made with the Participant. This will result in the **disclosure** of the Participant's personal information to the Researcher or to a partnered genetic counsellor. Correspondingly, the Researcher, or partnered genetic counsellor, will **collect** the Participant's personal information and **use** the personal information to convey the findings.

11. Summary of Steps

11.1 Simplified diagrams outlining the information flows for Process 1 (NHMS) and Process 2 (Biobank) are provided at **Attachment 1** to this PIA report.

Part D KEY CONCEPTS

12. Biomedical samples and personal information

12.1 As a PIA examines the impacts on personal privacy, a key threshold issue for this PIA is whether the Steps in Process 1 (NHMS) and Process 2 (Biobank) deal with the handling of 'personal information'.

12.2 Section 6(1) of the Privacy Act defines 'personal information' as:

> ***personal information*** means information or an opinion about an identified individual, or an individual who is reasonably identifiable:
> (a) whether the information or opinion is true or not; and
> (b) whether the information or opinion is recorded in a material form or not

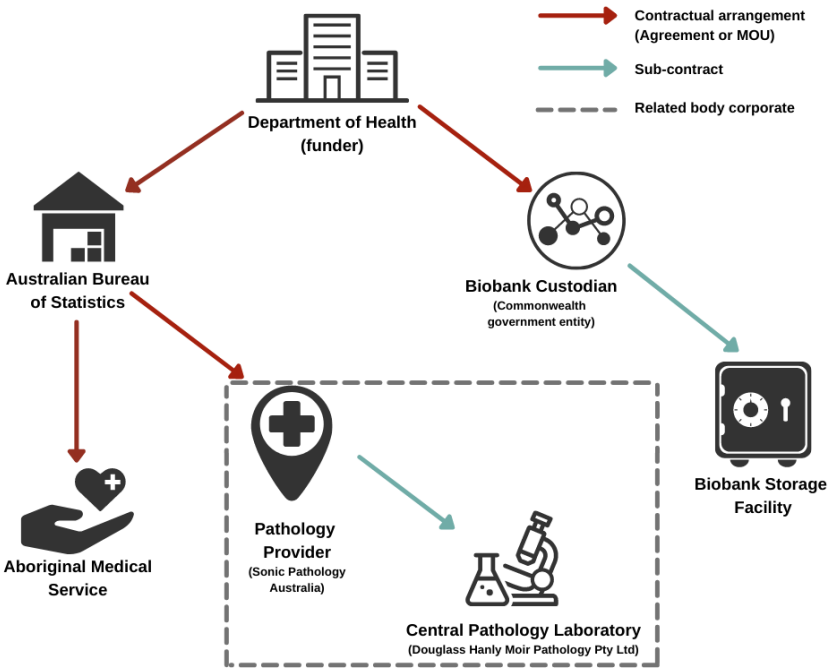
12.3 Biomedical samples for the NHMS and the Biobank are blood and urine samples of Participants. Applying the definition in the Privacy Act, a biomedical sample is not personal information because a biomedical sample, in and of itself, provides no information about an individual. If information was to be attached to the container in which the biomedical sample was stored (e.g., a label was attached to a vial), where that information was able to identify the person to whom the sample relates, that information would be personal information. The label may effectively disclose, for example, that the identified individual provided a biomedical sample for the NHMS.

12.4 When a biomedical sample is tested and analysed and results obtained as part of the NHMS, any results derived from the use of a biomedical sample will be personal information as those results will provide information about the relevant individual, such as, whether the person has high cholesterol. This will also be 'health information' (a form of 'sensitive information') under the Privacy Act. The Privacy Act has more stringent requirements in relation to the handling of sensitive information.

13. Entities involved in the delivery of the NHMS and Biobank

13.1 Set out below is a high level representation of the relationships between the relevant entities involved in delivering Process 1 (NHMS) and Process 2 (Biobank).[18]

[18] We note that for the purposes of the Biobank, it is likely that the Biobank Custodian would have arrangements with other entities, including, potentially an ICT provider for its systems, in addition to researchers seeking access to use any sample in the Biobank. However, this PIA does not examine those potential arrangements.



13.2 The Privacy Act applies to an 'APP entity'. Generally, an APP entity is either an 'agency' (which are largely Commonwealth government entities and/or office holders) or an 'organisation' (which include an individual, body corporate, partnership, unincorporated association, or trust). The obligations under the Privacy Act are mostly similar in their application to agencies and organisations, however there are some important differences.

13.3 An APP entity does not include:

13.3.1 a 'small business operator' which is an operator of a business with an annual turnover of less than $3 million (with some limited exceptions, such as organisations that provide a health service except in relation to an employee record);

13.3.2 a registered political party; or

13.3.3 a State or Territory authority.[19]

13.4 The table below summarises the application of the Privacy Act to the entities involved in the NHMS and Biobank.

[19] Privacy Act, s 6

Table 2: Application of Privacy Act to entities

Entity	Status as APP entity	Comment
Department of Health	Yes, as an agency	However, based on our understanding of intended arrangements, Health will not collect or hold any personal information of Participants. If this is the case, no requirements under the Privacy Act will apply to Health in connection with Participant Information.
ABS	Yes, as an agency	-
Biobank Custodian	Yes, as an agency (To be clarified)	The entity which is currently being considered for the role of Biobank Custodian is treated as an organisation in respect of its 'commercial activities' in accordance with s 7A of the Privacy Act. Given the funding arrangements for operation of the Biobank, we think it unlikely that the Biobank Custodian will be engaging in 'commercial activities' when acting as the Biobank Custodian and we have undertaken our analysis based on the assumption that it will be bound by the Privacy Act as an agency.
Sonic Pathology Australia (Pathology Provider)	Yes, as an organisation	Even if it is a small business operator, it provides a health service and therefore is an 'organisation'.
Douglass Hanly Moir (Central Pathology Laboratory)	Yes, as an organisation	Even if it is a small business operator, it provides a health service and therefore is an 'organisation'.
AMS	Yes, will be organisations	On the basis these provide a health service.
Operator of Biobank Storage Facility	Unknown	The arrangements for the Biobank Storage Facility have not yet been made. However, the operator of the Biobank Storage Facility will be receiving samples with no identifying information and therefore will not collect or hold any personal information about Participants.

14. Consent

14.1 In this section, we set out background information to contextualise our analysis of consent from a privacy lens for this PIA report.

14.2 Both the NHMS and the Biobank rely on the consent of individuals for participation. Consent was by far the most significant concern raised by stakeholders during consultation in relation to this PIA, as discussed in **Part E** – **Stakeholder Consultation and Community Expectations**. The literature on informed consent in the context of medical research is vast, with the issue of the use of samples in biobanks, in particular for genomic research, continuing to be a particular challenge, given its potential impact on persons broader than the research participant (such as family members).

14.3 A PIA's focus is on the handling of personal information, including when consent is required for an entity to collect, use and disclose personal information. An APP entity must comply with the APPs in the Privacy Act. An APP entity will also need to comply with any other relevant legislation, for example, any protected information provisions contained in its governing legislation (if relevant).

14.4 The ABS's activities are governed by the *Census and Statistics Act 1905* (Cth) and *Australian Bureau of Statistics Act 1975* (Cth). ABS's position is that the *Census and Statistics Act 1905* (Cth) does not cover the obtaining of consent for the NHMS (this is covered by the Privacy Act) but will cover how Participants Results are handled by the ABS once received (in addition to the Privacy Act). We understand that no specific legislation is intended to be introduced to govern the Biobank.

14.5 A consent to participate in research, whether a survey or medical research, is broader than a consent to handle personal information. In a consent to participate in research, the handling of personal information is a sub-component of the consents required for the research. Most notably researchers (including ABS for the NHMS) should meet the ethical requirements for research as set out in the *National Statement on Ethical Conduct in Human Research* (2007 - Updated 2018) (**National Statement**) for research involving human participants[20].

14.6 We note that while the elements required for informed consent under the Privacy Act and the National Statement are broadly the same, different terminology is used which can lead to confusion or persons unintentionally speaking at cross purposes. We consider some of the differences in terminology below.

Meaning of consent under the Privacy Act

14.7 For the purpose of the Privacy Act, consent can be express consent or implied consent. Though relying on implied consent raises particular risks. The word 'consent' is not further defined under the Privacy Act but in summary, there are four key elements that are needed in order to establish consent as expressed in the APP Guidelines:

14.7.1 the individual is adequately informed before giving consent;

14.7.2 the individual gives consent voluntarily;

14.7.3 the consent is current and specific; and

14.7.4 the individual has the capacity to understand and communicate their consent.

Consent for research

14.8 The National Statement provides that in seeking consent, researchers should consider:

14.8.1 the scope of the research and the information it will generate;

14.8.2 the plan for communication of findings;

14.8.3 health implications for participants and their relatives;

14.8.4 additional implications for participants and their families, such as insurance, employment, social stigma;

14.8.5 potential for reidentification;

14.8.6 any future sharing of information, including for research; and

14.8.7 future use of information and specimens, including commercial applications[21].

[20] It is beyond the scope of this PIA to consider the entirety of the National Statement.
[21] National Statement, at 3.3.10.

Informed consent models for research on stored biological samples

14.9 It is generally recognised that there are four primary models for consent for use of biological samples[22]:

14.9.1 *Specific consent* - Research participants are recontacted and asked to consent for each new use of their specimen or for information that is outside the scope of their original consent.

14.9.2 *Tiered consent* - At the time samples are collected, research participants are presented with a menu of options from which to choose, which may include general permission for future use, consent only for future uses related to the original study topic, consent for future uses unrelated to the original study topic, and specification that the investigators must obtain specific consent for any future use that differs from the original study.

14.9.3 *General permission* (referred to as 'unspecified' consent in the National Statement) - At the time samples are collected, research participants are asked to permit all future uses that a qualified ethical review board determines to be scientifically meritorious and ethically defensible.

14.9.4 *Presumed consent* - At the time samples are collected, research participants are informed that their specimens will be used in future research unless they expressly deny permission.

14.10 The National Statement further provides that '*the necessarily limited information and understanding about research for which extended or unspecified consent is given can still be sufficient and adequate for the purpose of consent*.[23]

14.11 More recently researchers have been employing 'dynamic consent' to deal with the challenges of genomic research. In summary:

> *Dynamic Consent uses internet-based platforms to create a communication interface to support ongoing participant-led management of their involvement in research studies. It allows participants to: develop greater understanding of the research; choose from more granular consent options and change consent choices over time (including for future use of their data); indicate preferences for return of results; and engage in the research process as much as they choose, all according to their own time frames.*
>
> *[It provides] opportunities for: two-way communication; to make changes to their choices about participation, and to be kept informed about the study.*[24]

14.12 We have further considered all of these issues in our analysis in **Part F**.

[22] Mello, M. M., & Wolf, L. E. (2010). The Havasupai Indian tribe case--lessons for research involving stored biologic samples. *N Engl J Med*, 363(3), 204-207. doi: 10.1056/NEJMp1005203.
[23] National Statement, at 2.2.14.
[24] Matilda A Haas et al, 'CTRL: a Dynamic Consent Platform for Genomic Research' European Journal of Human Genetics volume 29, pages 687–698 (2021).

Part E STAKEHOLDER FEEDBACK AND COMMUNITY EXPECTATIONS

15. Summary of stakeholder feedback

15.1 In March 2021, ABS held three two-hour sessions with mixed groups of stakeholders via teleconference on this PIA. Stakeholders consulted included peak health organisations, consumers, government, academics and advocacy groups. These groups were invited to participate based on:

15.1.1 consumer expertise;

15.1.2 involvement in preparations for the Study;

15.1.3 involvement in and/or knowledge of Commonwealth data integration activities and projects;

15.1.4 involvement in and/or knowledge of genomic research and biobanking;

15.1.5 special interest or expertise such as advocacy; and

15.1.6 representation of a key sector of Australian society.

15.2 At **Attachment 4** is a **Stakeholder Consultation Report** collating the feedback from these consultation sessions. Below is a summary of key stakeholder concerns and feedback:

15.2.1 An overarching concern was how to obtain fully informed consent for the NHMS and Biobank, including the ability of the ABS to communicate the complexities of the various aspects of the NHMS in order to obtain fully informed consent.

15.2.2 Stakeholders expressed concerns regarding the logistics of consent being collected at the same time as the point of collection of the biomedical sample.

15.2.3 Stakeholders expressed concerns about the 'bundled consent' for Tier 1, and expressed a strong preference for having consent to participate in the NHMS separate to consent for the integration of NHMS survey data with data in the MADIP as part of Tier 1 consent.

15.2.4 Some Stakeholders were supportive of considering dynamic consent mechanisms for Process 2.

15.2.5 Stakeholders were concerned about the return of a Participant's test results across Process 1 and Process 2. In particular, they sought clarity over:

(a) what constitutes a 'significant health risk';

(b) who will communicate the results to Participants; and

(c) if a Participant does not consent to the return of their test results, is there a process in place to handle that information appropriately.

15.2.6 Stakeholders raised concerns over the identity and role of the Biobank Custodian, and expressed a clear preference that the Biobank custodian should be an APP entity.

15.2.7 Stakeholders raised concerns around what steps will be taken by the Biobank Custodian to maintain contact over the lifespan of the biomedical sample, particularly with vulnerable groups of people.

15.2.8 In relation to research conducted using Biobank samples, Stakeholders expressed a view that genomic research rest results should be returned by an individual or entity that has genomic expertise or a genomic counsellor role, and not the Biobank Custodian.

15.2.9 Some stakeholders acknowledged that data derived from the biomedical sample can last indefinitely, as such consent should be indefinite to cover the future use of that data.

15.2.10 Stakeholders were concerned with the ability of Participants to withdraw consent from the Tier 2 and Tier 3 activities (i.e. storage of biomedical sample in the Biobank and further genomic testing of the biomedical sample).

15.2.11 Stakeholders expressed a concern that Participants lose control over the potential uses of their biomedical sample, while Participants may be able to withdraw their consent for any access to and use of their biomedical sample, until their consent has been withdrawn, they do not have control over what research projects are given access to their biomedical sample.

15.3 One stakeholder was particularly concerned with the implementation of the NHMS and Biobank given Australia's current regulation of privacy. In the stakeholder's opinion, a tort of privacy that provides a right to compensation for anyone who has experienced a serious breach of privacy is needed in Australia to adequately protect privacy of individuals. They also raised particular concerns with how health information was being handled by general practitioners and the stakeholder saw a lack of transparency for patients around arrangements between general practitioners and other entities.

15.4 We acknowledge the broader concerns with the Australian privacy regime, and the importance of considering the broader contextual privacy issues when looking at specific privacy risks for the NHMS and Biobank. However, we also acknowledge that these are matters that are beyond the control of ABS and the Biobank Custodian. This PIA is conducted from the perspective of considering compliance against current privacy laws and focuses on practical measures that can be taken by the ABS to mitigate against any specific privacy risks posed by the proposed implementation of the NHMS and Biobank. We are also cognisant that the Australian Government is currently undertaking a comprehensive review of the Privacy Act, the outcomes of which may address some of these broader concerns.

16. Community expectations

16.1 This PIA report also assesses risks based on our understanding of reasonable community expectations of privacy. For example, the *Australian Community Attitudes to Privacy Survey 2020* commissioned by the OAIC (**OAIC Survey**), contains useful information regarding current community expectations.[25] Relevantly:

16.1.1 70% of Australians see the protection of personal information as a major concern in their life;

16.1.2 almost 9 in 10 Australians (87%) want more control and choice over the collection and use of their personal information (2% do not);

16.1.3 40% of Australians are comfortable with government agencies using their personal details for research or policy-making purposes, while 27% are not comfortable;

[25] This survey was published in September 2020.

16.1.4 Australians believe that the biggest privacy risks facing the community are identity theft and fraud (76%), data security and data breaches (61%), digital services, including social media sites (58%) and smartphone apps (49%);

16.1.5 60% of Australians are reluctant to provide medical or health information to a business, organisation or government agency, with 8% more reluctant to provide this than any other kind of information;

16.1.6 when the community was asked how trustworthy they considered different types of organisation, the highest levels of trust were recorded for health service providers (70%), Federal Government departments (61%) and financial institutions (50%);

16.1.7 36% of the community are comfortable with the government sharing their personal information with other government agencies, but only 15% are comfortable with the government sharing this information with businesses in Australia; and

16.1.8 83% of Australians would like the government to do more to protect the privacy of their data, 24% feel their data is well protected, while 40% feel it is poorly protected.

Part F APP COMPLIANCE FOR NHMS

Below is an analysis of the key elements of the APPs that are relevant for Process 1 (**NHMS**). The analysis does not address those elements of the APPs which reflect ABS's broader compliance obligations, but considers those elements that specifically relate to the NHMS.

For reference, the full text of the APPs is at **Attachment 2.**

1. APP 1 – open and transparent management of personal information

1.1 APP 1 is intended to ensure that APP entities manage personal information in an open and transparent way. In our view, the success of the NHMS will largely depend on the Participants', and the public's, confidence in the processes and procedures employed for the Process. We consider that the Australian public would expect the ABS, as the entity responsible for conducting the NHMS, to be open and transparent about the handling of personal information in connection with the NHMS. We make the general observation that the ABS's website includes a substantial amount of information about its work, particularly on the different surveys it undertakes and we expect that it will take a similar approach to providing information about the NHMS. We consider this to be a privacy enhancing feature and demonstrates the ABS's commitment to acting openly and transparently.

1.2 We also consider that the commissioning of a PIA at an early stage of the development of the NHMS shows a commitment by the ABS to taking reasonable steps to implement practices, procedures, and systems to comply with the APPs in accordance with APP 1.2 and the APP Code (which requires agencies to undertake a written PIA for all "high privacy risk" projects or initiatives that involve new or changed way of handling personal information).

1.3 To ensure that personal information is managed in an open and transparent way, we **recommend** that the ABS consider**:**

1.3.1 publishing this PIA report, or a summary form of its findings and recommendations, on its website;

1.3.2 developing scripts for its contact centre staff to use when responding to questions from Participants about the NHMS and the Biobank (noting that once the Biobank is operational the Biobank Custodian will be primarily responsible for responding to queries about the Biobank), including in particular the role of the ABS in relation to the two processes; and

1.3.3 working with the Biobank Custodian on the scripts or other materials it will use in connection with Biobank and the NHMS, to ensure consistency in messaging; and

(**Recommendation 1**)

ABS Privacy Policy

1.4 APP 1.3 provides that an APP entity must have a clearly expressed and up to date privacy policy that contains all information prescribed by APP 1.4.

1.5 ABS has a specific Privacy Policy that sets out how it handles personal information that is collected for the purpose of the production of official statistic. The *ABS Privacy Policy for Statistical Information*[26], which will apply to the NHMS, is broadly consistent with the requirements under APP 1.4.

[26] https://www.abs.gov.au/about/legislation-and-policy/privacy/privacy-abs/abs-privacy-policy-statistical-information

2. APP 2 – anonymity and pseudonymity

2.1 APP 2.1 requires APP entities to give individuals the options of not identifying themselves, or of using a pseudonym, when dealing with the entity in relation to a particular matter, unless an exception under APP 2.2 applies.

2.2 Anonymity requires that an individual may deal with an APP entity without providing any personal information or identifiers. Pseudonymity requires that an individual may deal with an APP entity by using a name, term, or descriptor that is different to the individual's actual name.

2.3 Importantly, APP 2.2(b) provides that APP 2.1 does not apply if it is impracticable for the APP entity to deal with individuals who have not identified themselves, or who have used a pseudonym.

2.4 While we do acknowledge that, where possible, individuals should be able to use a pseudonym or remain anonymous, we do not consider that it would be practical for Participants to use a pseudonym, or to remain anonymous, in connection with all the steps relating to the NHMS. For example, when an ABS interviewer collects personal information from a Participant to facilitate the Reimbursement Arrangement it is not practical to deal with the Participant anonymously or using a pseudonym. For the NHMS itself, the identity of the Participant is required to collate the information across the IHMHS. We do note though that ABS' existing arrangements mean that Participants and other individuals can choose to contact the ABS' contact centre staff anonymously or use a pseudonym if they call to seek general information about the NHMS.

2.5 We therefore consider that the proposed implementation of the NHMS will result in the ABS complying with APP 2.1.

3. APP 3 – collection of solicited personal information

3.1 APP 3 only applies to personal information which is 'solicited' (APP 3.7). An APP entity 'solicits' personal information if it requests another entity (including an individual) to provide the personal information, or to provide a kind of information in which that personal information is included (section 6(1) of the Privacy Act). Personal information is also solicited if active steps are taken to facilitate the provision of personal information.[27]

3.2 It is relatively clear that in administering the NHMS and implementing the Biobank, the ABS and the Biobank Custodian respectively will be soliciting personal information.

Collection permitted under APP 3.1 and APP 3.2

3.3 Pursuant to APP 3.1, an APP entity can only collect personal information (other than sensitive information) that is reasonably necessary for or directly related to one or more of the agency's or organisation's functions or activities

3.4 Determining whether a collection of personal information is permitted under APP 3.1 requires a two-step process:

3.4.1 **Step 1** – identifying an APP entity's functions or activities; and

3.4.2 **Step 2** – determining whether the relevant collection of personal information is reasonably necessary for, or directly related to, one of those functions or activities.[28]

3.5 For **Step 1**, In our view, it is relatively clear that conducting NHMS, which is a survey that is part of the IHMHS is within the functions of the ABS.

[27] APP Guidelines, Chapter 3, paragraphs 3.4 – 3.8.
[28] APP Guidelines, Chapter 3, paragraphs 3.8 – 3.9.

3.6 For **Step 2**, Factors relevant to determining whether a collection of personal information is reasonably necessary for a function or activity include:

16.1.9 the primary purpose of collection;

16.1.10 how the personal information will be used; and

16.1.11 whether the entity could undertake the function or activity without collecting that personal information.

3.7 To be "directly related to" an agency's functions or activities, a clear and direct connection must exist between the personal information being collected and an agency's functions or activities.

3.8 In our view, the collection of personal information for the NHMS by the ABS will be directly related to the functions of the ABS.

Collection permitted under APP 3.3 and APP 3.4

3.9 We note that the Participants Results collected by the ABS for the purposes of the NHMS is sensitive information.

3.10 Under APP 3.3, except where an exception in APP 3.4 applies, an APP entity can only collect sensitive information about an individual if:

3.10.1 the collection satisfies the criteria for collection under APP 3.1 (i.e. the information is reasonably necessary for, or directly related to, one or more of the agency's functions or activities) – this is discussed in paragraphs 3.3 - 3.8 ; and

3.10.2 the individual has consented to the collection.

3.11 The ABS will be relying on the consent of individuals to participate in the NHMS, and in particular consent to the collection of their sensitive information by the ABS and the Pathology Provider (and any relevant sub-contractors) .

3.12 As discussed above, there are four key elements that are needed in order to establish consent:

16.1.12 the individual is adequately informed before giving consent;

16.1.13 the individual gives consent voluntarily;

16.1.14 the consent is current and specific; and

16.1.15 the individual has the capacity to understand and communicate their consent.

3.13 A particular challenge for the NHMS is ensuring that individuals are adequately informed before they give consent**.** In this context we consider that the ABS's intended process to leave Participation Information Sheets for the NHMS with potential Participants to consider, and then to collect the necessary consents at the time that a person presents at a Pathology Collection Centre or AMS, to be a good measure to support informed consent. This is because it will give potential Participants time to fully consider the issues and make further enquiries if required, such as the ability to review relevant website material or seek further information from the ABS contact centre.

3.14 In our view the ability to withdraw consent from participation in the NHMS is also a privacy enhancing feature, as it gives greater control to Participants.

3.15 We do note the limitations of withdrawal from the NHMS once survey data has been incorporated into the broader IHMHS dataset and de-identified or into MADIP. We consider this is reasonable noting that in both cases personal identifiers would have been removed from the Participant's data making it difficult to change or delete data that relates to a specific Participant.

3.16 We note that the OAIC Survey found that almost 9 in 10 Australians (87%) want more control and choice over the collection and use of their personal information. We consider this to be an important factor for the ABS to take into consideration in developing the NHMS and Biobank processes. In our view providing greater control to Participants enhances compliance with APP 3.

3.17 One matter of specific concern for stakeholders was that Tier 1 consent (consent to participate in the NHMS) was bundled with consent for data derived from the NHMS to be linked to other data sets such as MADIP. Bundling of consent is considered generally undesirable from a privacy perspective because it diminishes an individual's right to choose how their personal information is handled. On this point, stakeholder feedback reflected two perspectives:

16.1.16 there was concern that bundling too much into one question meant the consent may not be fully informed if Participants were not made fully aware of the MADIP process; and

16.1.17 that the bundled consent may deter participation in the NHMS as a person may wish to participate in the survey but may not wish to have their data linked more broadly.

3.18 Taking into account stakeholder views and best privacy practice, we **recommend** that the ABS review the proposed Tier 1 consent proposed which bundles participation in the NHMS with data linkage of results from the NHMS to the MADIP, to determine whether it is practicable to unbundle these consents, so that Participants are provided with choice about how information about them is used.

3.19 If for operational reasons the ABS considers it undesirable or not feasible to unbundle the consents in Tier 1, the ABS should explain its reasoning as to why it is they are bundled in any Participation Information Sheet and collection notice, so Participants can make an informed choice about participating in the NHMS. (**Recommendation 2**)

Collection by lawful and fair means

3.20 Another privacy principle, reflected in APP 3.5, is that collection of personal information must occur only by 'lawful and fair means'. A collection of personal information is lawful if it is not contrary to law. Conversely, a means of collection will not be lawful if a law, legal order or legal principle prevents that means of collection. For example, a collection will be unlawful if it is:

3.20.1 in breach of legislation, such as computer hacking, using telephone interception or a listening device except under the authority of a warrant, or requesting or requiring information with, or for the purposes of, an act of discrimination;

3.20.2 by a means that would constitute a civil wrong, such as by trespassing on private property or threatening damage to a person unless information is provided; or

3.20.3 contrary to a court or tribunal order, such as an injunction issued against the collector.

3.21 A "fair means" of collecting personal information is one that is not oppressive, does not involve intimidation or deception, and is not unreasonably intrusive. Whether a collection uses unfair means would depend on the circumstances.[29]

[29] APP Guidelines 3.62

3.22 In our view, taking measures to enhance openness and transparency in the management of personal information, as recommended in **Recommendation 1** would enable the ABS to further demonstrate that the personal information collected was done by fair means as Participants were fully made aware of all the relevant issues (that is, there was no deception or misrepresentations).

Collecting directly from the individual

3.23 Finally, another key privacy principle (reflected in APP 3.6) is that personal information about an individual should be collected only from the individual unless:

3.23.1 the individual consents to the collection of the information from someone other than the individual;

3.23.2 the entity is required or authorised by or under an Australian law, or a court/tribunal order, to collect the information from someone other than the individual; or

3.23.3 it is unreasonable or impracticable for the APP entity to collect the personal information from the individual.

3.24 As consent will be collected directly from Participants, APP 3.6 is met.

3.25 We consider that if the recommendations above are implemented, the ABS would be compliant with APP 3.

3.26 We note that any collection of personal information by the Pathology Provider (including any subcontractors, such as the Central Pathology Laboratory) or AMSs would also meet APP 3 as the collection of any personal information will be within the functions and activities of the relevant entity in providing the contracted services, if the form of the consent is sufficiently broad (as we understand is the intent). In our view implementing **Recommendation 4** concerning arrangements between ABS and the Pathology Provider (and if applicable, between the ABS and the AMSs) would further ensure that these entities only collect personal information that is reasonably necessary for them to carry out their contractual obligations.

3.27 For completeness we note that a Participant's GP will also collect personal information about the Participant when the Pathology Provider discloses the Participants Results to them. As this collection of personal information by the GP is based on the consent of the Participant (as expressly indicated on their Referral Form), the collection would be compliant with APP 3. We note that one stakeholder expressed the view that the Consent Form should alert Participants to the fact that a GP may be required to further disclose their personal information under other arrangements. We do not consider that ABS is required to do this to comply with APP 3 on the basis that GPs are separately bound by the Privacy Act (and other health record and privacy legislation in some states and territories) and these matters go to the GP's broader compliance (noting that GPs receive pathology results routinely outside of the NHMS).

3.28 However, we consider one step that the ABS could consider taking is including a statement in the Consent Forms along the lines of: '*I understand that I should contact my GP if I have questions about what happens to my personal information when it goes to my GP*'.

Minors

3.29 We note that the Biobank will not be collecting and storing biomedical samples of minors. We consider this to be privacy enhancing feature. We note that the consent for minors to participate in the NHMS will align with ABS's standard practices and we do not have any concerns regarding this.

4. APP 4 – dealing with unsolicited personal information

4.1 APP 4 applies where an APP entity receives unsolicited personal information (i.e. information that it receives but has taken no active steps to solicit). The objective of APP 4 is to ensure that personal information that is received by an APP entity is afforded privacy protection, even if the entity did not solicit the information.[30]

4.2 APP 4 requires the APP entity to determine whether or not the entity could have collected the information by considering whether:

4.2.1 the personal information it received is unsolicited;

4.2.2 the entity could have collected the personal information under APP 3;

4.2.3 the personal information is contained in a Commonwealth record; and

4.2.4 the information held by the entity should be destroyed or de-identified, or should it be retained and dealt with in accordance with the APPs.[31]

4.3 As a general rule, personal information provided to an APP entity that is additional to the information that has been requested by the entity should be treated as unsolicited personal information.

4.4 From our assessment, there appears to be very low risk of the ABS receiving unsolicited personal information in the context of the NHMS. It is feasible, though unlikely, that the Pathology Provider could provide information about non-Participants at the time it transfers Participants' Results to ABS through SFTP. To the extent that there is any risk, a protocol for sending Participants Results to the ABS from the Pathology Provider, which we have recommended as part of **Recommendation 4**, would assist in mitigating against this risk. ABS also has in place established policies and processes for handling unsolicited information, which would be employed in the event that it received unsolicited information in the context of the NHMS.

[30] APP Guidelines, Chapter 4, paragraph 4.4.
[31] APP Guidelines, Chapter 4, paragraph 4.3.

5. APP 5 – notification of the collection of personal information

5.1 APP 5 requires an entity that collects personal information about an individual to take reasonable steps to:

5.1.1 notify the individual of certain matters (referred to as 'APP 5 matters'); or

5.1.2 otherwise ensure that the individual is aware of those matters.

5.2 This notification must occur at or before the time of collection, or as soon as practicable afterwards.

5.3 The 'reasonable steps' test in APP 5 is an objective test, that considers whether a reasonable person in those circumstances would agree that the entity had acted reasonably in providing notice or ensuring awareness of the APP 5 matters. The reasonable steps for an entity will depend on circumstances that include:

5.3.1 the type of personal information collected, including whether it comprises of any sensitive information;

5.3.2 the possible adverse consequences for an individual as a result of the collection;

5.3.3 any special needs of the individual; and

5.3.4 the practicability, including time and cost involved.[32]

5.4 The OAIC has suggested that reasonable steps that an APP entity could consider include:

5.4.1 if an entity collects personal information directly from an individual who completes a form or uses an online facility – clearly and prominently displaying the APP 5 matters in the form or providing a readily accessible link to an APP 5 notice, and asking the individual to confirm that they have reviewed the notice before collecting their personal information;

5.4.2 if personal information is collected by telephone, explaining the APP 5 matters to an individual at the start of the call;

5.4.3 if the entity collects personal information from another entity, ensuring that the other entity has notified or made the individual aware of the relevant APP 5 matters (such as through an enforceable contractual arrangement); or

5.4.4 where it is not reasonable to notify or ensure awareness of the full range of APP 5 matters, alerting the individual to specific sections of its APP Privacy Policy or other general documents containing relevant information.[33]

Collection Notice for the NHMS

5.5 In our view a collection notice for the purpose of APP 5 should be included in the Participation Information Sheet for the NHMS. This sheet serves to provide the relevant information to potential Participants (and Participants) about Process 1 (NHMS) the purposes of obtaining informed consent from persons to participate in the NHMS.

5.6 The APP Guidelines make clear that an APP 5 notice can be provided in layers. For example a brief statement could be included in a form which is supplemented by a longer notice made available online or in brochures. We consider this to be a sound approach in circumstances where people may be overwhelmed by the length of consent documents to review for, as stakeholders recognised, as relatively complicated processes.

[32] APP Guidelines, Chapter 5, paragraph 5.4.
[33] APP Guidelines, Chapter 5, paragraph 5.6.

5.7 We therefore **recommend** that a layered approach is taken for the collection notice which will support collections, uses, disclosures for the NHMS. That is, a short notice is included in the relevant Participation Information Sheet with:

5.7.1 links or references to a publicly available website containing a more detailed collection notice, and more information (such as the ABS Privacy Policy for Statistical Information); and

5.7.2 a telephone number for people to call so they can listen to the full collection notice and relevant Privacy Policy or speak to someone if they have questions.

(**Recommendation 3**)

5.8 The collection notice (and Privacy Policy) should be available in a range of languages and otherwise also be in accessible format.

5.9 We note for completeness that the AMSs and the Pathology Provider are APP entities, and as such will also be required to comply with APP 5 in connection with their collections of personal information as part of the NHMS. We recommend that the more detailed collection notice that is developed by the ABS also reference the collections by those entities, so that a specific collection notice is not required in relation to the NHMS by these entities.

6. APP 6 – use or disclosure of personal information

6.1 APP 6 provides that an APP entity must not use or disclose personal information that was collected for a particular purpose (the primary purpose) for another purpose (a secondary purpose), unless the individual has consented to the use or disclosure of the information, or an exception in APP 6.2 or APP 6.3 applies.

6.2 In our view, the following uses of personal information will be for the primary purposes for which it was collected, namely, to facilitate the implementation of the NHMS by the ABS:

6.2.1 Participant Information is used by a Collection Centre to record details of the collection of the biomedical samples;

6.2.2 Participant Information is used by an AMS to record details of the collection of the biomedical samples;

6.2.3 Participant Information is used by the Central Pathology Lab to undertake analysis on the biomedical samples; and

6.2.4 Participant Information and Participant Results is used by the ABS in relation to the NHMS, including analysis and data linking to MADIP;

6.3 The following disclosures of personal information will be for the primary purposes for which it was collected, namely, to facilitate the implementation of the NHMS by the ABS:

6.3.1 Participant Information is disclosed by an AMS to the Central Pathology Laboratory and Pathology Provider;

6.3.2 Participant Information and Participant Results is disclosed by the Central Pathology Lab to the Pathology Provider;

6.3.3 Participant Information and Participant Results are disclosed by the Pathology Provider to the ABS;

6.3.4 Participant Information and Participant Results are disclosed by the Pathology Provider to the Participant; and

6.3.5 Participant Information and Participant Results are disclosed by the Pathology Provider to the Participant's GP.

6.4 We caution though that the finding of compliance against APP 6 is dependent on these purposes for which the information is collected being clearly communicated to Participants, so that consent for these purposes is appropriately obtained and valid.

6.5 There is therefore a risk that if the collection of personal information is not done appropriately, ABS will not be able to rely on the uses and disclosures being for the primary purposes of collection.

6.6 Any other use and disclosure will therefore be considered to be for a secondary purpose and the entities will need to have obtained consent from a Participant for the use or disclosure or otherwise rely on an exception in APP 6.2 and APP 6.3. The most practical way for the ABS to mitigate this risk is to implement **Recommendation 2** and **Recommendation 3** to ensure that appropriate consent will be obtained in relation to the NHMS.

7. APP 7 – direct marketing

7.1 APP 7 only applies to ***organisations*** as defined in the Privacy Act, rather than to agencies, and allows organisations to use personal information for the purposes of direct marketing in certain circumstances. This potentially applies to the Pathology Provider, to the Central Pathology Laboratory, and to AMSs.

Application of APP 7 to the ABS

7.2 Under section 7A of the Privacy Act, an act or practice of an agency may in the prescribed circumstances be treated as an act or practice of an organisation. This applies to:

7.2.1 a prescribed agency specified in Part 1 of Schedule 2 to the *Freedom of Information Act 1982* (Cth) (**FOI Act**); or

7.2.2 an agency specified in Division 1 of Part II of Schedule 2 to the FOI Act.

7.3 ABS is not one of the agencies specified under section 7A of the Privacy Act. Therefore, APP 7 does not apply to ABS.

Application of APP 7 to Pathology Provider

7.4 APP 7 applies to the Pathology Provider, as it is an ***organisation*** as defined in the Privacy Act.[34]

7.5 We note that the Pathology Provider, as part of its BAU activities undertakes direct marketing as evidenced in its Privacy Policy that provides:

> *We may use your personal information for marketing which is directly related to our services, in compliance with applicable laws, such as the* Privacy Act 1988 (Cth) *and* Spam Act 2003 (Cth)*. We may engage third parties, under contract, to provide marketing services on our behalf. You may advise us that you do not wish to receive direct marketing from us at any time by contacting us or by using the opt-out facilities provided in our client registration processes, informed consent procedures and the marketing communications you receive.*

7.6 We have assumed that the ABS does not wish the Pathology Provider to be able to use personal information gathered as part of the NHMS to directly market to Participants. We **recommend** that the ABS ensure that its contractual arrangements with the Pathology Provider include provisions to expressly provide that the Pathology Provider cannot use any personal information for direct marketing purposes (**Recommendation 4**). We also recommend that this extend to a requirement for the Pathology Provider to ensure that any subcontractors such as the Central Pathology Laboratory (and potentially AMSs, if they will be subcontracted to the Pathology Provider) have a similar prohibition.

7.7 If AMSs will be engaged directly by the ABS, we recommend that the ABS ensure it includes similar requirements to those in **Recommendation 4** (in relation to the Pathology Provider) in its arrangements with the AMSs.

[34] *Privacy Act 1988* (Cth), s 6(1).

8. APP 8 – cross-border disclosure of personal information

8.1 APP 8 requires APP entities to take particular steps if they intend on disclosing personal information to an overseas recipient. It is implicit that APP 8 only applies to personal information that is 'held' by an APP entity.[35]

8.2 In accordance with APP 8.1, before an APP entity is able to disclose personal information about an individual to an overseas recipient, it must take reasonable steps to ensure that the recipient does not breach the APPs in relation to that information. Further, under section 16C of the Privacy Act, where an entity discloses personal information to an overseas recipient, it is accountable for any act or practice of the overseas recipient that would breach the APPs.

Application to ABS

8.3 We understand that the ABS will be storing Participant Information on ICT infrastructure that is located in Australia and that there is no intention to disclose any Participant Information to an overseas recipient. However, we have not reviewed the contractual arrangements between the ABS and the Pathology Provider. Therefore, we are unaware of any provisions that may prohibit the disclosure of information to an overseas recipient. However, we have reviewed the Privacy Policies of both the Pathology Provider and note that the entity may disclose information to an overseas entity.

Pathology Provider

8.4 The Pathology Provider will hold copies of Participant Information on its ICT systems when it scans and saves electronic copies of the Participants' Consent Forms and Referral Forms.

8.5 Below is an extract from the Pathology Provider's APP 1 Privacy Policy (emphasis added):

> We may enter into arrangements with other related entities or *third parties outside of Australia to store, access or use data we collect, including personal information, in order to provide services to us (such as data processing, analysis, interpretation or the performance of specialised tests)*. In such cases, we will take reasonable steps to ensure that the third parties do not breach the APPs, including by requiring that the third party has information security measures and information handling practices in place that are of an acceptable standard and approved by us.
>
> The countries in which the recipients are likely to be located include, but are not limited to, those countries where the Sonic group operates (New Zealand, USA, UK, Ireland, Germany, Switzerland and Belgium).

8.6 As noted in the APP Guidelines, an APP entity will 'disclose' personal information where it shares the personal information with an overseas recipient, including when the entity engages a contractor located overseas to perform services on its behalf. We note that there is a risk that the Pathology Provider, based on our review of the Pathology Provider's privacy policy, may disclose Participant Information it collects as part of the NHMS, to a third party located overseas.

8.7 The Pathology Provider notes, in accordance with APP 8.1, that it will take reasonable steps to ensure third parties outside of Australia do not breach the APPs, and some of the measures it will take to ensure this. Further, in accordance with APP 1.3, the privacy policy also lists the potential countries where information may be disclosed. As such, we consider that the Pathology Provider is compliant with APP 8.

8.8 As noted above, in certain circumstances, an act or practice of an overseas recipient that would be a breach of the APPs will be taken to be an act or practice engaged in by the APP entity that disclosed the information (section 16C of the Privacy Act). We consider that by imposing this accountability on the Pathology Provider provides some enhanced privacy protection.

[35] APP Guidelines, Chapter 8, paragraph 8.4.

8.9 However, while the Pathology Provider could disclose Participant Information to an overseas recipient, we query whether this ***should*** be permitted to occur. In the OAIC Survey it was noted that 74% of Australians surveyed consider an organisation sending consumers' data to an overseas processing centre to be a misuse of personal information.

8.10 Therefore, we **recommend** that the ABS ensure that the contractual arrangements with the Pathology Provider include provisions that prohibit the storage, and disclosure, of Participant Information to any overseas entity for any reason without ABS' consent (including in relation to any storage of data, or data processing, analysis or interpretation services) (**Recommendation 4**).

9. APP 9 – adoption, use or disclosure of government related identifiers

9.1 APP 9 only applies to ***organisations*** as defined in the Privacy Act, rather than to agencies. Therefore, it will not apply to ABS, however it will apply to the Pathology Provider.

9.2 Under section 6 of the Privacy Act, ***government related identifiers*** are defined identifier of the individual that has been assigned by:

9.2.1 an agency; or

9.2.2 a State or Territory authority; or

9.2.3 an agent of an agency, or a State or Territory authority, acting in its capacity as agent; or

9.2.4 a contracted service provider for a Commonwealth contract, or a State contract, acting in its capacity as contracted service provider for that contract.[36]

9.3 In our view the ABS Reference Number and the unique identifier to be included on the Referral and Consent Form will be government identifiers. However, the use of these identifiers by the Pathology Provider when it returns Participants Results to the ABS and the disclosure of the unique identifier to the Biobank Custodian when it provides the inventory list, will be part of the contracted services, and would be compliant with APP 9.

[36] *Privacy Act 1988* (Cth), s 6(1).

10. APP 10 – quality of personal information

10.1 APP 10 requires APP entities to take reasonable steps (if any) to ensure that the personal information that the entity:

10.1.1 collects is accurate, up-to-date, and complete; and

10.1.2 uses or discloses is, having regard to the purpose of the use or disclosure, accurate, up-to-date, complete and relevant.

10.2 In the context of APP 10, the 'reasonable steps' that an APP entity should take will depend upon the circumstances, including:

10.2.1 the sensitivity of the personal information;

10.2.2 the nature of the APP entity (including its size, resources, and business models);

10.2.3 the possible adverse consequences for an individual if the quality of personal information is not ensured; and

10.2.4 the practicability, including time and cost involved. However, an entity is not excused from taking particular steps by reason only that it would be inconvenient, time-consuming or impose some cost to do so. Whether these factors make it unreasonable to take particular steps will depend on whether the burden is excessive in all the circumstances. [37]

10.3 It is implicit in the use of the phrase 'if any' in APP 10.1 that it will be reasonable for an entity to take no steps to ensure data quality in some circumstances. For example, where an entity collects personal information from a source known to be reliable (such as the individual concerned), it may be reasonable to take no steps to ensure data quality.[38]

Application of APP 10 to the ABS

10.4 In **Step 2**, the ABS will be collecting personal information directly from the Participant (or their parent/legal guardian). Where the individual provides the information themselves, we consider that it is reasonable for the ABS to assume this personal information will be accurate, up-to-date and complete). Therefore, in regard to this Step 2 we consider that it is reasonable for the ABS to take no additional steps to ensure data quality.

Application of APP 10 to the Pathology Provider

10.5 Both **Step 4** and **Step 5** also involve the collection of Participant Information by the Pathology Provider directly from the Participant (or their parent/legal guardian). Where the individual provides the information themselves, we consider that it is reasonable for the Pathology Provider to assume this personal information will be accurate, up-to-date and complete). Therefore, in regard to these **Steps 4** and **5**, we consider that it is reasonable for the Pathology Provider to take no additional steps to ensure data quality at the point of collection.

10.6 However, we note that Participant Information may be collected by Pathology Provider Personnel at one of 1500 Collection Centres, or by an AMS subcontractor. This may give rise to a risk that personal information may be collected and recorded in an inconsistent manner. As discussed above, informed consent of Participants is critical for the NHMS and Biobank. As consent is collected at the time a Participant presents at a Collection Centre or AMS and provides the signed consent forms, it is critical that Collection Centre ensure that any Consent Forms are complete prior to collecting the biomedical samples.

[37] APP Guidelines, Chapter 10, paragraph 10.6.
[38] APP Guidelines, Chapter 10, paragraph 10.7.

10.7 Similarly, **Step 7** involves a disclosure of Participant Information and Participant Results from the Central Pathology Laboratory to the Pathology Provider when Participant Results are uploaded to the Pathology Provider's ICT systems. While the Pathology Provider (and the Central Pathology Laboratory) have presumably been engaged by the ABS because these entities have established systems and processes in place which ensure the quality of the data they hold, again it will be important for there to be certainty that the personal information is collected and recorded in a consistent manner.

10.8 To further ensure quality of the personal information handled by the Pathology Provider, we **recommend** that the ABS ensure its contractual arrangements with the Pathology Provider include the ability to provide a protocol or direction that Pathology Provider personnel (including any subcontractors) are required to adhere to (for example, relating to the checking of consent forms and information inputted into the Pathology Provider ICT systems) to ensure that ABS receives quality personal information and to mitigate risk of mishandling (**Recommendation 4**).

10.9 **Step 8** involves the disclosure of Participant Information (including Participant Results) to the ABS via SFTP. This is an established method of securely transferring data which mitigates against the risk that data may become corrupted and, when collected by the ABS, may be inaccurate or incomplete. We assume that, in accordance with the ABS' usual practice, the Pathology Provider and the ABS will test the transfer methods to ensure the quality of personal information is maintained during data transfer. If this assumption is correct, we consider that there are no additional 'reasonable steps' required to be taken to ensure data quality in this **Step 8**.

10.10 At **Step 10**, where the Participant has consented, the Pathology Provider may disclose Participant Results to the GP in addition to the Participant. We consider that the primary privacy risks arising from these disclosures in the context of APP 10 are that:

10.10.1 the Participant Information will be inaccurate; and/or

10.10.2 the Participant Information will be irrelevant.

10.11 Participant Information will be inaccurate if it contains an error or defect, if it is misleading or based on erroneous personal information.[39] Given that the information to be disclosed is sensitive information, it is imperative that the disclosure of Participant Information and Participant Results is accurate. In addition, based on the sensitivity of the information, the Pathology Provider should ensure that it is only disclosing the part of the Participant Information and Participant Results that are relevant. In our view implementing the measures in **Recommendation 4** concerning the contract between ABS and the Pathology Provider would assist in addressing these quality of information concerns.

10.12 In **Step 12** the Pathology Provider will disclose the personal information of the Participant to the Biobank Custodian along with the secondary sample. The personal information will include the government related identifier (as discussed above). Given that this personal information will be disclosed the requirements of APP 10.2 apply. That is the APP entity, in this case the Pathology Provider, must take reasonable steps to ensure the information is accurate, up-to-date, complete and relevant while having regard to the purpose of the disclosure. As this is at the early stage of development it is not clear how this is intended to be achieved and without careful consideration there is a risk of loss of data. We therefore **recommend** that the ABS ensure its contractual arrangements with the Pathology Provider include provisions in relation to data quality and assurance steps that are required to be taken to minimise data corruption (**Recommendation 4**).

[39] Australian Government, Australian Privacy Principles Companion Guide, available online at https://www.aph.gov.au/~/media/wopapub/senate/committee/fapa_ctte/completed_inquiries/2010-13/priv_exp_drafts/guide/companion_guide.ashx

11. APP 11 – security of personal information

11.1 APP 11.1 requires an APP entity to take such steps as are reasonable to protect personal information from misuse, interference and loss, and from unauthorised access, modification or disclosure. The term "reasonable" is not defined in the Privacy Act, but the APP Guidelines provide that the term bears its ordinary meaning, as being based upon or according to reason and capable of sound explanation.[40] What is reasonable can be influenced by current standards and practices.[41]

11.2 APP 11.2 provides that if an APP entity holds personal information about an individual and entity no longer needs the information, the entity must take such steps as are reasonable in the circumstances to destroy the information or to ensure that the information is de-identified.

Process 1 (NHMS) - Application of APP 11 to ABS

Security of personal information

11.3 The ABS will use Participants Results in accordance with the NHMS protocols, which will involve:

11.3.1 de-identifying and aggregating the data, to draw health insights from the data and comparison of the aggregate results from the previous NHMS 2011-2013;

11.3.2 merging (linking) with survey responses from the NHS or NNPAS progressively throughout the survey cycle through the unique identifier allocated to the Participant at the time of interview; and

11.3.3 to prepare the NHMS data for inclusion in, and storage and the use as part of, the MADIP dataset.

11.4 ABS will use the standard process developed by the ABS for secure data linkage under the MADIP initiative. ABS has strong security arrangements for all of its information technology systems that will be used to handle Participant Information. This includes those used for the MADIP, which:

11.4.1 conform with information technology security arrangements set out in the Information Security Manual (**ISM**);

11.4.2 provide that data collection, data integration, and data assembly activities for MADIP information is only conducted by a dedicated team in an isolated secure environment – the Secure Data Integration Environment;

11.4.3 has no external connectivity (i.e. no email, access to internet, etc.) to mitigate against the risk of data exfiltration;

11.4.4 includes a secured internet gateway which is assessed by an Australian Signals Directorate accredited Infosec Registered Assessors Program assessor; and

11.4.5 includes an ongoing program of security audits and system accreditations, including an independent security assessment and penetration testing.

11.5 We understand that the ABS is satisfied that those systems are subject to appropriate security protections to ensure that Participant Information and Participant Results is protected from misuse, interference and loss, and from unauthorised access, modification or disclosure.

[40] APP Guidelines, Chapter B, paragraph B.105.
[41] *Bankstown Foundry Pty Ltd v Braistina* [1986] HCA 20 (Mason, Wilson and Dawson JJ at paragraph 12).

Retention of personal information

11.6 Participant Information held by the ABS will be contained in Commonwealth records, and the obligations in APP 11.2 will not apply. Importantly, ABS will comply with its record keeping obligations by destroying Participant Information in accordance with its usual archiving and destruction processes (in accordance with the Archives Act).

11.7 We understand that ABS will retain the aggregated and de-identified Participant Information in MADIP, while there is a business need to do so for the purposes of statistical and other research purposes research. Current practices of the ABS include reviewing the need to retain information and destroying information when there is no compelling business case for retention.

Process 1 (NHMS) - Application of APP 11 to Pathology Provider

Security of personal information

11.8 The Central Pathology Laboratory will undertake testing on the biomedical samples. Participants' test results will be uploaded and stored in the Pathology Provider's ICT systems (**Step 7**).

11.9 We understand that the Pathology Provider provides training to its staff on privacy and data security and has a comprehensive information security management system in place, which is monitored and regularly tested, including third party penetration testing. These protections are continually reviewed and improved as part of its compliance work with the Information Security Manual (**ISM**) and ISO27001.

11.10 We assume ABS is satisfied that those systems are subject to appropriate security protections to ensure that Participant Information is protected from misuse, interference and loss, and from unauthorised access, modification or disclosure. As an assurance measure, we **recommend** that the ABS ensure that the contractual arrangements between the ABS and the Pathology Provider include provisions in relation to data security obligations, including how the Pathology Provider must hold and transfer personal information to other entities in connection with the contracted services (**Recommendation 4**).

Retention of personal information

11.11 The Pathology Provider will retain the Participant Results for a period that is in accordance with established standard practice (**Step 7**).

11.12 ABS should ensure that reasonable steps will be taken to protect the security of all Participant Information which will be handled by the Pathology Provider in connection with the NHMS. We **recommend** that the ABS ensure that the contractual arrangements between the ABS and the Pathology Provider include provisions requiring the return of all documents with personal information or destruction of personal information collected in connection with the services provided as required by the ABS (**Recommendation 4**).

11.13 In addition, we **recommend** that the ABS ensure that the contractual arrangements between the ABS and the Pathology Provider include provisions regarding a Notifiable Data Breach, particularly in the event that sensitive Participant Information is disclosed to an incorrect or unauthorised individual (**Recommendation 4**).

12. APP 12 – access to personal information

12.1 Under APP 12, an APP entity is required to give an individual access to the personal information held by it unless particular exceptions apply (depending on whether the APP entity is an agency or organisation).

Application to ABS

12.2 As ABS is an agency, it must give an individual access to the personal information it holds unless an exception under APP 12.2 applies. Relevantly, APP 12.2 provides that an agency does not need to give access to an individual under APP 12.1 if the agency is required or authorised to refuse to give the individual access to the personal information by or under:

12.2.1 the FOI Act; or

12.2.2 any other Act of the Commonwealth (or a Norfolk Island enactment) that provides for access by persons to documents.[42]

12.3 By virtue of Schedule 2, Part II, Division 2 of the FOI Act, the above exemption applies to the ABS in relation to the NHMS. That is, the ABS will not be required to give an individual access to their personal information after the Participant Results have been collected from the Pathology Provider by the ABS. We note that Participants will be given the opportunity to request a copy of their test results on the Referral Form.

12.4 However, it is also important to note that personal information such as names and addresses are removed when combined with other datasets as part of the data integration process, which makes it unlikely the ABS would be able to locate information in the MADIP to update or correct, and in any case once the NHMS Data has been aggregated and de-identified it will no longer be personal information for the purposes of the Privacy Act.

13. APP 13 – correction of personal information

13.1 APP 13 requires an APP entity holding personal information to take such steps as are reasonable in the circumstances to permit correction of that information, except in limited circumstances.[43]

Application to ABS

13.2 As for APP 12, we assume that if ABS receives a request from an individual to correct their information that they hold, ABS will follow its standard procedures and processes to consider such a request and ensure that it meets the requirements of APP 13.

13.3 Importantly, we note that the ABS's 'MADIP Privacy Policy' provides:

You can apply to access or correct your information held by the agency which originally collected it, however it may not be possible for the ABS to correct or provide you with access to information that has been collected as part of the Census or which has been integrated with other datasets in the MADIP….It is also important to note that personal information such as names and addresses are removed when combined with other datasets as part of the data integration process, which makes it unlikely the ABS would be able to locate your information in the MADIP to update or correct.

13.4 Additionally, the ABS's 'Privacy Policy for Statistical Information' provides:

You have the right to request access to, and correction of, your personal information. We will take all reasonable steps to address your request. In some cases, we won't be able to provide your personal information as we have:

[42] If ABS were to refuse access to information by virtue of the exemption at APP 12.2, ABS must provide a written notice of this decision, in compliance with APP 12.9.
[43] If an APP entity refuses to correct the personal information as requested by an individual, it must give the individual a written notice that includes the matters specified in APP 13.3.

- *destroyed the physical forms, and*

- *deleted personal identifiers (such as name and address) from the statistical data, which we do as soon as possible.*

13.5 It is unlikely that ABS will be required to correct any personal information it holds in relation to the NHMS, as once the NHMS Data has been aggregated and de-identified it will no longer be personal information for the purposes of the Privacy Act, and there will effectively be no personal information to "correct".

Part G PRELIMINARY APP COMPLIANCE GUIDANCE IN RELATION TO THE BIOBANK

Below is our preliminary APP compliance guidance in relation to Process 2 (Biobank). It is intended to provide high level guidance to inform the development of the Biobank. We have set out in **Part F – APP Compliance for NHMS** a plain English explanation of the operation of each APP, and have not sought to do so again here.

For reference, the full text of the APPs is at **Attachment 2.**

1. APP 1 – open and transparent management of personal information

1.1 In relation to the Biobank, ABS's role is unclear at this stage, particularly in relation to its role in handling any research results obtained from the use of biomedical samples in the Biobank by researchers. Further, there is a general lack of clarity on the policies and processes of the Biobank Custodian (though we appreciate that this is a reflection of the early stage of development of the Biobank). This level of uncertainty raises the risk that the ABS and Biobank Custodian may be considered not to be meeting the principle of openness and transparency embodied in APP 1.

1.2 In clarifying the Biobank Custodian's role, we suggest it should be clarified whether it is intended that it would be engaging 'commercial activities' in providing Biobank Custodian services. Whether an entity is an 'agency' or 'organisation' impacts on its privacy requirements under the Privacy Act. As discussed in **Part D**, given the funding arrangements for operation of the Biobank, we think it unlikely that the Biobank Custodian would be engaging in 'commercial activities' (which would usually be associated with its activities associated with commercialisation of its research and development), and have undertaken our analysis based on the assumption that it will be bound by the Privacy Act as an agency.

1.3 To ensure that personal information is managed in an open and transparent way, we **recommend** that the ABS consider**:**

1.3.1 before commencement of the NHMS, the ABS consider confirming with the Biobank Custodian and Health the respective entities' role in the governance structure for the Biobank, and in particular any ABS role in relation to handling of any research results obtained from the use of biomedical samples in the Biobank by researchers. Any clarification could be supported by the development of a shared governance document which could provide clarity, for example, about ABS exercising its contractual rights against the Pathology Provider where the services of the Pathology Provider impact on the operations of the Biobank.

1.3.2 once the ABS's role has been confirmed in relation to the Biobank, placing these governance arrangements on a publicly available website so that Participants interested in participating in the Biobank can refer to this information when deciding whether or not to give their consent (this ideally should be one website covering all Biobank related matters, with relevant links from ABS websites). (**Recommendation 5**)

1.4 To ensure that personal information is managed in an open and transparent way in relation to the Biobank, we **recommend** that the Biobank Custodian, as part of developing its policies and processes, consider:

1.4.1 developing a consent framework or policy document setting out the reasoning for the consent processes that will be adopted for the Biobank (for example, tiered consent, or whether it will use dynamic consent tools) and how these will operate in practice (what the consent covers, how it can be withdrawn, implications of withdrawal where research has already been undertaken, how it intends to deal

with deceased persons, and data retention policies), and placing this on the Biobank website so that persons have a thorough understanding of the consent process including how it was developed;

1.4.2 after further development of its proposed policies and processes and consideration of the recommendations in this PIA report, undertaking a further new or supplementary PIA process to fully assesses the Biobank information flows, particularly in relation to matters that have not been decided at this early stage, such as any risks arising from the identity of, or arrangements with, the Biobank Storage Facility operator; the use of any third party ICT provider in developing and managing systems; and any systems or tools to handle dynamic consent processes which have the potential to capture further personal information about individuals in connection with the Biobank;

1.4.3 publishing any PIA report it undertakes, or a summary form of its findings and recommendations, on a dedicated website for the Biobank (**Biobank website**);

1.4.4 developing a standalone Privacy Policy for the Biobank which it provides on the Biobank website;

1.4.5 being as open and transparent as possible about the operation of the Biobank by placing any governance arrangements (particularly those relating to the roles of different government agencies in the operation of the Biobank) and any protocols developed (subject to the need to maintain any confidentiality in commercial in confidence material) on the Biobank website, ideally before the NHMS commences collecting personal information.

(**Recommendation 6**)

Biobank Custodian Privacy Policy

1.5 We note that the Biobank Custodian has a Privacy Policy which would need to be updated to deal with the Biobank. However, given the significance of the Biobank and the functions that the Biobank Custodian would be undertaking as the Biobank Custodian being fundamentally different to what it currently does, we see benefit in having a standalone Privacy Policy for the Biobank.

1.6 We **recommend** that the Biobank Custodian, as part of in developing its policies and processes, consider developing a standalone Privacy Policy for the Biobank which it provides on the Biobank website (**Recommendation 6**).

2. APP 2 – anonymity and pseudonymity

2.1 It would not be practical for the Biobank Custodian to engage with Participants anonymously or using pseudonym (except for any general contact line). This is because the Biobank Custodian will need to verify a person's identity to maintain contacts lists and manage ongoing consent arrangements for the Biobank.

2.2 We therefore consider that the proposed implementation of the Biobank Custodian will comply with APP 2.1.

3. APP 3 – collection of solicited personal information

3.1 APP 3 only applies to personal information which is 'solicited' (APP 3.7). The Biobank Custodian will be soliciting personal information in relation to the Biobank.

3.2 The Biobank Custodian will need to ensure that entering into an agreement to provide Biobank Custodian services and the delivery of the Biobank is within its functions and activities.[44]

3.3 The Biobank Custodian will be relying on the consent of individuals to participate in the Biobank, and in particular consent to the collection of their sensitive information by the Biobank Custodian.

3.4 A particular challenge for the Biobank is ensuring that individuals are adequately informed before they give consent**.** We note in this respect that if consent for the participation for the Biobank is collected by the ABS interviewer at the NHS and NNPAS interview, this will be less ideal than the proposed arrangement for the NHMS (from a privacy perspective), which enables people to consider all the material prior to providing their consent to participate in the NHMS by attending a Pathology Collection Centre. However, we consider that this issue should be addressed in any Privacy Impact Assessment undertaken by the Biobank Custodian, including as the role of the Pathology Provider in any handling of the Biobank Consent Form is further developed.

3.5 We note that the OAIC Survey found that almost 9 in 10 Australians (87%) want more control and choice over the collection and use of their personal information. We consider this to be an important factor for the Biobank Custodian to take into consideration in developing the Biobank processes. In our view providing greater control to Participants enhances compliance with APP 3.

3.6 In our view the ability to withdraw consent from participation in the Biobank is a privacy enhancing feature, as it gives greater control to Participants.

3.7 As discussed in **Part E,** consent to participate in the Biobank was of the greatest concern to stakeholders during consultation. Stakeholders acknowledged the challenge of preparing simple consent documentation for inherently complex issues that arise in the context of biobanks and future use for research. Simplifying consent documentation though the way it is structured is likely to aid in obtaining informed consent as there is less risk of confusion arising. We **recommend** that ABS with the Biobank Custodian consider implementing the following structure for consent documentation:

3.7.1 one Participation Information Sheet for the NHMS;

3.7.2 one Participation Information Sheet for the Biobank;

3.7.3 one Consent Form covering the NHMS;

3.7.4 one Consent Form covering the Biobank with each Tier of consent (Tier 2 and Tier 3) clearly separated on the Form; and

3.7.5 for Tier 2 and Tier 3 consents (and any other Tiers that may be determined in relation to the Biobank) Participants should clearly have the option at the beginning of the relevant section of the Form to indicate that they are not interested in that Tier.

3.8 The section in the Form relating to a Tier should include a series of statements that Participants are asked to agree with, such as, "I understand and agree to the following: I have read and understood the Participant Information Sheet, My sample and personal

[44] We have assumed that entering into the agreement (and acting as the Biobank Custodian) is within the functions and powers of the Commonwealth government entity currently proposed to undertake this role, under its governing legislation, but this should be confirmed (as part of **Recommendation 5**)

information will be used in research studies, My sample and rec*ords will not include my name and contact details when sent to researchers")*

3.9 We **recommend** that in developing the content of the Consent Form, the ABS and Biobank Custodian:

3.9.1 apply, as far as feasible, the strategies embodied by the *NSW Health Consent Toolkit* which provides a plain English approach to seeking informed consent in the context of biobanking; and

3.9.2 consider and apply research findings in relation to consent language in the biobanking context which includes using reassuring language, as set out in the work of Beskow et al, 'Developing model biobanking consent language: what matters to prospective participants?' *BMC Medical Research Methodology*, 119 (2020).

(**Recommendation 7**)

3.10 For the Biobank, Stakeholders acknowledged that a tiered consent model was appropriate to separate consent for genomic research, given that some Participants may have particular concerns about genomic research. In our view, this aspect of the tiered model is a privacy enhancing feature, as it provides greater control to individuals over their personal information.

3.11 However, we note that there was a significant amount of discussion about whether the tiered model should be taken further and whether dynamic consent tools could be used to facilitate ongoing consent of Participants once their samples were stored in the Biobank. In our view, such a measure would promote privacy best practice as it provides even greater control to persons on how their personal information is handled.

3.12 We **recommend** that the Biobank Custodian consider the feasibility of implementing a dynamic consent platform to provide an interface to support ongoing participant-led management of their involvement in research studies conducted using samples in the Biobank. Any position reached on the implementation of dynamic consent (why it has been implemented or not implemented) should be published on the Biobank website.

3.13 We **recommend** that the Biobank Custodian consider as part of establishing its process for the operation of the Biobank whether it is possible to have greater nuanced consent for the Biobank, that is, more tiers. For example, separate consents allowing Participants to choose to provide[45]:

3.13.1 consent for particular categories of research (including genomic research); or

3.13.2 consent for specific projects only.

(**Recommendation 8**)

3.14 We acknowledge to properly consider the feasibility of introducing dynamic consent models (including systems to implement) may not be possible to complete prior to the NHMS commencing. We note that dynamic consent would be an enhancement of the tiered model of consent for the NHMS and Biobank. We therefore **recommend** consent documentation provided to the Participants include for Tier 2 and Tier 3 consents (and any other Tiers that may be determined in relation to the Biobank) that a Participant consents to be further contacted by the Biobank Custodian (which will allow further refinement of consent models in the future (e.g., the introduction of dynamic consent) (**Recommendation 7**).

[45] The list below is premised on the assumption any future research must have the relevant ethics clearance.

3.15 Given the amount of interest in the consent mechanisms for the operation of the Biobank and to assist in transparency, we **recommend** that the Biobank Custodian, as part of developing its policies and processes, consider developing a consent framework or policy document setting out the reasoning for the consent processes that will be adopted for the Biobank (for example, tiered consent, or whether it will use dynamic consent tools) and how these will operate in practice (what the consent covers, how it can be withdrawn, implications of withdrawal where research has already been undertaken, how it intends to deal with deceased persons, and data retention policies), and placing this on the Biobank website so that persons have a thorough understanding of the consent process including how it was developed. (**Recommendation 6**)

3.16 In our view, taking measures to enhance openness and transparency in the management of personal information, as recommended in **Recommendation 6**, would enable the Biobank Custodian to further demonstrate that the personal information collected was done by fair means as Participants were fully made aware of all the relevant issues (that is, there was no deception or misrepresentations).

3.17 We consider that if the recommendations above are implemented, the Biobank Custodian would be compliant with APP 3.

4. APP 4 – dealing with unsolicited personal information

5. Like any entity, we note that it is also possible that the Biobank Custodian might receive unsolicited information. We expect that as part of developing its processes and procedures it will develop processes in relation to dealing with any unsolicited information.

6. APP 5 – notification of the collection of personal information

6.1 For similar reasons as for the NHMS, we **recommend** that a layered approach is taken for the collection notice which will support collections, uses, disclosures for the Biobank. That is, a short notice is included in the relevant Participation Information Sheet for the NHMS and Biobank with:

6.1.1 links or references to a publicly available website containing a more detailed collection notice, and more information (such as the *ABS Privacy Policy for Statistical Information* and Biobank Privacy Policy, more details about how information is used, and the consent framework in relation to the Biobank); and

6.1.2 a telephone number for people to call so they can listen to the full collection notice and relevant Privacy Policy or speak to someone if they have questions. (**Recommendation 8**)

6.2 The collection notices (and Privacy Policies) should be available in a range of languages and otherwise also be in accessible format.

7. APP 6 – use or disclosure of personal information

7.1 In our view, the following uses of personal information will be for the primary purposes for which it was collected, namely, to facilitate the operation of the Biobank by the Biobank Custodian:

7.1.1 Participant Information is used by the Pathology Provider to allocate unique identifiers for biological samples to be stored in the Biobank and create an inventory list; and

7.1.2 Participant Information is used by the Biobank Custodian for processes associated with the Biobank (e.g. managing consent of Participants, communications with Participants, considering notifications from researchers regarding actionable results).

7.2 The following disclosures of personal information will be for the primary purposes for which it was collected, namely to facilitate the operation of the Biobank by the Biobank Custodian:

7.2.1 ABS or Pathology Provider discloses Participant Information to the Biobank Custodian (which is being contemplated though the provision of the relevant Biobank Consent Form by ABS to the Biobank Custodian); and

7.2.2 Participant Information is disclosed by the Biobank Custodian to a Researcher or a partnered genetic counsellor to facilitate the delivery of actionable results to a Participant.

7.3 We caution though that the finding of compliance against APP 6 is dependent on these purposes for which the information is collected being clearly communicated to Participants, so that consent for these purposes is appropriately obtained and valid.

7.4 There is therefore a risk that if the collection of personal information is not done appropriately, the Biobank Custodian will not be able to rely on the uses and disclosures being for the primary purposes of collection.

8. Any other use and disclosure will therefore be considered to be for a secondary purpose and the entities will need to have obtained consent from a Participant for the use or disclosure or otherwise rely on an exception in APP 6.2 and APP 6.3. The most practical way for the Biobank Custodian to mitigate this risk is to implement **Recommendation 6** to **Recommendation 9** to ensure that appropriate consent will be obtained in the Biobank.

9. APP 7 – direct marketing

9.1 As discussed at **Table 2** and our discussion against APP 1 above, the Biobank Custodian could be an organisation for the purposes of s 7A of the Privacy Act. However, in our view (subject to confirmation from the Biobank Custodian) we do not consider the Biobank Custodian will be engaging in 'commercial activities' in its role as the Biobank Custodian. Accordingly, APP 7 does not apply to it.

10. APP 8 – cross-border disclosure of personal information

10.1 Below is an extract from the Biobank Custodian's current APP 1 privacy policy:

> We may disclose personal information overseas from time to time, for example in the course of a research project with an overseas entity, through publishing information or by storing information on a server located overseas. [The Biobank Custodian] will only disclose your information overseas in accordance with APP 8 and where certain conditions are met, for example, where the recipient is subject to a law or binding scheme substantially similar to the APPs, including mechanisms for enforcement, we have sought your consent, or we have ensured appropriate contractual measurements are met.

10.2 The privacy policy does not make it clear that the Biobank Custodian will take reasonable steps to ensure third parties do not breach APPs in relation to the information (i.e. APP 8.1).

10.3 In accordance, with APP 8.2, the requirement under APP 8.1 does not apply to the disclosure of personal information if:

10.3.1 the APP entity reasonably believes that

(a) the recipient of the information is subject to a law or binding scheme that has the effect of protecting the information in a substantially similar way to the APPs; and

(b) there are mechanisms the individual can access to take action to enforce the protection of that law or binding scheme (APP 8.2(a)); or

10.3.2 both of the following apply:

(a) the entity expressly informs the individual that if he or she consents to the disclosure of information, that APP 8.1 will not apply; and

(b) after being so informed, the individual consents to the disclosure (APP 8.2(b)).

10.4 We consider that the Biobank Custodian's privacy policy indicates a general compliance with APP 8.2(a) (at paragraph 8.15.1 above) and a general compliance with APP 8.2(b) (at paragraph 8.15.2 above). However, while the Biobank Custodian may be able to disclose personal information overseas in compliance with APP 8, we again query whether this ***should*** be permitted to occur.

10.5 We **recommend** that the funding arrangements between Health and the Biobank Custodian include provisions that expressly prevent the Biobank Custodian from disclosing Participant Information to any overseas recipient (including for the purposes of data storage).

10.6 This recommendation is made taking into account the sensitivities around data sovereignty for the general Australian public, and the particular sensitivities around data sovereignty for Aboriginal and Torres Strait Islander identifying Participants.

10.7 We understand that, at the time of writing this PIA report, the contractual arrangements regarding the funding and operation of the Biobank are being negotiated between Health and the Biobank Custodian. We **recommend** that ABS discuss with Health the importance of the Biobank Custodian also considering the above recommendation in relation to the Pathology Provider so that Health can ensure the appropriate protections are built into its arrangements with the Biobank Custodian).
(**Recommendation 10**)

10.8 We note that we have recommended that a standalone Privacy Policy be prepared for the Biobank (**Recommendation 6**), which should clearly explain whether or not any overseas disclosure of Participant Information may occur.

11. APP 9 – adoption, use or disclosure of government related identifiers

11.1 APP 9 only applies to ***organisations*** as defined in the Privacy Act, rather than to agencies. Therefore, it will not apply to ABS or the Biobank Custodian (if it will not be engaging in 'commercial activities' when acting as the Biobank Custodian).

11.2 Under section 6 of the Privacy Act, ***government related identifiers*** are defined identifier of the individual that has been assigned by:

11.2.1 an agency; or

11.2.2 a State or Territory authority; or

11.2.3 an agent of an agency, or a State or Territory authority, acting in its capacity as agent; or

11.2.4 a contracted service provider for a Commonwealth contract, or a State contract, acting in its capacity as contracted service provider for that contract.[46]

Application of APP 9 to the Pathology Provider

11.3 The Pathology Provider is an organisation within the meaning of section 6C of the Privacy Act and is therefore subject to APP 9. Under APP 9.2, the Pathology Provider must not use or disclose a government related identifier of an individual unless an exception applies.

[46] *Privacy Act 1988* (Cth), s 6(1).

11.4 The Pathology Provider will transfer any additional Participant biomedical sample(s) taken to the Biobank storage facility,[47] where the Participant has consented to this. The Pathology Provider will:

11.4.1 **use** Participant Information to create and allocate a unique identifier that will be associated with a particular biomedical sample for a Participant; and

11.4.2 **use** the unique identifier attributed to samples for a Participant to prepare an 'inventory list', which will contain no identifying information.

11.5 The biomedical sample(s) will be transferred for long term storage and will be accompanied by the inventory list.

11.6 The Pathology Provider will collect and use an ABS unique identifier. This ABS unique identifier is a government related identifier, consistent with the definition outlined in the Australian Privacy Principles. The Pathology Provider will collect and use this identifier as part of, and in accordance with, the contracted services provided to the ABS.

11.7 The Pathology Provider is prohibited from adopting the unique identifier attributed to a Participant's biomedical sample as its own identifier of the individual, unless the adoption of the government related identifier is authorised by law, or APP 9.3 applies. The adoption of the government related identifier is not authorised by law, nor does the exception under APP 9.3 apply, therefore the Pathology cannot adopt the unique as its own identifier for a Participant.

11.8 However, the use of the Participant's unique identifier to create an 'inventory list' that is subsequently disclosed to the Biobank Custodian (**Step 12**) will be authorised by the exception under APP 9.2(b), which provides that an organisation must not use or disclose a government related identifier of an individual unless the use or disclosure of the identifier is reasonably necessary for the organisation to fulfil its obligations to an agency or a State or Territory authority.

11.9 Given, the use of the unique identifier created by the Pathology Provider is integral to the creation of the inventory list that accompanies the biomedical samples to the Biobank, and the disclosure to the Biobank Custodian enables the Biobank Custodian to undertake its functions and activities, we consider that the use and disclosure will be reasonably necessary for the Pathology Provider to fulfill its obligations to the ABS.

11.10 However, we note that once it has provided the relevant unique number and transported the relevant biomedical samples to the biobank storage facility, there is no need for the Pathology Provider to retain the number. We therefore **recommend** that the ABS ensure that its contractual arrangements with the Pathology Provider include provisions that require the Pathology Provider to delete the unique identifier after a certain period of time so that it does not retain this number (**Recommendation 4**).

11.11 We also note for completeness, that while the ABS would have originally allocated the unique identifier, it will not hold information about who has consented to participate in the Biobank as it will not retain the Biobank Consent Forms.

12. APP 10 – quality of personal information

Application of APP 10 to the Pathology Provider

12.1 In **Step 12** the Pathology Provider will disclose the personal information of the Participant to the Biobank Custodian along with the secondary sample. The personal information will include the government related identifier (as discussed above). Given that this personal information will be disclosed the requirements of APP 10.2 apply. That is the APP entity, in this case the Pathology Provider, must take reasonable steps to ensure the information is accurate, up-to-date, complete and relevant while having regard to the purpose of the disclosure. As this is at the early stage of development it is not clear how this is intended to

[47] The Biobank storage facility may be operated by a third party engaged by the Biobank Custodian

be achieved and without careful consideration there is a risk of loss of data. We therefore **recommend** that the ABS ensure its contractual arrangements with the Pathology Provider include provisions in relation to data quality and assurance steps that are required to be taken to minimise data corruption (**Recommendation 4**).

Application of APP 10 to the Biobank Custodian

12.2 Under **Step 13** the Biobank Custodian will be using Participant Information it receives to:

12.2.1 process the withdrawal of Participant consent to store and use the biomedical samples;

12.2.2 maintain ongoing communication with Participants.

12.3 The potential adverse consequences for an individual if they choose to withdraw their consent to the ongoing use of their biomedical samples may be significant. Therefore, we consider it crucial that the quality of information is maintained for the use of Participant Information by the Biobank Custodian. Further, during consultation stakeholders voiced concerns regarding the need to maintain ongoing communication with Participants. Stakeholders noted that maintaining contact ought to be given considerable thought, particularly as vulnerable people often tend to change their contact details more frequently.

12.4 In addition, under **Step 14**, if there is a 'medically actionable health risk' or 'medically actionable genetic health risk' identified in a research project, the Researcher or Partnered Genetic Counsellor may need to contact the Participant in accordance with the Results Plan to give them the opportunity to know this information.[48]

12.5 Given the sensitivity of the information (and its interaction with consent requirements), the potential health risks and outcomes, and the vulnerability of some participants, we consider that the Biobank Custodian ought to take rigorous steps towards ensuring the ongoing quality of Participant Information for its future uses.

12.6 In our view, implementing **Recommendation 6** in relation to the development of policies and processes, including a consent framework setting out the process for managing consent and contact details, would be a reasonable step that the Biobank Custodian can take to ensure that personal information it collects, uses and discloses is accurate, up-to-date, complete and relevant.

13. APP 11 – security of personal information

Security of personal information

13.1 Whether the Pathology Provider will disclose to the Biobank Custodian the executed Biobank Consent Form is still under consideration. It is critical that the Biobank Custodian's ICT systems used to store Participant Information are secure.

13.2 To ensure that Participant Information is adequately protected from misuse, interference and loss, and from unauthorised access, modification or disclosure, during the stages of its lifecycle, we **recommend** that the ABS discuss with Health the importance of the Biobank Custodian also considering the privacy protections set out in **Recommendation 4** when entering into its arrangements with third parties that may involve handling of personal information in connection with the Biobank (so that Health can ensure the appropriate protections are built into its arrangements with the Biobank Custodian). (**Recommendation 10**).

[48] During consultation, Stakeholders raised the point that Participants have a right to **not** know this information as there may be life insurance implications once results are received. We understand that health insurance is protected from genetic discrimination, but life insurance is risk rated and does not have the same protections, therefore people have a right not to know and that right needs to be protected. As such, it is important that the Participant is given the opportunity to know this information, but with an opportunity to decide that they do not wish to know it.

13.3 This will include ensuring they clearly set out the Biobank Custodian's obligations in the event of an actual or suspected Notifiable Data Breach.

Retention of personal information

13.4 In response to stakeholder feedback, the ABS has decided that the biomedical samples will be stored indefinitely in the Biobank. As a consequence, so too will the accompanying Participant Information.

13.5 We note that Participant Information held by the Biobank Custodian will be contained in a Commonwealth record for the purposes of the Archives Act, such that the Biobank Custodian will comply with APP 11.2 in respect of information held by it through implementation of its usual archiving and destruction processes (in accordance with the Archives Act).[49]

13.6 As set out in our **Recommendation 6**, in considering the consent framework, the Biobank Custodian should consider its retention policy for personal information, including where a Participant withdraws their consent, the destruction of any biomedical samples.

14. APP 12 – access to personal information

16.2 It will be important that the Biobank Custodian will comply with its obligations under APP 12 to ensure that Participants have the ability to access their personal information that is held by the Biobank Custodian if they wish.

16.3 Although the Biobank Custodian will have obligations under APP 12 in its own right, we note that implementation of **Recommendation 5** will further assist in ensuring that the roles, responsibilities and obligations of the Biobank Custodian are built into its arrangements between Health and the Biobank Custodian).

15. APP 13 – correction of personal information

15.1 It will be important that the Biobank Custodian will comply with its obligations under APP 13 to ensure that Participants have the ability to access their personal information that is held by the Biobank Custodian if they wish.

15.2 Although the Biobank Custodian will have obligations under APP 13 in its own right, we note that implementation of **Recommendation 10** will further assist in ensuring that the roles, responsibilities and obligations of the Biobank Custodian are built into its arrangements between Health and the Biobank Custodian).

15.3 In our view, implementing **Recommendation 5** in relation to the development of policies and processes would also ensure that the Biobank Custodian can meet the obligations in APP 13.

[49] See, https://www.naa.gov.au/sites/default/files/2019-12/agency-ra-2002-04926193.pdf

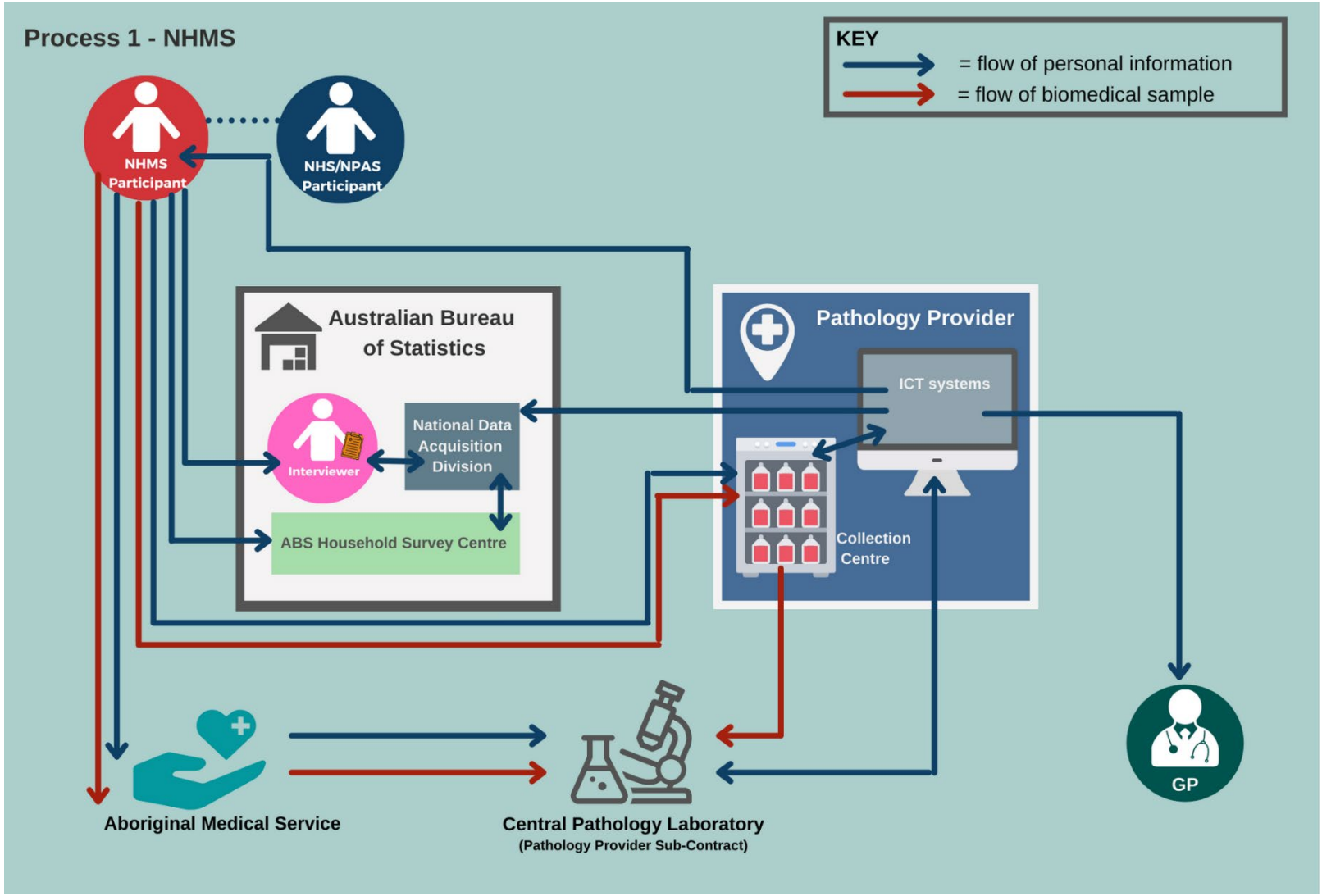
Part H GLOSSARY

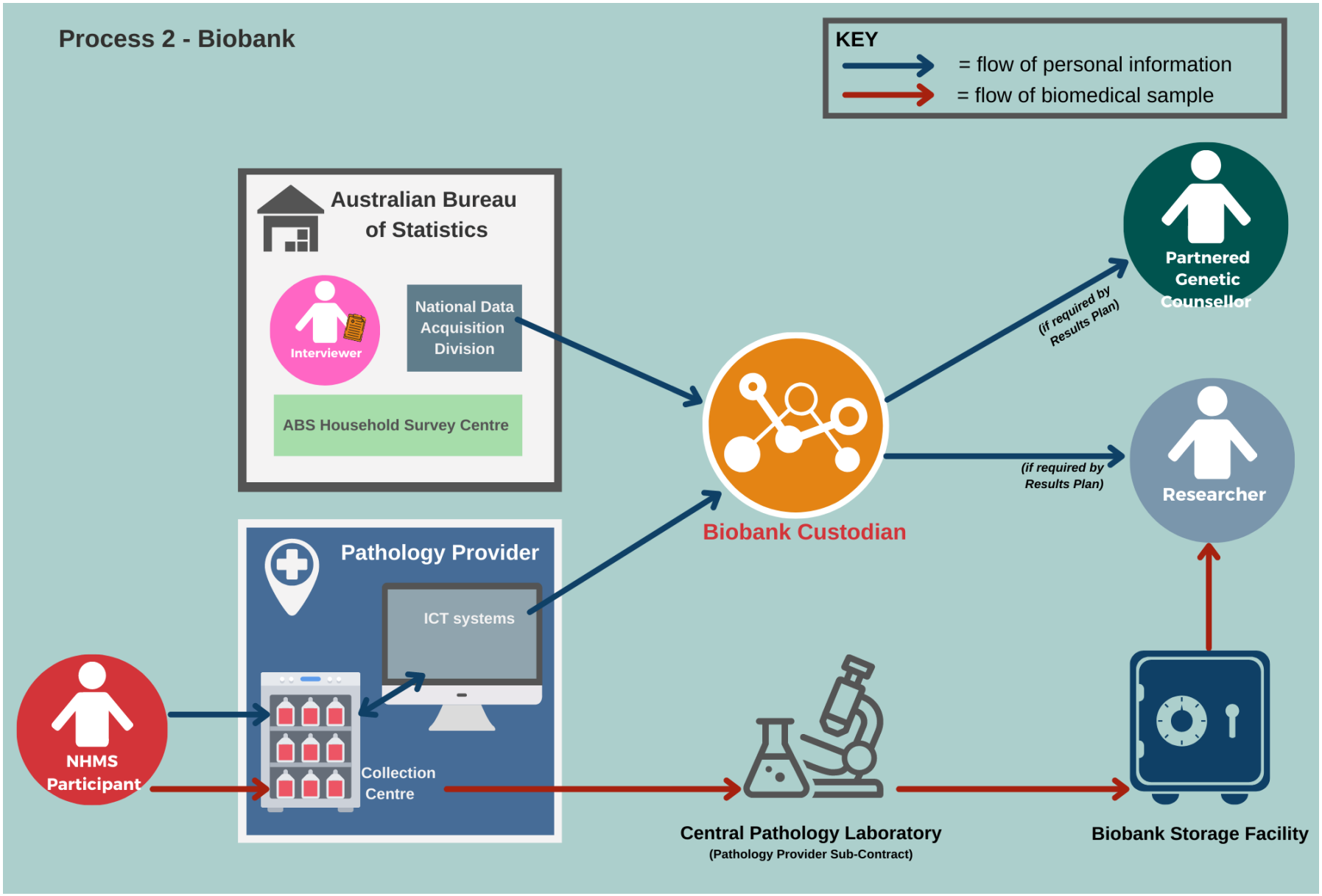
Definitions	
ABS	means the Australian Bureau of Statistics.
AMS	means an Aboriginal Medical Service.
APP	means the Australian Privacy Principles.
Biobank	means the repository of biomedical samples that were collected as part of the Study, where the Participant has consented to the storage and future use of those samples.
Biobank Consent Form	means the form provided by an ABS Interviewer to a Participant that refers the Participant to the Pathology Provider for the collection of their biomedical sample and collects the consent to participate in the NHMS.
Biobank Custodian	means the Commonwealth government entity who is responsible for establishment and management of the Biobank, including management of access to the biomedical samples in the Biobank.
Biobank storage facility	means the physical facility in which the biomedical samples comprising the Biobank are stored
Biobank website	means the dedicated website for the Biobank.
biomedical sample	means a sample of a Participant's blood and/or urine.
Central Pathology Laboratory	means the laboratory where the testing of the Participant's biomedical sample will occur which is run by Douglass Hanly Moir Pathology Pty Ltd
Collection Centre	means a collection centre of the Pathology Provider where a Participant's biomedical sample will be collected
Consent Form	means the consent form provided by an ABS Interviewer to a Participant in the NHMS.
General Population	means those Participants who are not part of the Indigenous Population.
GP	mean a Participant's general practitioner.
Guardian	means in relation to a child their Parent, Legal Guardian or Legally Authorised Representative
Health	means the Department of Health.
IHMHS	means the Intergenerational Health and Mental Health Study.

Definitions	
Indigenous Population	means those Participants who are Aboriginal or Torres Strait Islander persons.
MADIP	means the Multi-Agency Data Integration Project.
National Statement	means the *National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)*.
NHMS	means the 2022-2023 National Health Measures Study, the biomedical component of the IHMHS
NHS	means the National Health Study.
NNPAS	means the National Nutrition and Physical Activity Study.
OAIC	the Office the Australian Information Commissioner.
OAIC Survey	the *Australian Community Attitudes to Privacy Survey 2020* commissioned by the OAIC.
Participant	means a Participant in the NHMS
Participant Information	means the information about a Participant contained in a completed Consent Form and Referral Form for the Participant
Participant Information Sheet	means the information provided to a Participant at a face to face interview, which sets out information about the Study.
Participant Results	the health information contained in test results for a Participant under the NHMS
Pathology Collection Centre	means the collection centre that the biomedical samples will be collected from.
Pathology Provider	means the ABS' contract service provider, contracted to provide pathology services for the Study.
personal information	has the meaning given in section 6 of the Privacy Act.
PFAS	per- and poly-fluoroalkyl substances.
PIA	means the privacy impact assessment.
Privacy Act	means the *Privacy Act 1988* (Cth).
Referral and Consent Form for NHMS	means the form provided by an ABS Interviewer to a Participant that refers the Participant to the Pathology Provider for the collection of their biomedical sample and collects the consent to participate in the NHMS.
Reimbursement Arrangement	means the gift card that Participants will be provided when they provide a biomedical sample for the NHMS.

Definitions	
Researcher	means an individual or entity who makes a request to the Biobank Custodian seeking access to a biomedical sample held by the Biobank.
Secondary Sample	means biomedical sample(s) collected from a Participant for storage in the Biobank

Attachment 1 Diagrams of information flows





Attachment 2 Australian Privacy Principles

APP 1 – open and transparent management of personal information

1 Australian Privacy Principle 1—open and transparent management of personal information

1.1 The object of this principle is to ensure that APP entities manage personal information in an open and transparent way.

Compliance with the Australian Privacy Principles etc.

1.2 An APP entity must take such steps as are reasonable in the circumstances to implement practices, procedures and systems relating to the entity's functions or activities that:

(a) will ensure that the entity complies with the Australian Privacy Principles and a registered APP code (if any) that binds the entity; and

(b) will enable the entity to deal with inquiries or complaints from individuals about the entity's compliance with the Australian Privacy Principles or such a code.

APP Privacy policy

1.3 An APP entity must have a clearly expressed and up-to-date policy (the *APP privacy policy*) about the management of personal information by the entity.

1.4 Without limiting subclause 1.3, the APP privacy policy of the APP entity must contain the following information:

(a) the kinds of personal information that the entity collects and holds;

(b) how the entity collects and holds personal information;

(c) the purposes for which the entity collects, holds, uses and discloses personal information;

(d) how an individual may access personal information about the individual that is held by the entity and seek the correction of such information;

(e) how an individual may complain about a breach of the Australian Privacy Principles, or a registered APP code (if any) that binds the entity, and how the entity will deal with such a complaint;

(f) whether the entity is likely to disclose personal information to overseas recipients;

(g) if the entity is likely to disclose personal information to overseas recipients—the countries in which such recipients are likely to be located if it is practicable to specify those countries in the policy.

Availability of APP privacy policy etc.

1.5 An APP entity must take such steps as are reasonable in the circumstances to make its APP privacy policy available:

(a) free of charge; and

(b) in such form as is appropriate.

Note: An APP entity will usually make its APP privacy policy available on the entity's website.

1.6 If a person or body requests a copy of the APP privacy policy of an APP entity in a particular form, the entity must take such steps as are reasonable in the circumstances to give the person or body a copy in that form.

APP 2 – anonymity and **pseudonymity**

2 Australian Privacy Principle 2—anonymity and pseudonymity

2.1 Individuals must have the option of not identifying themselves, or of using a pseudonym, when dealing with an APP entity in relation to a particular matter.

2.2 Subclause 2.1 does not apply if, in relation to that matter:

(a) the APP entity is required or authorised by or under an Australian law, or a court/tribunal order, to deal with individuals who have identified themselves; or

(b) it is impracticable for the APP entity to deal with individuals who have not identified themselves or who have used a pseudonym.

3 Australian Privacy Principle 3—collection of solicited personal information

Personal information other than sensitive information

3.1 If an APP entity is an agency, the entity must not collect personal information (other than sensitive information) unless the information is reasonably necessary for, or directly related to, one or more of the entity's functions or activities.

3.2 If an APP entity is an organisation, the entity must not collect personal information (other than sensitive information) unless the information is reasonably necessary for one or more of the entity's functions or activities.

Sensitive information

3.3 An APP entity must not collect sensitive information about an individual unless:

(a) the individual consents to the collection of the information and:

(i) if the entity is an agency—the information is reasonably necessary for, or directly related to, one or more of the entity's functions or activities; or

(ii) if the entity is an organisation—the information is reasonably necessary for one or more of the entity's functions or activities; or

(b) subclause 3.4 applies in relation to the information.

3.4 This subclause applies in relation to sensitive information about an individual if:

(a) the collection of the information is required or authorised by or under an Australian law or a court/tribunal order; or

(b) a permitted general situation exists in relation to the collection of the information by the APP entity; or

(c) the APP entity is an organisation and a permitted health situation exists in relation to the collection of the information by the entity; or

(d) the APP entity is an enforcement body and the entity reasonably believes that:

(i) if the entity is the Immigration Department—the collection of the information is reasonably necessary for, or directly related to, one or more enforcement related activities conducted by, or on behalf of, the entity; or

(ii) otherwise—the collection of the information is reasonably necessary for, or directly related to, one or more of the entity's functions or activities; or

(e) the APP entity is a non-profit organisation and both of the following apply:

(i) the information relates to the activities of the organisation;

(ii) the information relates solely to the members of the organisation, or to individuals who have regular contact with the organisation in connection with its activities.

Note: For *permitted general situation*, see section 16A. For *permitted health situation*, see section 16B.

Means of collection

3.5 An APP entity must collect personal information only by lawful and fair means.

3.6 An APP entity must collect personal information about an individual only from the individual unless:

(a) if the entity is an agency:

(i) the individual consents to the collection of the information from someone other than the individual; or

(ii) the entity is required or authorised by or under an Australian law, or a court/tribunal order, to collect the information from someone other than the individual; or

(b) it is unreasonable or impracticable to do so.

Solicited personal information

3.7 This principle applies to the collection of personal information that is solicited by an APP entity.

APP 4 – dealing with unsolicited personal information

4 Australian Privacy Principle 4—dealing with unsolicited personal information

4.1 If:

(a) an APP entity receives personal information; and

(b) the entity did not solicit the information;

the entity must, within a reasonable period after receiving the information, determine whether or not the entity could have collected the information under Australian Privacy Principle 3 if the entity had solicited the information.

4.2 The APP entity may use or disclose the personal information for the purposes of making the determination under subclause 4.1.

4.3 If:

(a) the APP entity determines that the entity could not have collected the personal information; and

(b) the information is not contained in a Commonwealth record;

the entity must, as soon as practicable but only if it is lawful and reasonable to do so, destroy the information or ensure that the information is de-identified.

4.4 If subclause 4.3 does not apply in relation to the personal information, Australian Privacy Principles 5 to 13 apply in relation to the information as if the entity had collected the information under Australian Privacy Principle 3.

APP 5 – notification of the collection of personal information

5 Australian Privacy Principle 5—notification of the collection of personal information

5.1 At or before the time or, if that is not practicable, as soon as practicable after, an APP entity collects personal information about an individual, the entity must take such steps (if any) as are reasonable in the circumstances:

(a) to notify the individual of such matters referred to in subclause 5.2 as are reasonable in the circumstances; or

(b) to otherwise ensure that the individual is aware of any such matters.

5.2 The matters for the purposes of subclause 5.1 are as follows:

(a) the identity and contact details of the APP entity;

(b) if:

(i) the APP entity collects the personal information from someone other than the individual; or

(ii) the individual may not be aware that the APP entity has collected the personal information;

the fact that the entity so collects, or has collected, the information and the circumstances of that collection;

(c) if the collection of the personal information is required or authorised by or under an Australian law or a court/tribunal order—the fact that the collection is so required or authorised (including the name of the Australian law, or details of the court/tribunal order, that requires or authorises the collection);

(d) the purposes for which the APP entity collects the personal information;

(e) the main consequences (if any) for the individual if all or some of the personal information is not collected by the APP entity;

(f) any other APP entity, body or person, or the types of any other APP entities, bodies or persons, to which the APP entity usually discloses personal information of the kind collected by the entity;

(g) that the APP privacy policy of the APP entity contains information about how the individual may access the personal information about the individual that is held by the entity and seek the correction of such information;

(h) that the APP privacy policy of the APP entity contains information about how the individual may complain about a breach of the Australian Privacy Principles, or a registered APP code (if any) that binds the entity, and how the entity will deal with such a complaint;

(i) whether the APP entity is likely to disclose the personal information to overseas recipients;

(j) if the APP entity is likely to disclose the personal information to overseas recipients—the countries in which such recipients are likely to be located if it is practicable to specify those countries in the notification or to otherwise make the individual aware of them.

6 Australian Privacy Principle 6—use or disclosure of personal information

Use or disclosure

6.1 If an APP entity holds personal information about an individual that was collected for a particular purpose (the *primary purpose*), the entity must not use or disclose the information for another purpose (the *secondary purpose*) unless:

(a) the individual has consented to the use or disclosure of the information; or

(b) subclause 6.2 or 6.3 applies in relation to the use or disclosure of the information.

Note: Australian Privacy Principle 8 sets out requirements for the disclosure of personal information to a person who is not in Australia or an external Territory.

6.2 This subclause applies in relation to the use or disclosure of personal information about an individual if:

(a) the individual would reasonably expect the APP entity to use or disclose the information for the secondary purpose and the secondary purpose is:

(i) if the information is sensitive information—directly related to the primary purpose; or

(ii) if the information is not sensitive information—related to the primary purpose; or

(b) the use or disclosure of the information is required or authorised by or under an Australian law or a court/tribunal order; or

(c) a permitted general situation exists in relation to the use or disclosure of the information by the APP entity; or

(d) the APP entity is an organisation and a permitted health situation exists in relation to the use or disclosure of the information by the entity; or

(e) the APP entity reasonably believes that the use or disclosure of the information is reasonably necessary for one or more enforcement related activities conducted by, or on behalf of, an enforcement body.

Note: For *permitted general situation*, see section 16A. For *permitted health situation*, see section 16B.

6.3 This subclause applies in relation to the disclosure of personal information about an individual by an APP entity that is an agency if:

(a) the agency is not an enforcement body; and

(b) the information is biometric information or biometric templates; and

(c) the recipient of the information is an enforcement body; and

(d) the disclosure is conducted in accordance with the guidelines made by the Commissioner for the purposes of this paragraph.

6.4 If:

(a) the APP entity is an organisation; and

(b) subsection 16B(2) applied in relation to the collection of the personal information by the entity;

the entity must take such steps as are reasonable in the circumstances to ensure that the information is de-identified before the entity discloses it in accordance with subclause 6.1 or 6.2.

Written note of use or disclosure

6.5 If an APP entity uses or discloses personal information in accordance with paragraph 6.2(e), the entity must make a written note of the use or disclosure.

Related bodies corporate

6.6 If:

(a) an APP entity is a body corporate; and

(b) the entity collects personal information from a related body corporate;

this principle applies as if the entity's primary purpose for the collection of the information were the primary purpose for which the related body corporate collected the information.

Exceptions

6.7 This principle does not apply to the use or disclosure by an organisation of:

(a) personal information for the purpose of direct marketing; or

(b) government related identifiers.

7 Australian Privacy Principle 7—direct marketing

Direct marketing

7.1 If an organisation holds personal information about an individual, the organisation must not use or disclose the information for the purpose of direct marketing.

Note: An act or practice of an agency may be treated as an act or practice of an organisation, see section 7A.

Exceptions—personal information other than sensitive information

7.2 Despite subclause 7.1, an organisation may use or disclose personal information (other than sensitive information) about an individual for the purpose of direct marketing if:

(a) the organisation collected the information from the individual; and

(b) the individual would reasonably expect the organisation to use or disclose the information for that purpose; and

(c) the organisation provides a simple means by which the individual may easily request not to receive direct marketing communications from the organisation; and

(d) the individual has not made such a request to the organisation.

7.3 Despite subclause 7.1, an organisation may use or disclose personal information (other than sensitive information) about an individual for the purpose of direct marketing if:

(a) the organisation collected the information from:

(i) the individual and the individual would not reasonably expect the organisation to use or disclose the information for that purpose; or

(ii) someone other than the individual; and

(b) either:

(i) the individual has consented to the use or disclosure of the information for that purpose; or

(ii) it is impracticable to obtain that consent; and

(c) the organisation provides a simple means by which the individual may easily request not to receive direct marketing communications from the organisation; and

(d) in each direct marketing communication with the individual:

(i) the organisation includes a prominent statement that the individual may make such a request; or

(ii) the organisation otherwise draws the individual's attention to the fact that the individual may make such a request; and

(e) the individual has not made such a request to the organisation.

Exception—sensitive information

7.4 Despite subclause 7.1, an organisation may use or disclose sensitive information about an individual for the purpose of direct marketing if the individual has consented to the use or disclosure of the information for that purpose.

Exception—contracted service providers

7.5 Despite subclause 7.1, an organisation may use or disclose personal information for the purpose of direct marketing if:

(a) the organisation is a contracted service provider for a Commonwealth contract; and

(b) the organisation collected the information for the purpose of meeting (directly or indirectly) an obligation under the contract; and

(c) the use or disclosure is necessary to meet (directly or indirectly) such an obligation.

Individual may request not to receive direct marketing communications etc.

7.6 If an organisation (the *first organisation*) uses or discloses personal information about an individual:

(a) for the purpose of direct marketing by the first organisation; or

(b) for the purpose of facilitating direct marketing by other organisations;

the individual may:

(c) if paragraph (a) applies—request not to receive direct marketing communications from the first organisation; and

(d) if paragraph (b) applies—request the organisation not to use or disclose the information for the purpose referred to in that paragraph; and

(e) request the first organisation to provide its source of the information.

7.7 If an individual makes a request under subclause 7.6, the first organisation must not charge the individual for the making of, or to give effect to, the request and:

(a) if the request is of a kind referred to in paragraph 7.6(c) or (d)—the first organisation must give effect to the request within a reasonable period after the request is made; and

(b) if the request is of a kind referred to in paragraph 7.6(e)—the organisation must, within a reasonable period after the request is made, notify the individual of its source unless it is impracticable or unreasonable to do so.

Interaction with other legislation

7.8 This principle does not apply to the extent that any of the following apply:

(a) the *Do Not Call Register Act 2006*;

(b) the *Spam Act 2003*;

(c) any other Act of the Commonwealth, or a Norfolk Island enactment, prescribed by the regulations.

APP 8 – cross-border disclosure of personal information

8 Australian Privacy Principle 8—cross-border disclosure of personal information

8.1 Before an APP entity discloses personal information about an individual to a person (the *overseas recipient*):

(a) who is not in Australia or an external Territory; and

(b) who is not the entity or the individual;

the entity must take such steps as are reasonable in the circumstances to ensure that the overseas recipient does not breach the Australian Privacy Principles (other than Australian Privacy Principle 1) in relation to the information.

Note: In certain circumstances, an act done, or a practice engaged in, by the overseas recipient is taken, under section 16C, to have been done, or engaged in, by the APP entity and to be a breach of the Australian Privacy Principles.

8.2 Subclause 8.1 does not apply to the disclosure of personal information about an individual by an APP entity to the overseas recipient if:

(a) the entity reasonably believes that:

(i) the recipient of the information is subject to a law, or binding scheme, that has the effect of protecting the information in a way that, overall, is at least substantially similar to the way in which the Australian Privacy Principles protect the information; and

(ii) there are mechanisms that the individual can access to take action to enforce that protection of the law or binding scheme; or

(b) both of the following apply:

(i) the entity expressly informs the individual that if he or she consents to the disclosure of the information, subclause 8.1 will not apply to the disclosure;

(ii) after being so informed, the individual consents to the disclosure; or

(c) the disclosure of the information is required or authorised by or under an Australian law or a court/tribunal order; or

(d) a permitted general situation (other than the situation referred to in item 4 or 5 of the table in subsection 16A(1)) exists in relation to the disclosure of the information by the APP entity; or

(e) the entity is an agency and the disclosure of the information is required or authorised by or under an international agreement relating to information sharing to which Australia is a party; or

(f) the entity is an agency and both of the following apply:

(i) the entity reasonably believes that the disclosure of the information is reasonably necessary for one or more enforcement related activities conducted by, or on behalf of, an enforcement body;

(ii) the recipient is a body that performs functions, or exercises powers, that are similar to those performed or exercised by an enforcement body.

Note: For *permitted general situation*, see section 16A.

APP 9 – adoption, use or disclosure of government related identifiers

9 Australian Privacy Principle 9—adoption, use or disclosure of government related identifiers

Adoption of government related identifiers

9.1 An organisation must not adopt a government related identifier of an individual as its own identifier of the individual unless:

(a) the adoption of the government related identifier is required or authorised by or under an Australian law or a court/tribunal order; or

(b) subclause 9.3 applies in relation to the adoption.

Note: An act or practice of an agency may be treated as an act or practice of an organisation, see section 7A.

Use or disclosure of government related identifiers

9.2 An organisation must not use or disclose a government related identifier of an individual unless:

(a) the use or disclosure of the identifier is reasonably necessary for the organisation to verify the identity of the individual for the purposes of the organisation's activities or functions; or

(b) the use or disclosure of the identifier is reasonably necessary for the organisation to fulfil its obligations to an agency or a State or Territory authority; or

(c) the use or disclosure of the identifier is required or authorised by or under an Australian law or a court/tribunal order; or

(d) a permitted general situation (other than the situation referred to in item 4 or 5 of the table in subsection 16A(1)) exists in relation to the use or disclosure of the identifier; or

(e) the organisation reasonably believes that the use or disclosure of the identifier is reasonably necessary for one or more enforcement related activities conducted by, or on behalf of, an enforcement body; or

(f) subclause 9.3 applies in relation to the use or disclosure.

Note 1: An act or practice of an agency may be treated as an act or practice of an organisation, see section 7A.

Note 2: For *permitted general situation*, see section 16A.

Regulations about adoption, use or disclosure

9.3 This subclause applies in relation to the adoption, use or disclosure by an organisation of a government related identifier of an individual if:

(a) the identifier is prescribed by the regulations; and

(b) the organisation is prescribed by the regulations, or is included in a class of organisations prescribed by the regulations; and

(c) the adoption, use or disclosure occurs in the circumstances prescribed by the regulations.

Note: There are prerequisites that must be satisfied before the matters mentioned in this subclause are prescribed, see subsections 100(2) and (3).

APP 10 – quality of personal information

10 Australian Privacy Principle 10—quality of personal information

10.1 An APP entity must take such steps (if any) as are reasonable in the circumstances to ensure that the personal information that the entity collects is accurate, up-to-date and complete.

10.2 An APP entity must take such steps (if any) as are reasonable in the circumstances to ensure that the personal information that the entity uses or discloses is, having regard to the purpose of the use or disclosure, accurate, up-to-date, complete and relevant.

APP 11 – security of personal information

11 Australian Privacy Principle 11—security of personal information

11.1 If an APP entity holds personal information, the entity must take such steps as are reasonable in the circumstances to protect the information:

(a) from misuse, interference and loss; and

(b) from unauthorised access, modification or disclosure.

11.2 If:

(a) an APP entity holds personal information about an individual; and

(b) the entity no longer needs the information for any purpose for which the information may be used or disclosed by the entity under this Schedule; and

(c) the information is not contained in a Commonwealth record; and

(d) the entity is not required by or under an Australian law, or a court/tribunal order, to retain the information;

the entity must take such steps as are reasonable in the circumstances to destroy the information or to ensure that the information is de-identified.

APP 12 – access to personal information

12 Australian Privacy Principle 12—access to personal information

Access

12.1 If an APP entity holds personal information about an individual, the entity must, on request by the individual, give the individual access to the information.

Exception to access—agency

12.2 If:

(a) the APP entity is an agency; and

(b) the entity is required or authorised to refuse to give the individual access to the personal information by or under:

(i) the Freedom of Information Act; or

(ii) any other Act of the Commonwealth, or a Norfolk Island enactment, that provides for access by persons to documents;

then, despite subclause 12.1, the entity is not required to give access to the extent that the entity is required or authorised to refuse to give access.

Exception to access—organisation

12.3 If the APP entity is an organisation then, despite subclause 12.1, the entity is not required to give the individual access to the personal information to the extent that:

(a) the entity reasonably believes that giving access would pose a serious threat to the life, health or safety of any individual, or to public health or public safety; or

(b) giving access would have an unreasonable impact on the privacy of other individuals; or

(c) the request for access is frivolous or vexatious; or

(d) the information relates to existing or anticipated legal proceedings between the entity and the individual, and would not be accessible by the process of discovery in those proceedings; or

(e) giving access would reveal the intentions of the entity in relation to negotiations with the individual in such a way as to prejudice those negotiations; or

(f) giving access would be unlawful; or

(g) denying access is required or authorised by or under an Australian law or a court/tribunal order; or

(h) both of the following apply:

(i) the entity has reason to suspect that unlawful activity, or misconduct of a serious nature, that relates to the entity's functions or activities has been, is being or may be engaged in;

(ii) giving access would be likely to prejudice the taking of appropriate action in relation to the matter; or

(i) giving access would be likely to prejudice one or more enforcement related activities conducted by, or on behalf of, an enforcement body; or

(j) giving access would reveal evaluative information generated within the entity in connection with a commercially sensitive decision-making process.

Dealing with requests for access

12.4 The APP entity must:

(a) respond to the request for access to the personal information:

(i) if the entity is an agency—within 30 days after the request is made; or

(ii) if the entity is an organisation—within a reasonable period after the request is made; and

(b) give access to the information in the manner requested by the individual, if it is reasonable and practicable to do so.

Other means of access

12.5 If the APP entity refuses:

(a) to give access to the personal information because of subclause 12.2 or 12.3; or

(b) to give access in the manner requested by the individual;

the entity must take such steps (if any) as are reasonable in the circumstances to give access in a way that meets the needs of the entity and the individual.

12.6 Without limiting subclause 12.5, access may be given through the use of a mutually agreed intermediary.

Access charges

12.7 If the APP entity is an agency, the entity must not charge the individual for the making of the request or for giving access to the personal information.

12.8 If:

(a) the APP entity is an organisation; and

(b) the entity charges the individual for giving access to the personal information;

the charge must not be excessive and must not apply to the making of the request.

Refusal to give access

12.9 If the APP entity refuses to give access to the personal information because of subclause 12.2 or 12.3, or to give access in the manner requested by the individual, the entity must give the individual a written notice that sets out:

(a) the reasons for the refusal except to the extent that, having regard to the grounds for the refusal, it would be unreasonable to do so; and

(b) the mechanisms available to complain about the refusal; and

(c) any other matter prescribed by the regulations.

12.10 If the APP entity refuses to give access to the personal information because of paragraph 12.3(j), the reasons for the refusal may include an explanation for the commercially sensitive decision.

APP 13 – correction of personal information

13 Australian Privacy Principle 13—correction of personal information

Correction

13.1 If:

(a) an APP entity holds personal information about an individual; and

(b) either:

(i) the entity is satisfied that, having regard to a purpose for which the information is held, the information is inaccurate, out-of-date, incomplete, irrelevant or misleading; or

(ii) the individual requests the entity to correct the information;

the entity must take such steps (if any) as are reasonable in the circumstances to correct that information to ensure that, having regard to the purpose for which it is held, the information is accurate, up-to-date, complete, relevant and not misleading.

Notification of correction to third parties

13.2 If:

(a) the APP entity corrects personal information about an individual that the entity previously disclosed to another APP entity; and

(b) the individual requests the entity to notify the other APP entity of the correction;

the entity must take such steps (if any) as are reasonable in the circumstances to give that notification unless it is impracticable or unlawful to do so.

Refusal to correct information

13.3 If the APP entity refuses to correct the personal information as requested by the individual, the entity must give the individual a written notice that sets out:

(a) the reasons for the refusal except to the extent that it would be unreasonable to do so; and

(b) the mechanisms available to complain about the refusal; and

(c) any other matter prescribed by the regulations.

Request to associate a statement

13.4 If:

(a) the APP entity refuses to correct the personal information as requested by the individual; and

(b) the individual requests the entity to associate with the information a statement that the information is inaccurate, out-of-date, incomplete, irrelevant or misleading;

the entity must take such steps as are reasonable in the circumstances to associate the statement in such a way that will make the statement apparent to users of the information.

Dealing with requests

13.5 If a request is made under subclause 13.1 or 13.4, the APP entity:

(a) must respond to the request:

(i) if the entity is an agency—within 30 days after the request is made; or

(ii) if the entity is an organisation—within a reasonable period after the request is made; and

(b) must not charge the individual for the making of the request, for correcting the personal information or for associating the statement with the personal information (as the case may be).

Attachment 3 Material reviewed

1. *Indigenous Health Genomics: The legal, ethical and social issues* [Commissioned by the Department of Health] – drafted as at 10 February 2021.
2. *Essentially Ours Assessing the Regulation of the Collection and Use of Health-Related Genomic Information* [University of Tasmania and the University of Melbourne] – drafted as at 10 February 2021.
3. *Retention of Personal Identifiers for Statistical Purposes* [ABS] – drafted as at 10 February 2021.
4. *Response to the independent Privacy Impact Assessment of MADIP* [ABS et al] – drafted at 10 February 2021.
5. *MADIP Board Response to the 2019 Update of the Privacy Impact Assessment of MADIP* [ABS] – drafted as at 10 February 2021.
6. *Biobank Discussion Paper [ABS] – drafted as at 10 February 2021.*
7. *National Health Measures Study (NHMS) Pilot Study Data Management Plan* [ABS] – drafted as at 10 February 2021.
8. *Guardian 15 -17 Information Sheet* [ABS] – drafted as at 10 February 2021.
9. *Household and Biomedical Module Questions* [ABS] – drafted as at 10 February 2021.
10. *Test Protocols and Critical Limits* [ABS} – drafted as at February 2021
11. *Child Consent Form* [ABS] – drafted as at 10 February 2021.
12. *National Health Measures Survey Consultation Plan* [ABS] – drafted as at 10 February 2021.
13. *Child Participation Sheet* [ABS] – drafted as at 10 February 2021.
14. *Independent Privacy Impact Assessment (PIA) on the National Health Survey (NHS) Linkage Project* [ABS] – drafted as at 10 February 2021.
15. *Risk Subset for PIA* [ABS] – drafted as at 10 February 2021.
16. *Referral Form* [ABS] - drafted as at 10 February 2021.
17. *Adult and Child 12-17 Information Sheet* [ABS] – drafted as at 10 February 2021.
18. *Example Results Report* [ABS] – drafted as at 10 February 2021.
19. *Adult Consent Form* [ABS] – drafted as at 10 February 2021.
20. *Adult Participation Sheet* [ABS] – drafted as at 10 February 2021.
21. *National Health Measures Ethics Protocol* [ABS] – drafted as at 10 February 2021.
22. *National Health Measures Survey Overview* [ABS] – drafted as at 10 February 2021.
23. *NSW Health Consent Toolkit*, https://biobank.health.nsw.gov.au/researchers/nsw-health-consent-toolkit/

Attachment 4 Stakeholder Consultation Report

Consultation Report

May 2021

Contents

1. Introduction

1.1 This report presents the feedback and concerns of targeted consultation sessions that the Australian Bureau of Statistics (ABS) held with a range of stakeholders during March 2021 as part of the National Health Measures Study (the 'Study') Privacy Impact Assessment (PIA).

1.2 The Study will be the second biomedical study run by the ABS. The last study was conducted in 2011.

1.3 As one of the components of the Intergenerational Health and Mental Health Study commissioned by the Commonwealth Department of Health, the Study will provide updated data on selected biomedical markers of chronic disease, nutrition and environmental measures. This information will have a direct influence on improving health policy and service delivery collectively across Australian society. The Study aims to commence in January 2022.

1.4 The ABS is proposing to undertake integration of the Study's data with other data assets to maximise its use for health policy evaluation and research purposes. Integration of the Study data would commence at the conclusion of the study (March 2024).

1.5 Given this statistical collection falls outside the *Census and Statistics Act 1905* and the sensitive nature of the information collected in the Study, the ABS is undertaking a Privacy Impact Assessment (PIA) to formally examine the potential impacts of integrating the Study on the privacy of individuals, including in relation to:

1.5.1 the collection and use of biomedical samples and data for the purposes of the Study;

1.5.2 data integration of Study data to other data assets, like the Multi-Agency Data Integration Project ('MADIP'); and

1.5.3 storage of biomedical samples in a biobank for future health and genomic research.

1.6 Consultation is an essential part of conducting this PIA as it was an opportunity to inform stakeholders about the Study and the data integration infrastructure in the ABS, and to listen to stakeholder views on the proposed Study and the ABS's privacy management arrangements. Outcomes from consultation are being used to inform the risk analysis and recommendations for the PIA.

2. Our approach to consulting with stakeholders

2.1 The objectives of the consultation process were to

2.1.1 Inform stakeholders about:

(a) the Study;

(b) the Multi-Agency Data Integration Project (MADIP) and its current privacy practice and protections;

2.1.2 Listen to issues and concerns stakeholders may have about the Study.

2.2 The consultation sessions aimed to identify and discuss stakeholder views on the following topics.

2.2.1 linking Study data with other datasets, using the ABS's existing MADIP privacy protocols and data security infrastructure;

2.2.2 the ABS's existing governance, privacy and security protections for data integration projects;

2.2.3 the Study's consent model;

2.2.4 the implementation of a biobank; and

2.2.5 the distinction of responsibilities between the ABS, the biobank custodian and the pathology collector regarding ownership of biomedical samples in the biobank and managing Participants' consent.

2.3 Stakeholders consulted included peak health organisations, consumers, government, academics and advocacy groups. See 4. Appendix A: Stakeholders consulted for the NHMS PIA for a list of stakeholders who participated in consultation sessions.

2.4 These groups were invited to participate based on:

2.4.1 consumer expertise;

2.4.2 involvement in preparations for the Study;

2.4.3 involvement in and/or knowledge of Commonwealth data integration activities and projects;

2.4.4 involvement in and/or knowledge of genomic research and biobanking;

2.4.5 special interest or expertise such as advocacy; and

2.4.6 representation of a key sector of Australian society.

2.5 Several stakeholders who attended had been involved in previous consultations on government data integration.

2.6 Three two-hour sessions were held with mixed groups of stakeholders via teleconference during March 2021. Each of the sessions provided valuable feedback about the proposed Project.

3. Summary of stakeholder concerns

3.1 As a preliminary point, we note that the NHS PIA deals with two overarching distinct processes. For convenience, we refer to these as follows in this document:

3.1.1 **Process 1** – ABS processes for the conduct of the Study. This is the ABS controlled portion of the National Health Measures Study (NHMS) and involves:

(a) initial interview of participants in the NHMS (Participants);

(b) collection of consents and collection of biomedical sample(s);

(c) testing of each biomedical sample and preparation of the biomedical sample for storage;

(d) use and analysis of the data derived from the biomedical sample; and

(e) integration of the data into the Multi-Agency Data Integration Project (MADIP).

3.1.2 **Process 2** – processes relating to the Biobank. These processes are Biobank custodian controlled and involve:

(a) collection and storage of the biomedical sample in the Biobank storage facility;

(b) collection, storage and use of the personal information associated with each biomedical sample by the Biobank custodian;

(c) governance arrangements controlling access to and use of the biomedical sample for purposes of research or genomic testing; and

(d) destroying the biomedical sample if, and when, a Participant chooses to withdraw their consent for the use of their biomedical sample for research or genomic testing.

3.2 Set out in the table below is a high-level thematic breakdown of the issues and concerns that have been raised by stakeholders to date in relation to the NHMS PIA. Each concern has been allocated an identifying number. We note that consent was the most significant issue for stakeholders, and this cut across Process 1 and Process 2.

Process 1 specific concerns	**Process 2 specific concerns**	**Overarching concerns about consent**
Concern 1: Opt-in versus Opt-out consents	Concern 5: Biobank custodianship	Concern 10: Proposed consent model
Concern 2: Communication of health risks to Participants Concern 2A: What constitutes a 'significant health risk'? Concern 2B: Who will communicate results to Participants?	Concern 6: Maintaining contact with Participants	Concern 10A: bundled consent for tier one
Concern 3: Collection of consent at point of collection of sample	Concern 7: Returning results of testing to Participants	Concern 10B: Comprehension of complex consent
Concern 4: Data integration into MADIP Concern 4A: consumer lack of trust in inter-agency sharing of information Concern 4B: use of NHMS data for compliance of enforcement activities Concern 4C: Dissuading effects of combined consent	Concern 8: Rationale for 10-year consent and retention of biomedical sample	Concern 10C: Withdrawal of consent
	Concern 9: Mandatory return of study results for use by other researchers	Concern 10D: Consideration of permitted use and dynamic consent
		Concern 10E: Consent to contact Participants regarding actionable findings from future research

		Concern 11: Broader concerns about the privacy landscape in Australia

3.3 In the remainder of this section we provide a summary of each concern (as described above) expressed by stakeholders throughout the stakeholder consultation process in March 2021. We have prepared the summaries:

3.3.1 without attributing any particular concern to an individual or stakeholder. However, we have noted in parts where a concern was raised by a particular type of stakeholder (e.g. education or research organisation);

3.3.2 with responses that the ABS provided during the consultations. In some cases, the ABS simply indicated that it had heard the relevant concern but did not provide any further information, explanation or indication of future approach. In such cases, we have not included any "ABS comment at workshops"; and

3.3.3 with additional information, not provided during consultations, but included in this report for clarity.

3.4 **Process 1 concerns**

3.5 Stakeholders were invited to respond to ABS initiated questions and provide general feedback of Process 1. The following is a summary of concerns, opinions and key discussion points regarding Process 1.

Concern 1: Opt-in versus Opt-out consents

3.6 A key concern voiced by some stakeholders was that Participants are requested to give consents to several disclosures of their pathology results (i.e. to the Participant, to the Participant's GP, and/or to the Participant's My Health Record), however, the proposed mechanism for those consents are inconsistent. That is, two consents are 'opt-in' and one consent is 'opt-out'.

3.7 The NHMS, as currently proposed, will require the Participant to provide express consent before the pathology results will be disclosed to:

3.7.1 the Participant; and/or

3.7.2 the Participant's nominated general practitioner (**GP**).

3.8 That is, the Participant must ***opt-in*** to the disclosure of their results to the Participant and/or their GP.

3.9 However, a Participant must check the 'tick-box' to request that the pathology results are *not* disclosed to the Participant's My Health Record (if they have one). That is, the Participant must ***opt-out*** of this disclosure.

3.10 One concern raised by stakeholders is that many Participants, particularly those of culturally and linguistically diverse (**CALD**) background or with other comprehension difficulties, may not recognise that the consents to disclose are a mixture of opt-in and opt-out. This gives rise to a risk that consent to disclose personal information and health information will not be fully informed.

3.11 One stakeholder stated that the ABS should consider that disclosure to the My Health Record should be an opt-in disclosure because the NHMS is not distinctly a medical service. While the NHMS has medical implications, it is not a medical service. Further, another stakeholder stated that as a matter of best practice the consents to several disclosures of a Participant's personal information should be framed as ***opt-in*** for consistency and to ensure the consent will be fully informed.

3.12 **ABS comment at workshops:** The ABS understands that the proposed pathology form is consistent with current standard pathology processes, specifically regarding disclosure of information to My Health Record. However, the ABS has heard the concerns raised by stakeholders and will review the structure of the pathology collection form.

Additional Information: Uploading participant's NHMS results to My Health Record has since been removed from the Study's scope.

Concern 2: Communication of health risks to Participants

3.13 An issue of concern for many stakeholders across the consultation sessions was the return of the results of the sample testing. This concern applies to both Process 1 and Process 2. Regarding Process 1 in particular, stakeholders raised the following questions:

3.13.1 What constitutes a 'significant health risk'?

3.13.2 Who will communicate the results to Participants?

3.13.3 If a Participant does not consent to the return of their test results, is there a process in place to handle that information appropriately?

Concern 2A: What constitutes a 'significant health risk'?

3.14 As a general point of interest, and in response to the information flow diagram presented by the ABS, stakeholders were curious to know:

3.14.1 What was a 'significant health risk' for the purposes of returning results to Participants?

3.14.2 Will results indicating future health risks be communicated?

3.15 **ABS comment at workshops:** The ABS has taken into consideration the professional standards within pathology practice in the implementation of the NHMS, specifically the identified critical threshold limits that apply to certain health indicators.

The ABS notes that the NHMS will look at approximately 20 specific health indicators. Of those 20 health indicators, there are 6 that have an applicable 'critical threshold limit'. If a Participant's tested sample shows a level that falls outside of a 'critical threshold limit' they will be contacted. In this case, their blood sample would indicate that there is a serious and urgent medical issue and attention is required immediately (i.e. the Participant should head to the emergency department of their nearest hospital).

Additional Information: If Participants opt-in to receive their results the letter encourages them to consult their doctor on any results that are outside the normal range.

Concern 2B: Who will communicate results to Participants?

3.16 Stakeholders expressed that the appropriate person or group to communicate results should be the pathology provider or a medical practitioner. Further, stakeholders expressed some concern if results would be communicated by the ABS, noting that it was preferable that a medical professional contact Participants.

3.17 One stakeholder noted that if the testing laboratory will directly return results to Participants, then the ABS should also consider:

3.17.1 providing other supports to Participants (i.e. counselling services); and

3.17.2 clinical confirmation of findings.

3.18 **ABS comment at workshops:** The ABS has heard the concerns regarding additional supports to be offered to Participants and clinical confirmation of findings before reporting

findings are provided to Participants and will consider these issues further in the design of the NHMS.

Additional Information: ABS also notes that the results report the Participant receives from the Pathology Provider encourages them to follow-up with their doctor if they have any results that are outside of the normal range. These results will be marked with an asterisk (*).

Concern 3: Collection of consent at point of collection of sample

3.19 Stakeholders expressed opinions and concerns regarding the logistics of consent being collected at the same time as the point of collection of the biomedical sample. That is, it is currently proposed that the pathology provider will be responsible for collecting consent to participate in the NHMS and providing those consent forms to the ABS. Concerns that were expressed included that forms may go missing, biomedical samples and forms may be sent to the wrong lab, and concerns about the security of forms (as they include personal information).

3.20 One stakeholder commented that, assuming Participants are drawn from several States and Territories and will go to various locations, there is a significant concern regarding the logistics of the consent forms being provided back to the ABS. This stakeholder stated they would prefer to see consent to participate in the NHMS collected at the time of the initial interview with the ABS. When the Participant attends the pathology collection centre that would constitute a secondary level of consent.

3.21 Another stakeholder representing an educational institution put forth the notion of an online portal to collect electronic consent as an alternative to physical collection and transferral of consent forms.

3.22 Another stakeholder questioned the process if a Participant attends a pathology collection centre prepared to participate in the NHMS but forgets to bring their consent forms.

3.23 **ABS comment at workshops:** In the 2011 – 2013 study, the ABS arranged for collection of consent at the time of the interview. However, the ABS feels that Participants need more to consider the information that will be provided about the Study. In particular, considering the additional collection of a biomedical sample for inclusion in the Biobank and potential use for genomic testing could take more time.

Regarding logistics, the ABS has arranged with the pathology provider to have copies of consent forms and information packets on hand at each collection centre. Further, staff at the pathology collection centres will receive training on how to help Participants to complete forms and ensure forms are completed correctly.

Further, forms will be kept by the pathology provider to be sent on with the biomedical samples to the Biobank custodian, with electronic copies of consent forms will be sent to the ABS by Secure File Transfer Protocol (SFTP).

Concern 4: Data integration with MADIP

3.24 Stakeholders present at the consultations voiced several concerns regarding integration of NHMS survey data with MADIP data, including:

3.24.1 consumers' general lack of trust in inter-agency sharing of personal information, particularly given recent publicity on some high-profile initiatives (such as the 'Robodebt' scheme);

3.24.2 the difficulties in effectively communicating data integration to Participants, including the proposed integration of NHMS data into MADIP (this is also discussed further at paragraph 3.28, below);

3.24.3 concerns regarding the use of NHMS data for compliance or enforcement activities; and

3.24.4 problems in effectively combining the consent to participate in the NHMS and the consent to integrate data, within the first tier of consent.

Concern 4A: Consumer lack of trust in inter-agency sharing of information

3.25 A consumer stakeholder noted that, following 'Robodebt', the general population's trust in government regarding the sharing of personal information across multiple government platforms is virtually non-existent. Further, the stakeholder encouraged the ABS to address this issue from the outset to ensure maximum participation in the NHMS.

Concern 4B: use of NHMS data for compliance of enforcement activities

3.26 There was a general concern regarding who has access to MADIP data and what they may be able to use NHMS or MADIP data for. One stakeholder commented that while ABS does not intend to use a Participant's NHMS or MADIP data for enforcement or compliance activities, there is a potential risk that NHMS or MADIP data could be used for such purposes should the "intention" of ABS change.

3.27 **ABS comment at workshops:** ABS noted that 'Robodebt' was a scheme used for compliance measures. MADIP data may only be used for authorised research and analysis projects and cannot be used for compliance purposes. Before any researcher, including a researcher from a Commonwealth or State/Territory Agency, has access to the MADIP data they must apply for access and undergo a rigorous on-boarding process. Further, the relevant research process must go through a strict governance process before being approved. Any application made by a prospective researcher that suggested use of data for compliance or enforcement would not be approved for access.

Concern 4C: Dissuading effects of combined consent

3.28 Stakeholders raised concerns regarding the first tier of consent (being for consent to participate in the NHMS and to have their data integrated into MADIP). Several stakeholders raised the desirability of splitting the first tier of consent in two separate consents.

3.29 Currently the first tier of consent requests consent to participate in the NHMS (that is, the collection of their blood and/or urine sample for testing and for test results to be provided to the ABS). It is proposed that this consent will also allow the ABS to link the individual's NHMS data with their data obtained in other IHMHS studies and also for their data to be linked to MADIP.

3.30 Consumer representatives raised the potential of a four-tier "consent menu", so that tier one is split into separate consents, being:

3.30.1 consent to participate in the NHMS (that is, the collection of their blood and/or urine sample for testing, and for test results to be provided to the ABS); and

3.30.2 consent for the ABS to link the NHMS data with other data assets such as datasets contained in MADIP.

3.31 This suggestion was proposed as:

3.31.1 the combined consent in tier one may discourage the more 'data-wary' Participants from participating in the NHMS as they do not want their data to be linked with other data sets. Further, marginalised groups and those with stigmatised conditions may exclude themselves from the study cohort based on their preference to not have their data linked to other data assets i.e. MADIP; and

3.31.2 Participants ought to be able to provide specific and fully informed consent to data linkage after being informed about the relevant privacy risks, such that, if "complex" MADIP process are not conveyed to, and understood by Participants, then there is a risk that the consent will not be fully informed.

3.32 **ABS comment at workshops:** ABS previously undertook a separate PIA process specifically in relation to MADIP and recently undertook an updated PIA process. This PIA process examined the governance and other processes surrounding integration of data into MADIP and the subsequent use of that data for approved research projects. Any integration of NHMS study data, or subsequent use of that data for approved research projects, would be in accordance with the usual MADIP governance and processes.

ABS expressed the view that it is impractical to obtain separate consent for data linkage with data assets held in MADIP. The ABS acknowledged the difficulties in clearly explaining all of the governance and data protection mechanisms already in place for MADIP, given the amount of other information in the information packet. The ABS also noted there may be limited usefulness if the dataset that was integrated with MADIP did not contain the results of all Participants in the NHMS but a more limited group (that is, it would be a 'biased' dataset).

ABS generally tries to be as transparent as possible regarding the use of, and integration of, data in MADIP, as well as the types of research projects that will have access to data (including the researchers, the content of the research, the published results of studies etc).

3.33 **Process 2 concerns**

3.34 Stakeholders were invited to respond to ABS initiated questions and provide general feedback of Process 2 of the NHMS. The following is a summary of concerns, opinions and key discussion points regarding Process 2 of the NHMS.

3.35 It is important to note from the outset that the Commonwealth Department of Health (**Health**)/Biobank custodian is responsible for the implementation of the activities that occur under Process 2. While the ABS will provide stakeholder concerns to Health as a means of providing additional guidance and privacy enhancing strategies it does not have control over the implementation. That will be a matter for Health and the Biobank custodian selected by Health.

Concern 5: Biobank custodianship

3.36 Many stakeholders raised concerns over the identity and role of the Biobank custodian. Stakeholders expressed the following opinions:

3.36.1 the Biobank custodian should not be a private entity;

3.36.2 the Biobank custodian should be an APP entity; and

3.36.3 the ABS should have such a relationship with the Biobank custodian so that it is able to ensure the samples and data are being accessed in a manner that is aligned with the purposes for which it was initially collected.

3.37 Stakeholders acknowledged that the NHMS, particularly storage of biomedical samples and use of biomedical samples for research and genomic testing, is a very high-risk and complex undertaking. The majority of stakeholders were of the view that the Biobank custodian should not be a private entity. Further, many stakeholders held the view that the ABS should have input into the custodianship arrangement and be inclined to maintain a relationship with the Biobank custodian.

3.38 One stakeholder noted that if trust is lost in the establishment of this Biobank and its management of biomedical samples, it will be difficult for subsequent research groups and/or entities to attempt similar things.

3.39 **ABS comment at workshops:** The ABS notes the strong concerns expressed by the stakeholders. The Biobank custodian will not be the ABS and custodianship will not be a function of the ABS.

The identity of the Biobank custodian will be determined by the funder of the NHMS (i.e. Health). The procurements and arrangements are still under development so specifics

regarding the biobank custodian and storage facility cannot be disclosed at the time of these consultations.

Additional Information: Health have approached a Commonwealth agency (APP entity) regarding the custodianship of the biobank.

Concern 6: Maintaining contact with Participants

3.40 Several stakeholders representing education and research organisations questioned what steps will be taken by the Biobank to maintain contact with Participants over the 10-year lifespan of the biomedical sample within the Biobank storage facility. The views expressed highlighted the need for a strategy to ensure ongoing communication with the Participants that have contributed a biomedical sample.

3.41 One stakeholder noted that there is no appropriate 'one-size-fits-all' approach. Maintaining contact needs to be given considerable thought, especially as vulnerable groups of people often tend to change their contact details more frequently.

3.42 Stakeholders offered the following possible suggestions to enhance the ability to ensure an up-to-date and accurate record of personal information of Participants is maintained:

3.42.1 sending out newsletters at regular intervals (i.e. quarterly, annually etc.);

3.42.2 running the list of Participants against the national death index (to ensure persons who have died do not receive further newsletters or correspondence addressed to them, as this can cause distress to surviving relatives); and

3.42.3 community governance models (as adopted by some Aboriginal and Torres Strait Islander interest groups present at the consultations).

3.43 **ABS comment at workshops:** The ABS indicated that it would suggest to the Biobank custodian (when appointed) that it considers developing a form of regular newsletter to be distributed to Participants who contributed a biomedical sample to the Biobank. The newsletter could act as a mechanism to 'check-in' on original consent and maintain the accuracy of personal information details over time.

Concern 7: Returning results of testing to Participants

3.44 As stated above at Concern 4 (paragraphs 3.24 – 3.31.2), a key issue of concern for many stakeholders across the consultation sessions was the return of results of testing. In specific regard to Process 2, Stakeholders raised the following concerns:

3.44.1 Who will be delivering results of the further research to the Participants, and what supports will be available to Participants (i.e. genetic counsellor)?

3.44.2 How will consent be sought from Participants to be contacted regarding results of the future research (noting that there may be life insurance implications once results are received, and Participants should have the right to not know certain results)?

3.44.3 How will the Biobank custodian ensure consent obtained in relation to the results is contemporaneous with community attitudes at the time of the future research?

Concern 7A: who will communicate results and what supports will be available?

3.45 The majority of stakeholders were of the view that results of any future genomic research need to be returned by someone who has some genomic expertise or has a genomic counsellor role. Further, that results should not be returned by a third party (i.e. a pathology provider or the Biobank custodian).

3.46 Another stakeholder also inquired regarding what would happen if a researcher were to get an 'actionable result' but the Participant had already died. In such a case, would results be provided to a family member or the Participant's next of kin?

Concern 8: Rationale for 10-year consent and retention of biomedical sample

3.47 Stakeholders representing education and research institutions queried the rationale for only collecting consent for, and retaining biomedical samples for, 10 years. Stakeholders queried:

3.47.1 why the ABS was not seeking indefinite consent for storage and use of biomedical samples (and whether the sample itself should be expressly described as a 'donation' to the Biobank); and

3.47.2 what the implications might be for data derived from biomedical samples (i.e. would results have to be destroyed as the sample is destroyed).

3.48 Another stakeholder raised a concern regarding the ongoing funding of the Biobank as another consideration regarding the duration of consent, noting that government priorities and initiatives shift and change. The concern was that government funding may be discontinued prior to the close of the 10-year period.

Concern 8A: limited consent for storage and use of biomedical samples

3.49 One stakeholder asked whether it was intended that, after 10 years, the Biobank custodian would seek consent for further storage and use of the biomedical sample (and whether this would be practical or even possible). Another noted that there is no real reason to destroy the sample at 10 years and so there needn't be a limitation on the consent for use.

3.50 **ABS comment at workshops:** The ABS anticipates that the quality and quantity of the biomedical samples will be depleted over the course of 10 years, therefore consent has not been sought from Participants to retain and use the biomedical samples for a period greater than 10 years.

Concern 8B: implications for data derived from biomedical samples

3.51 It was noted by several research stakeholders that while the biomedical sample may be depleted over a 10-year period, the data derived from that biomedical sample can last indefinitely. As such, that consent should be indefinite to cover future use of that data. Another health stakeholder expressed concern that genomic data would be destroyed at the end of the 10-year period.

Concern 9: Mandatory return of study results for use by other researchers

3.52 During the consultation the ABS asked the question to stakeholders "does this group think researchers should mandatorily return results of testing on biomedical samples to the Biobank custodian so that others can utilise those findings without having to access the biomedical samples"?

3.53 The majority of stakeholders were in support of this.

3.54 Stakeholders representing research institutions indicated that research undertaken using the Biobank samples should contribute back to the asset and should not be 'siphoned off' for separate use. Stakeholders noted that the idea of contributing back to the national asset should be reflected in policy in the same way that it is for other national research infrastructure (e.g. infrastructure funded under the NCRIS initiative).

3.55 It was also noted that the open data and continual addition of data to specimens has been a key part of the overarching strategy for the assets held in the NSW Health Statewide Biobank.

3.56 One stakeholder expressed a concern, noting that while the most efficient use of genomic data and biomedical samples is to generate a 'big-data' view of genomic data, there is an increased risk of re-identification of Participants involved in such aggregation of data.

3.57 **Whole of NHMS concerns**

Concern 10: Proposed consent model

3.58 An overarching concern for the entire NHMS was how to obtain fully informed consent.

3.59 The proposed consent model for the NHMS is a three-tier model of consent. That is, consent to:

3.59.1 participate in the NHMS and for NHMS data to be linked to other data (e.g. MADIP data);

3.59.2 biomedical samples being stored long term in the Biobank and used for future biomedical testing; and

3.59.3 use of biomedical samples stored in the Biobank for genomic testing.

3.60 It is important to note that the three tiers of consent are for increased participation for the NHMS, it is not consent for three separate or independent aspects. That is, to participate in 'tier two' i.e. biomedical samples being stored in the Biobank, the Participant first needs to have consented to 'tier one'. Similarly, to consent in 'tier three', a Participant must consent to both 'tier one' and 'tier two'.

Concern 10A: bundled consent for tier one

3.61 Several stakeholders expressed concerns on the 'bundled consent' at tier one. Privacy stakeholders noted that by having consent to participate in the NHMS and consent to link data to other data assets (i.e. MADIP) it is possible that the ABS is 'bundling too much into one question' such that the consent may not be full informed if Participants are not made aware of the MADIP process. Conversely, another stakeholder supported the proposed consent model on the basis that it was impractical to collect consent for data linkage separately given the complexity of the explanation of all the privacy protections in place.

3.62 Other consumer interest groups suggested separating tier one consent into two separate consents; that is, splitting consent to participate from consent to data linkage as people may be interested in participating in the NHMS but not want data integrated further. This may, in turn, dissuade potential Participants from participating in the NHMS. As provided above, in relation to Concern 4, another stakeholder noted that marginalised groups or people with stigmatised conditions may consider excluding themselves based on the potential for further data linkage.

3.63 **ABS comment at workshops:** ABS undertook a separate PIA specifically for MADIP as discussed at paragraph 3.32.

Concern 10B: Comprehension of complex consent

3.64 Stakeholders were concerned regarding the ability of the ABS to communicate the complexities of the various aspects of the NHMS in order to obtain fully informed consent. For example, consumer representative stakeholders and privacy interest stakeholders noted that the ABS should take additional steps to help Participants to understand in simple English and non-English resources. One stakeholder considered that as well as material being provided in a variety of languages, there should be other opportunities for potential Participants to seek clarity (i.e. pamphlets, videos, phoning a hotline etc.).

3.65 In written feedback following the consultation process, one stakeholder commented that accessibility is an issue that could be met by ensuring that the accompanying information materials are available in a form that can be converted from text into other languages or into audio. The stakeholder noted this could also apply to information sent to the Participant later (i.e. feedback or medically actionable results).

3.66 **ABS comment at workshops:** ABS' current expectation is that informative pamphlets would be the first point of communications. Further, ABS will have an ABS hotline available for further questioning if pamphlet materials do not answer questions. ABS has noted that some biobanks use other information (i.e. online videos) and will consider further.

The ABS is also committed to training pathology providers to ensure that the consent they are obtaining is full informed.

3.67 Following the stakeholder consultation process, the ABS received written feedback from a stakeholder representing Aboriginal and Torres Strait Islander interests in response to the ABS use of Aboriginal Medical Service (AMS) facilities. This stakeholder noted that many Aboriginal and Torres Strait Islander people generally feel either unwelcome at AMS facilities or are unwilling to attend AMS facilities. This stakeholder further highlighted that the ABS may need further community engagement and an alternative plan for Aboriginal and Torres Strait Islander participants, particularly those in rural or remote communities.

3.68 An additional concern raised by stakeholders, regarding the complexity of consent that Participants will be giving, was that many Participants will not have a legal, biomedical, or statistical background. As a result, Participants may encounter significant difficulties navigating and comprehending the information that they will be provided. One privacy advocate stakeholder noted that such Participants are working with, or against (depending on perspective), a department that has huge resources at its disposal and a clear agenda to obtain a signature of consent 'on the dotted line'. This can be viewed as 'quite a hostile, unfair and oppressive consent model'.

Concern 10C: Withdrawal of consent

3.69 Stakeholders inquired regarding the ability of Participants to withdraw consent from the second and third tier of activities (i.e. storage of biomedical sample in the Biobank and further genomic testing of the biomedical sample).

3.70 **ABS comment at workshops:** Participants will be able to withdraw their consent from the second and third tiers of activity at any point. However, Participants will have to communicate that withdrawal to the Biobank custodian and not the ABS.

Concern 10D: Consideration of permitted use and dynamic consent

3.71 Some stakeholders expressed a concern that Participants lose control over the potential uses of their biomedical sample. While Participants may be able to withdraw their consent for any access to and use of their biomedical sample, until their consent has been withdrawn, they do not have control over what research projects are given access to their biomedical sample.

3.72 This was described as an 'open-ended use' by one stakeholder. This stakeholder noted that 'the more open ended the consent the more hostile', further that open-ended consent benefits the researcher only, and that this form of consent gives the illusions of 'formality of approval without transparency of use of data'.

3.73 A stakeholder from an Aboriginal and Torres Strait Islander interest group noted that 'consents need to be designed with a permitted use case in mind so that Participants can consider their level of comfort with a research project and to inform their consent'.

3.74 A stakeholder from a public health group noted, in the contrary, that consent obtained for future use at the commencement of the study may also impose unnecessary limitations of the future use of the biomedical samples. For example, what is considered unacceptable to research now may become acceptable eight years into the future, and vice versa. A

stakeholder from a privacy interest group argued that use of sophisticated tools, i.e. dynamic consent mechanisms, should be considered for improving consent.

3.75 A stakeholder from a research organisation supported open-ended consent provided participants are frequently contacted (e.g. newsletters) and researcher access protocols are met. This consent model is used extensively domestically and internationally, including the UK Biobank. The involvement of research champions within the biobank governance would convey confidence that research will be conducted in the public interest.

3.76 A stakeholder representing Aboriginal and Torres Strait Islander interests raised a concern regarding the potential for the use of biomedical sample data to lay claim, or exclude, ownership over land and/or cultural heritage.

3.77 **ABS comment at workshops:** With respect to the Aboriginal and Torres Strait Islander population, the ABS has received a number of these concerns [i.e. use of biomedical sample data to claim or exclude land ownership], as well as Aboriginal and Torres Strait Islander governance and data sovereignty. The ABS expects to consult further on this specifically with Aboriginal and Torres Strait Islander people in the coming months.

3.78 **Additional Information:** ABS notes that access to, and use of, any biomedical sample will be subject to a governance committee process and ethics committee approval. Further, we note that biomedical samples are not intended to be available for enforcement or compliance activities.

Concern 10E: Consent to contact Participants regarding actionable findings from future research

3.79 Some stakeholders noted that it is very difficult, when obtaining consent, to strike a balance between information overload and not providing enough information.

3.80 Stakeholders that participate in similar research activities (i.e. collection of samples or biobanking) indicated that they obtain consent from Participants to be contacted if a result indicates a 'medically actionable health risk', but then seek an additional consent from the individual before providing the actual results. That is, people are given an opportunity to refuse to know the information.

3.81 It was suggested that the initial consent sought should be in generic wording to the effect of:

> *"you have contributed a sample to a biobank, you have asked to be notified of information of relevance to your health. We have found something and if you would like to know about it please let us know. [Provision of general information about the implications of receiving the results, e.g. the information may have life insurance implications etc.] We will follow up if we don't hear from you."*

3.82 Several stakeholders noted that health insurance is protected from genetic discrimination. On the other hand, life insurance is risk rated and does not have the same protections. Therefore, people have a right not to know and that right needs to be protected.

3.83 Some stakeholders noted that it should be the responsibility of the researcher seeking access to the data assets (i.e. the biomedical samples) to come up with an ethically defensible plan on how and when to contact Participants should a 'medically actionable genetic health risk' be identified. Further, another stakeholder noted that researchers should, if they are not planning on returning results to Participants, provide a justification as to why. This stakeholder noted 'there should be a presumption that results are returned and done so in an ethically defensible way'.

3.84 It was noted by one stakeholder that perceptions of the individual, as well as perceptions of society, regarding what research projects are acceptable will change over time. This gave rise to a concern of ensuring that consent is contemporaneous with the attitudes of the day as a Participant may give their consent to be contacted if an actionable result arises when first deciding to participate in the NHMS. However, if that same Participant were to learn

about the complexities associated with health insurance and life insurance then there is a risk that that consent would be no longer be effectual.

3.85 Stakeholders suggested that a forward consent model be used at the initial consent point, and that forward consent should be framed as a hypothetical, with a secondary consent to receive that information should an actionable result arise.

3.86 One stakeholder noted that the Biobank Custodian should, when reviewing applications for access, require researchers to provide in that application, a mechanism for the return of medically actionable results.

3.87 **ABS comment at workshops:** The ABS is aware that the National Statement requirements will make it necessary for researchers to provide a mechanism for return of medically significant results. The ABS anticipates that the Researcher would provide some form of counselling service if information returned to Participants will include genetic information. The ABS acknowledges that the Researcher should be responsible for contacting Participants and should consult with the Biobank custodian to collect personal information in order to contact the relevant Participant. The Biobank custodian will be the only entity that retains control of personal information in Process 2 of the NHMS.

Concern 11: Broader concerns about the privacy landscape in Australia

3.88 We note that one stakeholder representing consumer interests raised a number of concerns relating to the privacy landscape in Australia, in particular, the limited avenue for persons to pursue recourse (for example, to sue for breach of privacy) if ‘something goes wrong’.

4. Appendix A: Stakeholders consulted for the NHMS PIA

- Australian Institute of Health and Welfare
- Australian Privacy Foundation
- Australian Research Data Commons
- Cancer Council Victoria
- Consumers Health Forum
- Consumers (sourced from Consumer Health Forum's consumer networks)
- Commonwealth Scientific and Industrial Research Organisation
- Department of Education, Skills and Employment
- Department of Health
- Department of Health and Human Services Victoria
- Department of Social Services
- Monash University
- National Centre for Indigenous Genomics
- Ngunnawal Aboriginal Corporation
- NSW Health
- Office of the Australian Information Commissioner
- Office of the National Data Commissioner
- University of Queensland
- Western Australia Health